



AIDS MEDICINES AND DIAGNOSTICS SERVICE

# SPECIFICATIONS AND QUANTITIES FOR EFFICIENT PROCUREMENT OF ESSENTIAL EQUIPMENT AND LABORATORY COMMODITIES FOR HIV

JANUARY 2014



**SPECIFICATIONS AND  
QUANTITIES FOR EFFICIENT  
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# ABBREVIATIONS AND ACRONYMS

AIDS	acquired immunodeficiency syndrome
ALY	atypical lymphocytes
AMDS	AIDS Medicines and Diagnostics Service
ANSI	American National Standards Institute
ASLM	African Society for Laboratory Medicine
ASTM	American Society for Testing and Materials
BAS	basophils
CDC	Centers for Disease Control and Prevention
CPS	Contracting and Procurement Service
CE-IVD	CE (European Commission) marked in vitro diagnostic device
CHAI	Clinton Health Access Initiative
CV	cell volume
DHHS	Department of Health and Human Services (USA)
DIN	Deutsches Institute für Normung
DLT	Diagnostics and Laboratory Technology
EDTA	ethylene diamine tetra-acetic acid
EHT	Essential Health Technologies
EIA	enzyme immunoassay
ELISA	enzyme-linked immunosorbent assay (interchangeable with above)
EOS	eosinophils
FIND	Foundation for Innovative New Diagnostics
GLI	Global Laboratory Initiative
GSSHealth	Global Scientific Solutions for Health
HCT	haematocrit
HGB	haemoglobin
HIV	human immunodeficiency virus
ISO	International Organization for Standardization
IVDD	In-Vitro Diagnostic Medical Devices Directive
JSI	John Snow, Inc.
LCD	liquid-crystal display
LIC	large immature cells
LYM	lymphocytes
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MON	monocytes
MPV	mean platelet volume
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health

NEU	neutrophils
PCR	polymerase chain reaction
PDW	platelet distribution width
PE	polyethylene
PfSCM	Partnership for Supply Chain Management
PLT	platelet count
RBC	red blood cell
RCF	relative centrifugal force
RCW	red cell distribution width
RDT	rapid diagnostic test
rpm	revolutions per minute
SCMS	supply chain management system
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SI	Système international d'unités (international system of units)
STB	Stop TB
TB	tuberculosis
TBCAP	Tuberculosis Coalition for Technical Assistance
UBRAF	Unified Budget Reporting Accountability Framework
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UPS	uninterruptible power supply
UoM	unit of measurement
URL	Uniform Resource Locator (website address)
USAID	United States Agency for International Development
WBC	white blood cell
WD	working distance
WHO	World Health Organization

# 1. BACKGROUND

## 1.1 Rationale

A consensus meeting of major stakeholders and partners who were charged with making recommendations on laboratory testing standardization and harmonization was held in Maputo on 22–24 January 2008.<sup>1</sup>

This meeting achieved the following major outcomes:

- definition of tests required at each level of the tiered, integrated laboratory network;
- publication of key considerations for maintenance of equipment at each level of laboratory network;
- a commitment by health care leaders to develop and adopt policies to standardize laboratory equipment and supplies.

As a follow-up to the Maputo meeting, a meeting jointly organized in Geneva in October 2008<sup>2</sup> by the World Health Organization (WHO) AIDS Medicines and Diagnostics Service (AMDS) of the HIV Department and the Diagnostics and Laboratory Technology unit of the Essential Health Technologies department (EHT/DLT) recommended the establishment of two technical working groups<sup>3</sup> aimed at improving the procurement of laboratory items.

One of the technical working groups was charged with sharing experiences on harmonization/standardization of laboratory items and the other group<sup>a</sup> was tasked with defining generic specifications to assist in the procurement of laboratory products. To this end WHO, with support from Centers for Disease Control and Prevention (CDC), developed the present tool on specifications and quantities for efficient procurement of essential equipment and laboratory commodities for HIV.

The ultimate purpose of the tool on specifications and quantities of laboratory items is to facilitate the efficient procurement of laboratory equipment and laboratory commodities required to:

- perform HIV diagnostic tests in adults, adolescent and children;

- monitor treatment outcomes in patients on antiretroviral therapy.

Many low-income and low–middle income countries<sup>4</sup> are developing and implementing national strategic plans for laboratory services as part of the effort towards overall health system strengthening and a key regulatory component that includes laboratory accreditation.<sup>5</sup> In addition, ministries of health are developing cost-saving and time-saving mechanisms to streamline their supply chain management systems. As part of this effort, countries have begun to establish national networks of tiered laboratories with standardized services at each level. This tool on specifications and quantities for efficient procurement of essential equipment and related laboratory commodities for HIV is part of this effort aiming at increasing performance and efficiency in the delivery of laboratory services.

WHO organized a technical working group meeting in Geneva on 21–22 June 2012 to review the first draft document. Several issues were discussed, including the criteria for selection of equipment that should be included in this tool. It was agreed that this tool will include only laboratory equipment and commodities that have been WHO prequalified or found on the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), WHO WebBuy and United Nations Children’s Fund (UNICEF) waiver lists for procurement by donor organizations, or other laboratory items found on the waiver lists for procurement by governmental and non-governmental programmes supported by international or multilateral development agencies. This tool will be regularly updated to take into account new technology development, changes on laboratory items prequalified by WHO, and the above procurement waiver lists.

## 1.2 Scope | Intended audience and use

The tool is intended to be used by, but not limited to, the following personnel for the stated purposes:

Personnel	Use
Staff responsible for the procurement of HIV-related laboratory commodities, e.g. ministry of health buyers, logisticians and national programme officers	<ul style="list-style-type: none"> <li>• Development of correct specifications and catalogue numbers</li> <li>• Listing of required accessories</li> <li>• Listing of optional accessories for review by laboratory technical staff</li> <li>• Guidance on installation and training</li> <li>• Identification of quality certificates</li> </ul>
Staff responsible for laboratory logistics, supply chain management, service planning and scale-up	<ul style="list-style-type: none"> <li>• Determination of appropriate laboratory network level for commonly used equipment</li> <li>• Identification of additional equipment required when establishing new testing services</li> <li>• Guidance on required quantities of items for bulk purchase</li> <li>• Shipping and storage conditions</li> <li>• Shelf-life</li> </ul>
Laboratory managers, supervisors and technical staff	<ul style="list-style-type: none"> <li>• Guidance on the suitability of equipment for the laboratory network level</li> <li>• Identification of the need for equipment installation, training, calibration and regular servicing</li> <li>• Equipment operating conditions</li> <li>• Expected quality standards</li> <li>• Identification of items required by test (can assist in work flow planning)</li> </ul>

a. Members of the working group on specification for efficient procurement of HIV laboratory equipment and related consumables: AFRO, AMDS, ASLM, CDC, CHAI, CPS, Crown Agents, EHT/DLT, FIND, GSSHealth, MSF, MSH, SCMS, STB, UNDP, UNICEF and USAID | DELIVER PROJECT.

## 2. MANAGEMENT OF LABORATORY COMMODITIES

### 2.1 Health systems and the role of laboratory services

The medical laboratory plays a key role in quality health service delivery and, just as a well-functioning health system must respond in a balanced way to a population's needs,<sup>6</sup> so too must a national diagnostic service.

This includes,<sup>7</sup>

- improving the health status of individuals, families and communities;
- defending the population against what threatens its health;
- protecting people against the financial consequences of ill health;
- providing equitable access to people-centred care;
- making it possible for people to participate in decisions affecting their health and health system.

To this end, appropriate processes must be in place in order to ensure the following key health system components function efficiently, transparently and economically:

- leadership and governance
- health information systems
- health financing
- human resources for health
- essential medical products and technologies
- service delivery.

The above health system components are equally applicable to a well-functioning laboratory service. Laboratory services, found under component 5 of the health system building blocks "Essential medical products and technologies",<sup>8</sup> support health systems in a variety of ways including:

- confirmation of disease/identification and drug susceptibility testing;
- identification and management of adverse effects (e.g. monitoring of pharmaceutical toxicity);
- screening of "at-risk" patients;
- disease surveillance studies;
- confirmation of medical intervention efficacy;
- quality control (e.g. pharmaceuticals quality, proficiency of testing);<sup>9</sup>
- education – training physicians, laboratory professionals and health care workers.

### 2.2 Laboratory service networks

In most countries, laboratories are organized as integrated systems in line with the country's health delivery network. The integrated system of laboratories is often structured to facilitate prompt diagnosis and treatment of the most common diseases and enable referral up the network to facilities capable

of providing specialized services when more sophisticated diagnostic testing or treatment is required or in the event of complications.

Generally, tiered laboratory networks fall into four main levels:<sup>1</sup>

- *level I* – primary: health post and health centre laboratories that primarily serve outpatients;
- *level II* – district: laboratories in intermediate referral facilities (e.g. district hospitals);
- *level III* – regional/provincial: laboratories in a regional/provincial referral hospital that may be part of a regional or provincial health bureau;
- *level IV* – national/multicountry: reference laboratory (national/multicountry public health reference laboratory for one or more countries).

The report resulting from the January 2008 Maputo Declaration on strengthening of laboratory systems<sup>10</sup> recommends standardized services at each tier,<sup>1</sup> ranging from rapid diagnostic tests (RDTs) and microscopy at level I to high throughput (i.e. large numbers of samples tested within a short time period), semi- and automated testing, where appropriate, at the higher levels.

### 2.3 The laboratory supply chain system

Supply chains are composed of numerous logistical processes to ensure efficient flow of commodities. Good management of supply chain processes ensures six basic customer rights:<sup>11</sup>

- the RIGHT commodities
- in the RIGHT quantities
- in the RIGHT condition, delivered
- to the RIGHT place
- at the RIGHT time
- for the RIGHT cost.

The supply chain (or logistics) system (Figure 1) is circular, with repetitive elements in each cycle. Each cycle and each activity within is linked. Customer service, product selection, quantification, procurement and inventory management are all affected by one another. As a result, a supply chain system can only be as strong as its weakest link.

Different countries manage health-related commodities in different ways, depending upon financial and human resources, local and regional need, and national infrastructure. Health-related commodities may be procured and managed centrally, regionally, locally and by specific departments or various programmes and stakeholders.

Laboratory commodity supply chain systems are complex due to the nature of the commodities in use, which in resource-limited settings are often challenging because of: limited resources for procurement; weak tracking and distribution; the existence of parallel systems (central, local and donor); and challenges in forecasting future needs.

Despite the complexities, the objectives of all laboratory commodity supply chains remain the same:<sup>11</sup>

- to ensure laboratories are able to provide patients with the appropriate, high-quality testing service to diagnose disease;
- to permit laboratory staff to carry out a high-quality, reliable, effective and efficient testing service;
- to guarantee that health care staff (such as physicians) have continuous access to the laboratory services required to manage patient care;
- to safeguard epidemiological studies that are required for disease outbreak and case contact analysis.

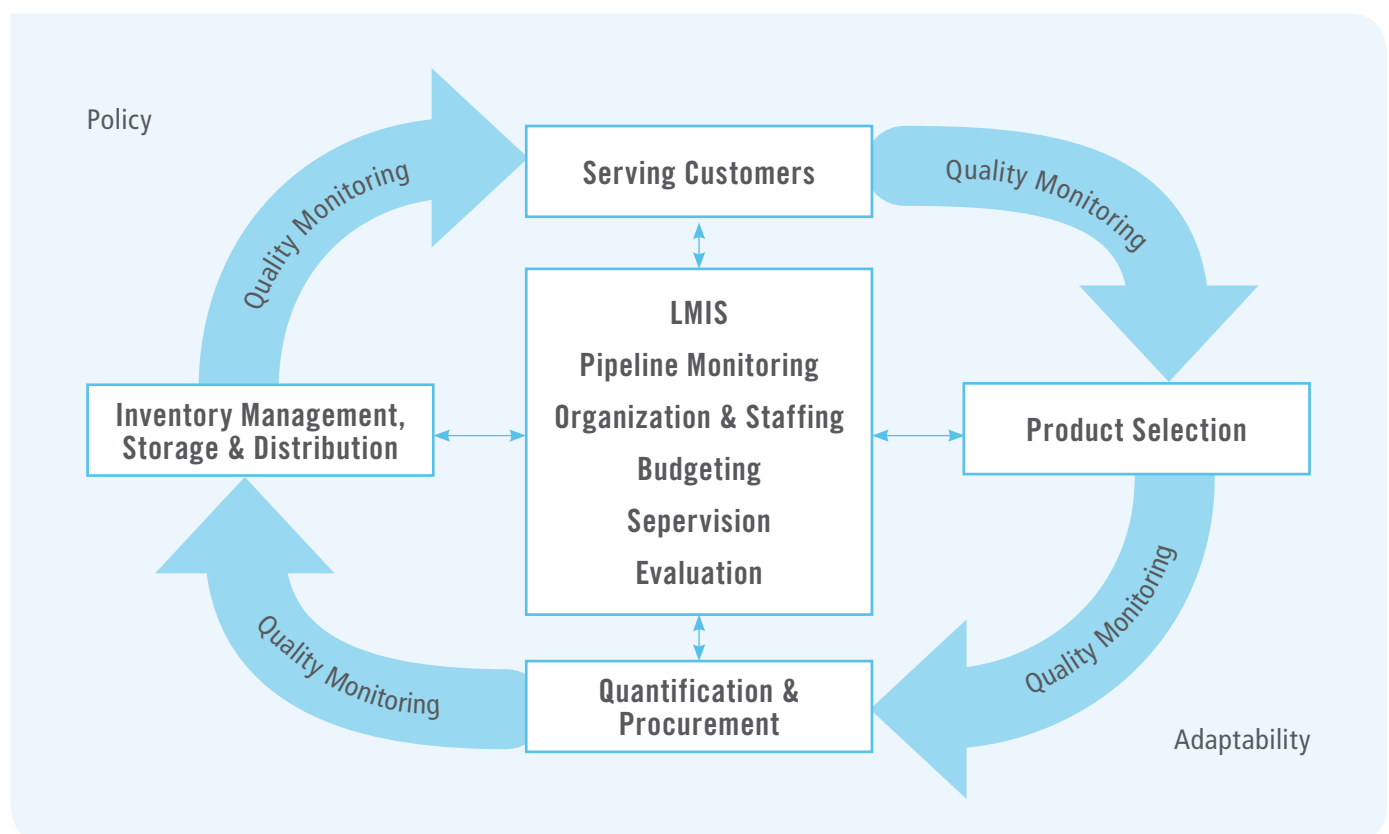
Laboratory commodities present a unique challenge to laboratory staff, laboratory managers, store managers, logisticians and other individuals responsible for aspects of laboratory supply chain management. Laboratory commodities are composed of a vast array of items with varying operational characteristics, shelf-life, installation, training, servicing, shipping, transportation, handling and storage requirements.

To address the specific requirements for such a vast array of items, and for the purposes of this tool, laboratory commodities have been broken down into the following categories:

- *Equipment*: machines, analysers, instruments used for or in testing.
- *Kits*: test kits and devices (e.g. HIV rapid test device) that test for, or are used in testing for, the component of interest.
- *Reagents and chemicals*: chemicals (solid and liquid) and reagents that test for, or are used in testing for, the component of interest.
- *Consumables*: test-specific and general items that are used once and discarded.
- *Durables*: reusable items such as glassware and plastic ware.

It is important to take note of these categories, as they will assist in the use of the tool.

**Figure 1. Task Order 1 (2011). LMIS, logistics management and information system.**  
From USAID I DELIVER PROJECT<sup>12</sup>



## 2.4 Challenges in laboratory commodity supply chain management

Laboratory and logistics professionals face numerous challenges when managing laboratory commodities. Lack of standardization often leads to a wide variety of available systems, each requiring specific reagents and technical support. Rapid changes in technology can sometimes result

in the withdrawal of certain commodities from the market while creating the need for rapid deployment of others. Laboratory and logistics professionals must balance the pros and cons of closed system instruments that may provide improved quality control, performance and after-sales service, but at greatly increased cost.

Some of the greatest challenges are faced in product selection, quantification and forecasting. Several defining

reports are available that address laboratory commodity selection, including WHO/AMDS consultations on laboratory commodities,<sup>2,3</sup> the Maputo meeting on standardization,<sup>10</sup> guides for developing laboratory commodity standardization plans,<sup>12,13</sup> and landscape reports on diagnostic products.<sup>14</sup> Furthermore, there are a number of guidelines to assist in the development of quantification and forecasting plans.<sup>15–17</sup> Therefore, in-depth descriptions of the issues surrounding quantification and forecasting will not be given here.

## 2.5 Standardization of laboratory commodities

The timeliness and accuracy of diagnostic results are reliant on the availability of laboratory commodities that meet minimum quality standards. In an effort to enhance quality and maintain efficiency, laboratory commodities should be standardized wherever possible throughout the tiered laboratory network.

Standardizing the type of platform (or equipment) for chemistry, haematology and CD4 across different laboratory levels offers many benefits including:

- cost reduction due to bulk procurement;
- ease of training and service due to a limited variety of platforms;
- higher manufacturer investment in regional/local service and distribution capability;
- minimal additional training needed when staff members move from laboratory to laboratory;
- better standardization of reference ranges and test results, thus better continuity of care for patients.

As with all policies and practices, the benefits must be weighed against the disadvantages. In the case of platform standardization, the single greatest risk is the potential to create monopolies in which a single or limited number of firms become the sole supplier of the majority of laboratory commodities. Monopolies can be damaging as the purchaser may lose bargaining power, resulting in price rises (particularly important when considering the cost of maintenance, reagents and consumables).

Other matters, such as the potential for corruption, future technology development and changes in need must be also considered.

## 3. WHY DEVELOP A TOOL FOR SPECIFICATION AND QUANTIFICATION?

A tool for specification and quantification of laboratory commodities can help laboratory and logistics professionals in the following ways:

- Appropriate specifications are critical to ensuring the supplier understands the end user's requirement and that transparent procedures are enforced and legal obligations stated.
- Appropriate specifications do more than describe the required product, they provide information on:
  - commodity requirement and function;
  - construction materials, dimensions and weight;
  - environmental requirements;
  - quality and regulatory requirements;
  - electrical requirements;
  - required and optional accessories;
- the need for installation, training, refresher training, servicing and maintenance.
- Itemized lists of commonly used commodities allow laboratory and logistics professionals to determine commodity need by test run and control.
- It is important to note that most controls have to be purchased separately or made in-house. Manufactured controls often have particular shipping and storage requirements and many have a short shelf-life.
- Details of inventory management requirements (e.g. shelf-life, storage conditions) can help laboratory and logistics professionals to plan orders and distribution.
- Approximate quantities of laboratory commodities required for a given test can assist in quantifications.
- Bundled items may aid in bulk purchasing and ease distribution.

## 4. WHO WILL BENEFIT FROM THE USE OF THIS TOOL?

This tool is intended to expand awareness and understanding about laboratory commodities and thus increase knowledge about laboratory supply chain management. It is targeted towards all laboratory supply chain personnel including:

- decision-makers and policy-makers at the central health system level;
- logisticians and supply chain managers at the central, regional and district levels;
- management and senior staff responsible for managing laboratory commodities at the central, regional, district and most peripheral levels.



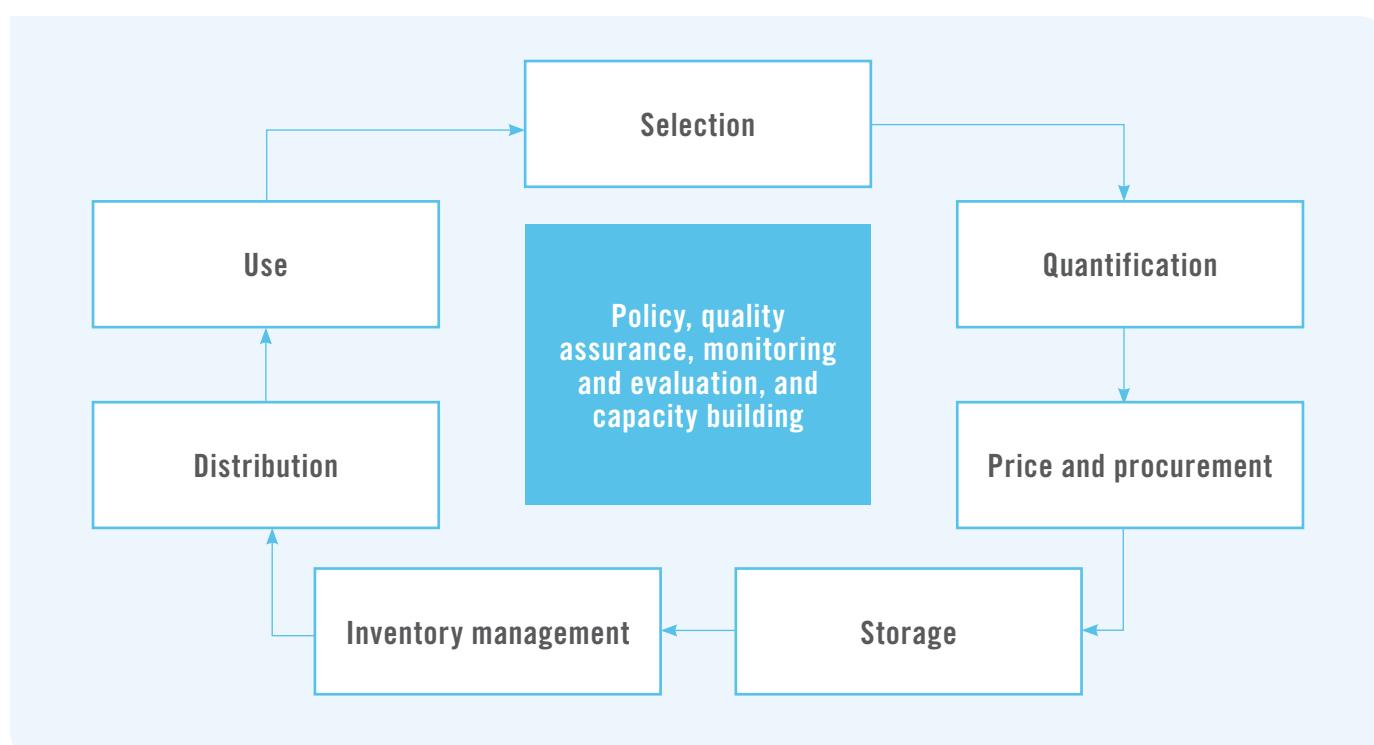
## 5. HOW CAN THIS TOOL HELP?

- Commonly used tests for HIV diagnosis and monitoring are listed with the most commonly used equipment, consumables, reagents, kits, chemicals and durables. This can be particularly useful for quantification planning in new sites or for new tests and arranging laboratory workflow.
- Commodities are listed with pertinent information concerning specifications:
  - required and optional accessories;
  - installation, training, service and maintenance requirements;
  - common shelf-life (from the manufacture);
  - shipping and storage conditions;
  - catalogue numbers (for branded items);
- links to package inserts, quality requirements and pack sizes (user-definable on Microsoft Excel tool).
- This information can help in the preparation of procurement requests, contracts and in distribution planning.
- Where possible (and based on particular assumptions, as described), laboratory commodities have been itemized and quantified on a per-test basis. Quantification information can make it easier to develop quantification and forecasting plans. In addition, items have been quantified in bulk to assist with larger procurements. Quantities in this tool are based upon assumptions and do not necessarily reflect the procedures used in all laboratories.

## 6. WHAT THIS TOOL CANNOT DO

- Commonly used commodities are based on manufacturers' package inserts. It is not possible to base these upon national standard operating procedures, as these may vary widely. As a result, the commodities described herein are only for guidance purposes. Managers should always quantify based on national/local standard operating procedures. This tool provides useful background information and a format for quantification but it must be tailored to the laboratory or country's specific need.
- This tool is not a substitute for guidelines used for supply chain management and inventory control. The following are key components of good supply chain management to ensure a constant supply of health products including laboratory commodities:
  - This tool is not a substitute for national policies and procedures. It should only be used to assist in the development of specifications and quantification plans.
  - This tool cannot provide forecasting information, which must be based on quality information from the field.

**Figure 2. Key considerations in the procurement and supply chain management cycle.**  
From World Health Organization.<sup>18</sup>



## 7. HOW THIS TOOL WAS DEVELOPED

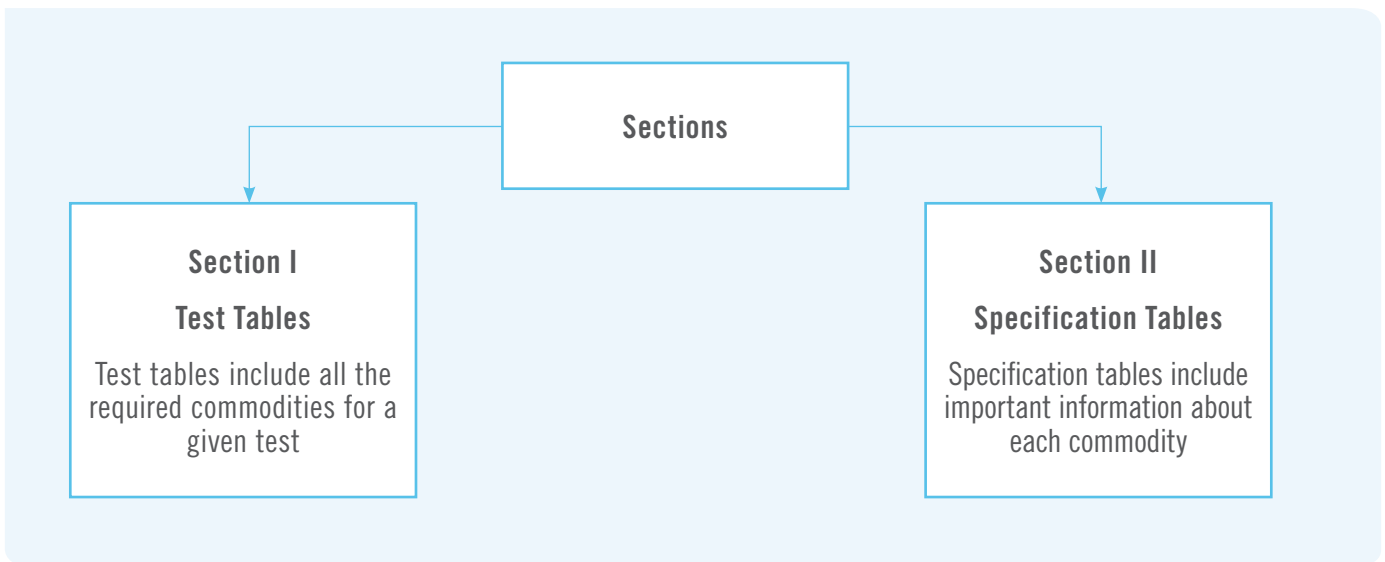
A number of methods were used to develop information for specifications and data on quantification. An overview of the methods employed is as follows:

- partner organizations supplying commodities were consulted throughout the process;
- the WHO technical working group on laboratory supplies was consulted throughout this process;
- manufacturers' package inserts were followed and required commodities listed and quantified;
- package inserts were obtained from the manufacturer's website or from an appropriate source;
- the most recent and accurate information was obtained by all possible means;
- in the event of missing data, manufacturers were contacted and asked to provide input.

## 8. CONTENT OVERVIEW

This tool is divided into two main sections with different tables in each:

- Test tables in Section I display all the required commodities by test and include some estimates to assist with deciding the quantities of items required for a given number of tests.
  - Specification tables in Section II provide important information on each commodity.
- The test and specification tables are linked via the item number, which appears in the first column of the test table for each item.



### Section I | Test tables

Test tables are listed according to each test type and provide information on each laboratory commodity required for the test. Where possible, laboratory commodities are grouped into suggested scalable units. The number of items required for scaling up to 1000 tests varies, depending upon each laboratory's standard procedure and the unit of measure for a particular commodity.

Test tables include the following information:

- *Item no.:* this unique number links the test table item to the specification table.
- *Item name:* includes the most commonly used name or names of the commodity.
- *Catalogue no.:* "generic" indicates that no manufacturer-specific product is required for that particular test; a number indicates the catalogue or part number for that commodity found on the manufacturer's web site or partner commodities list.
- *Commodity code:* indicates the type of commodity and enables the user to select the corresponding specification table:
  - E = Equipment (includes equipment, in addition to the analyser, required to perform each test)
  - B = Kit
  - R = Reagent (includes chemicals)
  - C = Consumable.
  - D = Durable (includes reusable items such as glassware, etc.)
- *Unit of measure (UoM):* the smallest possible unit per pack (e.g. 20 tests per kit).
- *No. of tests per UoM:* details the number of tests a single UoM can perform.
- *No. of tests:* a standard figure of 1000 tests is included for every kit to show how many kits will be needed to perform 1000 tests.
- *No. of basic units required:* shows the number of basic units required (most often the same as the number of tests, especially for kits of individual tests).



- *No. of UoM units required*: number of units required to perform 1000 tests.
- *Shelf-life*: where possible, the manufacturer's shelf-life has been stated. Note that this is the shelf-life from the point of sale NOT from receipt of delivery.
- *Cold/cool chain*: indicates where special shipping and storage environmental conditions are required – specific information must be taken from the manufacturer's product insert.
- *UN hazard code*: this section cannot be completed at this time but may be filled in future reports.
- *Document/package/link*: the URL for more information has been provided where possible.
- *Comment*: additional information deemed pertinent to the product.

Test tables are listed according to type as follows:

#### *IA | Sample Collection and Transport*

This section includes commonly used sample collection methods, including dried blood spot and venepuncture.

#### *IB | HIV RDT and EIA*

This section is divided into currently available HIV RDTs and higher throughput enzyme immunosorbent assays (EIA). RDTs are commonly in use at every laboratory network level whereas enzyme-linked immunosorbent assays (ELISA) are most commonly used at the tertiary (i.e. level III) and central levels.

#### *IC | Nucleic Acid Testing for Viral Load and Early Infant Diagnosis*

These tests include the commonly available, kit-based, quantitative nucleic-acid-based diagnostic tests for viral load and early infant diagnosis and are grouped together, as there is significant overlap between the technologies. These tests are almost exclusively used at the central level and occasionally used at tertiary levels, depending upon infrastructure.

#### *ID | Non-nucleic Acid Testing for Viral Load and Early Infant Diagnosis*

These tests include the commonly available, kit-based, qualitative non-nucleic-acid diagnostic tests for viral load and early infant diagnosis and are grouped together, as there is significant overlap between the technologies. These tests are almost exclusively used at the central and (occasionally) tertiary levels.

#### *IE | CD4 Enumeration*

A range of flow cytometers is included from very high throughput systems used at the tertiary and central levels through to medium throughput, point-of-care and dual-purpose CD4/haematology analysers.

Some tests are run on a specific analyser, for example a flow cytometer. Where an analyser is used in the testing process, the test table is preceded by an analyser table that provides the following information:

- name of the analyser
- description
- pre-installation requirements
- operating conditions

- items supplied with the analyser
- required accessories
- optional accessories
- throughput
- installation
- training
- maintenance/calibration
- URL.

## **Section II | Specifications**

The specification section is divided according to commodity type: equipment, kits, reagents, consumables and durables. Each item is listed in the specification table according to the item number.

### *IIA | Equipment*

Equipment specifications include information on the following:

- item number
- catalogue number
- item description/specification
- required accessory
- optional accessory
- installation, training, maintenance, service and calibration requirements
- contract requirements.

### *IIB | Kits*

Kits are listed along with the following:

- item number
- item name
- description/specification
- catalogue number
- pack type
- quantity per pack
- cool/cold chain
- links to existing guidelines
- shelf-life constraints
- additional comments.

### *IIC | Reagents*

Reagents and chemicals are listed along with the following:

- item number
- item name
- description/specification
- catalogue number
- pack type
- quantity per pack
- cool/cold chain
- links to existing guidelines
- shelf-life constraints.

### *IID | Consumables*

Information on consumables includes the following:

- item number
- item name
- catalogue number
- description/specification

- pack type
- quantity per pack
- additional comments.

### IIE | Durables

Durables specifications include information on the following:

- item number
- item name
- catalogue number
- description/specification
- pack type
- required accessory.

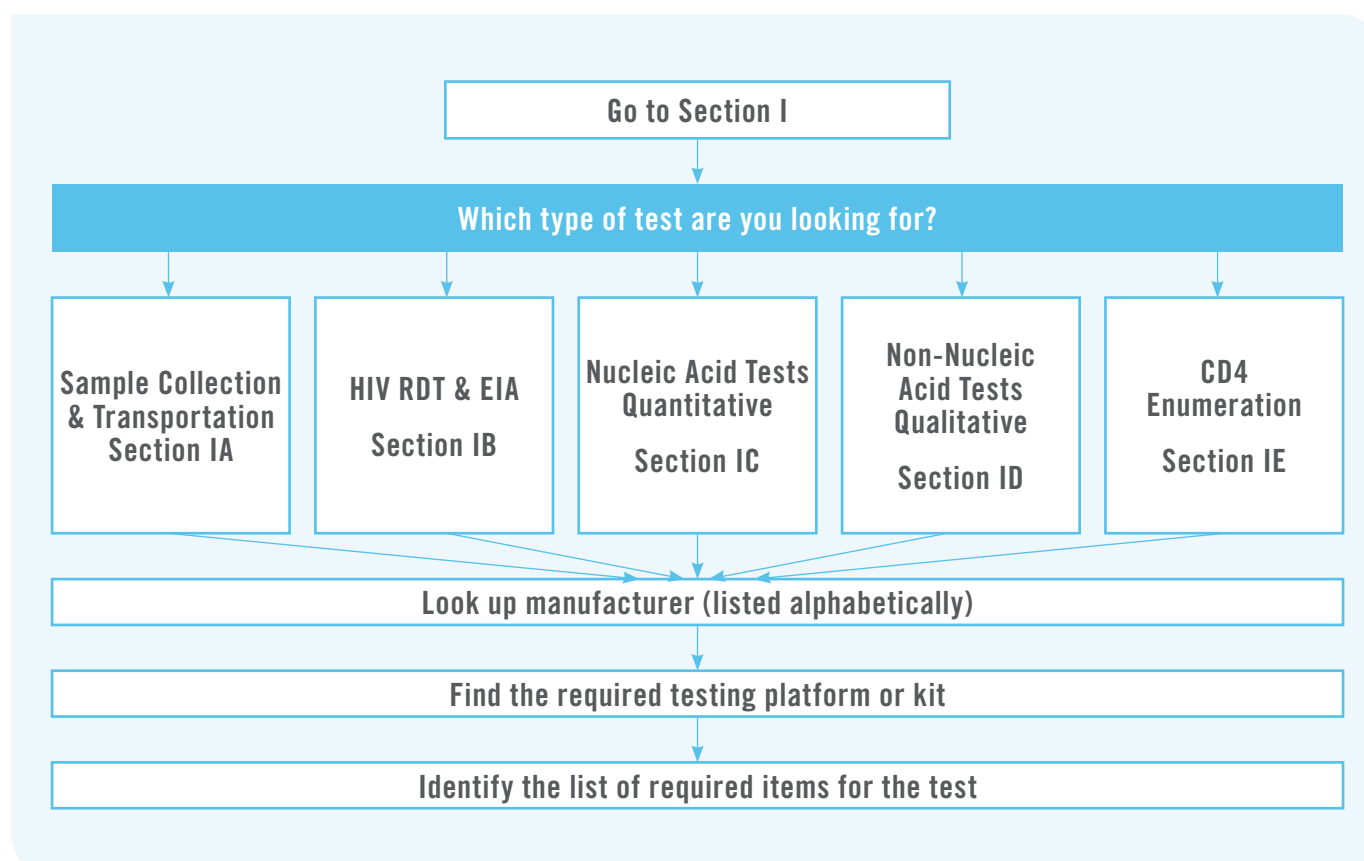
## 9. HOW TO USE THIS TOOL

The information contained within the tool may be used in a variety of ways, to:

- define the required commodities for a particular test;
- find the approximate quantity of each commodity per test;
- identify laboratory commodity specifications and gather useful information on quality, installation, service requirements, shipping, storage, handling and shelf-life;
- to determine the numbers of packs required to perform 1000 tests.

### 9.1 Flow chart for identifying the required types of commodity for a particular test using the test tables

The following flow chart explains the best way to find the information you are looking for:



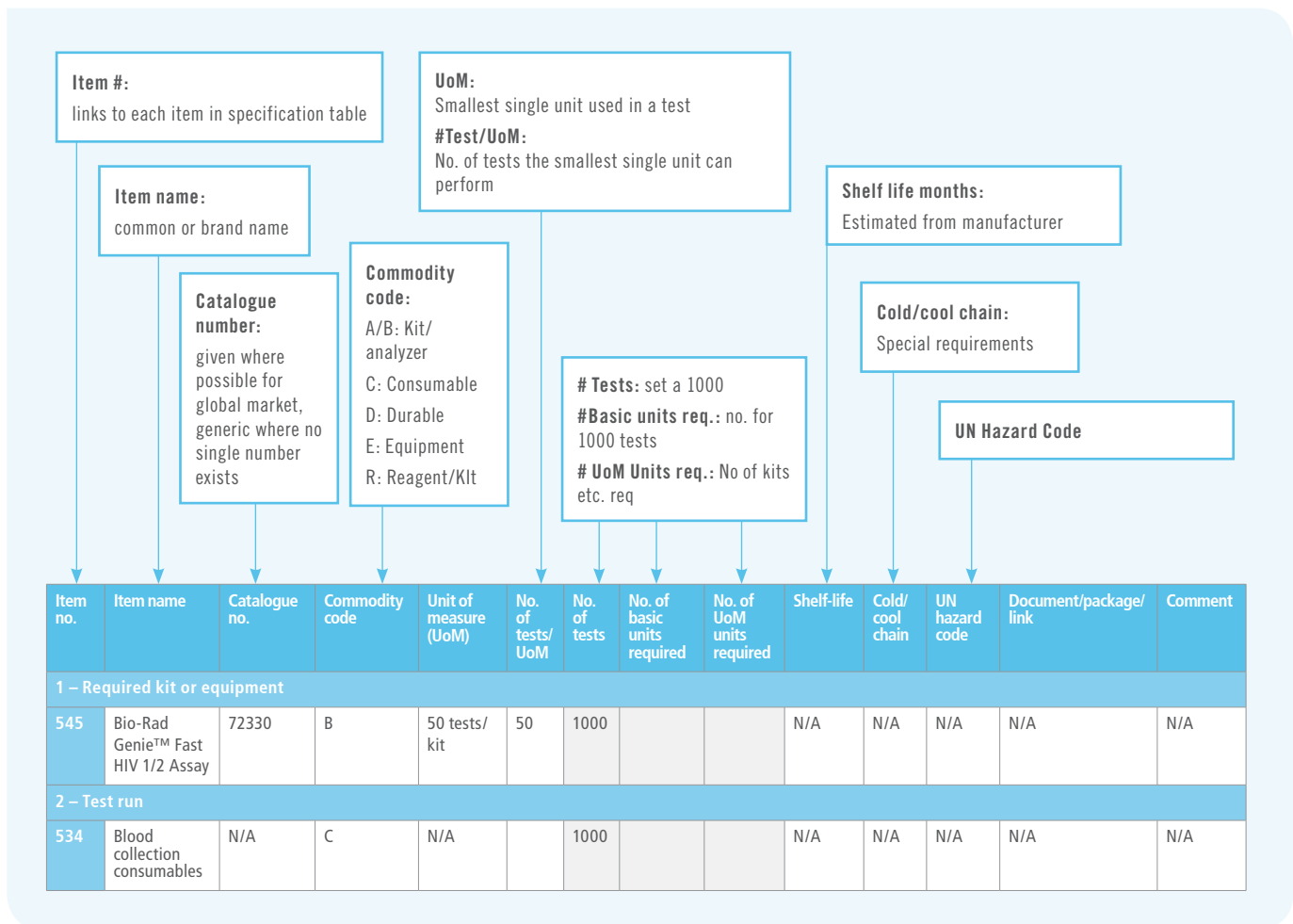
#### 9.1 Why do I need to know the types of commodities for each test?

This information is particularly useful if you want to create a list of standard commodities required for each test and/or at each level of service. You can also use it as the starting point for guidance on commodity quantities – remember that your standard operating procedures may differ from those of the manufacturers' package inserts so be prepared to create your own tables of commodities.

Finally, you may want to use this information to arrange workflow in your laboratory, i.e. to ensure all the required items are available close to the testing bench, within easy reach of the tester.

## 9.2 Information contained within the test tables

When you find the table displaying the commodities for the test you want, you will see the following information:



### 9.2a Will quantification data tell us exactly how much of each commodity to procure?

No, commodity data per test will not tell you how much of each commodity to procure. You will need to multiply the quantities of commodities by the average number of tests per facility and scale up based on the numbers of facilities. Once you have calculated the total quantities of commodities, you will need to make important adjustments to the numbers. To do this, follow the recommended quantity adjustment steps in Section 11.0.

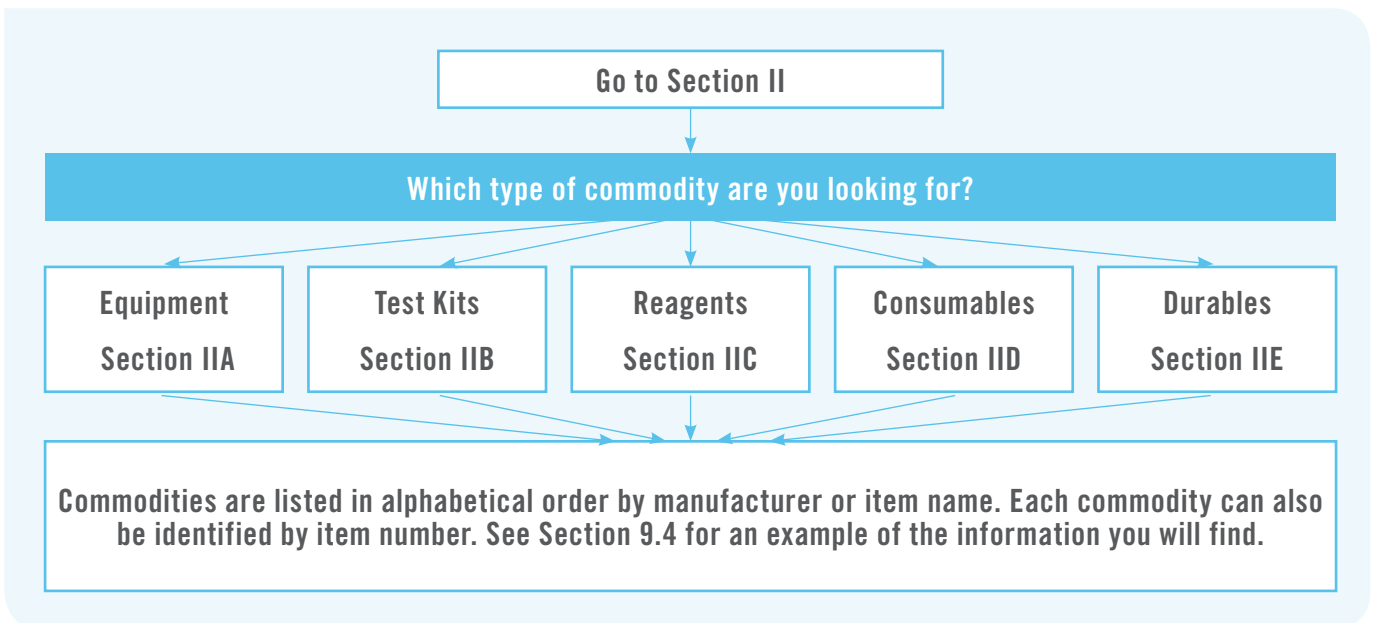
### 9.2b. Why are items arranged by item type?

Item types are commonly used groupings to distinguish between different kinds of laboratory commodity that may be used, handled and ordered in different ways. These include:

- E = Equipment: machines, analysers, instruments used for or in testing.
- B = Kits: test kits and devices that are used to test for the component of interest.
- R = Reagents and chemicals (solid and liquid), that accompany the test kit.
- C = Consumables: test-specific and general items that are often used once and discarded.
- D = Durables: reusable items such as glassware and plasticware.

It is important to understand the differences between these items, as this is how you will find more information about them in the tool.

## 9.3 Identify specifications for a commodity using the specifications tables



### 9.3a Why are specifications important?

A good specification or product description will ensure the end user gets the correct commodity to perform a test.

Specifications are also important when it is necessary to procure generic, i.e. non-branded, items. Some tests require branded items and these commodities have been listed where necessary.

## 9.4 Information contained within the specifications tables | Example section IIC

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/ pack	Cold/cool chain	Shelf-life (months)
450	Abbott m Sample Preparation System RNA	04J70-24, 02K02-24	RNA sample preparation kit	N/A	96	Unknown	Unknown
451	Abbott m2000rt Optical Calibration Kit	4J71-93	Optical calibration kit for Abbott m2000rt RealTime PCR analyser	Kit		Unknown	Unknown
464	Abbott RealTime HIV-1 Calibrator Kit	6L18-70	Calibrator kit for each new lot of Abbott RealTime HIV-1 Test Kit used	Pack		Yes	Unknown

## 9.5 Working with “scalable units”

It is important to recognize that there are inherent challenges associated with scaling up quantities of laboratory commodities. Unlike pharmaceuticals, some laboratory commodities may be used in multiple platforms or for multiple tests and use/quantities per test may vary by country, region, locality and site, depending upon the prevailing standards employed. A classic example is provided by blood collection supplies where needle holders

are difficult to quantify and often result in an overwhelming excess of the commodity. Such wastage must be avoided at all costs. It is therefore essential that national programmes identify laboratory commodity quantities required according to the site and country requirements. This tool can help guide the decision-making process on quantities but **should never** be used as a tool for quantification, which requires a much greater level of complex input data. Estimates for the number of commodities required for 1000 tests are shown in the three shaded columns of the table in Section 9.2.

# 10. CONTROLS

Please note that, where possible, controls have been included in quantifications. These are clearly indicated in the tables. For controls performed per a specific time period, for example HIV RDTs (where controls

are recommended for daily use in addition to kit lot number changes and incidents), the tool only indicates the requirement for the control material and not the quantity.

# 11. QUANTIFICATION ADJUSTMENT STEPS

Quantification should always be based on more than one source of information. For detailed technical information on quantification of laboratory commodities, the user is referred to other tools that have been developed for this purpose. The most recent ones are:

**USAID | DELIVER PROJECT:** Quantification of health commodities: laboratory commodities companion guide forecasting consumption of laboratory commodities accessed at: ([http://deliver.jsi.com/dlvr\\_content/resources/allpubs/guidelines/QuanHealCommLabo.pdf](http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/QuanHealCommLabo.pdf)).<sup>17</sup>

**USAID | DELIVER PROJECT.** *The logistics handbook: a practical guide for the supply chain management of health commodities.* Arlington, VA, USAID | DELIVER, Task Order 1. 2011.<sup>19</sup>

The following are recommended sources of information that can be used to perform quantification:

- *Quantification by test*  
This tool provides quantification data by test according to manufacturers' recommendations and package inserts. Programmes should refine this information to suit standards employed at the country, regional or site level.
- *Consumption data*  
These data are obtained from historical data on quantities of a product used and are typically reported by sites per month or per quarter. Daily consumption data can be found in laboratory registers and aggregated consumption data can be found in monthly and annual facility-level and programme-level reports where a logistics management and

information system captures these data from service delivery points.

- *Service statistics data*  
These historical data, captured at the programme level or facility level, include the number of patient visits to facilities, services provided, or people who received a specific testing service within a given time period. **These data must be used with caution, as they do not capture repeat testing, quality control and training tests at the laboratory level.**
- *Demographic/morbidity data*  
These data reflect the proportion of a specific population estimated to be affected and estimates of the number of episodes of a given health condition that will occur in a common denominator of the population. **These data must be used with caution, as they do not capture repeat testing, quality control and training tests at the laboratory level.**
- *Programme/target data*  
These data are not related to the actual numbers of patients being served, volume of commodities being used, or capacity of the supply chain to manage the volume of commodities required. These data are best used for advocacy and resource mobilization, not for procurement of commodities. **Avoid using these data in laboratory commodity quantification.**

Once the quantification per test has been performed, it is recommended<sup>12</sup> that the following quantification adjustment steps be employed:

- product wastage
- lead time stock
- buffer stock.

## 11.1 Product wastage

Laboratory testing always results in some wastage of supplies as a result of spillage, incorrect measurement, expired products or other damage. In an effective process safety management system, wastage should be minimized and should never exceed 3–10% of the total quantity required.

## 11.2 Lead time stock

Lead time stock is the stock kept on hand and used between the times the new stock is ordered and received and available for use.

Lead time is the amount of time (in months) it takes from the issue of an order until the commodity is received and available for use. Examples of lead times include:

- *The central level*  
The time central store issues an order until the supply has been received in the central store and is ready for distribution to the site. Note that lead time includes all steps (e.g. ministry of health approvals, finance release, customs inspections, delivery to the central store, etc.).
- *The laboratory level*  
The time the laboratory manager issues an order until the supply has been received in the laboratory store and is ready for use. Note that lead time includes all steps (e.g. district/central level approvals, finance release, customs inspections, delivery to the central store, distribution to the laboratory, accessioning and receipt by the laboratory store, etc.).

It is crucial that the central and site levels maintain a record of the lead time for every laboratory commodity. The lead time will likely differ for different types of commodity (e.g. expensive items may require longer approval times, short shelf-life items may have to be expedited).

To calculate lead time stock:

Total lead time stock required for each laboratory commodity:

Lead time stock required = average monthly requirement × number of months.

## 11.3 Buffer stock

This is an estimate of stock kept on hand to protect against:

- delayed deliveries
- markedly increased usage/demand
- other unexpected events.

Accuracy of buffer stock requirements depends upon close monitoring of stock levels and incidents over a period of time. Monitoring should be continual and the quality of buffer stock requirement data will increase over time.<sup>20</sup>

The total buffer stock is measured in months:

Buffer stock required = annual requirement/12 (= monthly requirements) × number of months buffer stock is required.

Logisticians and laboratory managers should maintain records for every laboratory commodity.

In view of the link between HIV and TB, specifications for TB laboratory items were recommended to be referred to in this tool. WHO has already published the specifications for TB laboratory equipment and supplies in the "*Guidance for countries on the specifications for managing TB laboratory equipment and supplies*" which can be found under Section 3 "*Logistics/Supply Management Tool*" at the following link: [http://www.who.int/tb/laboratory/tool\\_set/en/index.html](http://www.who.int/tb/laboratory/tool_set/en/index.html).<sup>21</sup>

WHO recently published a manual for procurement of diagnostics and related laboratory items and equipment. It provides detailed information which is complementary to this tool. For more information the users are referred to the following link: [http://www.who.int/diagnostics\\_laboratory/procurement/131024\\_procurement\\_of\\_diagnostics\\_finalversion.pdf](http://www.who.int/diagnostics_laboratory/procurement/131024_procurement_of_diagnostics_finalversion.pdf)<sup>22</sup>

Other useful information in the procurement process is the WHO list of prequalified diagnostic products<sup>23</sup>, the list of diagnostics eligible to tender for procurement by WHO<sup>24</sup> and the list of diagnostic test kits for HIV classified according to the Global Fund Quality Assurance Policy and HIV equipment prequalified by WHO<sup>25</sup>.



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# SECTIONS

## SECTION IA: COMMODITIES BY SAMPLE COLLECTION: DRIED BLOOD SPOT

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
264	Dried blood spot collection cards	Generic	B	100 cards/pack	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
332	Humidity indicator card	Generic	C	100 cards/pack	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
366	Silica gel packs	Generic	C	100 packs/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
362	Bag, sealable plastic specimen	Generic	C	100 bags/pack	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
267	Forceps, non-metallic	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
239	Bag, biohazardous wastes	Generic	C	100 bags/pack		1000			N/A	N/A	N/A	N/A	N/A
263	Dressing/adhesive plaster/band aid strip	Generic	C	1 roll/pack		1000			N/A	N/A	N/A	N/A	N/A
368	Swab, 70% alcohol	Generic	C	100 swabs/box	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
266	Fine-tip marker pen (black)	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
270	Gloves, medium	Generic	C	100 gloves/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
338	Lancet, infant	Generic	C	100 lancets/box	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
392	Dried blood spot card drying rack	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
402	Laboratory coat, medium	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
393	Goggles/eye protection	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IA: COMMODITIES BY SAMPLE COLLECTION: HEEL/FINGERSTICK

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
251	Capillary tubes (EDTA)	Generic	C	50 tubes/box	50	1000	1000	20	18 months	Yes	N/A	N/A	N/A
239	Bag, biohazardous wastes	Generic	C	100 bags/pack		1000			N/A	N/A	N/A	N/A	N/A
263	Dressing/adhesive plaster/band aid strip	Generic	C	1 roll/pack		1000			N/A	N/A	N/A	N/A	N/A
368	Swab, 70% alcohol	Generic	C	100 swabs/box	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
266	Fine-tip marker pen (black)	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
335	Labels, adhesive (for labelling tubes/containers)	Generic	C	100 labels/roll	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
270	Gloves, medium	Generic	C	100 gloves/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
336	Lancet, 21G	Generic	C	100 lancets/pack	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
402	Laboratory coat, medium	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
393	Goggles/eye protection	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
408	Rack, test tubes, 14-mm diameter	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IA: COMMODITIES BY SAMPLE COLLECTION: VENOUS BLOOD

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
372	Tourniquet, adult	Generic	C	1 unit		1000			N/A	N/A	N/A	NA	N/A
241	Blood collection needle, 21G	Generic	C	20 needles/box	20	1000	1000	50	N/A	N/A	N/A	N/A	N/A
240	Needle holder	Generic	C	250 needle/holders		1000			N/A	N/A	N/A	N/A	N/A
270	Gloves, medium	Generic	C	100 gloves/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
335	Labels, adhesive (for labelling tubes/containers)	Generic	C	100 labels/roll	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
266	Fine-tip marker pen (black)	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
368	Swab, 70% alcohol	Generic	C	100 swabs/box	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
242	Blood collection tubes (EDTA, lavender)	Generic	C	100 tubes/pack	100	1000	1000	10	N/A	Yes	N/A	<a href="http://gssh.co/wi0T66">http://gssh.co/wi0T66</a>	N/A
263	Dressing/adhesive plaster/band aid strip	Generic	C	1 roll/pack		1000			N/A	N/A	N/A	N/A	N/A
364	Sharps container, medium	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
239	Bag, biohazardous wastes	Generic	C	100 bags/pack	50	1000			N/A	N/A	N/A	N/A	N/A
268	Gauze pad	Generic	C	100 pads/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
402	Laboratory coat, medium	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
409	Scissors	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
405	Phlebotomy chair, with arm rest	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
406	Phlebotomy grips (for patients to squeeze)	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
408	Rack, test tubes, 14-mm diameter	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
393	Goggles/eye protection	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: ACON Biotech MaxLINE HIV 1/2/O Tri-line

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
553	Acon Biotech MaxLINE HIV 1/2/O Tri-line	AVTUB-30	B	30 tests/kit	30	1000	1000	34	N/A	Unknown	N/A	N/A	N/A
2 – Test run													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box	50	1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
17	Centrifuge, benchtop, non-refrigerated	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: ALERE/Chembio Clearview® COMPLETE HIV 1/2**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf -life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
542	Alere/Chembio Clearview® COMPLETE HIV 1/2	N/A	B	25 tests/kit	25	1000	1000	40	N/A	No	N/A	N/A	N/A
<b>2 – Test run</b>													
268	Gauze pad	Generic	C	100 pads/box		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
368	Swab, 70% alcohol	Generic	C	100 swabs/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
541	Alere/Chembio Clearview® HIV Reactive/Non-reactive Controls	92112	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: ALERE/Chembio Clearview® HIV 1/2 STAT-PAK

Item no.	Item name	Catalogue no.	Commodity Code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
540	Alere/Chembio Clearview® HIV 1&2 STAT-PAK	92110	B	20 tests/kit	20	1000	1000	50	N/A	No	N/A	N/A	N/A
2 – Test run													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
541	Alere/Chembio Clearview® HIV Reactive/Non-reactive Controls	92112	R	N/A		1000			N/A	N/A	N/A	N/A	N/A



## SECTION IB: HIV RDT & EIA: Alere Determine™ HIV-1/2 Ag/Ab Combo

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
200	Alere Determine™ HIV-1/2 Ag/Ab Combo (100)	7D2647	B	100 tests/kit	100	1000	1000	10	12 months	No, store between 2° – 30 °C	N/A	<a href="http://gssh.co/1cG55gh">http://gssh.co/1cG55gh</a>	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
252	Alere Capillary Tubes (EDTA)	7D2227	C	100 tubes/pack	100	1000	1000	10	12–18 months	Yes	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
349	Pipette tip, 5–20 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
40	Pipette/pipettor 20	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
199	Alere Determine™ Chase Buffer	7D2247	R	ml/bottle		1000			12–18 months	Yes	N/A	N/A	N/A
<b>3 – Control</b>													
476	Alere HIV RDT Controls	7D2626	R	Kit	100	1000		10	N/A	Yes, store at 4°C	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: Alere Determine™ HIV-1/2 Serum/plasma (20 tests/kit)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
201	Alere Determine™ HIV-1/2 (20)	7D2346	B	20 tests/kit	20	1000	1000	50	12 months	No, store between 2° – 30 °C	N/A	<a href="http://gssh.co/15zrKBP">http://gssh.co/15zrKBP</a>	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			12–18 months	Yes	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
476	Alere HIV RDT Controls	7D2626	R	N/A	100	1000		10	N/A	Yes, store at 4°C	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: Alere Determine™ HIV-1/2 Serum/Plasma (100 tests/kit)**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
200	Alere Determine™ HIV-1/2 Ag/Ab Combo (100)	7D2647	B	100 tests/kit	100	1000	1000	10	12 months	No, store between 2° – 30 °C	N/A	<a href="http://gssh.co/15zrkBP">http://gssh.co/15zrkBP</a>	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
476	Alere HIV RDT Controls	7D2626	R	N/A	100	1000		10	N/A	Yes, store at 4°C	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: Alere Determine™ HIV-1/2 Whole Blood (20 tests/kit)

Item #	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
203	Alere Determine™ HIV-1/2 WB20 (20)	7D2352	B	20 tests/kit	20	1000	1000	50	12 months	No, store between 2° – 30 °C	N/A	<a href="http://gssh.co/15zrKBP">http://gssh.co/15zrKBP</a>	N/A
2 – Test run													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
252	Alere Capillary Tubes (EDTA)	7D2227	C	100 tubes/pack	100	1000	1000	10	12–18 months	Yes	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
199	Alere Determine™ Chase Buffer	7D2247	R	ml/bottle		1000			12–18 months	Yes	N/A	N/A	N/A
3 – Control													
476	Alere HIV RDT Controls	7D2626	R	N/A	100	1000		10	N/A	Yes, store at 4°C	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: Alere Determine™ HIV-1/2 Whole Blood (100 tests/kit)**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
202	Alere Determine™ HIV-1/2 (100)	7D2347	B	100 tests/kit	100	1000	1000	10	12 months	No, store between 2° – 30 °C	N/A	<a href="http://gssh.co/15zrKBP">http://gssh.co/15zrKBP</a>	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
252	Alere Capillary Tubes (EDTA)	7D2227	C	100 tubes/pack	100	1000	1000	10	12–18 months	Yes	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
199	Alere Determine™ Chase Buffer	7D2247, 7D2243	R	ml/bottle		1000			12–18 months	Yes	N/A	N/A	N/A
<b>3 – Control</b>													
476	Alere HIV RDT Controls	7D2626	R	N/A	100	1000		10	N/A	Yes, store at 4°C	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: Alere/Organics Ltd ImmunoComb® HIV 1&amp;2 Bispot

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
190	Alere ImmunoComb® HIV 1&2 Bispot	60432002	B	36 tests/kit	36	1000	1000	28	N/A	Yes	N/A	<a href="http://gssh.co/15zusHI">http://gssh.co/15zusHI</a>	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
409	Scissors	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
476	Alere HIV RDT Controls	7D2626	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: AniLabsystems Ltd HIV EIA - 96 Well**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
188	AniLabsystems Ltd ELISA – 96-well (1 plate)	61 11 011	B	96 plates/pack	88	1000	1000	12	N/A	Yes	N/A	<a href="http://bit.ly/vr6G60">http://bit.ly/vr6G60</a>	Controls included in kit
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
347	Pipette tip, 100–1000 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
375	Tube, microcentrifuge, 1.0 ml, with caps	Generic	C	tubes/pack		1000			N/A	N/A	N/A	N/A	N/A
389	Bottle, dispensing/wash	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
394	Graduated cylinder, 1000 ml	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
107	Water, distilled	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: Biolytical Insti HIV-1/ HIV-2 Antibody Test (without support materials)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of test per UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/Link	Comment
<b>1 – Required kit or equipment</b>													
550	bioLytical INSTI™ HIV-1/HIV-2 Antibody Test (with support materials)	90-1022	B	48 tests/kit	48	1000	1000	21	N/A	No	N/A	<a href="http://gssh.co/1cGZBrx">http://gssh.co/1cGZBrx</a>	N/A
<b>2 – Test run</b>													
268	Gauze pad	Generic	C	100 pads/box		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
552	bioLytical HIV RDT Controls	80-1037	R	8 tests/kit		1000			N/A	Yes	N/A	N/A	N/A
<b>1 – Required kit or equipment</b>													
551	bioLytical INSTI™ HIV-1/HIV-2 Antibody Test (for laboratory use only)	90-1021	B	48 tests/kit	48	1000	1000	21	N/A	No	N/A	N/A	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
552	bioLytical HIV RDT Controls	80-1037	R	8 tests/kit		1000			N/A	Yes	N/A	N/A	N/A



## SECTION IB: HIV RDT & EIA: Bionor™ HIV-1&2 Confirmatory Test

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
535	Bionor™ HIV-1&2 Confirmatory Test	Unknown	B	250 tests/kit	250	1000	1000	4	12	No	N/A	<a href="http://gssh.co/1efw8GX">http://gssh.co/1efw8GX</a>	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
536	Bionor™ testing station	Unknown	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: Bio-Rad Genie™ Fast HIV 1/2 Assay

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
545	Bio-Rad Genie™ Fast HIV 1/2 Assay	72330	B	50 tests/kit	50	1000			N/A	N/A	N/A	N/A	N/A
2 – Test run													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT & EIA: Biorad Multispot HIV-1/HIV-2 Rapid Test

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
537	Biorad Multispot HIV-1/HIV-2 Rapid Test	25228	B	50 tests/kit	50	1000	1000	20	12	Yes	N/A	N/A	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
342	Paper Towels, 2-ply, 3-part Fanfold	2016604	C	1 roll		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
377	Tubes, test, 12 mm x 75 mm, with caps	Generic	C	100 tubes/pack		1000			N/A	N/A	N/A	N/A	N/A
408	Rack, test tubes, 14-mm diameter	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
531	Sodium hypochlorite solution (0.5%)	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: Calypte Aware™ HIV-1/2 BSP

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
532	Calypte Aware™ HIV-1/2 BSP	Unknown	B	50 tests/kit	50	1000	1000	20	N/A	N/A	N/A	N/A	N/A
2 – Test run													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
533	Calypte Aware™ HIV-1/2 BSP controls	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT & EIA: Calypte AWARE™ HIV-1/2 OMT

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
539	Calypte Aware™ HIV-1/2 OMT	Unknown	B	50 tests/kit	50	1000	1000	20	N/A	No	N/A	N/A	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
533	Calypte Aware™ HIV-1/2 BSP controls	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: Chembio HIV 1/2 Stat-Pak®

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
204	Chembio HIV 1/2 Stat-Pak®	HIV101	B	20 tests/kit	20	1000	1000	50	N/A	No	N/A	N/A	N/A
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
349	Pipette tip, 5–20 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
40	Pipette/pipettor 20	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: Chembio HIV 1/2 Stat-Pak® dipstick**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
206	Chembio HIV 1/2 Stat-Pak® Dipstick	HIV303	B	30 tests/kit	30	1000	1000	34	24 months	No	N/A		Need lancet (and alcohol swab), OR a test tube
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
375	Tube, microcentrifuge, 1.0 ml, with caps	Generic	C	Tubes/pack	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
407	Rack, test tubes, 0.5 ml/1.5 ml/2.0 ml centrifuge	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: CS Innovation EZ-TRUST™ Rapid Anti-HIV (1&amp;2)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
543	CS Innovation EZ-TRUST™ Rapid Anti-HIV (1&2)	Unknown	B	Unknown kit		1000			N/A	No	N/A	<a href="http://gssh.co/17P4klr">http://gssh.co/17P4klr</a>	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A



**SECTION IB: HIV RDT & EIA: EY Laboratories Inc. InstantCHEK™ HIV 1+2 (40 tests)**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
215	EY Laboratories Inc. InstantCHEK™ HIV 1+2 (40)	8-1003-40	B	40 tests/kit	40	1000	1000	25	12–15 months	No	N/A		Controls included
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: EY Laboratories Inc. InstantCHEK™ HIV 1+2 (100 tests)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
214	EY Laboratories Inc. InstantCHEK™ HIV 1+2 (100)	8-1003-100	B	100 tests/kit	100	1000	1000	10	12–15 months	No	N/A		Controls included
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: Bio-Rad Genscreen™ ULTRA HIV Ag-Ab (96 tests)**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
563	Bio-Rad Genscreen™ ULTRA HIV Ag-Ab (96)	72386	B	96-well kit	96	1000	1000	11	N/A	Yes	N/A	<a href="http://gssh.co/15E90dq">http://gssh.co/15E90dq</a>	3 controls required for each test batch, therefore 96 tests includes control runs
<b>2 – Test run</b>													
107	Water, distilled	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
106	Sodium hypochlorite solution (5–10%)	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
342	Paper Towels, 2-ply, 3-part Fanfold	2016604	C	1 roll		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
360	Pipette, serological, 5.0 ml	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
361	Reagent reservoirs for ELISA	Generic	C	units/pack		1000			N/A	N/A	N/A	N/A	Pack size varies depending upon manufacturer
389	Bottle, dispensing/wash	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
394	Graduated cylinder – 1000 ml	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
30	Incubator, general purpose	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
32	Microplate/ELISA plate reader	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
33	Microplate/ELISA plate washer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: Genscreen Ultra HIV Ag-Ab (480 Tests)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
564	Bio-Rad Genscreen™ ULTRA HIV Ag-Ab (480)	72388	B	480-well kit	96	1000	1000	11	N/A	Yes	N/A	<a href="http://gssh.co/15E90dq">http://gssh.co/15E90dq</a>	3 controls required for each test batch, therefore 480 tests includes control runs
2 – Test run													
107	Water, distilled	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
106	Sodium hypochlorite solution (5–10%)	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
342	Paper Towels, 2-ply, 3-part Fanfold	2016604	C	1 roll		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
360	Pipette, serological, 5.0 ml	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
361	Reagent reservoirs for ELISA	Generic	C	units/pack		1000			N/A	N/A	N/A	N/A	Pack size varies depending upon manufacturer
389	Bottle, dispensing/wash	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
394	Graduated cylinder –1000 ml	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
30	Incubator, general purpose	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
32	Microplate/ELISA plate reader	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
33	Microplate/ELISA plate washer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: Hema Diagnostic Systems Rapid 1-2-3® HEMA EXPRESS®**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
560	Hema Diagnostic Systems Rapid 1-2-3® HEMA EXPRESS®	HIV-0207-WB	B	50 tests/kit	50	1000	1000	20	N/A	No	N/A	N/A	N/A
<b>2 – Test run</b>													
268	Gauze pad	Generic	C	100 pads/box		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: Trinity Biotech PLc Uni-Gold™ Recombigen® HIV

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
558	Trinity Biotech plc Uni-Gold™ Recombigen® HIV	1206506	B	20 tests/kit	20	1000	1000	50	N/A	No	N/A	<a href="http://bit.ly/vdixbg">http://bit.ly/vdixbg</a>	N/A
2 – Test run													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: Trinity Biotech plc Uni-Gold™ HIV**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
229	Trinity Biotech plc Uni-Gold™ HIV	1206502	B	20 tests/kit	20	1000	1000	50	N/A	Yes	N/A	<a href="http://bit.ly/vdixbg">http://bit.ly/vdixbg</a>	N/A
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: SD Bioline HIV-1/2 3.0 Serum/Plasma

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
565	SD Bioline HIV-1/2 3.0	03FK10	B	30 tests/kit	30	1000	1000	34	N/A	1–30°C	N/A	N/A	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	Required if using whole blood
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000	1000		N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A



**SECTION IB: HIV RDT & EIA: SD Bioline HIV-1/2 3.0 Whole Blood**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
565	SD Bioline HIV-1/2 3.0	03FK16	B	25 tests/kit	25	1000	1000	40	24 months	1–30°C	N/A	N/A	Blood collection supplies included
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000	1000		N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: SD BIOLINE HIV AG/AB COMBO WHOLE BLOOD

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
561	SD Bioline HIV Ag/Ab Combo	03FK35	B	25 tests/kit	25	1000	1000	40	N/A	1–30°C	N/A	N/A	Kit for serum/ plasma. Additional supplies needed for whole blood
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000	1000		N/A	N/A	N/A	N/A	N/A
3 – Control													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: SD BIOLINE HIV AG/AB COMBO SERUM/PLAMSA**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
<b>1 – Required kit or equipment</b>													
562	SD Bioline Ag/Ab Combo	03FK30	B	30 tests/kit	30	1000	1000	34	N/A	1–30°C	N/A	N/A	Kit for serum/plasma. Additional supplies needed for whole blood
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000	1000		N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: KHB SHANGHAI KEHUA BIO-ENGINEERING CO LTD HIV 1+2 ANTIBODY (COLLOIDAL GOLD)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
198	KHB Shanghai Kehua Bio-engineering Co. Ltd HIV (1+2) Antibody (Colloidal Gold)	KH-T02	B	50 tests/kit	50	1000	1000	20	15 months	No	N/A		N/A
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
349	Pipette tip, 5–20 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
44	Pipette/pipettor, multichannel 10–100	Generic	E	1 pipette		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
106	Sodium hypochlorite solution (5–10%)	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
107	Water, distilled	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: SHANGHAI KEHUA BIOENGINEERING CO ANTI-HIV 1 + 2 ANTIBODIES ELISA DIAGNOSTIC**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
191	KHB Shanghai Kehua Bio-engineering Co. Ltd Anti-HIV 1+2 ELISA	KH-T-10	B	96-well kit		1000			N/A	No	N/A		N/A
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
342	Paper Towels, 2-ply, 3-part Fanfold	2016604	C	1 roll		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
360	Pipette, serological, 5.0 ml	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
361	Reagent reservoirs for ELISA	Generic	C	units/pack		1000			N/A	N/A	N/A	N/A	N/A
389	Bottle, dispensing/wash	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
394	Graduated cylinder, 1000 ml	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
30	Incubator, general purpose	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
32	Microplate/ELISA plate reader	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
33	Microplate/ELISA plate washer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: SAVYON DIAGNOSTICS HIVSAV 1/2/0 RAPID SEROTEST™

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
547	Savyon Diagnostics HIVSav 1/2/0 Rapid Serotest™	B41112	B	50 tests/kit	50	1000	1000	20	N/A	No	N/A	N/A	N/A
2 – Test run													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: QUALPRO DIAGNOSTICS RETROCHECK HIV 1&2**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
224	Qualpro Diagnostics Retrocheck HIV 1&2	HIV-110050	B	50 tests/kit	50	1000	1000	20	N/A	N/A	N/A	<a href="http://bit.ly/t82MH6">http://bit.ly/t82MH6</a>	N/A
<b>2 – Test run</b>													
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: PREMIER MEDICAL CORPORATION LTD FIRST RESPONSE HIV 1-2-0

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
544	Premier Medical Corporation Ltd, First Response HIV 1-2-0	Unknown	B	N/A		1000			N/A	N/A	N/A	N/A	N/A
2 – Test run													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
349	Pipette tip, 5–20 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
467	Tubes, test, 13 mm	Generic	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
40	Pipette/pipettor 20	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A



**SECTION IB: HIV RDT & EIA: ORGENICS LTD DOUBLECHECKGOLD™ HIV 1&2 (100)**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
208	Organics Ltd DoubleCheckGold™ HIV 1&2 (100)	70633100	B	100 tests/kit	100	1000	1000	10	N/A	Yes	N/A	<a href="http://bit.ly/tm4414">http://bit.ly/tm4414</a>	N/A
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
349	Pipette tip, 5–20 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
40	Pipette/pipettor 20	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: ORASURE TECHNOLOGIES INC. ORAQUICK ADVANCE® RAPID HIV-1/2 ANTIBODY

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
217	Orasure Technologies Inc. OraQuick ADVANCE® Rapid HIV-1/2 Antibody	Unknown	B	100 tests/kit	100	1000	1000	10	N/A	Yes	N/A	<a href="http://bit.ly/tLSPSk">http://bit.ly/tLSPSk</a>	N/A
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
519	Orasure Technologies Inc. OraQuick ADVANCE® Rapid HIV-1/2 Antibody	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: MEDINOSTICS INTERNATIONAL HIV 1 / 2 GOLD RAPID SCREEN TEST**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life (months)	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
554	Medinostics International HIV 1/2 Gold Rapid Screen Test	Unknown	B	N/A		1000			N/A	N/A	N/A	N/A	N/A
<b>2 – Test run</b>													
268	Gauze pad	Generic	C	100 pads/box		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: MEMMIRA REVEAL™ HIV

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
<b>1 – Required kit or equipment</b>													
555	Memmira Reveal™ Rapid HIV Antibody Test (Reveal HIV)	815311000768	B	N/A		1000			18 months	No	N/A	N/A	<a href="http://www.medmira.com/images/uploads/RIABPIS0001EN_Rev_2_2_(print_11x17)_Reveal_International_consolidated_PI_(EN).pdf">http://www.medmira.com/images/uploads/RIABPIS0001EN_Rev_2_2_(print_11x17)_Reveal_International_consolidated_PI_(EN).pdf</a>
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: MEDINOSTICS INTERNATIONAL HIV 1/2 GOLD RAPID SCREEN TEST**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
554	Medinostics International HIV 1/2 Gold Rapid Screen Test	Unknown	B	N/A		1000			N/A	N/A	N/A	N/A	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: JAL INNOVATION ICARE ONE STEP ANTI-HIV(1&amp;2) TRI-LINE TEST

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
549	JAL Innovation, iCARE HIV Tri-line Rapid Screen	Unknown	B	Kit		1000			N/A	No	N/A	N/A	N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tips, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: JAL INNOVATION ICARE HIV 1&2**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
548	JAL Innovation, iCARE HIV Tri-line Rapid Screen	IT1001F	B	Kit		1000			N/A	N/A	N/A	N/A	N/A
<b>2 – Test run</b>													
268	Gauze pad	Generic	C	100 pads/box		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: J. MITRA &amp; CO. PVT. LTD HIV TRI-DOT (200)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
227	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT	IR130200	B	200 tests/kit	200	1000	1000	5	15 months	Yes	N/A	N/A	N/A
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
517	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT, negative control	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
518	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT, positive control	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A



**SECTION IB: HIV RDT & EIA: J. MITRA & CO. PVT. LTD HIV TRI-DOT (10)**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
225	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT	IR130010	B	10 tests/kit	10	1000	1000	100	15 months	Yes	N/A	<a href="http://bit.ly/uVDmXl">http://bit.ly/uVDmXl</a>	N/A
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
517	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT, negative control	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
518	J. Mitra & Co. Ltd TRI-DOT, positive control	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: J. MITRA &amp; CO. PVT. LTD HIV TRI-DOT (50)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
228	J. Mitra & Co. Ltd TRI – DOT (50)	IR130050	B	50 tests/kit	50	1000	1000	20	15 months	Yes	N/A	<a href="http://bit.ly/uVDmXl">http://bit.ly/uVDmXl</a>	N/A
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
517	J. Mitra & Co. Ltd HIV TRI-DOT, negative control	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
518	J. Mitra & Co. Ltd HIV TRI-DOT, positive control	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: J. MITRA & CO. PVT. LTD HIV TRI-DOT (100)**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
226	J. Mitra & Co. Pvt. Ltd TRI-DOT (100)	IR130100	B	100 tests/kit	100	1000	1000	10	15 months	Yes	N/A	<a href="http://bit.ly/uVDmXl">http://bit.ly/uVDmXl</a>	N/A
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box	50	1000	2000	20	N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
517	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT, negative control	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
518	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT, positive control	Unknown	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IB: HIV RDT &amp; EIA: INTEC PRODUCTS INC. ADVANCED QUALITY™ RAPID ANTI-HIV (1&amp;2) TEST

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
216	InTec Products Inc. ADVANCED QUALITY™ Rapid Anti-HIV(1&2) Test	ITP02002	B	40 tests/kit	40	1000	1000	25	N/A	No	N/A	<a href="http://gssh.co/tWQ4nZ">http://gssh.co/tWQ4nZ</a>	Controls included
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A

**SECTION IB: HIV RDT & EIA: TRINITY BIOTECH PLC UNI-GOLD™ RECOMBIGEN® HIV**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
558	Trinity Biotech plc Uni-Gold™ Recombigen® HIV	1206506	B	20 tests/kit	20	1000	1000	50	N/A	No	N/A		N/A
<b>2 – Test run</b>													
534	Blood collection consumables	N/A	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
460	Controls, HIV negative, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
459	Controls, HIV positive, in-house or purchased	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IC: NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR

Diagnostic characteristics	Description of characteristics
Name of analyser	m2000rt instrument for real-time amplification and detection.
Name of test	Abbott RealTime HIV-1 assay (can be used with one of three methods of sample preparation: (i) manual (for laboratories with low throughput requirements); (ii) automated sample preparation using m24sp instrument (for laboratories with mid-throughput requirements; or (iii) automated sample preparation using m2000sp instrument (for laboratories with high throughput requirements))
Catalogue no.	Manual sample preparation: 6L18-90, 6L18-80, 6L18-70, 2G31-90, 2G31-80, 2G31-70, 4J70-24, 1L68-00, 6L83-00, 9K15-01 m24 sample preparation: 6L18-90, 6L18-80, 6L18-70, 2G31-90, 2G31-80, 2G31-70, 4J70-24, 1L68-00, 6L83-00, 9K15-01, 03N06-01 m2000sp automated sample preparation: 6L18-90, 6L18-80, 6L18-70, 2G31-90, 2G31-80, 2G31-70, 4J70-24, 1L68-00, 6L83-00, 9K15-01, 9K14-02
Description	In vitro PCR assay for quantitation of HIV-1 RNA in plasma over the range of 40 to 10,000,000 copies/mL. It is intended for use as an aid for disease prognosis and for assessment of viral response to antiretroviral treatment. Not for donor screening for HIV-1. Not a diagnostic test to confirm the presence of HIV-1 infection.  This assay is designed to detect Group M subtypes A - H, Group O, and Group N. One copy of HIV-1 RNA is equivalent to $1.7 \pm 0.1$ international units (IU) based on the WHO 1st International Standard for HIV-1 RNA for nucleic acid-based techniques (NIBSC 97/656).  Instrumentation to perform Abbott RealTime HIV-1 assay includes m24 instrument for automated sample preparation (optional), m2000sp instrument for automated sample preparation (optional), and m2000rt instrument for real-time amplification and detection. Package of m2000sp with m2000rt is marketed as the Abbott m2000 RealTime System and provides automation from bar-coded laboratory tube through patient result.
Pre-installation requirements	Suitable for level III and IV laboratories with stable 24-h power
Operating conditions	m2000sp and m2000rt: 15–30°C; 30–80% humidity non-condensing at 30°C or below; 0–2000 m altitude m24: 15–35°C; 5%–80% humidity non-condensing at 30°C or below; 0–2000 m altitude
Items supplied with analyser	Data station, monitor and printer, and bar-code scanner (hand-held in case of m24) are supplied with m24, m2000sp, and m2000rt.
Required accessories	Abbott RealTime HIV-1 m2000 ROW System Combined Application CD-ROM 1L68-09 or higher
Optional accessories	Unknown
Turnaround time	m24: extraction time (incl. loading of instrument) ~ 3.5 hours m2000sp: from 2.5 hours for 24 samples to 5.5 hours for 96 samples m2000rt: Amplification and detection cycle ~ 3 hours.
Capacity (per run)	m24: from 1 to 24 samples m2000sp: 93 patient samples + 3 controls; m2000rt: 93 patient samples + 3 controls
Throughput per technician / per day	m24: up to 48 samples (2 batches of 24 samples) per 8 hour day m2000sp: Up to 192 samples (2 batches of 96 samples) per 8 hour day; m2000rt: Up to 288 samples (sample preparation and extraction can be limiting factor)

## SECTION IC: NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR

Sample needed and stability	m2000sp and m24: Freshly drawn whole blood may be held at 15 – 30° C for up to 6 hours or at 2 – 8° C for up to 24 hours prior to centrifugation. After centrifugation, plasma, which is required for the Abbott RealTime HIV-1 qualitative assay, may be stored at 15 – 30° C for up to 24 hours or at 2 – 8° C for up to 5 days. If longer storage is required, may be stored at -70° C. m2000rt: PCR-ready samples from manual or m2000sp sample preparation/extraction protocol
Sample preparation and protocol complexity	m2000sp automated sample preparation: Moderately complex. Steps include vortexing (assay calibrators, each control and specimens), pipetting, centrifuge, etc). Once 96 well plate is loaded and placed in m2000rt, process is walk away
Reagent stability and storage requirements	Maximum shelf-life upon manufacture: Abbott RealTime HIV-1 Amplification Reagent Kit 2G31-90: 18 months (except for ThermoStable rTth Polymerase Enzyme 56685: Per control date on vendor certificate of analysis) Abbott RealTime HIV-1 Control Kit 2G31-80: 18 months Abbott RealTime HIV-1 Calibrator Kit 2G31-70: 18 months Abbott mSample Preparation SystemRNA Kit 04J70-24: 18 months Reagents, controls, and calibrators must be shipped on dry ice and must be stored at ≤ -10oC when not in use; reagent may be reused up to 3 times within 2 weeks; the Abbott mSample Preparation SystemRNA (4 X 24 Preps) must be stored at 15-30° C
Cost per test	\$25 to \$40 depending on volumes and negotiations with Abbott
Cost per instrument	m2000sp automated sample preparation: \$120000 USD m24: \$90000 USD m2000rt: \$38,000 USD (with m2000sp) – Add \$6,000 USD for all manual extraction items
Installation	Yes
Training	Fully-trained laboratory technician required; dedicated training on instrument
Maintenance/calibration	Routine preventative maintenance required for m2000sp, m24, and m2000rt. In case of breakdown, vendor-trained technician required to repair.
Internal QC	Controls are included as part of reagent kit and required for each preparation run for FDA-approved assays
External QA	m2000rt: Amenable to external QA
URL	<a href="http://www.abbottmolecular.com/products/infectious-diseases/realtime-pcr/hiv-1-assay.html">http://www.abbottmolecular.com/products/infectious-diseases/realtime-pcr/hiv-1-assay.html</a>

## SECTION IC | NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
1 – Required kit or equipment													
449	Abbott Molecular Inc. Abbott RealTime HIV -1 Amplification Reagent Kit	6L18-902G31-90,	B	Kit	96	1000	1000	10	18 months	Yes	N/A	Yes	Store at ≤ -10°C
464	Abbott Molecular Inc. Abbott RealTime HIV -1 Calibrator Kit	2G31-70, 6L18-70	C	Kit	12	1000		83	18 months	Yes	N/A	Yes	Store at ≤ -10°C. The amount of reagents is enough for 12 calibrating events performed occasionally
463	Abbott Molecular Inc. Abbott RealTime HIV -1 Control Kit	2G31-80, 6L18-80	C	Kit	8	1000		125	18 months	Yes	N/A	Yes	Store at ≤ -10°C. The amount of controls is sufficient for 12 runs (up to 1116 specimens)
	Abbott m2000rt instrument	9K15-01	E	N/A	N/A				N/A	N/A	N/A	N/A	N/A
	Abbott m2000sp instrument with software version 2.0 or higher	9K14-02	E	N/A	N/A				N/A	N/A	N/A	N/A	Required if automated sample preparation chosen
	Abbott m24 instrument	03N06-01	E	N/A	N/A				N/A	N/A	N/A	N/A	Required if automated specimen extraction chosen
	Abbott RealTime HIV-1 Application CD-ROM	1L68-00, 6L83-00	E	N/A	N/A				N/A	N/A	N/A	N/A	N/A
2 – Test run													
450	Abbott mSample Preparation Systems <sup>RNA</sup>	4J70-24	C	Kit	96	1000		10	18 months	No	N/A	N/A	N/A
468	Abbott Molecular Inc. Abbott 96 Deep-Well Plate	4J71-30	C	Pack	32	1000		31	N/A	N/A	N/A	N/A	For m2000sp and m24 instruments only
453	96-Well Optical Reaction Plates	4J71-70	C	Pack	20	1000		50	N/A	N/A	N/A	N/A	N/A
455	Abbott Molecular Inc. Abbott Adhesive Cover Applicator	9K3201	C	Unit	1	1000			N/A	N/A	N/A	N/A	Supplied with m2000rt instrument



SECTION IC | NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
469	Abbott Molecular Inc. Abbott Master Mix Tube	4J71-80	C	Pack	150 Tubes/ Caps	1000		7	N/A	N/A	N/A	N/A	For m2000sp and m24 instruments only
454	Abbott Molecular Inc. Abbott Optical Adhesive Covers	4J71-75	C	Pack	100	1000			N/A	N/A	N/A	N/A	N/A
452	Abbott Molecular Inc. Abbott Reaction Vessels, 5 ml	4J71-20	C	Pack	2000	1000		1	N/A	N/A	N/A	N/A	For m2000sp only
474	Abbott Molecular Inc. Abbott Reagent Vessels, 200 ml	4J71-60	C	Pack	90	1000		11	N/A	N/A	N/A	N/A	N/A
	1.4 ml Internal Control Vial	03N19-01	C	N/A	N/A				N/A	N/A	N/A	N/A	For m24 only
	1.4 ml Internal control Vial Cap	03N20-01	C	N/A	N/A				N/A	N/A	N/A	N/A	For m24 only
456	Abbott Molecular Inc. Abbott RealTime Splash- Free Support Base	9K3101	C	Pack	5	1000		200	N/A	N/A	N/A	N/A	N/A
376	Tubes, microcentrifuge, 1.5 ml, screw cap	04G71-50 or generic equivalent	C	N/A					N/A	N/A	N/A	N/A	For manual sample preparation
	Stand, magnetic separator for 5-ml reaction vessels	Generic	D	1 Unit					N/A	N/A	N/A	N/A	For manual sample preparation. Can be ordered as m2000 mSample Preparation System Start Up Kit (02N28-03)
507	Stand, magnetic separator for 1.5-ml tubes	Generic	D	1 unit					N/A	N/A	N/A	N/A	
	Eppendorf PCR Cooler or StrataCooler 96 benchtop cooler	Generic	D	1 unit					N/A	N/A	N/A	N/A	
457	Abbott Molecular Inc. Abbott m2000 Sample Preparation System Start Up Kit	2N28-03	D	N/A		1000			N/A	N/A	N/A	N/A	For manual sample preparation.
	Rack, test tubes 5 ml	Generic	D	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation

## SECTION IC | NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
407	Rack, test tubes, 0.5 ml, 1.5 ml, 2.0 ml centrifuge	Generic	D	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
29	Dry heating block for 5 ml reaction vessels (capable of achieving 50°C)	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
29	Dry heating block for 1.5 ml tubes (capable of achieving 75°C)	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
412, 413	Thermometer	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
46	Timer, digital	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
	Plate, 96 well polypropylene	Generic	C	N/A					N/A	N/A	N/A	N/A	For manual sample preparation (optional)
17	Centrifuge, benchtop, non-refrigerated	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
472	Applicator, cotton-tip	Generic	C			1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiples sizes, powder-free	Generic	C	100 gloves/ box		1000			N/A	N/A	N/A	N/A	N/A
347	Pipette tip, 100–1000 µl	Generic	C	96 tips/ box		1000			N/A	N/A	N/A	N/A	N/A
	Pipette tip, 1000µl disposable	4J71-10	C	96 tips/ box, 12 boxes/ case					N/A	N/A	N/A	N/A	Specifically for use with m2000sp and m24
	Pipette tip, 200µl disposable	4J71-17	C	96 tips/ box, 12 boxes/ case					N/A	N/A	N/A	N/A	Specifically for use with m2000sp and m24

SECTION IC | NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
	Repeat pipettor, 40-50 µl	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual Sample preparation (optional)
	Pipette tips, repeater/dispenser, 50 µl	Generic	C	N/A					N/A	N/A	N/A	N/A	For manual Sample preparation (optional)
	Pipette, transfer disposable	Generic	C	N/A					N/A	N/A	N/A	N/A	For manual Sample preparation (optional)
31	Microcentrifuge capable of 2000 g (non-refrigerated)	Generic	E	1 unit					N/A	N/A	N/A	N/A	N/A
	Centrifuge capable of 5000 g (for centrifuging the Abbott 96-well optical reaction plate)	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
348	Pipette tip, 100– 1000 µl filter/ aerosol barrier	Generic	C	96 tips/ box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/ box		1000			N/A	N/A	N/A	N/A	N/A
352	Pipette tip, 10–200 µl filter/ aerosol barrier	Generic	C	96 tips/ box		1000			N/A	N/A	N/A	N/A	N/A
475	Tubes, microcentrifuge, 1.7 ml, RNase- free	Generic	C	100 tubes/ pack		1000			N/A	N/A	N/A	N/A	N/A
466	Tubes, test, 16 mm	Generic	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
470	Biosafety cabinet class I/II	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
385, 386, 387	Biohazardous waste container, solid waste	Generic	D	1 unit					N/A	N/A	N/A	N/A	N/A
494	Liquid waste container	Generic	D	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation

## SECTION IC | NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
401-403	Lab coat	Generic	C	1 unit					N/A	N/A	N/A	N/A	N/A
393	Goggles/eye protection	Generic	C	1 unit					N/A	N/A	N/A	N/A	N/A
237, 238, 239	Bag, biohazardous wastes	Generic	C	N/A					N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
451	Abbott m2000rt Optical Calibration Kit	4J71-93	R	Kit		1000			N/A	N/A	N/A	N/A	N/A
471	Water, RNase/DNase free	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IC: NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Diagnostic characteristics	Description of characteristics
Name of analyser	m2000rt instrument for real-time amplification and detection.
Name of test	Abbott RealTime HIV-1 Qualitative assay (can be used with one of two methods of sample preparation: (i) manual (for laboratories with low throughput requirements) or (ii) automated sample preparation using m2000sp instrument (for laboratories with high throughput requirements))
Catalogue no.	Manual sample preparation: 4N66-90, 4N66-80, 6K12-24, 9K15-01, 4N66-01 and 4N66-66 (optional). m2000sp automated sample preparation: 4N66-90, 4N66-80, 6K12-24, 9K15-01, 9K14-02, 4N66-01 and 4N66-66 (optional)
Description	Abbott RealTime HIV-1 Qualitative assay is in vitro amplification assay for the qualitative detection of HIV-1 nucleic acids from human plasma and dried blood spots (DBS). It is intended to be used as an aid in the diagnosis of HIV-1 infection in pediatric and adult subjects. This assay is not intended to be used as a donor screening test for HIV-1. Assay sensitivity is 110 copies/mL for plasma samples and 2500 copies/mL for whole blood samples using the DBS procedure. This assay is designed to detect Group M subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G, subtype H and Group N, Group O. One copy of HIV-1 RNA is equivalent to 1.7 ± 0.1 international units (IU) based on the WHO 1st International Standard for HIV-1 RNA for nucleic acid-based techniques (NIBSC 97/656). Instrumentation to perform Abbott RealTime HIV-1 Qualitative assay includes m2000sp instrument for automated sample preparation (optional) and m2000rt instrument for real-time amplification and detection. Package of m2000sp with m2000rt is marketed as the Abbott m2000 RealTime System and provides automation from bar-coded laboratory tube through patient result.
Pre-installation requirements	Suitable for level III and IV laboratories with stable 24-h power
Operating conditions	15–30oC; 30–80% humidity non-condensing at 30oC or below; 0–2000 m altitude
Items supplied with analyser	Data station, monitor and printer, and bar-code scanner are supplied with m2000sp and m2000rt.
Required accessories	Abbott RealTime HIV 1 Qualitative m2000 System Combined Application CD ROM 4N66-01 or higher
Optional accessories	N/A
Turnaround time	m2000sp: from 2.5 hours for 24 samples to 5.5 hours for 96 samples m2000rt: Amplification and detection cycle ~ 3 hours.
Capacity (per run)	m2000sp automated sample preparation: Up to 94 patient samples + 2 controls per run m2000rt: Up to 94 patient samples + 2 controls per run
Throughput per technician per day	m2000sp automated sample preparation: Up to 188 samples (2 batches of 94 samples) per 8 hour day; m2000rt: Up to 282 samples per technician per day (sample preparation and extraction can be limiting factor)
Sample needed and stability	m2000sp or manual sample preparation: Freshly drawn whole blood may be held at 15 – 30° C for up to 6 hours or at 2 – 8° C for up to 24 hours prior to preparing plasma samples through centrifugation or prior to preparing DBS samples. After centrifugation, plasma may be stored at 15 – 30° C for up to 24 hours or at 2 – 8° C for up to 5 days. If longer storage is required, may be stored at -10 to -30oC for up to 30 days or at -70° C. Multiple freeze/thaw cycles should be avoided and should not exceed three freeze/thaw cycles. DBS may be made on Whatman 903 card (or equivalent) using blood obtained from a heel- or finger-stick or collected in a blood collection tube. DBS cards may be stored at 15-30oC for up to 12 weeks or at 2-8oC or -10oC or colder for up to 12 weeks. m2000rt: PCR-ready samples from manual or m2000sp sample preparation/extraction protocol

## SECTION IC: NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Sample preparation and protocol complexity	m2000sp automated sample preparation: Moderately complex. Steps include vortexing (assay calibrators, each control and specimens), pipetting, centrifuge, etc). Once 96 well plate is loaded and placed in m2000rt, process is walk away
Reagent stability and storage requirements	m2000sp automated sample preparation: Moderately complex. Steps include vortexing (assay calibrators, each control and specimens), pipetting, centrifuge, etc). Once 96 well plate is loaded and placed in m2000rt, process is walk away
Reagent stability and storage requirements	Maximum shelf-life upon manufacture: Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit 4N66-90: 18 months (except for Thermostable RTth Polymerase Enzyme 56685: Per control date on vendor certificate of analysis) Abbott RealTime HIV-1 Qualitative Control Kit 4N66-80: 18 months Abbott mSample Preparation SystemDNA Kit 6K12-24 : 18 months  Reagents, controls, and calibrators must be shipped on dry ice and must be stored at $\leq -10^{\circ}\text{C}$ when not in use; reagent may be reused up to 3 times within 2 weeks; the Abbott mSample Preparation SystemDNA must be stored at $15-30^{\circ}\text{C}$
Cost per test	Unknown
Cost per instrument	m2000sp automated sample preparation: \$120000 USD m2000rt: \$38,000 USD (with m2000sp) – Add \$6,000 USD for all manual extraction items
Installation	Yes
Training	Fully-trained lab tech required; dedicated training on instrument
Maintenance/calibration	Routine preventative maintenance required for m2000sp and m2000rt. In case of breakdown, vendor-trained technician required to repair.
Internal QC	Controls are included as part of reagent kit and required for each preparation run for FDA-approved assays
External QA	m2000rt: Amenable to external QA
URL	<a href="http://www.abbottmolecular.com/products/infectious-diseases/realtime-pcr/realtime-hiv1-qualitative.html">http://www.abbottmolecular.com/products/infectious-diseases/realtime-pcr/realtime-hiv1-qualitative.html</a>

**SECTION IC: NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
	Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit	4N66-090,	B	Kit	96	1000		10	N/A	Yes	N/A	Yes	Store at ≤ -10°C
	Abbott RealTime HIV-1 Qualitative Control Kit	4N66-080	C	Kit	12 runs	1000		46	N/A	Yes	N/A	Yes	Store at ≤ -10°C
	Abbott m2000rt instrument with software version 3.0 or higher	9K15-01	E	N/A	N/A				N/A	N/A	N/A	N/A	N/A
	Abbott m2000sp instrument with software version 4.0 or higher	9K14-02	E	N/A	N/A				N/A	N/A	N/A	N/A	Required if automated sample preparation chosen
	Abbott RealTime HIV-1 Qualitative m2000 System Combined Application CD-ROM	4N66-01	E	N/A	N/A				N/A	N/A	N/A	N/A	N/A
<b>2 – Test run</b>													
451	Abbott m2000rt Optical Calibration Kit	4J71-93	R	Kit					N/A	N/A	N/A	N/A	N/A
	ABBOTT M5sample Preparation System DNA	6K12-24	C	Kit	96	1000		10	N/A	N/A	N/A	N/A	N/A
468	Abbott Molecular Inc. Abbott 96 Deep-Well Plate	4J71-30	C	32 Plates/pack	32	1000		31	N/A	N/A	N/A	N/A	For m2000sp instrument only
453	96-Well Optical Reaction Plates	4J71-70	C	20 plates/pack	20	1000		50	N/A	N/A	N/A	N/A	N/A
454	Abbott Molecular Inc. Optical Adhesive Covers	4J71-75	C	100/pack		1000		10	N/A	N/A	N/A	N/A	N/A

## SECTION IC: NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/link	Comment
455	Abbot Molecular Inc. Abbott Adhesive Cover Applicator	9K32-01	C	N/A	1000	1000			N/A	N/A	N/A	N/A	Supplied with m2000rt instrument
469	Abbott Molecular Inc. Master Mix Tubes/Caps	4J71-80	C	150 Tubes/ Caps/pack	150	1000		7	N/A	N/A	N/A	N/A	For m2000sp instrument only
	13 mm Sample racks	4J72-82	D	N/A					N/A	N/A	N/A	N/A	Supplied with m2000sp instrument
452	Abbott Molecular Inc. Reaction Vessels, 5 ml	4J71-20	C	2000 vessels/ pack	2000	1000		0.5	N/A	N/A	N/A	N/A	N/A
474	Abbott Molecular Inc. Reagent Vessels, 200 ml	4J71-60	C	90 vessels/ pack	90	1000		11	N/A	N/A	N/A	N/A	For m2000sp instrument only
456	Abbott Molecular Inc. Abbott Splash- Free Support Base	9K31-01	C	5ea/pack	5	1000		200	N/A	N/A	N/A	N/A	N/A
376	Tubes, microcentrifuge, 1.5 ml, screw cap	04G71-50 or generic equivalent	C	N/A					N/A	N/A	N/A	N/A	For manual sample preparation
	Stand, magnetic separator for 5-ml reaction vessels	Generic	D	1 Unit					N/A	N/A	N/A	N/A	For manual sample preparation. Can be ordered as m2000
507	Stand, magnetic separator for 1.5-ml tubes	Generic	D	1 unit					N/A	N/A	N/A	N/A	mSample Preparation System Start Up Kit (02N28-03)
	Eppendorf PCR Cooler or StrataCooler 96 benchtop cooler	Generic	D	1 unit					N/A	N/A	N/A	N/A	



**SECTION IC: NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
457	m2000 mSample Preparation System Start Up Kit	02N28-03	E	N/A					N/A	N/A	N/A	N/A	For manual sample preparation
	Rack, reaction vessels, 5 ml	Generic	D	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
407	Rack, test tubes, 0.5 ml, 1.5 ml, 2.0 ml centrifuge	Generic	D	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
29	Dry heating block for 5 ml reaction vessels (capable of achieving 50oC)	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
29	Dry heating block for 1.5 ml tubes (capable of achieving 75oC)	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
412, 413	Thermometer	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
46	Timer, digital	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
	Plate, 96 well polypropylene	Generic	C	N/A					N/A	N/A	N/A	N/A	For manual Sample preparation (optional)
	Abbott Molecular Inc. Bulk mLysisDNA Buffer	2N77-01	R	500ml					N/A	N/A	N/A	N/A	For DBS processing only
477	Tubes, Centrifuge, 50 ml (NUNC or equivalent)	Generic	C	N/A					N/A	N/A	N/A	N/A	For DBS processing only (Optional)

## SECTION IC: NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/link	Comment
40, 41, 42	Calibrated pipettes/pipettors, 20-1000 µl	Generic	E	1 unit					N/A	N/A	N/A	N/A	N/A
348, 352	Pipette tip, 20–1000 µl filter/ aerosol barrier	Generic	C	96 tips/box					N/A	N/A	N/A	N/A	N/A
	Pipette tip, 1000 µl disposable	4J71-10	C	96 tips/box, 12 boxes/case					N/A	N/A	N/A	N/A	Specifically for use with m2000sp
	Pipette tip, 200 µl disposable	4J71-17	C	96 tips/box, 12 boxes/case					N/A	N/A	N/A	N/A	Specifically for use with m2000sp
	Repeat pipettor, 40-50 µl	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual Sample preparation (optional)
	Pipette tip, repeater/dispenser, 50 µl	Generic	C	N/A					N/A	N/A	N/A	N/A	For manual Sample preparation (optional)
	Pipette, transfer disposable	Generic	C	N/A					N/A	N/A	N/A	N/A	For manual Sample preparation (optional)
56	Vortex mixer	Generic	E	1 unit					N/A	N/A	N/A	N/A	N/A
31	Microcentrifuge capable of 2000 g (non-refrigerated)	Generic	E	1 unit					N/A	N/A	N/A	N/A	N/A
	Centrifuge capable of 5000 g (for centrifuging the Abbott 96-well optical reaction plate)	Generic	E	1 unit					N/A	N/A	N/A	N/A	For manual sample preparation
471	RNase/DNase free water (Eppendorf or equivalent)	Generic	R	N/A					N/A	N/A	N/A	N/A	N/A

SECTION IC: NUCLEIC ACID-BASED TEST: ABBOTT MOLECULAR INC. REALTIME HIV-1

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/link	Comment
	USP Grade 190-200 proof ethanol (95% - 100% Ethanol)	Generic	R	N/A					N/A	N/A	N/A	N/A	DO NOT use ethanol that contains denaturants
470	Biosafety cabinet class I/II	Generic	E	N/A					N/A	N/A	N/A	N/A	N/A
385, 386, 387	Biohazardous waste container, solid waste	Generic	D	1 unit					N/A	N/A	N/A	N/A	N/A
494	Liquid waste container	Generic	D	1 unit					N/A	N/A	N/A	N/A	No bleach should be allowed to contact liquid waste. For manual sample preparation
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box					N/A	N/A	N/A	N/A	N/A
401-403	Lab coat	Generic	C	1 unit					N/A	N/A	N/A	N/A	N/A
393	Goggles/eye protection	Generic	C	1 unit					N/A	N/A	N/A	N/A	N/A
237, 238, 239	Bag, biohazardous wastes	Generic	C	N/A					N/A	N/A	N/A	N/A	N/A
472	Applicator, Cotton-tip	Generic	C	N/A					N/A	N/A	N/A	N/A	N/A

## SECTION IC: NUCLEIC ACID-BASED TEST: BIOMERIEUX NUCLISENS EASYQ® SYSTEM

Diagnostic characteristics	Description of characteristics
Name of test	NucliSENS EasyQ HIV assay v 2.0 (can be performed in semi-automated or automated mode)
Catalogue no.	Semi-automated: 200305, 200293, 200292, 285056, 200309 and 285033 Automated: 280140, 280130, 280131, 280132, 280133, 280134, 285056, 200309 and 285033
Description	The NucliSENS HIV Solution is an automated system combining semi-automated or automated (optional) nucleic acid extraction with nucleic acid sequence-based amplification and real-time detection using molecular beacon probes. It includes bioMérieux NucliSENS® miniMAG® extraction system for a semi-automated extraction, bioMérieux NucliSENS® easyMAG® extraction system for an automated extraction, and bioMérieux NucliSENS EasyQ® amplification and detection system for an automated amplification and detection. NucliSENS EasyQ HIV assay v 2.0 is part of the NucliSENS HIV Solution. It is a nucleic acid amplification assay for the quantitative determination of HIV-1 RNA in human EDTA plasma and EDTA whole blood spotted on cards (DBS). This assay is based on NASBA, an isothermal transcription-based amplification method, which amplifies RNA from an RNA target. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of anti-retroviral therapy by measuring changes in plasma/DBS (from EDTA whole blood) HIV-1 RNA levels during the course of anti-retroviral treatment. The linear range of the NucliSENS EasyQ HIV assay v 2.0 is from 10 to 10,000,000 copies/mL. The assay can detect HIV-1 subtypes A, B, C, D, F, G, H, J, CRF01_AE, and CRF02_AG. Sample size is 0.1ml, 0.5 ml, or 1ml.
Pre-installation requirements	Suitable for level III and IV laboratories
Operating conditions	15°C - 30°C (4°C – 45°C for miniMAG); maximum relative humidity 80% ((0% for miniMAG), non-condensing at 30°C; maximum altitude 2500 meters (2000 meters for EasyQ® and miniMAG)
Items supplied with analyser	Data station (may be linked with LIS using NucliSENtral™ software); bar-code scanner (included with bioMérieux NucliSENS® easyMAG®).
Required accessories	NucliSENS® easyMAG® configuration 280140, NucliSENS EasyQ® configuration 200309, Mini Strip Centrifuge 285056
Optional accessories	Printer
Turnaround time	bioMérieux NucliSENS® miniMAG® : 12 samples: 45 minutes (1 miniMAG system) 24 samples: 60 minutes (2 miniMAG systems) bioMérieux NucliSENS® easyMAG®: 24 samples, lysis on board: 60 minutes 24 samples, lysis off board: 40 minutes bioMérieux NucliSENS EasyQ®: ~1.5 hours for 48 samples; 1 hour for NucliSENS EasyQ HIV-1 assay v 2.0
Capacity (per run)	bioMérieux NucliSENS® miniMAG® : 12 patient samples (no controls) bioMérieux NucliSENS® easyMAG®: 1-24 patient samples per run bioMérieux NucliSENS EasyQ®: Up to 48 patient samples (minimum is 8 patient samples)

## SECTION IC: NUCLEIC ACID-BASED TEST: BIOMERIEUX NUCLISENS EASYQ® SYSTEM

Diagnostic characteristics	Description of characteristics
Throughput per technician / per day	<p>bioMérieux NucliSENS® miniMAG® : Up to 144 specimens (6 runs of 24 – 2 miniMAGs at the same time)</p> <p>bioMérieux NucliSENS® easyMAG®: Up to 168 extractions – lysis on board workflow Up to 240 extractions – lysis in tube workflow</p> <p>bioMérieux NucliSENS EasyQ®: 192 samples (4 runs of 48)</p>
Sample needed and stability	<p>bioMérieux NucliSENS® miniMAG® : 100 – 1,000 µL plasma for NucliSENS EasyQ HIV assay (sensitivity is higher with larger sample). DBS protocol available (CE-marked protocol on EDTA whole blood on capillary whole blood)</p> <p>bioMérieux NucliSENS® easyMAG®: 100 – 1,000 µL plasma for NucliSENS EasyQ HIV assay (LOD is better with larger sample). DBS protocol available (CE-marked protocol 100µL EDTA whole blood and on 100µL capillary whole blood). bioMérieux NucliSENS EasyQ®: Eluates extracted with miniMAG or easyMAG. Can be stored at 2° C – 8° C; all reagents are stable until expiration date</p>
Sample preparation and protocol complexity	<p>bioMérieux NucliSENS® miniMAG® : Plasma or DBS are transferred to a lysis tube. After addition of silica, washing steps are performed on the miniMAG system. Reagents are then ready to use.</p> <p>bioMérieux NucliSENS® easyMAG®: Entire extraction process takes place in a single sample compartment, which minimizes potential sample loss and cross contamination. Reagents are ready-to-use.</p> <p>bioMérieux NucliSENS EasyQ®: Moderate complexity. Dehydrated reagents are quickly reconstituted.</p>
Reagent stability and storage requirements	<p>bioMérieux NucliSENS® miniMAG® : The NucliSENS Magnetic Extraction Reagent, 200293 should be stored at 2-8 °C; shelf-life upon manufacture is 18 months</p> <p>The NucliSENS Lysis Buffer (2ml), 200292 should be stored at 2-30°C; shelf-life upon manufacture is 24 months</p> <p>bioMérieux NucliSENS® easyMAG®: The NucliSENS easyMAG extraction Buffer 1, 280130 should be stored at 2-30°C; shelf-life upon manufacture is 24 months NucliSENS easyMAG extraction Buffer 2, 280131 should be stored at 2-30°C; shelf-life upon manufacture is 18 months NucliSENS easyMAG extraction Buffer 3, 280132 should be stored at 2-8°C; shelf-life upon manufacture is 15 months NucliSENS easyMAG extraction Lysis Buffer, 280134 should be stored at 2-30°C; shelf-life upon manufacture is 24 months NucliSENS easyMAG magnetic silica, 280133 should be stored at 2-8°C; shelf-life upon manufacture is 18 months</p> <p>bioMérieux NucliSENS EasyQ®: NucliSENS EasyQ HIV-1 v 2.0 test kit should be stored at 2° C – 8° C; shelf-life upon manufacture is 18 months</p>
Cost/test	<p>The average price per test of EasyQ HIV assay v 2.0, including extraction and detection/ amplification is about €8.00 (\$23.75).</p>
Cost/instrument	<p>bioMérieux NucliSENS® miniMAG® : Approximately €6,800 (\$9,000) bioMérieux NucliSENS® easyMAG® : Approximately €2,000 (\$95,000) bioMérieux NucliSENS EasyQ® : Approximately €7,100 (\$49,000)</p>

## SECTION IC: NUCLEIC ACID-BASED TEST: BIOMERIEUX NUCLISENS EASYQ® SYSTEM

Installation	Yes
Training	Fully-trained lab tech required; dedicated training on instrument, which requires strong computer skills
Maintenance/calibration	Routine preventative maintenance required. In case of breakdown, vendor-trained technician required to repair
Internal QC	Yes, a synthetic calibrator added in a known concentration at the extraction stage, functions as an internal control for the isolation, amplification and detection procedure
External QA	Unknown
URL	<a href="http://www.biomerieux-diagnostics.com/servlet/stt/bio/clinical-diagnostics/dynPage?doc=CNL_PRD_CPL_G_PRD_CLN_75">http://www.biomerieux-diagnostics.com/servlet/stt/bio/clinical-diagnostics/dynPage?doc=CNL_PRD_CPL_G_PRD_CLN_75</a>

SECTION IC: NUCLEIC ACID-BASED TEST: BIOMÉRIEUX NUCLISENS EASYQ® SYSTEM

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
488	BioMérieux NucliSENS EasyQ®HIV-1 V2.0	285033	B	48 tests/kit	48	1000	1000	21	24	Yes	N/A	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	N/A
2 – Test run													
489	BioMérieux Biohit Tips	280146	C	48		1000			N/A	N/A	N/A	N/A	N/A
490	BioMérieux NucliSENS® easyMAG® disposables	280135	C	48		1000			N/A	N/A	N/A	N/A	N/A
492	BioMérieux NucliSENS EasyQ® 8-Tube Caps	285051	C	48		1000			N/A	N/A	N/A	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	N/A
493	BioMérieux NucliSENS EasyQ® 8-Tube Strips	285048	C	48		1000			N/A	N/A	N/A	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	N/A
491	BioMérieux Strip Plates Greiner	278303	C	48		1000			N/A	N/A	N/A	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
348	Pipette tip, 100–1000 µl filter/aerosol barrier	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
352	Pipette tip, 10–200 µl filter/aerosol barrier	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
500	Pipette tip, 1–5 ml filter/aerosol barrier	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
350	Pipette tip, 5–20 µl filter/aerosol barrier	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IC: NUCLEIC ACID-BASED TEST: BIOMÉRIEUX NUCLISENS EASYQ® SYSTEM

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/link	Comment
371	Tissues, wipes	Generic	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
371	Tissues, wipes	Generic	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
503	Tube strips, PCR, 0.2 ml RNase-free with caps	Generic	C	100 tubes/pack		1000			N/A	N/A	N/A	N/A	Alternate to item 502
502	Tubes, microcentrifuge, 1.5 ml, RNase free	Generic	C	100 tubes/pack		1000			N/A	N/A	N/A	N/A	N/A
494	Waste container with cap	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
409	Scissors	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
507	Stand, magnetics separator for 1.5 ml tubes	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
17	Centrifuge, benchtop, non-refrigerated	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
31	Microcentrifuge (non-refrigerated)	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
495	Mixer, roller	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
39	Pipette/pipettor 1	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
40	Pipette/pipettor 20	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A



SECTION IC: NUCLEIC ACID-BASED TEST: BIOMÉRIEUX NUCLISENS EASYQ® SYSTEM

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/ link	Comment
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
499	Pipette/pipettor 5000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
506	Thermoshaker	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
508	Vacuum system, 1.5 litres/m	Generic	E	N/A		1000			N/A	N/A	N/A	N/A	Alternate
56	Vortex mixer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
498	Water bath	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
483	BioMérieux NucliSENS® easyMAG® Extraction Buffer 1	280130	R	4000 ml/pack		1000			24	Yes	N/A	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	N/A
484	BioMérieux NucliSENS® easyMAG® Extraction Buffer 2	280131	R	4000 ml/pack		1000			18	Yes	N/A	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	N/A
485	BioMérieux NucliSENS® easyMAG® Extraction Buffer 3	280132	R	4000 ml/pack		1000			15	Yes	N/A	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	N/A
486	BioMérieux NucliSENS® easyMAG® Extraction Lysis Buffer	280134	R	4000 ml/pack		1000			24	Yes	N/A	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	N/A
487	BioMérieux NucliSENS® easyMAG® Magnetic Silica	280133	R	4000 ml/pack		1000			18	Yes	N/A	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	N/A
104	Ethanol (70%) for cleaning	Generic	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
504	Sodium hypochlorite solution (1%)	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
496	Controls, HIV RNA negative, commercial	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
497	Controls, HIV RNA positive, commercial	N/A	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IC: NUCLEIC ACID-BASED TEST: COBAS®

Diagnostic characteristics	Description of characteristics
Name of analyser	COBAS® TaqMan® 48 Analyser or COBAS® TaqMan® 96 Analyser for automated amplification and detection
Name of test	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0
Catalogue no.	Taqman® 48: 03279332001, 03051315001, 05212294190, 03587797190, 04862392001, 05807875001 and 05527503001 Taqman® 96: 03121453001, 03051315001, 05212294190, 03587797190, 04862392001, 05807875001, 05527503001 and 28127387001
Description	The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0 (v2.0) is a nucleic acid amplification test for the quantitation of HIV-1 RNA in plasma using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® 48 Analyser or COBAS® TaqMan® 96 Analyser for automated amplification and detection. The test can quantitate HIV-1 RNA over the range of 20–10 000 000 copies/ml. One copy of HIV-1 RNA is equivalent to 1.7 ± 0.1 international units (IU) based on the WHO 1st International Standard for HIV-1 RNA for nucleic acid-based techniques (NIBSC 97/656). The test is intended for use in conjunction with clinical presentation and other markers of disease progress for the clinical management of HIV-1 group M and HIV-1 group O infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment. The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 is not intended for use as a screening test for the presence of HIV-1 in blood or blood products or as a diagnostic test to confirm the presence of HIV-1 infection.
Pre-installation requirements	Suitable for level III and IV laboratories with stable 24-h power
Operating conditions	15–32°C; 24–80% humidity, non-condensing (up to 32°C); 0–2000 m altitude
Items supplied with analyser	AMPLILINK SOFTWARE, bar-code scanner (on COBAS AmpliPrep: on-board bar-code scanner for reagent racks, reagent cassettes and specimen clips
Required accessories	Data Station for the AMPLILINK software (e.g. (custom-built PC with Microsoft® Windows® XP), with printer HP 1320 (printer interface: LPT interface via parallel port).
Optional accessories	COBAS p 630 instrument 05527503001 Docking Station 28127387001 (for COBAS® TaqMan® 96 Analyser)
Turnaround time	COBAS® AmpliPrep System: Three racks of 24 specimens in approximately 5 hours; 216 seconds processing time per specimen COBAS® TaqMan® 48 Analyser: Amplification and detection cycle takes 3 hours 5 minutes COBAS® TaqMan® 96 Analyser: Amplification and detection cycle takes 3 hours 5 minutes, including automated transfer from COBAS AmpliPrep to a docking station
Capacity (per run)	COBAS® AmpliPrep System: 72 samples per run (maximum), which can be analysed simultaneously. Batch size is 24 specimens per run. COBAS® TaqMan® 48 Analyser: 2 independent segments of 24 samples each up to 2 different tests on board simultaneously; each thermal cycle can run individual PCR profiles. COBAS® TaqMan® 96 Analyser: 24 samples per K-carrier. Up to 4 K-carriers can be amplified and detected at one time. Up to 8 K-carriers can be present on the instrument.

## SECTION IC: NUCLEIC ACID-BASED TEST: COBAS®

Throughput per technician / per day	<p>COBAS® AmpliPrep System: Up to 168 specimens per 8 hour shift, based on testing combinations and laboratory workflow</p> <p>COBAS® TaqMan® 48 Analyser: Including processing time on AmpliPrep, 48 samples (on an 8 hour shift)</p> <p>COBAS® TaqMan® 96 Analyser: Including processing time on AmpliPrep, 96 samples (on an 8 hour shift)</p>
Sample needed and stability	<p>COBAS® AmpliPrep System: 1,000 µL of plasma or 70 µL DBS. Plasma may be transported/stored at 2 – 8° C for 5 days or frozen at -70° C; DBS can be stored up to 12 weeks at 30° C.</p> <p>COBAS® TaqMan® 48 Analyser: PCR-ready set-up samples from AmpliPrep; processed specimens and controls should not be exposed to light after completion of specimen and control preparation.</p> <p>COBAS® TaqMan® 96 Analyser: PCR-ready set-up samples from AmpliPrep; processed specimens and controls should not be exposed to light after completion of specimen and control preparation.</p>
Sample preparation and protocol complexity	<p>COBAS® AmpliPrep System: Plasma transferred to a properly identified, sterile screw-cap, polypropylene tube after centrifugation. Requires test-specific, bar-coded, ready-to-use COBAS AmpliPrep Kits. Reagents are all liquid and ready to use, but specimens require mixing to HIV-1 RNA uniformity prior to testing.</p> <p>COBAS® TaqMan® 48 Analyser and COBAS® TaqMan® 96 Analyser: Once removed from the COBAS AmpliPrep Instrument, processed specimens and processed controls may be stored in the output tubes at 2 – 8° C for up to one day (24 hours). Preparation of reagent cassettes for amplification and extraction is moderately complex</p>
Reagent stability and storage requirements	<p>The COBAS AmpliPrep/COBAS TaqMan HIV-1 Test version 2.0, 05212294190, should be stored at 2° C to 8° C; shelf-life 18 months</p> <p>The COBAS AmpliPrep/COBAS TaqMan Wash Reagent, 03587797190, should be stored at 2° C to 30° C; shelf-life 24 months.</p>
Cost per test	<p>COBAS® TaqMan® 48 Analyser: TaqMan HIV-1 Test v2.0: \$11 – \$25 in resource-limited settings; range is dependent on instrument purchase, reagent rental and volume-based tiered pricing.</p> <p>COBAS® TaqMan® 96 Analyser: TaqMan HIV-1 Test v2.0: \$20 – \$30 per test (least developed countries); \$35 – \$90 per test elsewhere</p>
Cost per instrument	<p>COBAS® AmpliPrep System: Approximately \$80,000 – \$100,000</p> <p>COBAS® TaqMan® 48 Analyser: \$40,000 – \$50,000</p> <p>COBAS® TaqMan® 96 Analyser: \$100,000 – \$110,000, including docking station</p>
Installation	Yes
Training	Fully-trained lab tech required; 3–5 days dedicated training on instrument, refresher training may be required
Maintenance/calibration	Annual maintenance. Routine preventative maintenance required. In case of breakdown, vendor-trained technician required to repair.
Internal QC	Controls are included as part of reagent kit
External QA	Amenable to EQA
URL	<a href="http://molecular.roche.com/instruments/Pages/COBASAmpliPrepCOBAS_TaqManSystem.aspx">http://molecular.roche.com/instruments/Pages/COBASAmpliPrepCOBAS_TaqManSystem.aspx</a>



**SECTION IC: NUCLEIC ACID-BASED TEST: COBAS®**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box					N/A	N/A	N/A	N/A	N/A
348	Pipette tip, 100–1000 µl filter/ aerosol barrier	Generic	C	96 tips/box					N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	E	1 unit					N/A	N/A	N/A	N/A	N/A
371	Tissues, wipes	Generic	C	N/A					N/A	N/A	N/A	N/A	N/A
494	Waste container with cap	Generic	C	1 unit					N/A	N/A	N/A	N/A	
31	Microcentrifuge (non-refrigerated)	Generic	E	1 unit					N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit					N/A	N/A	N/A	N/A	N/A
104	Ethanol (70%) for cleaning	Generic	C	N/A					N/A	N/A	N/A	N/A	N/A

## SECTION IC: NUCLEIC ACID-BASED TEST: SIEMENS HEALTHCARE DIAGNOSTICS VERSANT®

Diagnostic characteristics	Description of characteristics
Name of analyser	VERSANT kPCR Molecular System
Name of test	VERSANT HIV-1 RNA 1.0 Assay (kPCR)
Catalogue no.	10375763, 10375764, 04801677, 04801685, 10467524
Description	The VERSANT® HIV-1 RNA 1.0 Assay (kPCR)* is an in vitro nucleic acid amplification assay for quantitative measurement of HIV-1 RNA in fresh or frozen human plasma samples using the VERSANT kPCR Molecular System. The assay detects viral RNA over the range of 37 copies/ml to 11000000 copies/ml (referenced to the WHO HIV RNA 2nd International Standard (97/650) for IU/ml). The assay can detect Group M subtypes A, C, D, F, G, H, circulating recombinant forms AE and AG, and Group O VERSANT kPCR Molecular System consists of the Sample Preparation Module for nucleic acids extraction, and the Amplification Detection Module, along with VERSANT kPCR software. Closed-tube processing eliminates the need for clean room operations
Pre-installation requirements	Suitable for level III and IV laboratories
Operating conditions	18–30°C; 30–80% humidity, non-condensing; 0–2000 m altitude
Items supplied with analyser	VERSANT kPCR Molecular System 10467524 includes the following: VERSANT kPCR Molecular System SP with Heater/Shaker, 10282928 VERSANT kPCR Molecular System SP Workstation w/ Barcode Scanner, 10702391 VERSANT kPCR Molecular System AD, 10282939 VERSANT kPCR Molecular System AD Workstation w/ Barcode Scanner, 10702393 VERSANT kPCR Molecular System SP System Software v1.1 CD, 10471298 VERSANT kPCR Molecular System AD System Software v1.1CD, 10471300 VERSANT kPCR Molecular System Test Definitions Non-US v1.1 CD, 10471299 VERSANT kPCR Molecular System On-Line Help v1.1 CD, 10471301 VERSANT kPCR Molecular System Software v1.1 Installation Kit, 10471297
Required accessories	N/A
Optional accessories	N/A
Turnaround time	Sample preparation system set-up <10 minutes; sample extraction <3 hours; amplification and detection <3 hours
Capacity (per run)	96 samples (89 clinical samples, 4 calibrators, and 3 controls) run in 6 hours
Throughput per technician / per day	up to 178 patient results per shift.
Sample needed and stability	Up to 500 µL input volume or 1 DBS (50 – 100µL); whole blood collected in EDTA tubes can be stored for 6 hours at room temperature or for up to 24 hours at 2° – 8°C before centrifugation; plasma may be stored for up to 24 hours at room temperature or for up to 5 days at 2° – 8°C.
Sample preparation and protocol complexity	(i) load the dedicated sample preparation reagents into a trough; (ii) place them on the module; (iii) load plasma samples onto the sample carrier; and (iv) place the sample carriers on the auto load tray of the VERSANT Sample Prep module. From that point, sample prep module is fully automated.

## SECTION IC: NUCLEIC ACID-BASED TEST: SIEMENS HEALTHCARE DIAGNOSTICS VERSANT®

Reagent stability and reagent stability	The VERSANT HIV-1 RNA Assay 1.0 (kPCR), IVDD (Box 1), 10375763: Store at -30 to -10 °C; shelf-life 12 months; The VERSANT HIV-1 RNA Assay 1.0 (kPCR) IVDD (Box 2), 10375764: Store at -90 to -60 °C; shelf-life 12 months The VERSANT Sample Preparation 1.0 Reagents, IVDD (Box 1), 04801677: Store at 15 to 30 °C; shelf-life 24 months. The VERSANT Sample Preparation 1.0 Reagents, IVDD (Box 2), 04801685: Store at 2 to 8 °C; shelf-life 24 months.
Cost/test	Unknown
Cost/instrument	Unknown
Installation	Yes
Training	Fully trained lab technician, 3–5 days dedicated training on instrument, refresher training may be required
Maintenance/calibration	Routine preventative maintenance required. In case of breakdown, vendor-trained technician required to repair.
Internal QC	Controls are included as part of reagent kit and required for each preparation run.
External QA	Amenable to EQA
URL	<a href="http://www.healthcare.siemens.com/molecular-diagnostics/molecular-diagnostics/in-vitro-diagnostics/versant-hiv-1-rna-1-assay">http://www.healthcare.siemens.com/molecular-diagnostics/molecular-diagnostics/in-vitro-diagnostics/versant-hiv-1-rna-1-assay</a>

## SECTION IC: NUCLEIC ACID-BASED TEST: SIEMENS HEALTHCARE DIAGNOSTICS VERSANT®

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
1 – Required kit or equipment													
447	VERSANT® HIV-1 RNA 1.0 (kPCR) Kit, IVDD Box 1	10375763,	B	Kit	96	1000		11	N/A	Yes	N/A	N/A	N/A
	VERSANT® HIV-1 RNA (kPCR) Kit, IVDD Box 2	10375764	B	Kit	4 sets Calibrators and Controls	1000			N/A	Yes	N/A	N/A	N/A
	VERSANT kPCR Molecular System		E	Unit		N/A			N/A	N/A	N/A	N/A	N/A
2 – Test run													
528	VERSANT® Sample Preparation 1.0 Reagents, IVDD (Box 1 and Box 2)	04801677, 04801685	B	96 tests/ kit	96	1000	1000	11	N/A	Yes	N/A	N/A	N/A
348	Pipette tip, 100–1000-µl filter/aerosol barrier	Generic	C	96 tips/ box		1000			N/A	N/A	N/A	N/A	N/A
359	Pipette, serological, 10.0 ml	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
530	Pipette, serological, 25.0 ml	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
524	VERSANT® 1000-µl Pipette Tips	US: 06635759	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
525	VERSANT® 300-µl Pipette Tips	US: 06635767	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
526	VERSANT® 96-well, 2-ml Nuclease-free, Sterile Deep-well Plates	US: 06691055	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
529	VERSANT® Barcoded 96-well Semi-skirted Polypropylene Plates for PCR	US: 06653412	C	N/A		1000			N/A	N/A	N/A	N/A	N/A



SECTION IC: NUCLEIC ACID-BASED TEST: SIEMENS HEALTHCARE DIAGNOSTICS VERSANT®

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/ package/ link	Comment
523	VERSANT® Large and Small Reagent Troughs	US: 10489008	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
527	VERSANT® Optical Caps, 8 x strip	US: 06653439	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
377	Tubes, test, 12 mm x 75 mm, capped	Generic	C	100 tubes/ pack		1000			N/A	N/A	N/A	N/A	N/A
31	Microcentrifuge (non-refrigerated)	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
531	Sodium hypochlorite solution (0.5%)	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
471	Water, RNase/DNase free	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION ID: NON-NUCLEIC ACID-BASED TEST: CAVIDI EXAVIR™

Diagnostic characteristics	Description of characteristics
Name of analyser	Separation equipment for Cavidil ExaVir™ Load Version 3
Name of test	Cavidil ExaVir™ Load kit
Catalogue no.	55011
Description	The Cavidil ExaVir™ Load kit is a quantitative test intended to measure activity of reverse transcriptase (RT) enzyme in plasma. RT serves as a marker of retroviral replication and the level of RT enzymatic activity can be correlated to the viral load. The assay can measure any HIV type or subtype, including O- and N-groups, with high accuracy. Measuring range of the assay is 200 to 600 000 copies equivalents/ml (or 1 to 3000 fg RT/ml), with between-assay variation 2-3% and within-assay variation 4-8%. The Cavidil ExaVir™ Load kit is not intended to be used as a screening test for HIV, nor is it to be used as a diagnostic test to confirm the presence of HIV infection. The Cavidil ExaVir™ Load is a manual assay performed with standard ELISA equipment and the ExaVir Separation equipment
Pre-installation requirements	Suitable for level II laboratories
Operating conditions	Unknown
Items supplied with analyser	Separation equipment for Cavidil ExaVir™ Load Version 3 includes: column holder, waste collector, lysate collector, collector tube rack, vacuum pump, ExaVir Load Analyser software, waste container, buffer dispenser, vacuum tubing
Required accessories	Standard ELISA plate reader, vortex, 33°C incubator, freezer, computer with Microsoft Excel and Adobe Reader, in-line filters for sheath container
Optional accessories	N/A
Turnaround time	48 hours for each batch of 30 samples, including 5 hours of hands-on time for the operator
Capacity (per run)	30 samples
Throughput per technician / per day	30 samples per batch, up to 180 samples per week
Sample needed and stability	- 1 ml plasma prepared from EDTA anticoagulated whole blood and separated from cells within four hours of the collection of the blood. The plasma samples must be frozen once before analyzed in the ExaVir Load kit. Storage of plasma samples should be at or below -20°C. Long-term storage (more than six months) of plasma samples should be at or below -60°C.
Sample preparation and protocol complexity	Plasma samples are processed to separate virus particles from other plasma components. The virions are then lysed and the resulting lysates are added to an RT assay solution containing an RNA template, a primer, and an RT substrate. After incubation of the reaction mix for 18 to 24 hours, the product is detected by an enzyme-linked monoclonal antibody in the presence of a colorimetric substrate. Multistep protocol of moderate complexity

## SECTION ID: NON-NUCLEIC ACID-BASED TEST: CAVIDI EXAVIR™

Reagent stability and reagent stability	Store the kit reagents at between -14 and -25°C until use. If stored at those conditions the ExaVir Load kit reagents can be used until the expiry date found on the kit label. If delivered unfrozen, the kit should be refrozen and stored between -14 and -25°C or stored at 4 to 8°C for usage within a week. Store the kit consumables at between 18 and 33°C until use. All kit components are for one-time-use only.
Cost/test	Unknown
Cost/instrument	Unknown
Installation	Yes (very simple, without involvement of vendor-trained technician)
Training	Yes
Maintenance/calibration	Required annually
Internal QC	1 Positive and 1 negative controls are included into each run
External QA	N/A
URL	<a href="http://www.cavidi.se/ExaVirLoad.aspx">http://www.cavidi.se/ExaVirLoad.aspx</a>

## SECTION ID: NON-NUCLEIC ACID-BASED TEST: CAVIDI EXAVIR™

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
230	Cavidi ExaVir™ Load Kit – CE IVD	55011	R	30 tests/kit	30	1000	1000	34	12 months	Yes	N/A	N/A	N/A
2 – Test run													
54	Cavidi ExaVir™ Load Start-up Equipment (Separation)	N/A	A	1 unit		1000			N/A	N/A	N/A	<a href="http://gssh.co/sb1111">http://gssh.co/sb1111</a>	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
342	Paper Towels, 2-ply, 3-part Fanfold	2016604	C	1 roll		1000			N/A	N/A	N/A	N/A	N/A
348	Pipette tip, 100-1000 µl filter/aerosol barrier	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
352	Pipette tip, 10–200 µl filter/aerosol barrier	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
360	Pipette, serological, 5.0 ml	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
360	Pipette, serological, 5.0 ml	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
360	Pipette, serological, 5.0 ml	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
361	Reagent reservoirs for ELISA	Generic	C	units/pack		1000			N/A	N/A	N/A	N/A	Unit of measure varies with manufacturer
395	Graduated cylinder, 100 ml	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
396	Graduated cylinder, 2000 ml	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
30	Incubator, general purpose	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
32	Microplate/ELISA plate reader	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
36	Mixer, rotary (end-over-end)	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
44	Pipette/pipettor, multichannel 10–100	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
107	Water, distilled	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
101	DuPont™ Virkon® disinfectant	N/A	R	1		1000			N/A	N/A	N/A	N/A	N/A

## SECTION ID: NON-NUCLEIC ACID-BASED TEST : PERKINELMER ULTRA SENSITIVE P24 ANTIGEN

Diagnostic characteristics	Description of characteristics
Name of analyser	PerkinElmer Life and Analytical Sciences Inc. Alliance HIV-1 P24 ANTIGEN ELISA Kit
Name of test	Alliance HIV-1 P24 ANTIGEN ELISA Kit
Catalogue no.	NEK050001KT (1 x 96-well plate); NEK050A001KT (2 x 96-well plate); NEK050B001KT (5 x 96-well plate)
Description	The Alliance HIV-1 p24 Antigen ELISA is for the detection of HIV-1 and HIV-0 Subtypes in human serum, plasma and cell culture supernatants. This kit provides reagents for immune complex disruption (ICD) of antigen/antibody complexes in serum and plasma samples and proprietary antibodies increasing the sensitivity of the assay. The ELAST p24 ELISA Amplification System also improves the sensitivity of Alliance HIV1 p24 ELISA kits by approximately 25-fold while extending the dynamic range of the assay. FOR RESEARCH USE ONLY (RUO).
Pre-installation requirements	Suitable for level II laboratories
Operating conditions	Unknown
Items supplied with analyser	N/A
Required accessories	PerkinElmer HIV-1 p24 Confirmatory Reagents
Optional accessories	ELAST p24 ELISA Amplification System
Turnaround time	~5.5 hours of incubation for serum or plasma samples, or ~ 4 hours of incubation for cell culture supernatants and non-ICD format serum/plasma samples in addition to several hours of hands-on time for the operator
Capacity (per run)	Up to 88 patient samples (each plate or partial plate must include one substrate blank, three Negative Control, two Positive Control, and two Immune Complex Control wells)
Throughput per technician / per day	Up to 88 patient samples
Sample needed and stability	Serum and plasma samples should be processed on the same day as collected. If samples are not assayed on the day of collection, they should be stored frozen at -20°C or below until tested. Clear, nonhemolyzed specimens should be used whenever possible.
Sample preparation and protocol complexity	Immune Complex Disruption (ICD) of Serum/Plasma Samples: combine Triton X-100, plasma samples, glycine reagent in non-coated microplate, incubate for ~ 1 hour; neutralize for ~20 min, transfer to antibody-coated microplate; incubate for ~2 hours; wash, add detector antibody, incubate for ~ 1 hour; wash plate; incubate for ~ 30 minutes with streptavidin-HRP; wash plate; incubate with OPD substrate for ~ 30 minutes; stop the reaction, read plate. Non-ICD format for cell culture supernatant or serum/plasma: skip 1 hour incubation in non-coated microplate and proceed directly to incubation in antibody-coated microplate.

## SECTION ID: NON-NUCLEIC ACID-BASED TEST : PERKINELMER ULTRA SENSITIVE P24 ANTIGEN

Reagent stability and reagent stability	Stop Solution, Plate Wash Concentrate, 20X, and Plate Covers may be stored at room temperature (15–30°C). All other kit components should be kept refrigerated at 2–8°C.
Cost/test	~ USD \$2000 per 192 test kit
Cost/instrument	N/A
Installation	N/A
Training	Yes
Maintenance/calibration	N/A
Internal QC	Each run should include positive control, negative control and immune complex controls
External QA	N/A
URL	<a href="http://www.perkinelmer.com/Catalog/Family/ID/AllianceR%20HIV1%20P24%20ELISA%20Kit">http://www.perkinelmer.com/Catalog/Family/ID/AllianceR%20HIV1%20P24%20ELISA%20Kit</a>

## SECTION ID: NON-NUCLEIC ACID-BASED TEST : PERKINELMER ULTRA SENSITIVE P24 ANTIGEN

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/ link	Comment
1 – Required kit or equipment													
193	PerkinElmer Life and Analytical Sciences Inc. Alliance HIV-1 P24 ANTIGEN ELISA Kit	1 plate: NEK-050001KT; 2 plates: NEK050A-001KT; 5 Plates: NEK-050B001KT	B	1, 2, or 5 plates/kit	96, 192, or 480	1000	11	12	N/A	Yes	N/A	<a href="http://tinyurl.com/88ldodl">http://tinyurl.com/88ldodl</a>	N/A
2 – Test run													
267	Forceps, non-metallic	Generic	C	unit		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
347	Pipette tip, 100–1000 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
349	Pipette tip, 5–20 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
361	Reagent reservoirs for ELISA	Generic	C	units/pack		1000			N/A	N/A	N/A	N/A	Unit of measure varies with manufacturer
360	Pipette, serological, 5.0 ml	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
375	Tube, microcentrifuge, 1.0 ml, with cap	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
405	Microtitre plate lid	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
412	Thermometer, digital	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
29	Heating block	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A



**SECTION ID: NON-NUCLEIC ACID-BASED TEST : PERKINELMER ULTRA SENSITIVE P24 ANTIGEN**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/ link	Comment
30	Incubator, general purpose	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
32	Microplate/ELISA plate reader	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
33	Microplate/ELISA plate washer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	
35	Microtitre plate shaker	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
37	P24, PerkinElmer, Quanti-Kin Detection System Software	N/A	E	1		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
40	Pipette/pipettor 20	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
107	Water, distilled	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IE: CD4: ALERE PIMA™

Diagnostic characteristics	Description of characteristics
Name of analyser	Alere Pima™ Analyser
Name of test	Pima™ CD4 Test
Catalogue no.	260100025, 260100100, 260300003
Description	Pima™ CD4 is an automated, image-based immune haematology test intended for the rapid in vitro enumeration of CD3+/CD4+ T cells (T-helper cells) absolute count in capillary or venous whole blood. Pima™ CD4 is intended to be used for the on-going monitoring of absolute CD4 lymphocyte counts in patients with documented diagnosis of an immunodeficiency disease. The Pima™ CD4 test is intended for in vitro diagnostic use. The Pima™ CD4 test comprises a disposable Pima™ CD4 test cartridge and the Pima™ Analyser. The disposable Pima™ CD4 test cartridge takes up approximately 25 µL of sample and contains dried reagents needed to perform the test. The Pima™ CD4 test is performed within the Pima™ CD4 test cartridge and no part of the Pima™ Analyser has contact with the sample at any time in the testing process.
Pre-installation requirements	Could be used at all laboratory levels if qualified staff available
Operating conditions	Temperature: 10–40°C; altitude: 0–2000 m; relative humidity: 10–95% (no condensation); storage temperature: 2–50°C; environment: protect from direct sunlight, humidity and dust
Items supplied with analyser	260300003 Pima Analyser: 1x Pima Analyser (2603000001), 1x Pima Bead Standard (2604000011), 1x power transformer, 1x EU power cable 260300004 Instrument and Accessory pack: 1x Pima Analyser (2603000001), 1x power transformer, 1x EU Power cable, 1x Pima Bead Standard (2604000011), 1 x Pima Printer (2604000007), 1 x Pima Analyser Bag (2604000001), 1 x Connectivity Pack I (2604000015) 260300006 Pima Analyser (CN): 1x Pima Analyser with Chinese user interface, 1x power transformer, 1x EU power cable, 1x Pima Bead Standard (2604000011)
Required accessories	None
Optional accessories	2604000007 Alere Pima™ Printer: includes 1xPima Printer, 1xPima Printer User Guide, 1xRoll Thermal Paper I, coated, non-adhesive; 2604000001 Pima™ Analyser bag; 2604000009 Pima™ Printer paper I; 2604000010 Pima™ Printer Paper II; Volumetric or transfer pipette (for venous blood); UPS/voltage regulator; 2604000017 Alere Power Pack (External Battery) incl. connector cable for Pima Analyser; 2604000040 Alere Solar Solution: 1xSolar Panel (2604000041), 1xPower Pack (2604000015); 2604000015 Alere connectivity Pack 1: Samba3G-E modem with USB extension cable; 2604000016 Alere Connectivity Pack 2: CT63 Terminal USB powered modem with mini USB connection cord and external FME antenna; 25604000046 Alere connectivity Pack 3: USB to Ethernet adapter. All the connectivity solutions come with a free Alerenet sim, Data, Free hosting on a tier 4 secure server and free use of the Datapoint Analytics Package.
Turnaround time	20 minutes
Capacity (per run)	3 tests per hour, no batching capability
Throughput per technician / per day	24 tests/8 hour day
Sample needed and stability	25 µL of capillary (fingertick) blood wicked directly into the sample collector contained in the Pima cartridge or 25 µL of venous blood collected in EDTA anti-coagulant tube. Cartridge must be inserted and tested within 5 minutes of sample application. When using venous blood, sample is stable for 36 hours from time of draw
Sample preparation and protocol complexity	No sample preparation required. Walk-away operation.

## SECTION IE: CD4: ALERE PIMA™

Reagent stability and reagent stability	The Alere Pima™ CD4 cartridge should be stored at 2-30°C temperature range. Shelf life is 12 months at 2° – 30°C
Cost/test	\$6 to \$12
Cost/instrument	\$6500 to \$12000
Installation	No
Training	2 days
Maintenance/calibration	Not required
Internal QC	Each Alere Pima™ CD4 cartridge includes internal reagent control, instrument control, reagent expiry control, and sample volume control. The Pima Bead Standard is an internal standard for daily quality control (QC) on the Pima Analyser. It comprises two ready-to-use test cartridges, Pima Beads [Normal] and Pima Beads [Low], with set amounts of _fluorescent spots. Daily QC should be performed before testing of patient samples or after any relocation of the Pima Analyser. Each test takes approx. 7 minutes.
External QA	Compatible with Pima: QASI and UK-NEQAS
URL	<a href="http://alerehiv.com/hiv-monitoring/alere-pima-cd4/">http://alerehiv.com/hiv-monitoring/alere-pima-cd4/</a>

## SECTION IE: CD4: ALERE PIMA™

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/ link	Comment
<b>1 – Required kit or equipment</b>													
58	Alere Pima™ CD4 Test Cartridge	260100100	B	Kit	100	1000	1000	10	12 months	N/A	N/A	<a href="http://pimatest.com/fileadmin/Manuals/Downloads/Manuals/EN/PI-PIMA-01-05-EN_web.pdf">http://pimatest.com/fileadmin/Manuals/Downloads/Manuals/EN/PI-PIMA-01-05-EN_web.pdf</a>	N/A
448	Alere Pima™ CD4 Test Cartridge	260100025	B	Kit	25	1000	1000	40	12 months	N/A	N/A		This is the same kit as the item no.58, only with 25 cartridges per kit instead of 100.
<b>2 – Test run</b>													
254	Alere Printer Paper 1	260400009	C	pack	10 roll/ pack	1000		2	N/A	N/A	N/A	N/A	Required if customer uses Alere Pima™ Printer
	Alere Printer Paper 2	260400010	C	pack	10 roll/ pack	1000		2	N/A	N/A	N/A	N/A	Required if customer uses Alere Pima™ Printer
	Finger Stick Collection Kit	260400199	C	Kit	100	1000		10	N/A	N/A	N/A	N/A	Only for finger stick procedure
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000	1000		N/A	N/A	N/A	N/A	Only for venepuncture procedure
<b>3 – Control</b>													
57	Alere Pima™ Bead Standard	260400011	R	N/A		1000			6 months from opening the kit	N/A	N/A	N/A	N/A

## SECTION IE: CD4: APOGEE AUTO 40

Diagnostic characteristics	Description of characteristics
Name of analyser	Apogee Auto40 Flow Cytometer
Name of test	N/A (Consult Apogee)
Catalogue no.	N/A
Description	The Apogee Auto40 analyser is bench top no-lyse, no-wash volumetric flow cytometer equipped with a green 113 laser at 532 nm, a side scatter detector, two fluorescence channels for enumeration of CD4 count and CD4% of total lymphocytes, as well as CD8 counts and CD4:CD8 ratio. The Apogee Auto40 uses volumetric sampling system instead of beads to deliver sample to the flow cell at a precisely controlled rate. The manufacturer does not manufacture reagents.
Pre-installation requirements	Suitable for level III and IV laboratories depending upon required throughput, may be suitable for some level II laboratories.
Operating conditions	5–35°C room temperature, < 90% humidity
Items supplied with analyser	Data station (Internal PC running Windows XP), monitor
Required accessories	Not detailed, UPS/voltage regulator
Optional accessories	Printer, bar-code scanner
Turnaround time	3 minutes, after 25 minutes incubation
Capacity (per run)	Maximum of 20 samples per hour
Throughput per technician / per day	Maximum of 160 samples
Sample needed and stability	50 µl of blood collected in EDTA according to standard protocol
Sample preparation and protocol complexity	Process: (i) Run control sample of Apogee calibration beads; (ii) add 50µL of blood to tube; (iii) vortex (iv) incubate in dark room for 25 minutes (v) add 450 µL of buffer; (vi) vortex; (vii) choose test type and run sample.
Reagent stability and storage requirements	Reagents are stable for 9 months when stored at 3° – 30° C (37.4° – 86° F); no refrigeration is required
Cost/test	\$2.50 per test for absolute CD4 count; \$3.50 per test for % CD4
Cost/instrument	Approximately \$27,000
Installation	Yes
Training	1 day

**SECTION IE: CD4: APOGEE AUTO 40**

Maintenance/calibration	12-month service interval recommended. In case of breakdown, vendor-trained technician required to repair.
Internal QC	Yes; Apogee beads
External QA	Compatible with CD4 EQA programs (manual analysis only)
URL	<a href="http://www.apogeeflow.com/public_downloads/Auto40_brochure_2-4.pdf">http://www.apogeeflow.com/public_downloads/Auto40_brochure_2-4.pdf</a>

## SECTION IE: CD4: APOGEE AUTO 40

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
482	Apogee CD4 Reagents (no information available from manufacturer)	1467	B	100 tests/kit	1	1000	1000	1000	9 months	No	N/A	N/A	N/A
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
347	Pipette tip, 100–1000 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
59	Apogee Reagent Tubes	Unknown	D	Tubes/pack		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
75	Apogee Control Beads	N/A	R	Unknown		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IE: CD4: BECTON DICKINSON FACSCALIBUR™

Diagnostic characteristics	Description of characteristics
Name of analyser	Becton Dickinson FACSCalibur™
Name of test	BD Tritest™ CD4/CD8/CD3 with Trucount Tubes
Catalogue no.	Unknown
Description	The BD FACSCalibur™ system is an automated bench top, bead-based classical single platform multicolour flow cytometer. It incorporates an alignment-free optical design, interbeam compensation and dual-laser technology. Performs absolute and percentage CD4 counts, immunophenotyping, residual white blood cell enumeration, DNA analysis. The instrument has an optional loader that provides walkaway automation for routine applications, and an optional high throughput sampler (HTS) for automated sample acquisition from 96- and 384-well microtiter plates
Pre-installation requirements	Suitable for level III and IV laboratories depending upon required throughput
Operating conditions	Storage temperature: 0–49°C; operating temperature: 16–29°C; operating relative humidity: 10–90% relative non-condensing
Items supplied with analyser	Flow cytometer and BD FACStation™ workstation
Required accessories	BD FACFlow™ supply system, Mac computer, printer, UPS/voltage regulator
Optional accessories	Automated sample loader, bar-code scanner
Turnaround time	60 minutes for 40 tests run on a rack, including incubation time
Capacity (per run)	40 tests per hour, after approximately 30 minute incubation time
Throughput per technician / per day	Approximately 200 samples
Sample needed and stability	At least 100µL whole blood collected in either 2mL or 4 mL K2 EDTA anticoagulant tubes; staining to take place w/n 72 hours of blood draw; analysis to take place w/n 6 hours of staining.
Sample preparation and protocol complexity	Required. Process: (i) blood is collected and added to tube to which reagent has been added; (ii) sample is vortexed and incubated; (iii) fixative (lyse) is added to the tube, which is vortexed and incubated; and (iv) sample is vortexed and run on the instrument.
Reagent stability and storage requirements	Reagents are stable for 12 months from date of manufacture when stored at 2° – 30° C; transient exposure (shipping delay or temperature incursion) of 10 days at 50° C (122° F).
Cost/test	Volume based; ranges from approximately \$3.00 – \$7.00 per test
Cost/instrument	Approximately \$75,000 – \$100,000
Installation	Yes
Training	2–5 days



**SECTION IE: CD4: BECTON DICKINSON FACSCALIBUR™**

Maintenance/calibration	Required annually. In case of breakdown, vendor-trained technician required to repair.
Internal QC	BD provides bead-based controls
External QA	Compatible with CD4 EQA programs
URL	<a href="http://www.bdbiosciences.com/documents/BD_FACSCalibur_instructions.pdf">http://www.bdbiosciences.com/documents/BD_FACSCalibur_instructions.pdf</a>

## SECTION IE: CD4: BECTON DICKINSON FACSCALIBUR™

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
480	BD Tritest™ CD4/CD8/CD3 with Trucount Tubes	340401	R	50 tests/kit	50	1000	1000	20	N/A	Yes	N/A	N/A	N/A
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
340	Normal blood (EDTA)	Generic	C	N/A		1000			24 h	N/A	N/A	N/A	N/A
478	Petri dish with cover	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
347	Pipette tip, 100–1000 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
477	Tubes, centrifuge, 50 ml	Generic	C	N/A		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
60	BD FACST™ Cleaning Solution	340346	R	5 litres/pack		1000			N/A	N/A	N/A	<a href="http://gssh.co/UYJKFb">http://gssh.co/UYJKFb</a>	N/A
65	BD FACST™ Flow Sheath Fluid	342003	R	20 litres/pack		1000			N/A	N/A	N/A	<a href="http://gssh.co/UYJKFb">http://gssh.co/UYJKFb</a>	N/A
61	BD FACST™ Rinse Solution	340345	R	5 litres/pack		1000			N/A	N/A	N/A	<a href="http://gssh.co/UYJKFb">http://gssh.co/UYJKFb</a>	N/A

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/ link	Comment
106	Sodium hypochlorite solution (5–10%)	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
107	Water, distilled	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
478	Petri dish with cover	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
479	BD Trucount™ Controls	340335	R	30/pack		1000			N/A	Yes	N/A	N/A	N/A

## SECTION IE: CD4: BECTON DICKINSON FACSCOUNT™

Diagnostic characteristics	Description of characteristics
Name of analyser	Becton Dickinson FACSCount™ system
Name of test	BD FACSCount Reagent Kit (Absolute CD4, CD8, CD3 counts) BD FACSCount CD4 Reagent Kit (Absolute and percentage CD4 counts)
Catalogue no.	337858, 340166, 340167, 339010
Description	The BD FACSCount™ system is a bead based, no-lyse, no-wash dedicated analyser for enumeration of CD4 absolute counts and percentages or CD4, CD8 and CD3 T-cell counts. For use with whole blood. Reportable range: CD4 1–2000 cells/μl, CD8 1–2000 cells/μl, CD3 1–3500 cell/μl. Convection-cooled laser, precision less than 10% CV
Pre-installation requirements	Suitable for level II, III and IV laboratories depending upon required throughput
Operating conditions	Unknown
Items supplied with analyser	BD FACSCount™ system (computer, monitor, and printer are integrated into instrument), workstation, coring station
Required accessories	Cleaning tubes (343685), caps for cleaning tubes (343514), pipette tips in bulk (340293), thermal paper roll (332839), pre-programmed electronic pipette (50 μl) plus three spare batteries, workstation for sample preparation, CD4 software disk, UPS/voltage regulator, barcode reader
Optional accessories	N/A
Turnaround time	60 – 90 minute incubation, 2 – 3 minutes per test
Capacity (per run)	20 per hour, after initial 60 – 90 minute incubation
Throughput per technician / per day	30–80/day
Sample needed and stability	50 μl of whole blood collected in EDTA anticoagulant and stored at 20oC to 25oC (68oF to 77oF); staining to take place w/n 48 hours of blood draw; analysis to take place w/n 48 hours of staining. Minimum of 200 μl of whole blood is required for the test.
Sample preparation and protocol complexity	Required. Process: (i) blood is collected and added to tube; (ii) sample is vortexed and incubated; (iii) fixative is added to the tube, which is vortexed and incubated; and (iv) sample is vortexed and run on the instrument
Reagent stability and storage requirements	BD FACSCount™ Reagent kit: must be stored at 2° – 8° C (36° – 46° F); shelf-life is 23 months BD FACSCount™ Control kit: must be stored at 2° – 8° C (36° – 46° F); shelf-life 24 months
Cost/test	Volume based; ranges from approximately \$3.50 – \$10.00 per test
Cost/instrument	Approximately \$30,000
Installation	Yes
Training	2–5 days

**SECTION IE: CD4: BECTON DICKINSON FACSCOUNT™**

Maintenance/calibration	Required annually. In case of breakdown, vendor-trained technician required to repair.
Internal QC	BD provides bead-based controls
External QA	Compatible with CD4 EQA programs
URL	<a href="http://www.bdbiosciences.com/instruments/facscount/index.jsp">http://www.bdbiosciences.com/instruments/facscount/index.jsp</a>

## SECTION IE: CD4: BECTON DICKINSON FACSCOUNT™

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/ link	Comment
1 – Required kit or equipment													
63	BD FACSCount™ CD4 Reagent Kit (50)	339010 Alt	B	50 tests/kit	50	1000	1000	20	6 months	Yes	N/A	<a href="http://gssh.co/t4FHu5">http://gssh.co/t4FHu5</a>	Alternative product. For enumeration of absolute and percentage CD4 counts
66	BD FACSCount™ Reagent Kit (50)	340167	B	50 tests/kit	50	1000	1000	20	23 months	Yes	N/A	<a href="http://gssh.co/t4FHu5">http://gssh.co/t4FHu5</a>	For enumeration of absolute CD4, CD8, and CD3 counts
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
478	Petri dish with cover	Generic	C	1 unit		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–20 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
370	Thermal paper	322839	C	1 rolls/ pack		1000	2	1000	N/A	N/A	N/A	<a href="http://gssh.co/uYJKFb">http://gssh.co/uYJKFb</a>	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
60	BD FACSCount™ Cleaning Solution	Unknown	R	5 litres/ pack	1	1000	3	1000	N/A	N/A	N/A	<a href="http://gssh.co/uYJKFb">http://gssh.co/uYJKFb</a>	N/A
62	BD FACSCount™ Flow Sheath Fluid	Unknown	R	20 litres/ pack	1	1000	5	1000	N/A	N/A	N/A	<a href="http://gssh.co/uYJKFb">http://gssh.co/uYJKFb</a>	N/A
3 – Control													
340	Normal blood (EDTA)	Generic	C	N/A		1000			24 h	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box	1	1000	4000	1000	N/A	N/A	N/A	N/A	N/A
62	BD FACSCount™ CD4 Control Kit (25)	340166	R	25 tests/kit		1000	1000		24 months	N/A	N/A	<a href="http://gssh.co/uYJKFb">http://gssh.co/uYJKFb</a>	N/A

## SECTION IE: CD4: BLUE OCEAN LG100 (BECKMAN COULTER)

Diagnostic characteristics	Description of characteristics
Name of analyser	Blue Ocean LG100 (Beckman Coulter) <sup>b</sup>
Name of test	N/A
Catalogue no.	Unknown
Description	Blue Ocean LG100 is a medium throughput flow cytometer that performs CD4, CD4%. Blue Ocean LG100 Load & Go™ sample processing is an automated, dedicated load-and-go system for counting CD4 cells, CD4% and other subsets of lymphocytes (including percentage and absolute counts of T cells, B cells and NK cells)
Pre-installation requirements	Suitable for level III and IV laboratories depending upon required throughput, may be suitable for some level II laboratories
Operating conditions	Unknown
Items supplied with analyser	Not detailed
Required accessories	Not detailed, UPS/voltage regulator
Optional accessories	Not detailed
Turnaround time	Unknown
Capacity (per run)	Unknown
Throughput per technician / per day	100 tests/day
Sample needed and stability	Unknown
Sample preparation and protocol complexity	Unknown
Reagent stability and storage requirements	Unknown
Cost/test	Unknown
Cost/instrument	Unknown
Installation	Yes
Training	2–5 days
Maintenance/calibration	Required annually

**SECTION IE: CD4: BLUE OCEAN LG100 (BECKMAN COULTER)**

Internal QC	Unknown
External QA	Unknown
URL	<a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a>

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b. Beckman Coulter acquired Blue Ocean in March 2012. Currently, the product is in the development pipeline, undergoing the rigorous testing required to receive the necessary registration with the regulatory bodies. We will update the information about the analyser when it will receive market authorization and registered with regulatory authorities.



## SECTION IE: CD4: BLUE OCEAN LG100 (BECKMAN COULTER)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
509	Blu-O™ LSA-1 Monoclonal Antibody Panel, CE-IVD	N00011426	B	50 tests/kit	50	1000	1000	20	N/A	N/A	N/A	N/A	N/A
<b>2 – Test run</b>													
515	Blu-O™ Deep Well Plate, CE-IVD	N00011415	C	50 plates/pack		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
516	Blu-O™ Instrument Waste Container	N00011542	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
513	Blu-O™ Enzymatic Cleaner, CE-IVD	N00011411	R	750 ml/bottle		1000			N/A	N/A	N/A	N/A	N/A
510	Blu-O™ Lysing Reagent Kit, CE-IVD	N00011418	R	100 tests/kit		1000			N/A	N/A	N/A	N/A	N/A
512	Blu-O™ Sheath Solution, CE-IVD	N00011410	R	10 litres/pack		1000			N/A	N/A	N/A	N/A	N/A
514	Blu-O™ Sodium Hypochlorite Solution, CE-IVD	N00011412	R	200 ml/pack		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
511	Blu-O™ Whole Blood Control Kit, CE-IVD	N00011421	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IE: CD4: BLUE OCEAN LG250 (BECKMAN COULTER)

Diagnostic characteristics	Description of characteristics
Name of analyser	Beckman Coulter Blue Ocean LG250 <sup>c</sup>
Name of test	N/A
Catalogue no.	Unknown
Description	High throughput flow cytometer that performs CD4, CD4%
Pre-installation requirements	Suitable for level III and IV laboratories depending upon required throughput
Operating conditions	Unknown
Items supplied with analyser	Not detailed
Required accessories	Not detailed, UPS/voltage regulator
Optional accessories	Not detailed
Turnaround time	Unknown
Capacity (per run)	Unknown
Throughput per technician / per day	300 tests/day
Sample needed and stability	Unknown
Sample preparation and protocol complexity	Unknown
Reagent stability and storage requirements	Unknown
Cost/test	Unknown
Cost/instrument	Unknown
Installation	Yes
Training	2–5 days
Maintenance/calibration	Required annually
Internal QC	Unknown

**SECTION IE: CD4: BLUE OCEAN LG250 (BECKMAN COULTER)**

External QA	Unknown
URL	<a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a>

c. Beckman Coulter acquired Blue Ocean in March 2012. Currently, the product is in the development pipeline, undergoing the rigorous testing required to receive the necessary registration with the regulatory bodies. We will update the information about the analyser when it will receive market authorization and registered with regulatory authorities.

## SECTION IE: CD4: BLUE OCEAN LG250 (BECKMAN COULTER)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/ link	Comment
1 – Required kit or equipment													
509	Blu-O™ LSA-1 Monoclonal Antibody Panel, CE-IVD	N00011426	B	50 tests/kit	50	1000	1000	20	N/A	N/A	N/A	N/A	N/A
2 – Test run													
515	Blu-O™ Deep Well Plate, CE-IVD	N00011415	C	50 plates/pack		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
516	Blu-O™ Instrument Waste Container	N00011542	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
513	Blu-O™ Enzymatic Cleaner, CE-IVD	N00011411	R	750 ml/bottle		1000			N/A	N/A	N/A	N/A	N/A
510	Blu-O™ Lysing Reagent Kit, CE-IVD	N00011418	R	100 tests/kit		1000	1000	10	N/A	N/A	N/A	N/A	N/A
512	Blu-O™ Sheath Solution, CE-IVD	N00011410	R	10 litres/pack		1000			N/A	N/A	N/A	N/A	N/A
514	Blu-O™ Sodium Hypochlorite Solution, CE-IVD	N00011412	R	200 ml/pack		1000			N/A	N/A	N/A	N/A	N/A
3 – Control													
511	Blu-O™ Whole Blood Control Kit, CE-IVD	N00011421	R	N/A		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IE: CD4: EPICS XL FLOW CYTOMETER (BECKMAN COULTER)

Diagnostic characteristics	Description of characteristics
Name of analyser	Beckman Coulter EPICS XL flow cytometry system <sup>d</sup>
Name of test	CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent
Catalogue no.	626551, 6607013
Description	<p>The tetraONE SYSTEM for EPICS XL flow cytometry systems and CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent combine four-color fluorescent monoclonal antibody reagents, quality control reagents, an optional absolute count reagent, and software for automated analysis of lymphocyte populations in whole blood using EPICS XL flow cytometry systems with SYSTEM II Software.</p> <p>The system with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 is intended "For In Vitro Diagnostic Use" and allows simultaneous identification and enumeration of total CD3+, total CD4+, total CD8+, dual CD3+/CD4+ and dual CD3+/CD8+ T lymphocyte population percentages and absolute counts. The system also provides the T4/T8 ratio.</p> <p>Beckman Coulter EPICS XL flow cytometer is a bench-top bead based classical single platform and multicolour flow Cytometer. The instrument has an air-cooled 488nm 15mw laser</p>
Pre-installation requirements	Suitable for level III and IV laboratories depending upon required throughput
Operating conditions	Keep the room temperature between 16°C and 32°C and do not let it change more than 5°C/h. Keep the humidity between 5% and 80%, without condensation
Items supplied with analyser	Cytometer, power supply, workstation (monitor, computer, keyboard and mouse)
Required accessories	UPS/voltage regulator
Optional accessories	Multi-tube carousel loader, printer, bar-code printer, barcode scanner, data storage, network kits, workstation/network server, fourth fluid litres (fl) sensor, random-access memory (RAM) upgrade kits, multiple software options
Turnaround time	Unknown
Capacity (per run)	Unknown
Throughput per technician / per day	30–300/day
Sample needed and stability	100µl of venous blood sample (perform in duplicate, 200µl total per specimen)
Reagent stability and storage requirements	Unopened reagent is stable to the expiration date on the vial label when stored at 2-8°C. Opened vials are stable for 90 days when stored at 2-8°C. Return reagent to 2-8°C immediately after use. Do not freeze. Minimize exposure to light.
Cost/test	Unknown
Cost/instrument	Unknown

**SECTION IE: CD4: EPICS XL FLOW CYTOMETER (BECKMAN COULTER)**

Installation	Yes
Training	2–5 days
Maintenance/calibration	Required annually
Internal QC	Beckman Coulter offers a number of quality control reagents to standardize flow cytometer performance and assure quality of test reagents
External QA	Unknown
URL	<a href="https://www.beckmancoulter.com/wisportal/techdocs?docname=4237298CA.pdf">https://www.beckmancoulter.com/wisportal/techdocs?docname=4237298CA.pdf</a>

d. This instrument is on the list of products to be discontinued, as it utilizes DOS system. Beckman is shifting toward new FC 500 series. Currently, Beckman Coulter EPICS XL flow cytometry system for sale and will schedule to discontinue support Dec 31, 2016. The Cytomics FC 500 series replaces the Epics XL-MCL

## SECTION IE: CD4: EPICS XL FLOW CYTOMETER (BECKMAN COULTER)

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
74	Beckman Coulter CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent	6607013	R	vial	100	50	1000	1000	N/A	N/A	N/A	<a href="http://gssh.co/s6XU9g">http://gssh.co/s6XU9g</a>	2–8°C, do not freeze, limit exposure to light
	tetraONE SYSTEM Software (Version 4.0) on EPICS® XL™ flow cytometry systems with four fluorescence sensors		E	Unit	1	1000			N/A	N/A	N/A	N/A	N/A
2 – Test run													
268	Gauze pad	Generic	C	100 pads/box		1000			N/A	N/A	N/A	N/A	N/A
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000			N/A	N/A	N/A	N/A	N/A
349	Pipette tip, 5–20 µl	Generic	C	96 tips/box	96	1000	1000	11	N/A	N/A	N/A	N/A	N/A
377	Tubes, test, 12 mm x 75 mm, capped	Generic	C	100 tubes/pack		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
40	Pipette/pipettor 20	Generic	E	1 unit	1000				N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit	1000				N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit	1000				N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	E	1 unit	1000				N/A	N/A	N/A	N/A	N/A
73	Beckman Coulter IsoFlow™ Sheath Fluid	8546859	R	10 litres/bottle	1000				N/A	N/A	N/A	<a href="http://gssh.co/x5uEk9">http://gssh.co/x5uEk9</a>	N/A
104	Ethanol (70%) for cleaning	Generic	R	N/A	1000				N/A	N/A	N/A	N/A	N/A
106	Sodium hypochlorite solution (5–10%)	Generic	R	N/A	1000				N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
67	Beckman Coulter CYTO-COMP™ Cell Kit	6607023	R	5 ml/bottle	1000				N/A	N/A	N/A	<a href="http://gssh.co/sbndMj">http://gssh.co/sbndMj</a>	2–8°C, do not freeze
68	Beckman Coulter CYTO-COMP™ Reagent Kit	6607021	B	50 tests/kit	1000	50	1000	20	N/A	N/A	N/A	<a href="http://gssh.co/sqQV1x">http://gssh.co/sqQV1x</a>	2–8°C, do not freeze
69	Beckman Coulter COULTER® CYTO-TROL™ Control Cells Kit	6604248	R	50 tests/kit	1000	50	1000	20	N/A	N/A	N/A	<a href="http://gssh.co/rPTg2N">http://gssh.co/rPTg2N</a>	2–8°C, do not freeze
71	Beckman Coulter Flow-Check™ Fluorospheres	6605359	R	30 ml/bottle	1000				N/A	N/A	N/A	<a href="http://gssh.co/sWO34o">http://gssh.co/sWO34o</a>	2–8°C, do not freeze, limit exposure to light
72	Beckman Coulter Flow-Set™ Fluorospheres	6607007	R	30 ml/bottle	1000				N/A	N/A	N/A	<a href="http://gssh.co/vYCHJ1">http://gssh.co/vYCHJ1</a>	2–8°C, do not freeze, limit exposure to light



## SECTION IE: CD4: MILLIPORE GUAVA

Diagnostic characteristics	Description of characteristics
Name of analyser	Millipore Guava Auto CD4/CD4% system
Name of test	Guava Auto CD4/CD4% Kit
Catalogue no.	0500-2430
Description	The Guava Auto CD4/CD4% system is two-colour cytometer based on microcapillary technology to analyse cells without the use of sheath fluid or beads. Provides the ability to measure both absolute and percentage CD4 counts as well as total lymphocyte count.
Pre-installation requirements	Suitable for level II and III laboratories
Operating conditions	Temperature: 15 – 35°C (59 – 95°F); humidity: 10 – 90%
Items supplied with analyser	Guava Auto CD4/CD4% base system; Guava® AutoCD4/CD4% Software Module (0500-2390), laptop
Required accessories	T-Cell Monitoring Start-up Accessory Kit (0500-2400), UPS with power conditioner (international)
Optional accessories	Bar-code scanner
Turnaround time	2 minutes, after 45 minute incubation
Capacity (per run)	≥ 100 samples per day
Throughput per technician / per day	≥ 100 samples/day
Sample needed and stability	10 µL whole blood collected in EDTA anticoagulant. Blood samples should be stored in blood collection tubes at 18-25°C and be tested within 48 hours after they are obtained.
Sample preparation and protocol complexity	Process: (i) Add 10µL of Guava reagents to tube (ii) add 10 µL of blood from patient; (iii) incubate 30 minutes (iv) add 380 µL of Guava lyse solution; (v) incubate sample 15 minutes in darkness; (iv) sample is run on the instrument.
Reagent stability and storage requirements	Reagents must be stored at 2° – 8° C (36° – 46° F); reagents are shipped with 12 months of shelf life.
Cost/test	\$2.50 per test for CD4/CD4% (including the distribution margin), regardless of volume
Cost/instrument	\$2.50 per test for CD4/CD4% (including the distribution margin), regardless of volume
Installation	Yes
Training	1day

**SECTION IE: CD4: MILLIPORE GUAVA**

Maintenance/calibration	2-year service plan (cat. no. 0500-5310), annual maintenance. In case of breakdown, vendor-trained technician required to repair.
Internal QC	Guava Check beads
External QA	Compatible with CD4 EQA programs
URL	<a href="http://www.millipore.com/publications.nsf/a73664f9f981af8c852569b9005b4eee/18cf257647b5f5d885257a63004eec18/\$FILE/DS3882ENFU.pdf">http://www.millipore.com/publications.nsf/a73664f9f981af8c852569b9005b4eee/18cf257647b5f5d885257a63004eec18/\$FILE/DS3882ENFU.pdf</a>

**SECTION IE: CD4: MILLIPORE GUAVA AUTO CD4/CD4% SYSTEM**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
76	Millipore Guava Auto CD4/CD4% Kit (100 tests)	4500-0480	B	100 tests/kit	100	1000	1000	10	12 months	N/A	N/A	<a href="http://gssh.co/19jq0K6">http://gssh.co/19jq0K6</a>	Antibody cocktail: 2–8°C, do not freeze, limit exposure to light. Lysing solution: 18–25°C, do not freeze
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
343	Paper wipes, small	Generic	C	Units/pack		1000			N/A	N/A	N/A	N/A	N/A
347	Pipette tip, 100–1000 µl	Generic	C	96 tips/box		1000	1000		N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000	2000		N/A	N/A	N/A	N/A	N/A
376	Tubes, microcentrifuge, 1.5 ml, screw cap	Generic	C	Tubes/pack	100	1000	1000	10	N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
81	Millipore Guava® Instrument Cleaning Fluid	4200-0140	R	10 ml/pack		1000			N/A	N/A	N/A	<a href="http://gssh.co/ubxxVT">http://gssh.co/ubxxVT</a>	N/A
105	Sodium hypochlorite solution (20%)	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
107	Water, distilled	Generic	R	N/A		1000			N/A	N/A	N/A	N/A	N/A
<b>3 – Control</b>													
376	Tubes, microcentrifuge, 1.5 ml, screw cap	Generic	C	Tubes/pack	100	1000	1000	10	N/A	N/A	N/A	N/A	Unit of measure varies with manufacturer
80	Millipore Guava® Check Kit	4500-0020	R	1 test/kit		1000			N/A	N/A	N/A	<a href="http://gssh.co/ubxxVT">http://gssh.co/ubxxVT</a>	N/A

## SECTION IE: CD4: PARTEC CYFLOW® COUNTER

Diagnostic characteristics	Description of characteristics
Name of analyser	Partec CyFlow® Counter
Name of test	Partec CD4 Easy Count Kit Partec CD4 Easy Count Kit – dry Partec CD4% Easy Count Kit/Partec CD4% Easy Count Kit (PE&PEDy647) - dry
Catalogue no.	CY-S-3022 or CY-S-3073 (fully automated)
Description	The CyFlow® Counter is a portable flow cytometer dedicated for routine CD4 and CD4% counting as well as total lymphocyte and white blood cell counting. The Partec CyFlow is a volumetric system. Also, it does not require optical alignment and laser adjustment. The CyFlow Counter can be combined with a CyFlow sample preparation and autoloading system. The system allows 10, 20, 30 or 40 samples at a time to be loaded on a tray; alternatively, 96 well plates can be used. Whereas typical CyFlow Counter throughput is about 250 samples per day, this added capability allows for acquisition of up to 400 samples per day, making the system a compact, but high-throughput option. Reagents are available both in dry and liquid (for sample preparation and autoloading system) form.
Pre-installation requirements	Suitable for level II and III laboratories
Operating conditions	Temperature: 10° – 40°C (50° – 104°F); humidity: <95% non-condensing; maximum altitude: 3,000m (9,843 feet)
Items supplied with analyser	Depends upon automation requirement; Premium Starter Kit (reagents, accessories, pipettes, consumables, UPS); dedicated Intel® CPU integrated into instrument; data storage of approximately 20,000 data sets; USB port; 8.4" TFT color touch screen integrated into instrument; option to connect other printers; built-in thermal printer integrated into instrument
Required accessories	UPS/voltage regulator, In-line filters for sheath container
Optional accessories	Barcode Reader (Cy-S-3022), auto-prep and loading station
Turnaround time	After 15 minutes incubation, 40 – 70 seconds per test
Capacity (per run)	250 tests/day or 400 tests/day with auto-prep and loading station
Throughput per technician / per day	250 tests/day or 400 tests/day with auto-prep and loading station
Sample needed and stability	20 µL whole blood collected in EDTA anticoagulant; unstained anti-coagulated blood can be stored at room temperature (18° – 25°C) for up to 48 hours; alternatively anti-coagulated blood can be refrigerated at 2° – 8°C for up to 7 days prior to sample processing. CD4 mAB-stained blood samples can be stored at room temperature (18° – 25°) for up to 24 hours or alternatively refrigerated at 2° – 8° for at least 72 hours.
Sample preparation and protocol complexity	Process for dry reagents only: (i) add blood to Partec CD4 tube containing dry mAB reagent; (ii) incubate 15 minutes at room temperature in the dark; (iii) add pre-filled buffer to tube; (iv) run sample in CyFlow Counter. For liquid reagents: (i) add blood to a test tube; (ii) add 20 µL of liquid mAB reagent to tube; (iii) incubate 15 minutes at room temperature in the dark; (iv) add 820 µL no lyse buffer and shake gently; (v) run sample on the Partec device. In either case, the process for CD4% requires the addition of a second buffer.
Reagent stability and storage requirements	Dry reagents may be stored at up to 35° Celsius. Maximum shelf life: 6 months. No cooling chain required. No cooling storage required. Liquid reagents must be stored at 2° – 8° C (36° – 46° F) in the dark. Maximum shelf life: 12 months.

## SECTION IE: CD4: PARTEC CYFLOW® COUNTER

Cost/test	€1.75 (~\$2.30 per test for absolute CD4 and €2.50 (~\$3.30) for CD4 absolute and percentage, high volume discounts available
Cost/instrument	Approximately \$22,220; higher with the addition of auto-preparation and auto-loading unit
Installation	Yes
Training	1–2 days
Maintenance/calibration	Annual maintenance In case of breakdown, vendor-trained technician required to repair (generally available locally). Alternatively, instrument replacement possible.
Internal QC	Instrument supports QC (Partec CountCheck beads as non-biological controls and Partec ControlBlood – dry as biological controls)
External QA	Compatible with CD4 EQA programs.
URL	<a href="http://www.partec.com/instrumentation/products.html?&amp;tx_cycloproductfinder_cyc_pf_display[product]=1017&amp;tx_cycloproductfinder_cyc_pf_display[action]=show&amp;tx_cycloproductfinder_cyc_pf_display[controller]=Product">http://www.partec.com/instrumentation/products.html?&amp;tx_cycloproductfinder_cyc_pf_display[product]=1017&amp;tx_cycloproductfinder_cyc_pf_display[action]=show&amp;tx_cycloproductfinder_cyc_pf_display[controller]=Product</a>

**SECTION IE: CD4: PARTEC CYFLOW® – DRY REAGENTS CD4 ABSOLUTE ONLY**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
82	Partec CD4 easy count kit – dry	05-8401-d	B	100 tests/kit	100	1000	1000	10	12 months	N/A	N/A	<a href="http://gssh.co/14kmUY9">http://gssh.co/14kmUY9</a>	N/A
84	Partec CD4% Easy Count Kit (PE&PEDY647) - dry	05-8405 -d	B	100 tests/kit	100	1000	1000	10	12 months	N/A	N/A	<a href="http://gssh.co/14kmUY9">http://gssh.co/14kmUY9</a>	N/A
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box		1000	2000		N/A	N/A	N/A	N/A	N/A
408	Rack, test tubes, 14-mm diameter	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
92	Partec Sheath Fluid	04-4007	R	5 litres/ bottle		1000	20		N/A	N/A	N/A	<a href="http://gssh.co/vDKKMF">http://gssh.co/vDKKMF</a>	N/A
<b>3 – Control</b>													
88	Partec CountCheck Beads (Green)	05-4011	R	50 tests/kit		1000			12 months	N/A	N/A	N/A	N/A

## SECTION IE: CD4 PARTEC CYFLOW® – WET REAGENTS CD4% &amp; ABSOLUTE

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests required	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
1 – Required kit or equipment													
83	Partec CD4 Easy Count Kit (100)	05-8401	B	100 tests/kit	100	1000	1000	10	12 months	N/A	N/A	<a href="http://gssh.co/14kmUY9">http://gssh.co/14kmUY9</a>	N/A
85	Partec CD4% Easy Count Kit (PE&PEDy647) (100)	05-8405	B	100 tests/kit	100	1000	1000	10	12 months	N/A	N/A	<a href="http://gssh.co/14kmUY9">http://gssh.co/14kmUY9</a>	N/A
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
258	Partec CyFlow® Tubes, 3.5 ml	04-2000	C	500 tubes/ pack	500	1000	2000	2	N/A	N/A	N/A	<a href="http://gssh.co/vDKKMF">http://gssh.co/vDKKMF</a>	N/A
347	Pipette tip, 100–1000 µl	Generic	C	96 tips/box	96	1000	3000	11	N/A	N/A	N/A	N/A	N/A
351	Pipette tip, 10–200 µl	Generic	C	96 tips/box	96	1000	5000	11	N/A	N/A	N/A	N/A	N/A
408	Rack, test tubes, 14-mm diameter	Generic	D	1 unit		1000			N/A	N/A	N/A	N/A	N/A
42	Pipette/pipettor 1000	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
41	Pipette/pipettor 200	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
46	Timer, digital	Generic	E	1 unit		1000			N/A	N/A	N/A	N/A	N/A
92	Partec CyFlow®Sheath Fluid	04-4007	R	5 litres/ bottle		1000	40		N/A	N/A	N/A	<a href="http://gssh.co/vDKKMF">http://gssh.co/vDKKMF</a>	N/A



Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
3 – Control													
87	Partec Control Blood – Dry	05-8993	R	10 tests/kit		1000			12	N/A	N/A	<a href="http://gssh.co/uzknGN">http://gssh.co/uzknGN</a>	N/A
88	Partec CountCheck Beads (Green)	05-4011	R	50 tests/kit		1000			12	N/A	N/A	N/A	N/A

## SECTION IE: CD4 PARTEC CYFLOW® MINIPOC

Diagnostic characteristics	Description of characteristics
Name of analyser	Partec CyFlow® miniPOC
Name of test	Partec Reagent Kit for CyFlow® miniPOC
Catalogue no.	CY-S-3033
Description	Mini, portable CD4 and CD4% counter for routine HIV immune status monitoring and follow-up, weight less than 5 kg, rechargeable battery (4–5 h). The device is used with Partec dry CD4 reagents (making it a closed system), which eliminates the need for cold chain or cold storage.
Pre-installation requirements	Temperature: 10° – 40°C (50° – 104°F); humidity: <95% noncondensing; maximum altitude: 3,000 m (9,843 ft)
Operating conditions	Analyser: Dedicated Intel® Atom™ CPU integrated into instrument; Windows™-based analysis software; data storage of approximately 20,000 data sets; USB port; 5.7" color touch screen integrated into instrument; built-in thermal printer integrated into instrument; option to connect other printers; connection system via GSM module
Items supplied with analyser	Analyser: Dedicated Intel® Atom™ CPU integrated into instrument; Windows™-based analysis software; data storage of approximately 20,000 data sets; USB port; 5.7" color touch screen integrated into instrument; built-in thermal printer integrated into instrument; option to connect other printers; connection system via GSM module
Required accessories	UPS/voltage regulator, In-line filters for sheath container
Optional accessories	CY-S-3091   Transportation Bag for CyFlow® miniPOC, CY-S-3095   Rechargeable High Efficiency Lithium Battery Dock for CyFlow® miniPOC, operation independent from regular power supply CY-S-3098   Solar Panel + Battery Dock for CyFlow® miniPOC
Turnaround time	15 minutes incubation; 40 – 70 seconds per test
Capacity (per run)	Up to 250 tests/day
Throughput per technician / per day	Up to 250 tests/day (manual)
Sample needed and stability	20 µL whole blood collected in EDTA anticoagulant; analysis within 48 hours when stored at room temperature; unstained anti-coagulated blood can be stored at room temperature (18° – 25°C) for up to 48 hours; alternatively anti-coagulated blood can be refrigerated at 2° – 8°C for up to 7 days prior to sample processing. CD4 mAB-stained blood samples can be stored at room temperature (18° – 25°) for up to 24 hours or alternatively refrigerated at 2° – 8° for at least 72 hours.
Sample preparation and protocol complexity	Process for dry reagents only: (i) add 20µL blood to Partec CD4 tube containing dry mAb reagents; (ii) incubate 15 minutes at room temperature in the dark; (iii) add pre-filled buffer to tube; (iv) after gently shaking the tube, refill volume from sample tube into syringe; (v) attach syringe to CyFlow mini POC.
Reagent stability and storage requirements	No cooling chain required. No cooling storage required. Dry reagents may be stored at up to 35°C and have a maximum shelf life of 6 months.
Cost/test	€3.00 (~\$3.96) per test for absolute CD4 and CD4 percentage combined, high volume discounts available

## SECTION IE: CD4 PARTEC CYFLOW® MINIPOC

Cost/instrument	~€7,100 (~\$9,380). Partec offers a "point-of-care" package (including, instrument, reagents for 5,000 tests, 36-month instrument warranty) with an effective instrument price of ~\$4,000.
Installation	No
Training	1–2 days
Maintenance/calibration	Annual maintenance. In case of breakdown, vendor-trained technician required to repair (generally available locally). Alternatively, instrument replacement possible.
Internal QC	Supports internal QC (Partec CountCheck beads as non-biological controls and Partec ControlBlood – dry as biological controls).
External QA	Compatible with CD4 EQA programs
URL	<a href="http://www.partec.com/instrumentation/products.html?&amp;tx_cycloproductfinder_cyc_pf_display%5Bproduct%5D=1015&amp;tx_cycloproductfinder_cyc_pf_display%5Baction%5D=show&amp;tx_cycloproductfinder_cyc_pf_display%5Bcontroller%5D=Product">http://www.partec.com/instrumentation/products.html?&amp;tx_cycloproductfinder_cyc_pf_display%5Bproduct%5D=1015&amp;tx_cycloproductfinder_cyc_pf_display%5Baction%5D=show&amp;tx_cycloproductfinder_cyc_pf_display%5Bcontroller%5D=Product</a>

## SECTION IE: CD4 PARTEC CYFLOW® MINIPOC

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/ UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/ link	Comment
1 – Required kit or equipment													
91	Partec Reagent Kit for CyFlow® miniPOC	05-8409-d	B	20 tests/kit	20	1000	1000	50	N/A	N/A	N/A	<a href="http://gssh.co/tuaFLL">http://gssh.co/tuaFLL</a>	N/A
2 – Test run													
505	Gloves – multiple sizes, powder-free	Generic	C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A
86	Partec Cleaning Fluid	04-4009	R	250 ml/bottle		1000			N/A	N/A	N/A	<a href="http://gssh.co/vDKKMF">http://gssh.co/vDKKMF</a>	N/A
90	Partec Decontamination Fluid	04-4010	R	250 ml/bottle		1000			N/A	N/A	N/A	<a href="http://gssh.co/vDKKMF">http://gssh.co/vDKKMF</a>	N/A
92	Partec Sheath Fluid	04-4007	R	5 litres/ bottle		1000			N/A	N/A	N/A	<a href="http://gssh.co/vDKKMF">http://gssh.co/vDKKMF</a>	N/A
3 – Control													
87	Partec Control Blood –Dry	05-8993	R	10 tests/kit		1000			12	N/A	N/A	<a href="http://gssh.co/uzknGN">http://gssh.co/uzknGN</a>	N/A

## SECTION IE: CD4: POINTCARE NOW

Diagnostic characteristics	Description of characteristics
Name of analyser	PointCare NOW analyser
Name of test	PointCare NOW Reagent Kit 100
Catalogue no.	36008
Description	The PointCare NOW™ system measures CD4 absolute count and %CD4, WBC count and haemoglobin, as well as total count and percentage lymphocytes, monocytes, neutrophils and eosinophil. The system uses forward light scattering (rather than the fluorescent dyes) to distinguish lymphocytes from white blood cells, and then uses a colloidal gold label to change the natural light scatter characteristics of the CD4 subclass of lymphocytes in order to perform the CD4 enumeration. The PointCare NOW instrument comes pre-calibrated from the factory, which eliminates the need for calibration by the instrument operator. The system is fully automated: there are no manual sample preparation steps for pipetting, incubation, vortexing and the like.
Pre-installation requirements	Suitable for level II and III laboratories
Operating conditions	Temperature: 18° – 34° C (64° – 93° F); humidity: <80%
Items supplied with analyser	PointCare NOW System Installation Package (36008) includes instrument, barcode reader, USB flash drive, preventive-maintenance kit, user manual, reusable waste container, on-site installation, & operator training, 1-year limited warranty.
Required accessories	UPS/voltage regulator
Optional accessories	Portable travel case (holds instrument, printer, barcode reader, power cords, reagents, etc.); portable battery pack; folding solar panel
Turnaround time	8 minutes
Capacity (per run)	1 sample per run
Throughput per technician / per day	~40 – 50 samples; no batching capabilities; walk-away operation.
Sample needed and stability	40 µL whole blood collected in 2 mL or 4 mL vacuum K2 EDTA anticoagulant tubes provided by PointCare. Sample is stable for 8 hours from time of draw
Sample preparation and protocol complexity	No sample preparation steps. (i) Draw venous blood into PointCare-supplied tube; (ii) scan sample ID with barcode reader; (iii) insert unopened sample tube into instrument slot and press “run” button.
Reagent stability and storage requirements	Reagents are stable for 12 months from date of manufacture when stored at 2° – 30° C (36° – 86° F); transient exposure (shipping delay or temperature excursion) of 10 days at 50°C (122° F). Daily Check Controls: 6 months from date of manufacture when stored at 2° to 42° C (36° to 108° F); transient exposure (shipping delay or temperature excursion) of 10 days at 50° C (122° F)
Cost/test	About \$10.00 per test, including Daily Check™ controls

**SECTION IE: CD4: POINTCARE NOW**

Cost/instrument	Approximately \$25,000
Installation	Yes
Training	1–2 days
Maintenance/calibration	Annual maintenance; In case of breakdown, vendor-trained technician required to repair.
Internal QC	53 check points monitored and recorded on every sample; Daily Check™ controls (heat stable, synthetic, bead-based reagents) Low and Normal levels run once a day
External QA	Is not needed
URL	<a href="http://www.pointcare.net/index.php/products/pointcare-now">http://www.pointcare.net/index.php/products/pointcare-now</a>

**SECTION IE: CD4: POINTCARE NOW**

Item no.	Item name	Catalogue no.	Commodity code	Unit of measure (UoM)	No. of tests/UoM	No. of tests	No. of basic units required	No. of UoM units required	Shelf-life	Cold/cool chain	UN hazard code	Document/package/link	Comment
<b>1 – Required kit or equipment</b>													
93	PointCare NOW Reagent Kit	36000	B	100 tests/kit	100	1000	1000	10	Reagents: 12 months, Daily check control: 6 months	No	N/A	N/A	
<b>2 – Test run</b>													
505	Gloves – multiple sizes, powder-free		C	100 gloves/box		1000			N/A	N/A	N/A	N/A	N/A

## SECTION IIA: EQUIPMENT

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
1	Balance, precision	Generic	Precision balance (readability = 0.001 g). Electronic precision balance: capacity approx. 500 g, readability: 0.001 g, pan size: approx. 100 mm diameter, enclosed pan, LCD screen, stabilization time: +/- 3 s, repeatability: 0.001 g (standard deviation), linearity: 0.002 g, automatic internal calibration, operational temperature, 10–40°C. Vendor should check user manual and provide recommended weights for external calibration. Must include traceable certification	Must be supplied with manufacturer recommended calibration weight/s (regardless of capability for internal calibration)	N/A	No	Yes	Yes	Calibrate annually, when moved/ changes in temperature – can be performed in-house
8	Beckman Coulter TQ-Prep™ Workstation	6605429	TQ-Prep™ Workstation for no-wash whole blood sample preparation. Intersample and interlaboratory consistency and reproducibility. Standard 32-tube carousel, intended primarily for laboratories with a high test volume (at least 300 tests/ month), the TQ-Prep™ Workstation uses the revolutionary lyse and fix technology introduced more than a decade ago with the TQ-Prep™ Workstation and IMMUNOPREP Reagent System. 32 samples in 24 min	UPS/voltage regulator	N/A	Yes	No	Yes	As above
235	BioMérieux NucliSENS EasyQ® HIV-1 v2.0 (auto)	280140	NucliSENS® easyMAG® Ref. 280 140 - Throughput: 24 extractions in 45 min	N/A	N/A	N/A	N/A	N/A	N/A
536	Bionor Testing Station	Unknown	To be used with the Bionor™ HIV-1&2 Confirmatory Test, consists of a rocking platform with magnets, aspirator, lamp and waste container and is self-contained. Can be operated on 230 V, optionally 115 V or 12 V	Must be supplied with manufacturer recommended calibration weight/s (regardless of capability for internal calibration)	N/A	No	Yes	Yes	N/A



Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
470	Biosafety cabinet class I/II	Generic	Biosafety cabinet for working with potentially infectious materials. Type-tested to EN 12469 (or equivalent) for biosafety cabinets, ISO 14644.1 Class 3 air quality. IEC 61010-1 electrical safety and IEST-RP filtration. Work access opening approx. 200 mm with audible alarm. Main construction: high quality (304) stainless steel. Panels and work surface to be constructed from stainless steel with welded monolithic sealed structure. Viewing panel constructed from Plexiglas (or suitable equivalent) and can be raised via sliding mechanism. Cabinet should be supplied with height-adjustable stand on lockable castors. Two internal electrical outlets (user to specify type)	Anemometer, UPS/voltage regulator	Vacuum, electrical outlets	Yes	Yes	Annual	Annual service, recalibrate when moved
2	Calculator	Generic	Basic calculator, solar-powered or rechargeable battery	Spare batteries (x 3 sets)	N/A	No	No	No	N/A
17	Centrifuge, benchtop, non-refrigerated	Generic	Centrifuge with brushless motor and lid lock during operation. Up to at least 4000 relative centrifugal force (RCF). Digital display showing time remaining rpm and RCF. Run options: short/pulse mode, timed and continuous	Swing-out rotor with 4 or 6 buckets OR fixed angle rotor with 12 or more places. Rotor or buckets must come with aerosol-tight lids. Adapters or rotors (if fixed angle), minimum of 12 places for 5-ml, 7-ml and 10-ml blood collection tubes. Adapters for 50 ml tubes	N/A	No	Yes	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
18	Centrifuge, haematocrit	Generic	Haematocrit centrifuge, approx. 16 000 g, braking mechanism, 12–24-place rotor with safety mechanism/separation in case of tube breakage	Rotor	N/A	No	Yes	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds etc.
	Centrifuge for centrifuging 96-well plates	Generic	Centrifuge for centrifugation of 96-well plates. Capable of up to 5 000g.	Plate rotor/block for 96-well plates	N/A	No	No	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
19	Chemistry analyser, generic for level III–IV tertiary/central	Generic	Wet or dry chemistry analyser. Capable of operating at approx. 300–400 tests/h. Fully automatic, random and continuous access with reagent refrigeration/heating capacity. Built-in electrolyte testing unit. Operating temperature: 15–32°C, humidity: 25–80%. Automatic sample dilution. Data handling: internal or external printer; storage capacity for > 10 000 results; integrated and automatic quality control; RS232 serial port, connection for remote diagnostics. Automatic system maintenance. Must be ISO/CE/FDA or equivalent approved for clinical use	UPS/voltage regulator	Bar code reader and software	Yes	Yes	Yes	Annual maintenance plan, 3-year service. At least 3 full days training (refresher training within 6 months where applicable)
20	Chemistry analyser, generic for level II–III district/tertiary	Generic	Wet or dry chemistry analyser. Capable of at approx. 100–200 tests/h. Fully automatic, random access with reagent refrigeration/heating capacity. Operating temperature: 15–32°C, humidity: 25–80%. Automatic sample dilution. Data handling: internal or external printer; storage capacity for > 10 000 results; integrated and automatic quality control. Must be ISO/CE/FDA or equivalent approved for clinical use	Must be provided with electrolyte testing unit to include all parts for full operation (testing of K, Na, Cl and CO <sub>2</sub> ). UPS/voltage regulator	N/A	Yes	Yes	Yes	Annual maintenance plan, 3-year service. At least 3 full days training (refresher training within 6 months where applicable)
21	Chemistry analyser, generic for level II/ district	Generic	Wet or dry chemistry analyser. Capable of at least 20 tests/h. Small footprint. No reagent mixing required. Able to use capillary and venous blood, plasma or serum samples. Built-in printer. Data interface for connection to external computer. Must be ISO/CE/FDA or equivalent approved for clinical use. Simple built-in quality control	Must be provided with electrolyte testing unit to include all parts for full operation (testing of K, Na, Cl and CO <sub>2</sub> ). UPS/voltage regulator	N/A	Yes	Yes	Yes	Annual maintenance plan, 3-year service. At least 3 full days training (refresher training within 6 months where applicable)
22	Chemistry analyser, generic for level II–III district/tertiary	Generic	Colorimeter (manual chemistry, basic, low throughput). Wavelength range: 325–900 nm, filter selection: 340, 410, 430, 470, 490, 520, 540, 80, 600 nm. Calculation modes: absorbance, transmission concentration, factor kinetic (rate and end point) (sample and reagent blank). LCD with option for up to 50 programmes. Absorbance range: 0.000–1.999; absorbance resolution: 0.001. Stability: < ± 0.005 A in any 15-min period. Warm-up < 20 min. Reproducibility: ± 1% using same cuvette. RS232 output. Can be powered using car battery	Must be supplied with fully operational flame photometer for K, Na, Cl and CO <sub>2</sub> testing. Battery pack/solar. UPS/voltage regulator	Basic tool/cleaning kit	Yes	Yes	Yes	Annual maintenance plan, 3-year service. At least 3 full days training (refresher training within 6 months where applicable)

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
520	COBAS® AmpliPrep K-tube Capper (motorized)	03516539001	COBAS® AmpliPrep K-tube Capper (motorized)	N/A	N/A	N/A	N/A	N/A	N/A
462	Computer with Microsoft Excel (97 or later) and Adobe Reader	N/A	Computer with Microsoft Excel (97 or later) and Adobe Reader for Cavid ExaVir™	N/A	N/A	N/A	N/A	N/A	N/A
9	Flow cytometer, level II/district	Generic	Manual/semi-automatic flow cytometer. Capability to measure CD4 absolute count and CD4 percentage. Gas, solid state or diode laser. Precision: < 10% CV. Small footprint/portable up to approx. 45 cm (w), 40 cm (h), 60 cm (d). Throughput: up to 50 samples/day. Built-in data entry and analysis software. Must be able to connect to computer for data export	Start-up reagents, buffers and supplies for 250 tests, 3-month supply of control material. UPS/voltage regulator, ideally with battery backup	N/A	Yes	Yes	Yes	Annual maintenance plan, 3- year service. At least 3 full days training (refresher training within 6months where applicable)
10	Flow cytometer, level I-II/primary or district	Generic	Manual flow cytometer. Capability to measure CD4 absolute count and CD4 percentage. Gas, solid state or diode laser. Precision: < 10% CV. Small footprint/portable. Throughput: up to 20 samples per day. No commodities required in addition to kit. Controls included in kit. Built-in data entry and analysis software, runs on rechargeable battery/solar	Start-up reagents, buffers and supplies for 250 tests, 3-month supply of control material. Software for CD4 absolute count and % analysis; carrycase; battery pack/ solar UPS/voltage regulator	N/A	Yes	N/A	Yes	Annual maintenance plan, 3- year service. At least 1 full day training (refresher training within 6 months where applicable)
11	Flow cytometer, level III-IV/tertiary	Generic	Flow cytometer. Capable of analysing up to five optical parameters. Light source: gas, solid state or diode laser (ultraviolet, violet, green, yellow or red lasers optionally available). Optics: 1-5 optical parameters, fixed or modular. Flow system: pump speed continuously adjustable, fluid pressure continuously adjustable; fluid level indicators for full waste and low fluid. Offered with computer and operating system for multiparametric data acquisition, display, data analysis and instrument control	Start-up reagents, buffers and supplies for 250 tests, 3-month supply of control material. UPS/voltage regulator	Bar coder	Yes	Yes	Yes	Annual maintenance plan. At least 3-full days training (refresher training within 6 months where applicable)

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
23	Haematology analyser, level II–III	Generic	Haematology analyser for use in primary/secondary health care facilities (appropriateness depends upon technical level of staff, power supply and workload). Low throughput haematology analyser (up to 60 tests/h), 3- or 5-part differential. Capable of providing the following parameters (minimum requirements): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW, MPV. Precision: all parameters except platelets < 3.5% CV, platelets < 6% CV. Digital display and built-in printer. Must be ISO/CE/FDA or equivalent approved for clinical use	UPS/voltage regulator	N/A	Yes	Yes	Yes	Annual maintenance plan, 3-year service. At least 2 full days training (refresher training within 6 months where applicable)
24	Haematology analyser, level III–IV	Generic	Haematology analyser (medium–high throughput) for use in tertiary and teaching hospital facilities (appropriateness depends upon technical level of staff and workload), > 100 tests/h, 5-part differential. Capable of providing the following parameters (minimum requirements): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, PDW (% and number), NEU, LYM, MON, EOS, BAS, ALY (% and number) and LIC (% and number). Precision: all parameters (except platelets) < 3% CV, platelets < 5% CV. Digital display or computer, built-in or supplied printer	UPS/voltage regulator	N/A	Yes	Yes	Yes	Annual maintenance plan, 3-year service. At least 2 full days training (refresher training within 6 months where applicable)
25	Haemoglobinometer, handheld, generic, level II–III	Generic	Haematology analyser for use in primary/secondary health care facilities (appropriateness depends upon technical level of staff, power supply and workload). Low throughput haematology analyser (up to 60 tests/h), 3- or 5-part differential. Capable of providing the following parameters (minimum requirements): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW, MPV. Precision: all parameters (except platelets) < 3.5% CV, platelets < 6% CV. Digital display and built-in printer. Must be ISO/CE/FDA or equivalent approved for clinical use	Carry case	N/A	No	Yes	N/A	Refer to guide
26	Haemoglobinometer, handheld, generic	Generic	Haemoglobinometer, handheld, capability of storing at least 500 quality control and test results, measurement range: at least 10–2000 mg/dl, capillary, venous or whole blood. Connection to printer/ computer, rechargeable battery/solar	Carry case plus sufficient consumables for 250 tests	N/A	No	Yes	N/A	Refer to guide

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
28	Hand tally counter	Generic	Hand tally counter, single register, range 0–9999, with zero reset knob	N/A	N/A	No	No	No	N/A
29	Heating block	Generic	Heating block incubator, compact design, capacity for 2 x heating blocks, temperature range: ambient to +120°C, LCD display	Blocks for 1.0-ml, 1.5-ml and 2.0-ml tubes and 5ml reaction vessels	N/A	No	Yes	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds etc.
27	HemoCue® Haemoglobinometer (handheld)	N/A	Haemoglobinometer, handheld, capillary, venous or whole blood, measurement range 0–25.6 g/dl, results in 60 s, AC adapter/batteries, connection for printer/computer, built-in quality control	Carry case	N/A	No	Yes	N/A	N/A
30	Incubator, general purpose	Generic	General-purpose incubator, stainless steel, weldless interior, minimum of three adjustable stainless steel shelves. Adjustable feet for levelling. Warm air or water jacket design. Full length inner glass door. Heating elements isolated from internal chamber for safety. LED display with audible/visual over-temperature alarm. Access port for connection to chart recorder. Medium sized, approx. size: 20–150 litres. Range: ambient to +60°C (min), accuracy: ± 0.5°C	Carry case plus sufficient consumables for 250 tests	N/A	No	Yes	N/A	Refer to guide
31	Microcentrifuge (non-refrigerated)	Generic	Microcentrifuge for centrifugation of small test tubes (0.2-, 0.5-, 1.0-, 1.5- and 2.0-ml tubes). Capable of up to 14 000 rpm. Compact design with brushless motor and lid lock during operation. Digital display showing time remaining and rpm. Run options: pulse mode, timed and continuous. Timer in 1-s increments	Rotors for 1.0-ml, 1.5-ml and 2.0-ml tubes, aerosol-resistant rotor lid, UPS/voltage regulator	N/A	No	No	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
32	Microplate/ELISA plate reader	Generic	Microplate reader for 96-well microtitre plates. Includes variable-speed shaker. Alphanumeric keypad, LCD display and capability to create, edit or run at least 10 protocols. Wavelength range 380–900 nm (minimum), dynamic range 0–4.0 optical density (OD), resolution 0.001 OD, accuracy < 2%, linearity < 1%, repeatability < 1.5%	Blocks for 1.0-ml, 1.5-ml and 2.0-ml tubes	N/A	No	Yes	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
33	Microplate/ELISA plate washer	Generic	Microplate washer for 96-well microtitre plates. Includes capacity for timed shaking and soak, times programmable up to 50 min. To include 3 x 1-litre (minimum volume) bottles (wash, rinse and waste), low wash bottle liquid volume sensor and interchangeable 8 x and 12 x manifolds. Alphanumeric keypad, LCD display and capability to create, edit or run at least 10 protocols. Dispense precision $\leq 4\%$ CV, residual volume $\leq 3 \mu\text{l/well}$	Buffer, water and waste bottles (1 litre minimum), UPS/voltage regulator	N/A	No	No	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
34	Microscope, light	Generic	Standard light microscope, optical system: infinity corrected optics. Illumination: Koehler illumination for transmitted light, halogen bulb 30 W (minimum) and/or LED, light intensity indicator. Eye pieces: adjustable interpupillary distance: 48–75 mm, antifungus x10 field number 18. Objectives: antifungus, plan achromatic objectives, 4x (0.10 working distance [WD]), 10x (0.25 WD), 40x (0.65 WD), 100x oil (1.25 WD). Condenser: Abbe condenser (1.25). Stage: area approx. 140 x 135 mm, travelling range: 76 mm (X) x 30 mm (Y)	Spare bulbs, immersion oil (ISO or DIN) specs 58–884 compliant). Lens tissue – lintless, no scratching, safe to use on coated lens and specially prepared for cleaning microscope lenses, filters and other glass surface	N/A	No	Yes	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
35	Microtitre plate shaker	Generic	Shaker for 96-well microtitre plates, digital timer, speed control, rotation speed at least 150–1000 rpm	UPS/voltage regulator	N/A	No	No	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
495	Mixer, roller	Generic	Mixer for rolling/rocking tubes		N/A	No	No	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
36	Mixer, rotary (end-over-end)	Generic	Rotary mixer/end-over-end mixer table, able to accommodate a range of bottles and flasks, programmable	Adapters for 25-ml and 50-ml tubes	N/A	No	No	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
37	P24, Perkin Elmer, Quanti-Kin Detection System Software	N/A	Software for Perkin Elmer non- nucleic acid test (non-NAT)	Unknown	N/A	N/A	N/A	N/A	N/A
39	Pipette/pipettor 1	Generic	Single channel pipette/pipettor (0.1–1 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	Pipette stand (1 per set of 1-µl, 10-µl, 100-µl and 1000-µl pipettes), spare parts kit, washers, etc., depending on model/ manufacturer	N/A	No	Yes	No	N/A
40	Pipette/pipettor 20	Generic	Single channel pipette/pipettor (1–20 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	Pipette stand (1 per set of 1-µl, 10-µl, 100-µl and 1000-µl pipettes), spare parts kit (washers, etc. – depends upon model/ manufacturer)	N/A	No	Yes	No	N/A
41	Pipette/pipettor 200	Generic	Single channel pipette/pipettor (10–200 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	Pipette stand (1 per set of 1-µl, 10-µl, 100-µl and 1000-µl pipettes), spare parts kit (washers, etc. – depends upon model/ manufacturer)	N/A	No	Yes	No	N/A
499	Pipette/pipettor 5000	Generic	Single channel pipette/pipettor (1000–5000 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl accuracy ± 0.12 µl	Pipette stand (1 per set of 1-µl, 10-µl, 100-µl and 1000-µl pipettes), spare parts kit (washers, etc. – depends upon model/ manufacturer)	N/A				N/A

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
43	Pipette/pipettor mechanical repeater/dispenser	Generic	Adjustable repeater pipette for 1.0–10 ml volumes	N/A	N/A				Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
42	Pipette/pipettor 1000	Generic	Single channel pipette/pipettor (10–1000 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	Pipette stand (1 per set of 1-µl, 10-µl, 100-µl and 1000-µl pipettes), spare parts kit (washers, etc. – depends upon model/manufacturer)	N/A	No	Yes	No	N/A
44	Pipette/pipettor, multichannel 10–100	Generic	Multichannel (8 or 12) channel pipette/pipettor (1–10/20 µl). Mechanical, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	N/A	N/A	No	Yes	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
45	Pipette/pipettor, multichannel digital 10–100	Generic	Multichannel (8 or 12) channel pipette/pipettor (1–10/20 µl). Digital, programmable, adjustable volume with tip ejector, autoclavable, precision better than 0.08 µl, accuracy ± 0.12 µl	Spare batteries (x5), stand	N/A	No	Yes	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
	Repeat pipettor,	Generic	Repeater pipettor adjustable to 40–50 µl volumes	N/A	N/A	No	Yes	No	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
38	40–50 µl	N805-0200	Thermal cycler/PCR machine, GeneAmp 9700, blocks to accommodate 0.5-ml tubes, 96 0.2-ml tubes, a 96-well plate, or dual 384-well plates. Small footprint, PCMCIA card and RS485 communications ports, Peltier heating, graphical programming interface, and an optional MAX Mode	UPS/voltage regulator	N/A	Yes	Yes	Yes	Should be serviced as part of general laboratory equipment. Depends on site, funds, etc.
506	Thermoshaker	Generic	Shaking heating block capable of mixing and warming microcentrifuge tubes, up to 100°C with accuracy ±/– 2°C at 60°C, mixing frequency of approx. 1200–1400 rpm	N/A	N/A	N/A	N/A	N/A	N/A



Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
46	Timer, digital	Generic	Digital laboratory timer, multichannel (2 or more), channels may be independent, count-up or count-down, audible sound signals end of pre-set time	Spare batteries (x 5)	N/A	No	No	N/A	N/A
47	Timer, mechanical	Generic	Mechanical timer, up to 60–120 min in 1-min intervals. Reset at any time. Audible sound at end of pre-set time	N/A	N/A	No	No	N/A	N/A
508	Vacuum system – 1.5 litres/m	Generic	Vacuum system – 1.5 litres/m for NuclSENS EasyQ® protocol can be substituted with dedicated pipettes	N/A	N/A	N/A	N/A	N/A	N/A
56	Vortex mixer	Generic	Vortex mixer. Application: laboratory mixer for vortex different size tubes; handles small (0.5-ml, 1-ml, 2-ml, 3-ml, 5-ml, 10-ml) and larger (15-ml, 50-ml) test tubes. Variable speed, epoxy coated to reduce chemical and mechanical erosion. Suction feet for stability. Adjustable speed, 300–3000 rpm. Continuous or touch option. Provided with flat rubber platform	Platform attachment for 1.5-ml, 2.0-ml, 10-ml, 15-ml and 50-ml tubes	N/A	No	No	No	N/A
498	Water bath	Generic	Circulating water bath, stainless steel tank, digital, ambient +5 °C max 100°C. Corrosion resistant exterior for easy cleaning. Constant mixing for even temperature distribution in the working volume and increased heat transfer. Temperature uniformity $\pm 0.05^{\circ}\text{C}$	National Institute of Science and Technology (NIST) or equivalent traceable certificate thermometer, floating tube holders for 1.0-ml, 1.5-ml and 2.0-ml tubes. UPS/voltage regulator	N/A	N/A	N/A	N/A	N/A

## SECTION IIB: KITS

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
449	Abbot Molecular Inc. Abbott RealTime HIV-1 Amplification Reagent Kit	6L18-90, 2G31-90,	In vitro PCR assay for quantitation of HIV-1 in plasma	Kit	24	Yes	N/A	N/A	N/A
	Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit	4N66-90	Kit is a constituent of Abbott RealTime HIV-1 Qualitative assay, which is intended for the qualitative detection of HIV-1 nucleic acids from human plasma and dried blood spots (DBS). Kit contains internal control and amplification reagent pack, which includes thermostable rth polymerase enzyme, HIV-1 oligonucleotide reagent, and activation reagent	Kit	96 tests; 4 x 24 tests/ pack	Ship on dry ice; store at $\leq -10^{\circ}\text{C}$ when not in use	Yes	18 months (except for Thermostable rth Polymerase Enzyme 56685: Per control date on vendor certificate of analysis)	<a href="http://www.abbottmolecular.com/products/infectious-diseases/realtime-pcr/realtime-hiv1-qualitative.html#sthash.e03g35i9.dpuf">http://www.abbottmolecular.com/products/infectious-diseases/realtime-pcr/realtime-hiv1-qualitative.html#sthash.e03g35i9.dpuf</a>
553	Acon Biotech, MaxLINE HIV 1/2/O Tri-line	AVTUB-30	Rapid test for qualitative detection of antibodies to HIV -1, HIV-2 and HIV-1 subtype O in serum or plasma	Kit		Unknown	N/A	N/A	N/A
200	Alere Determine™ HIV-1/2 Ab/Ab Combo x 100	7D2647	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum and plasma. Sample size 50 $\mu\text{l}$	Kit	100	Yes	<a href="http://gssh.co/1cGS5gh">http://gssh.co/1cGS5gh</a>	9	N/A
446	Alere Determine™ HIV-1/2 x 100	7D2343	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum and plasma. Sample size 50 $\mu\text{l}$	Kit	100	Yes	<a href="http://gssh.co/1cGS5gh">http://gssh.co/1cGS5gh</a>	9	N/A
201	Alere Determine™ HIV-1/2 x 20	7D2342	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum and plasma. Sample size 50 $\mu\text{l}$	Kit	20	Yes	<a href="http://gssh.co/1cGS5gh">http://gssh.co/1cGS5gh</a>	9	N/A
202	Alere Determine™ HIV-1/2 x 100	7D2353	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in whole blood. Includes chase buffer. Sample size 50 $\mu\text{l}$	Kit	100	Yes	<a href="http://gssh.co/1cGS5gh">http://gssh.co/1cGS5gh</a>	9	N/A
203	Alere Determine™ HIV-1/2 x 20	7D2352	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in whole blood. Includes chase buffer. Sample size 50 $\mu\text{l}$	Kit	20	Yes	<a href="http://gssh.co/1cGS5gh">http://gssh.co/1cGS5gh</a>	9	N/A

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
448	Alere Pima™ CD4 Test Cartridge	260100025	Disposable cartridge used to collect and run sample in the CD4 analyser	Kit	25	N/A	N/A	12	N/A
58	Alere Pima™ CD4 Test Cartridge	260100100	Disposable cartridge used to collect and run sample in the CD4 analyser	Kit	100	N/A	N/A	12	N/A
187	Ani LabSystems Ltd ELISA – 480 wells (5 plates)	61 11 012	In vitro enzyme immunoassay for the detection of antibodies to HIV in serum or plasma. Sample size 50 µl, controls included in kit	5 plates	480	N/A	<a href="http://bit.ly/vvr6G60">http://bit.ly/vvr6G60</a>	N/A	N/A
188	Ani LabSystems Ltd ELISA – 96 wells (1 plate)	61 11 011	In vitro enzyme immunoassay for the detection of antibodies to HIV in serum or plasma. Sample size 50 µl, controls included in kit	Pack	96	Yes	<a href="http://bit.ly/vvr6G60">http://bit.ly/vvr6G60</a>	N/A	N/A
189	Ani LabSystems Ltd ELISA – 960 well (10 plates)	61 11 013	In vitro enzyme immunoassay for the detection of antibodies to HIV in serum or plasma. Sample size 50 µl, controls included in kit	10 plates	960	N/A	<a href="http://bit.ly/vvr6G60">http://bit.ly/vvr6G60</a>	N/A	N/A
482	Apogee CD4 Reagents (no information available from manufacturer)	1467	Apogee CD4 reagents	Kit	100	No	N/A	9	N/A
63	BD FACSCount™ CD4 Reagent Kit (50)	339010 Alt	Enables simultaneous enumeration of absolute counts and determination of CD4 percentages in unlysed whole blood. It is an essential tool in paediatric CD4 testing	Kit	50	Yes	N/A	6	Alternative product
64	BD FACSCount™ CD4 & CD3 Reagent Kit (50)	342512	Allows uncoupling of CD4 and CD3 enumerations from CD8. Single-tube format reduces cost and sample processing time, allowing limited resources to go further in the HIV/AIDS treatment programme	Kit	50	Yes	N/A	6	N/A
66	BD FACSCount™ CD4 & CD3 Reagent Kit (50)	340167	A 50-test kit in unit test format that uses a no-lyse, no-wash, whole blood method for enumeration of absolute CD4, CD8, and CD3 counts. Designed for use in the FACSCount™ system	Kit	50	Yes	N/A	6	N/A
68	Beckman Coulter CYTO-COMP™ Reagent Kit	6607021	Kit comprises four sets of two-colour reagents used in conjunction with the CYTO-COMP™ Cell Kit to establish and monitor colour compensation settings for multicolour analysis	Kit	50	Yes	<a href="http://gssh.co/sgQVtX">http://gssh.co/sgQVtX</a>	N/A	2–8°C, do not freeze

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
74	Beckman Coulter CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent	6607013	For simultaneous identification and enumeration of total CD3+, total CD4+, total CD8+, dual CD3+/CD4+ and dual CD3+/CD8+ T lymphocyte population percentages and absolute counts. 1, 2, 3 The system also provides the T4/T8 ratio. This kit is a liquid combination of four murine monoclonal antibodies. Each antibody is labeled with a different color fluorochrome.	Kit	100	Yes		N/A	2–8°C, do not freeze, limit exposure to light
551	bioLytical INSTI™ HIV-1/HIV-2 Antibody Test (for laboratory use only)	90-1021	Single-use, rapid, flow-through in vitro qualitative immunoassay for the detection of antibodies to HIV-1 and HIV -2 in EDTA whole blood, fingerstick blood, serum or EDTA-plasma	Kit	48	No	N/A	N/A	N/A
550	bioLytical INSTI™ HIV-1/HIV-2 Antibody Test (with support materials)	90-1022	Single-use, rapid, flow-through in vitro qualitative immunoassay for the detection of antibodies to HIV-1 and HIV -2 in EDTA whole blood, fingerstick blood, serum or EDTA-plasma	Kit	48	No	N/A	N/A	N/A
488	BioMérieux NucliSENS EasyQ® HIV-1 V2.0	285033	NucliSENS® reagents for amplification	Kit	48	Yes	<a href="http://gssh.co/zw6kyy">http://gssh.co/zw6kyy</a>	24	N/A
535	Bionor™ HIV-1&2 Confirmatory Test	Unknown	Peptide-based magnetic particle EIA for individual detection of IgG antibodies against recombinant p24 (CORE), synthetic peptides togp41 (TM1), synthetic peptides togp120/recombinant gp41 (ENV) and synthetic peptides to gp36 (TM2)	Kit	250	No	N/A	12	N/A
537	Bio-Rad Multispot HIV-1/HIV-2 Rapid Test	25228	RDT for detection and differentiation of HIV-1 and HIV-2 antibodies in serum and plasma	Kit	50	Yes	N/A	12	N/A
545	Bio-Rad Genie™ Fast HIV 1/2 Assay	72330	RDT for detection of HIV-1 and HIV-2 antibodies in serum, plasma and whole blood	Kit	50	N/A	N/A	N/A	N/A
509	Blu-O™ LSA-1 Monoclonal Antibody Panel, CE-IVD	N00011426	Four-colour monoclonal antibody cocktail (CD45/CD4/CD8/CD3) for enumerating total T cells, T helper and T cytotoxic cell subsets	Kit	50	N/A	N/A	N/A	N/A

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
539	Calypte Aware™ HIV-1/2 OMT	98140	Single-use, qualitative, visually read, in vitro immunoassay for detection of antibodies to HIV-1 and HIV-2	Kit	50	No	N/A	N/A	N/A
532	Calypte Aware™ HIV-1/2 BSP	Unknown	Qualitative, visually read, in vitro immunoassay for detection of antibodies to HIV-1 and HIV-2 in whole blood, serum or plasma	Kit	50	N/A	N/A	N/A	N/A
458	Cavidi ExaVir™ Load v3.0	Unknown	Quantitative determination of reverse transcriptase activity as a marker of retroviral replication (includes two boxes: reagents and consumables)	Kit	30	Yes	<a href="http://gssh.co/QLwLdr">http://gssh.co/QLwLdr</a>	N/A	N/A
540	Chembio Clearview® HIV 1/2 STAT-PAK®	92110	Single-use immunochromatographic test for detection of antibodies to HIV-1 and HIV-2 for whole blood, serum and plasma	Kit	20	No	N/A	N/A	N/A
204	Chembio HIV 1/2 Stat-Pak®	HIV101	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum, plasma or whole blood. Includes chase buffer. Sample size 5 µl	Kit	20	Yes	N/A	N/A	N/A
206	Chembio HIV 1/2 Stat-Pak® Dipstick	HIV303	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum, plasma, or whole blood. Includes chase buffer. Sample size 5 µl	Kit	30	No	N/A	24	N/A
542	Chembio Clearview® COMPLETE HIV 1/2	N/A	Single-use immunochromatographic test for detection of antibodies to HIV-1 and HIV-2. Includes lancet	Kit	25	No	N/A	N/A	N/A
231	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0	03542998190	Real-time PCR kit for quantitative determination of HIV in clinical samples	Kit	48	N/A	N/A	N/A	N/A
543	CS Innovation Rapid Anti-HIV (1&2)	Unknown	Colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of antibodies to HIV-1 and HIV-2 in whole blood, serum or plasma	Kit		No	N/A	N/A	N/A
209	Origenics Ltd DoubleCheckGold™ HIV 1&2 (20)	70633020	Single reagent immunoassay for qualitative detection of antibodies to HIV-1, HIV-2 and HIV-1 Group O, in serum or plasma. Sample size 10 µl	Kit	20	N/A	N/A	N/A	N/A

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
264	Dried blood spot collection cards	Generic	Filter paper, Guthrie cards, Whatman 903™ Specimen Collection cards (high-quality blood collection paper: 903 or 2992)	Pack	100	N/A	N/A	N/A	N/A
210	Enzygnost® Anti-HIV 1/2 Plus	OQFK135	Siemens Healthcare Diagnostics Enzygnost® Supplementary Reagents (Marburg, Germany)			N/A	N/A	N/A	N/A
211	Enzygnost® Anti-HIV 1/2 Plus a	OQFK215	Siemens Healthcare Diagnostics Enzygnost® Supplementary Reagents (Marburg, Germany)			N/A	N/A	N/A	N/A
212	Enzygnost® Anti-HIV1/2 Plus b	OUPV175	Siemens Healthcare Diagnostics Enzygnost® Supplementary Reagents (Marburg, Germany)			N/A	N/A	N/A	N/A
214	EY Laboratories Inc. InstantCHEK™ HIV1+2 (100)	8-1003-100	Direct flow through RDT for the detection of antibodies to HIV-1 and HIV-2. Sample size 50 µl	Kit	100	No	N/A	12–15	Controls included
215	EY Laboratories Inc. InstantCHEK™ HIV1+2 (40)	8-1003-40	Direct flow through RDT for the detection of antibodies to HIV-1 and HIV-2. Sample size 50 µl	Kit	40	No	N/A	12–15	Controls included
213	Premier Medical Corporation Ltd First Response® HIV 1-2-O Card Test	I05FRC30	Rapid chromatographic immunoassay for qualitative detection of antibody to HIV-1, HIV-2 in serum, plasma or whole blood			N/A	<a href="http://bit.ly/t3shf6">http://bit.ly/t3shf6</a>	N/A	N/A
197	Fujirebio Inc. PA SERODIA® HIV-1/2	226063	In vitro diagnostic test kit for detection of antibodies HIV-1 and HIV-2 in serum and plasma		220	N/A	N/A	N/A	N/A
196	Fujirebio Inc. PA SERODIA® HIV-1/2	220658	In vitro diagnostic test kit for detection of antibodies to HIV-1 and HIV-2 in serum and plasma	Kit	100	N/A	N/A	N/A	N/A
560	Hema Diagnostic Systems Rapid 1-2-3® HEMA EXPRESS®	HIV-0207-WB	Rapid immunochromatographic test for qualitative detection and differentiation of antibodies to HIV in whole blood, serum or plasma	Kit	50	N/A	N/A	N/A	N/A
190	Alera ImmunoComb® HIV 1&2 BiSpot	60432002	Indirect solid-phase EIA for qualitative and differential detection of antibodies to HIV-1 and HIV-2 in serum or plasma	Kit	36	Yes	<a href="http://gssh.co/15zusHL">http://gssh.co/15zusHL</a>	N/A	N/A

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
216	InTec Products Inc. ADVANCED QUALITY™ Rapid Anti-HIV(1&2) Test	ITP02002	Immunochromatographic RDT for detection of antibodies to HIV-1 and HIV-2 in serum, plasma or whole blood. Includes chase buffer. Sample size 5 µl	Kit	40	No	<a href="http://gssh.co.tz/WQ4nZ">http://gssh.co.tz/WQ4nZ</a>	N/A	Controls included
225	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT (10)	IR130010	Visual, rapid, sensitive and accurate immunoassay for differential detection of HIV-1 and HIV-2 antibodies (IgG) in serum or plasma using HIV-1 and HIV-2 antigens immobilized on an immunofiltration membrane	Kit	10	Yes	<a href="http://bit.ly/uVDmml">http://bit.ly/uVDmml</a>	15	N/A
226	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT (100)	IR130100	Visual, rapid, sensitive and accurate immunoassay for differential detection of HIV-1 and HIV-2 antibodies (IgG) in serum or plasma using HIV-1 and HIV-2 antigens immobilized on an immunofiltration membrane	Kit	100	Yes	<a href="http://bit.ly/uVDmml">http://bit.ly/uVDmml</a>	15	N/A
227	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT (200)	IR130200	Visual, rapid, sensitive and accurate immunoassay for differential detection of HIV-1 and HIV-2 antibodies (IgG) in serum or plasma using HIV-1 and HIV-2 antigens immobilized on an immunofiltration membrane	Kit	200	Yes	<a href="http://bit.ly/uVDmml">http://bit.ly/uVDmml</a>	15	N/A
228	J. Mitra & Co. Pvt. Ltd HIV TRI-DOT (50)	IR130050	Visual, rapid, sensitive and accurate immunoassay for differential detection of HIV-1 and HIV-2 antibodies (IgG) in serum or plasma using HIV-1 and HIV-2 antigens immobilized on an immunofiltration membrane	Kit	50	Yes	<a href="http://bit.ly/uVDmml">http://bit.ly/uVDmml</a>	15	N/A
549	JAL Innovation iCARE HIV Tri-line Rapid ScreenTest	IT1002H	Colloidal gold enhanced RDT for qualitative detection of antibodies to HIV1 and HIV-2 in whole blood, serum or plasma	Kit	40	No	N/A	N/A	N/A
198	KHB Shanghai Kehua Bio-engineering Co. Ltd HIV (1+2) Antibody (Colloidal Gold)	KH-T02	Lateral flow immunochromatographic test	Kit	50	No	N/A	15	N/A
554	Medinostics International HIV 1/2 Gold Rapid Screen Test	815311000775	Rapid test for qualitative detection of antibodies to HIV-1 and HIV-2 in whole blood, serum or plasma	Kit	30	N/A	N/A	N/A	N/A

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
555	Medmira Reveal™ Rapid HIV Antibody Test (Reveal HIV)	815311000768	Qualitatively detects antibodies to HIV-1 and HIV-2 in whole blood, serum or plasma	Kit	30	No	N/A	18	N/A
76	Millipore Guava® Auto CD4 CD4% Kit (100)	4500-0480	Two-colour direct immunofluorescence reagent kit for enumeration of mature CD4+ T lymphocytes and determination of CD4 T cells as a percentage of total lymphocytes in blood	Kit	100	Yes	<a href="http://gssh.co/19jq0K6">http://gssh.co/19jq0K6</a>	N/A	Antibody: 2–8°C, do not freeze, limit exposure to light; lysing solution: 18–25°C, do not freeze
77	Millipore Guava® Auto CD4 CD4% Kit (1000)	4500-0490	Two-colour direct immunofluorescence reagent kit for enumeration of mature CD4+ T lymphocytes and determination of CD4 T cells as a percentage of total lymphocytes in blood	Kit	100	Yes	<a href="http://gssh.co/19jq0K6">http://gssh.co/19jq0K6</a>	N/A	Antibody: 2–8°C, do not freeze, limit exposure to light; lysing solution: 18–25°C, do not freeze
78	Millipore Guava® Auto CD4 CD4% Kit (500)	4500-0485	Two-colour direct immunofluorescence reagent kit for enumeration of mature CD4+ T lymphocytes and determination of CD4 T cells as a percentage of total lymphocytes in blood	Kit	500	Yes	<a href="http://gssh.co/19jq0K6">http://gssh.co/19jq0K6</a>	N/A	Antibody: 2–8°C, do not freeze, limit exposure to light; lysing solution: 18–25°C, do not freeze
79	Millipore Guava® Express CD3 CD4 Kit	4500-0150	Two-colour direct immunofluorescence reagent kit for enumeration of mature CD4(+) T lymphocytes in blood	Kit	100	Yes	<a href="http://gssh.co/17Pkdi2">http://gssh.co/17Pkdi2</a>	N/A	Antibody reagents and dilution buffer 2–8°C, do not freeze, shield from light; lysing solution and fixative 18–25°C, do not freeze or refrigerate
217	Orasure Technologies Inc. OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test	N/A	Single-use, qualitative immunoassay	Kit	100	Yes	<a href="http://bit.ly/tLSPSk">http://bit.ly/tLSPSk</a>	N/A	N/A
218	Orasure Technologies Inc. OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test	5x4-0010	Qualitative immunochromatographic test. Oral swab or 5-µl sample	Kit	100	N/A	N/A	N/A	N/A



Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
219	OraSure Technologies Inc. OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test	5x4-0012	Qualitative immunochromatographic test. Oral swab or 5-µl sample	Kit	500	N/A	N/A	N/A	N/A
220	Orgenics Ltd DoubleCheckGold™ HIV 1&2 (100)	60332000	Lateral flow assay	Kit	100	Yes	N/A	N/A	N/A
221	Orgenics Ltd DoubleCheckGold™ HIV 1&2 (WB 100)	N/A	N/A	Kit	100	N/A	N/A	N/A	<a href="http://www.alere.com/www/en/product-details/doublecheckgold-hiv-1-2.html">http://www.alere.com/www/en/product-details/doublecheckgold-hiv-1-2.html</a>
83	Partec CD4 Easy Count Kit (100)	05-8401	Identifies and enumerates the CD4+ helper/inducer T lymphocyte subset	Kit	100	N/A	<a href="http://gssh.co/14kmUY9">http://gssh.co/14kmUY9</a>	12	N/A
84	Partec CD4% Easy Count Kit (PE&PE-Dy647) – dry (100)	05-8405-d	Identifies and enumerates the CD4+ helper/inducer T lymphocyte subset and CD45+ leukocytes in blood samples. For use in Partec CyFlow® Counter and Partec CyFlow® SL_3	Kit	100	N/A	<a href="http://gssh.co/14kmUY9">http://gssh.co/14kmUY9</a>	12	N/A
85	Partec CD4% Easy Count Kit (PE&PE-Dy647) (100)	05-8405	Identifies and enumerates the CD4+ helper/inducer T lymphocyte subset and CD45+ leukocytes in blood	Kit	100	N/A	<a href="http://gssh.co/14kmUY9">http://gssh.co/14kmUY9</a>	12	N/A
91	Partec Reagent Kit for Cyflow miniPOC	D5-8409-d	Partec miniPOC CD4% Count Kit – dry contains all required reagents, the dry mAb tubes and consumables for 20 CD4/CD4% tests. No other materials necessary	Kit	20	N/A	<a href="http://gssh.co/14kmUY9">http://gssh.co/14kmUY9</a>	N/A	N/A
82	Partec CD4 Easy Count Kit – Dry (100)	05-8401-d	CD4 absolute count reagents for HIV monitoring and AIDS patient follow-up in ready-prepared dry/lyophilized form in ready-to-use test tubes	Kit	100	N/A	<a href="http://gssh.co/14kmUY9">http://gssh.co/14kmUY9</a>	12	N/A
193	PerkinElmer Life and Analytical Sciences Inc. HIV-1 p24 ELISA (1 plate)	NEK050	Detects HIV-1 p24 core antigen (HIV-1 p24) in serum or plasma and in cell culture supernatant	Kit	1	Yes	<a href="http://tinyurl.com/88ldodl">http://tinyurl.com/88ldodl</a>	N/A	N/A
194	PerkinElmer Life And Analytical Sciences Inc. HIV-1 p24 ELISA (2 plates)	NEK050A	Detects HIV-1 p24 core antigen (HIV-1 p24) in serum or plasma and in cell culture supernatant	Kit	2	N/A	<a href="http://tinyurl.com/88ldodl">http://tinyurl.com/88ldodl</a>	N/A	N/A

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
195	PerkinElmer Life and Analytical Sciences Inc. HIV-1 p24 ELISA (5 plates)	NEK050B	Detects HIV-1 p24 core antigen (HIV-1 p24) in serum or plasma and in cell culture supernatant	Kit	5	N/A	<a href="http://tinyurl.com/88ldodl">http://tinyurl.com/88ldodl</a>	N/A	N/A
93	PointCare NOW Reagent Pack	Unknown	Assay reagent intended for use in the PointCare NOW in vitro diagnostics instrument to provide CD4 positive lymphocytes cell count	Kit	100	Yes	N/A	See comment	Store: LiquiPack: 2–30°C, Gold & Controls: 2–42°C, Bleach kit and Super-wash: ambient.
544	Premier Medical Corporation Ltd First Response® HIV 1-2-O	105FRS50	Rapid chromatographic immunoassay for qualitative detection of antibody to HIV-1 and HIV-2	Kit	50	N/A	N/A	N/A	N/A
222	Qualpro Diagnostics Retrocheck HIV 1&2 (WB)	Unknown	N/A	Kit		N/A	<a href="http://gssh.co/1efkLdk">http://gssh.co/1efkLdk</a>	N/A	N/A
224	Qualpro Diagnostics Retrocheck HIV 1&2 (50)	HIV-110050	Immunochromatography, two-site capture immunoassay for detection of HIV-1 and HIV-2 antibodies in serum/plasma and whole blood. Sample size 50 µl	Kit	50	N/A	<a href="http://gssh.co/1efkLdk">http://gssh.co/1efkLdk</a>	N/A	N/A
223	Qualpro Diagnostics Retrocheck HIV 1&2 (100)	HIV-110100	Immunochromatography, two-site capture immunoassay for detection of HIV-1 and HIV-2 antibodies in serum/plasma and whole blood. Sample size 50 µl	Kit	100	N/A	<a href="http://gssh.co/1efkLdk">http://gssh.co/1efkLdk</a>	N/A	N/A
547	Savyon Diagnostics HIVSav 1/2/0 Rapid SeroTest™	B41112	Rapid test for qualitative detection of antibodies to HIV-1, HIV-2 and HIV subtype O in whole blood, serum or plasma	Kit	50	No	N/A	N/A	N/A
191	KHB Shanghai Kehua Bio-engineering Co. Ltd Anti-HIV 1+2 ELISA	KH-T-10	EIA kit for the detection of antibodies to HIV- 1 and HIV-2	Kit	1	N/A	N/A	N/A	N/A
528	Siemens VERSANT® Sample Preparation 1.0 Reagents Kit, IVDD (Box1 and Box 2)	04801677, 04801685	Sample preparation kit intended for the isolation and purification of nucleic acids for in vitro diagnostic applications	Kit	96	Yes	N/A	24	N/A

Item no.	Item name	Catalogue no.	Description/specification	Required accessory	Optional accessory	Installation	Calibration	Service	Contract requirements
447	Siemens VERSANT® HIV-1 RNA (kPCR) Kit, IVDD Box 1	10375763,	Reagents to perform <i>in vitro</i> nucleic acid amplification VERSANT HIV-1 RNA 1.0 assay for quantitative measurement of HIV-1 RNA in fresh or frozen plasma	Kit	96	Yes	N/A	12	N/A
	Siemens VERSANT® HIV-1 RNA (kPCR) Kit, IVDD Box 2	10375764	Calibrators and controls to perform VERSANT HIV-1 RNA 1.0 assay	Kit	4 sets Calibrators and Controls	Yes	N/A	12	N/A
557	Span Diagnostics Ltd Signal HIV	51FT100-60	<i>In vitro</i> qualitative screening test to diagnose HIV in serum or plasma	Kit	100	Yes	N/A	N/A	N/A
229	Trinity Biotech plc Uni-Gold™ HIV	1206502	Single reagent assay for detection of antibodies to HIV-1 and HIV-2 in serum, plasma or whole blood	Kit	20	Yes	<a href="http://bit.ly/vdixbg">http://bit.ly/vdixbg</a>	N/A	N/A
558	Trinity Biotech plc Uni-Gold™ Recombigen® HIV	1206506	Single reagent assay for detection of antibodies to HIV-1 and HIV-2 in serum, plasma or whole blood	Kit	20	No	<a href="http://bit.ly/vdixbg">http://bit.ly/vdixbg</a>	N/A	N/A
192	United Biomedical Inc. HIV 1/2 EIA	600441	ELISA for qualitative detection of circulating antibodies to HIV-1 and HIV-2 in whole blood	Kit	192	N/A	<a href="http://gssh.co/zPZpLY">http://gssh.co/zPZpLY</a>	15	N/A

## SECTION IIC: REAGENTS

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Cold/cool chain	Shelf-life (months)
	Abbott Molecular Inc. Bulk mlysisDNA Buffer	2N77-01	Buffer for sample preparation from dry blood spot (DBS) specimens for Abbott RealTime HIV-1 Qualitative assay	Bottle	500 ml	N/A	N/A
	USP Grade 190-200 proof ethanol (95% - 100% Ethanol)	Generic	Ethanol, 190 proof or 200 proof, that meets USP testing specifications	Bottle	Vary	N/A	N/A
450	Abbott m Sample Preparation System RNA	04J70-24,	RNA sample preparation kit	N/A	96	Unknown	18 months
	Abbot mSample Preparation System <sub>DNA</sub>	6K12-24	Kit for sample preparation (extraction, concentration, and purification) for Abbott RealTime HIV-1 Qualitative assay.	Kit	4x24 preps	Ambient temperature	18 months
451	Abbott m2000rt Optical Calibration Kit	4J71-93	Optical calibration kit for Abbott m2000rt RealTime PCR analyser	Kit		Unknown	Unknown
464	Abbott RealTime HIV-1 Calibrator Kit	2G31-70, 6L18-70	Calibrator kit for each new lot of Abbott RealTime HIV-1 Test Kit used	Pack		Yes	18 months
463	Abbott RealTime HIV-1 Control Kit	2G31-80, 6L18-80	Control kit for each run of Abbott RealTime HIV-1 Test Kit	Pack		Yes	18 months
	Abbott RealTime HIV-1 Qualitative Control Kit	4N66-80	Kit contains positive and negative controls to perform Abbott RealTime HIV-1 Qualitative assay. 1 positive and 1 negative controls are required per run.	Kit	2 controls with 12 vials per control	Ship on dry ice; store at $\leq -10^{\circ}\text{C}$ when not in use	18 months
199	Alere Determine™ Chase Buffer	7D2247, 7D2243	Chase buffer for RDT HIV whole blood kit	Bottle		Yes	12-18
476	Alere HIV RDT Controls	7D2626	Positive/negative control material for Alere HIV RDTs	N/A	100	Yes	Unknown
57	Alere Pima Bead Standard	260400011	Internal standards for daily control consisting of 2 ready-to-use cartridges, 1 low and 1 normal, consisting of immobilized fluorescent beads	N/A		Yes	6 month from opening the kit regardless of the number of tests done
254	Alere Printer Paper 1	260400009	Thermal paper, coated, non-adhesive for Pima printer (pima printer is optional accessory for Pima Analyser)	Pack	10 rolls	No	Unknown
	Alere Printer Paper 2	260400010	Thermal paper, coated, non-adhesive for Pima printer (pima printer is optional accessory for Pima Analyser)	Pack	10 rolls	No	Unknown

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Cold/cool chain	Shelf-life (months)
75	Apogee Control Beads	N/A	Control beads for use with Apogee CD4 Analyser	Unknown		Yes	Unknown
60	BD FACSClean™ Cleaning Solution, 5 litres	340346	1% sodium hypochlorite (NaOCl), 0.8% sodium hydroxide (NaOH) (5 litres)	Pack	5	No	Unknown
65	BD FACFlow™ Sheath Fluid	342003	BD FACFlow™ Sheath Fluid	Pack	20	No	Unknown
61	BD FACSRinse Solution (5 litres)	340345	Water, sodium azide, potassium chloride and potassium phosphate, dibasic	Pack	5	No	Unknown
62	BD FACSCount™ CD4 Control Kit	340166	Includes zero, low, medium and high control beads for use in setting up the FACSCount™ system and checking linearity	Kit	25	Yes	> 6
480	BD Tritest™ CD4/CD8/CD3 with Trucount™ Tubes	340401	For enumeration of mature T (CD3+), helper/inducer T (CD3+CD4+) and suppressor/cytotoxic T (CD3+CD8+) lymphocytes	Kit	50	Yes	Unknown
479	BD Trucount™ Controls	340335	Controls for BD FACSCalibur™ – low, medium and high level counting control beads for absolute counting procedures	N/A	30	Yes	Unknown
67	Beckman Coulter CYTO-COMP™ Cell Kit	6607023	A preparation of lyophilized human lymphocytes and reconstitution buffer used in conjunction with the CYTO-COMP™ Reagent Kit to establish and monitor colour compensation settings for multicolour analysis	Bottle	5	Yes	Unknown
69	Beckman Coulter COULTER® CYTO-TROL™ Control Cells Kit	6604248	Used to assess the activity of monoclonal antibodies by flow cytometry	Kit	50	Yes	Unknown
70	Beckman Coulter FlowCARE™ PLG Kit	627808	FlowCARE™ PLG CD4 Reagent (CD45-FITC/CD4-PE) 300T	Kit	300	Unknown	Unknown
71	Beckman Coulter Flow-Check™ Fluorospheres	6605359	Consist of 10-µm polystyrene fluorescent microspheres suspended in aqueous medium, used to verify instrument optical alignment and fluidics	Bottle	30	Unknown	Unknown
72	Beckman Coulter Flow-Set™ Fluorospheres	6607007	A suspension of fluorospheres (fluorescent microbeads) used as an aid in optimizing a flow cytometer for quantitative analysis of leukocytes	Bottle	30	Unknown	Unknown
73	Beckman Coulter IsoFlow™ Sheath Fluid (10 litres)	8546859	Formulated for use in flow cytometers, for low particle and fluorescence backgrounds to ensure superior signal to noise ratio measurements	Bottle	10	N/A	Unknown

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Cold/cool chain	Shelf-life (months)
552	bioLytical HIV RDT Controls	80-1037	Control material for bioLytical RDTs for HIV	Kit	8	Yes	Unknown
483	BioMérieux NuclISENS® easyMAG® Extraction Buffer 1	280130	NuclISENS® reagents for nucleic acid isolation	Pack	4000	Yes	24
484	BioMérieux NuclISENS® easyMAG® Extraction Buffer 2	280131	NuclISENS® reagents for nucleic acid isolation	Pack	4000	Yes	18
485	BioMérieux NuclISENS® easyMAG® Extraction Buffer 3	280132	NuclISENS® reagents for nucleic acid isolation	Pack	4000	Yes	15
486	BioMérieux NuclISENS® easyMAG® Extraction Lysis Buffer	280134	NuclISENS® reagents for nucleic acid isolation	Pack	4000	Yes	24
487	BioMérieux NuclISENS® easyMAG® Magnetic Silica	280133	NuclISENS® reagents for nucleic acid isolation	Pack	29	Yes	18
513	Blu-O™ Enzymatic Cleaner, CE-IVD	N000111411	Resides on board the instrument. Used in automatic cleaning cycles such as instrument start up and shutdown	Bottle	750	No	Unknown
510	Blu-O™ Lysing Reagent Kit, CE-IVD	N000111418	Consists of one Blu-O™ Lysing Reagent A (lysing agent) and one Blu-O™ Lysing Reagent B (quenching agent)	Kit	100	No	Unknown
512	Blu-O™ Sheath Solution, CE-IVD (10 litres)	N000111410	Non-fluorescing, low particulate, iso-osmotic solution	Pack	10	No	Unknown
514	Blu-O™ Sodium Hypochlorite Solution, CE-IVD	N000111412	Used in automatic cleaning cycles and may also be initiated by the user as needed	Pack	200	No	Unknown
511	Blu-O™ Whole Blood Control Kit, CE-IVD	N000111421	Used to monitor Blue Ocean systems (each, 3 × 2.5 ml normal control and 3 × 2.5 ml CD4 low control)	N/A	N/A	Yes	Unknown
533	Calypte® Aware HIV-1/2 BSP Controls	Unknown	Controls for Calypte HIV Rapid Test	N/A	Unknown	Yes	Unknown
230	Cavidi ExaVir™ Load Kit, CE-IVD	55011	ELISA-based method of determining viral load that makes it possible to perform viral load testing in simple laboratory environments	Kit	30	Yes	12

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Cold/cool chain	Shelf-life (months)
541	Chembio Clearview® HIV Reactive/Non-reactive Controls	92112	Controls for Chembio Clearview® RDT	N/A	Unknown	Yes	Unknown
445	COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent	P/N 03587797	Real-time PCR kit for HIV quantification – contains wash reagent	N/A	5	Unknown	Unknown
460	Controls, HIV negative, in-house or purchased	N/A	In-house controls are required for some HIV RDTs and for CaviDi ExaVir™ v3.0	N/A	N/A	Yes	0.25
459	Controls, HIV positive, in-house or purchased	N/A	In-house controls are required for some HIV RDTs and for CaviDi ExaVir™ v3.0	N/A	N/A	Yes	0.25
496	Controls, HIV RNA negative, commercial	N/A	Commercial controls required for viral load assays	N/A	N/A	Yes	Unknown
497	Controls, HIV RNA positive, commercial	N/A	Commercial controls required for viral load assays	N/A	N/A	Yes	Unknown
104	Ethanol (70%) for cleaning	Generic	Ethanol (70%)	N/A	N/A	N/A	N/A
95	Glycerol	Generic	Glycerol, analytical grade	N/A	1	N/A	N/A
517	J. Mitra & Co. Ltd TRI-DOT negative control	Unknown	Rabbit serum tested non-reactive for HBsAg	N/A	N/A	Yes	Unknown
518	J. Mitra & Co. Ltd TRI-DOT, positive control	Unknown	Rabbit serum positive for antibodies to HIV-1 and HIV-2, contains sodium azide	N/A	N/A	Yes	Unknown
97	Methanol	N/A	Methanol, analytical grade	N/A	1	N/A	N/A
80	Millipore Guava® Check Kit	4500-0020	Used in routine maintenance and automated instrument quality control procedures. Helps ensure that Guava® Instrument is optimized for peak performance	Kit	1	Yes	Unknown
81	Millipore Guava® Instrument Cleaning Fluid	4200-0140	Used in routine maintenance and automated instrument quality control procedures. Helps ensure that Guava® Instrument is optimized for peak performance	Pack	100	No	Unknown
86	Partec Cleaning Fluid	04-4009	A buffered detergent solution for cleaning the sample lines and cuvettes of flow cytometry systems to reduce the accumulation of cellular debris and/or bubbles. Cleaning solution contains a wetting agent, buffer solution and preservatives	Bottle	250	No	Unknown

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Cold/cool chain	Shelf-life (months)
87	Partec Control Blood – Dry	05-8993	Dry stabilized blood samples for quality control and external quality assessment	Kit	10	No	12
88	Partec CountCheck Beads (Green)	05-4011	CountCheck Beads are QC particles for absolute counting quality control on flow cytometers with green 532nm laser emission. Concentration: 20 000–25 000 counts/ml. Approved concentration with each lot. Recommended weekly quality control with standard settings	Kit	50	Yes	12
89	Partec Cyluse®	05-5010	Erythrocyte lysing reagent kit for wash and no wash procedures		200	No	Unknown
90	Partec Decontamination Fluid	04-4010	Partec decontamination fluid		250	No	Unknown
92	Partec Sheath Fluid	04-4007	High purity sheath fluid for flow systems	Bottle	5	No	Unknown
531	Sodium hypochlorite solution (0.5%)	Generic	Regular/concentrated bleach (0.5% sodium hypochlorite – NaOCl)	N/A	1	No	N/A
504	Sodium hypochlorite solution (1%)	Generic	Regular/concentrated bleach (1% sodium hypochlorite – NaOCl)	N/A	1	No	N/A
105	Sodium hypochlorite solution (20%)	280133	Regular/concentrated bleach (20% sodium hypochlorite – NaOCl)	N/A	1	No	N/A
106	Sodium hypochlorite solution (5–10%)	Generic	Regular/concentrated bleach (5–10% sodium hypochlorite – NaOCl)	N/A	1	No	N/A
99	Sulfuric acid (2M H2SO4)	Generic	Sulfuric acid (2M H2SO4)		1	No	N/A
559	Trinity Biotech plc Uni-Gold™ Recombigen® HIV Controls	1206530	Controls for Trinity Biotech, Uni-Gold™ Recombigen® HIV	Kit		Yes	Unknown
101	DuPont™ Virkon® Disinfectant	N/A	DuPont™ Virkon® Disinfectant	N/A	1	N/A	N/A
107	Water, distilled	Generic	Water, distilled	N/A	N/A	N/A	N/A
471	Water, RNase/DNase free	Generic	Water, RNase/DNase free	Bottle	N/A	N/A	N/A



## SECTION IID: CONSUMABLES

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Comment
468	Abbott RealTime 96 Deep-Well Plate	4J71-30	Abbott RealTime 96 deep-well plate	Pack	N/A	N/A
453	Abbott RealTime 96-Well Optical Reaction Plates	4J71-70	N/A	N/A	N/A	N/A
455	Abbott RealTime Adhesive Cover Applicator	9K3201, 4J71-75	Plastic cover for real-time PCR plates	N/A	N/A	N/A
457	Abbott RealTime m2000 m Sample Preparation System Start Up Kit	0 02N28-03	Eppendorf Cooler and 2 magnetic stands, magnetic stands for 1 x 5 ml reaction vessel and 1 x 1.5 ml tube, 1.5 ml screw top microfuge tubes and caps	N/A	N/A	N/A
469	Abbott RealTime Master Mix Tube	4J71-80	Tube used for real-time PCR into which master mix reagents are loaded	N/A	N/A	N/A
454	Abbott RealTime Optical Adhesive Covers	4J71-75	Covers for real-time PCR plates that minimize interfering fluorescence and eliminates auto-fluorescent	N/A	N/A	N/A
452	Abbott RealTime Reaction Vessels (5 ml)	4J71-20	Reaction vessels for Abbott RealTime HIV-1 assay	N/A	N/A	N/A
474	Abbott RealTime Reagent Vessels (200 ml)	4J71-60	Reagent vessels for Abbott RealTime HIV-1 assay	N/A	N/A	N/A
456	Abbott RealTime Splash-Free Support Base	9K3101		N/A	N/A	N/A
236	Alcohol wipes	Generic	Alcohol pads/wipes, approx. 30 mm x 30 mm individually wrapped	N/A	100	N/A
253	Alere Fingershick Sample Collection Kit	260400199	Contains necessary items to collect fingershick sample	N/A	100	N/A
254	Alere Printer Paper	260400009	Thermal paper required for printer	Pack	10	N/A
472	Applicator, cotton-tip	Generic	Wooden or plastic stick with cotton tip used as a swab	N/A	N/A	N/A
383	Applicator, wooden	Generic	Wooden stick used for a variety of functions	N/A	N/A	N/A
237	Bag, biohazardous waste, large	Generic	High-density polyethylene biohazardous waste bag for floor-standing container (approx. 60 litres), must display international biohazard symbol, autoclavable up to 134°C, must meet country standards for impact and tear	Pack	100	N/A

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Comment
238	Bag, biohazardous waste, medium	Generic	High-density polyethylene biohazardous waste bag for floor-standing container (approx. 35 litres), must display international biohazard symbol, autoclavable up to 134°C, must meet country standards for impact and tear	Pack	100	N/A
239	Bag, biohazardous waste, small	Generic	High-density polyethylene biohazardous waste bag for counter top (approx. 5–7 litres), must display international biohazard symbol, autoclavable up to 134°C, must meet country standards for impact and tear	Pack	100	N/A
362	Bag, sealable plastic specimen	Generic	Resealable specimen bag, clear, attached external document pocket	Pack	100	N/A
255	Becton Dickinson Cleaning Tubes	343685	Cleaning tubes for FACSCount™ system – purchase with caps	Pack	20	N/A
489	BioMérieux Biohit Tips	280146	NucliSENS® consumables for nucleic acid isolation	Pack	48	N/A
490	BioMérieux NucliSENS® easyMAG® disposables	280135	NucliSENS® consumables for nucleic acid isolation	Pack	48	N/A
492	BioMérieux NucliSENS EasyQ® 8-Tube Caps	285051	NucliSENS® Consumables for amplification	Pack	48	N/A
493	BioMérieux NucliSENS EasyQ® 8-Tube Strips	285048	NucliSENS® Consumables for amplification	Pack	48	N/A
491	BioMérieux Strip Plates Greiner	278303	NucliSENS® Consumables for nucleic acid isolation	Pack	48	N/A
534	Blood collection consumables	N/A	Blood collection consumables required for HIV RDT – see sample collection section	N/A	N/A	N/A
241	Blood collection needle, 21G	Generic	21G needle for blood collection	Box	20	N/A
242	Blood collection tubes EDTA (lavender)	Generic	Spray-coated K2EDTA, lavender top for whole blood haematology determinations, preferably plastic, volume depends upon standard operating procedures and availability	Pack	100	N/A
247	Blood collection tubes thrombin (orange)	Generic	Thrombin-based clot-activator, orange top for stat serum determinations in chemistry, preferably plastic, volume depends upon standard operating procedures and availability.	Pack	100	N/A

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Comment
248	Blood collection, BD Vacutainer Safety-Lok	N/A	Blood collection, BD Vacutainer Safety-Lok blood collection set	Pack	50	N/A
515	Blu-O™ Deep Well Plate, CE-IVD	N000111415	96-well microplate with conical bottoms in each well that optimize the sample preparation process of the system	Pack	50	N/A
249	Capillary tube sealant	Generic	Sealant for sealing capillary tubes	N/A	N/A	N/A
250	Capillary tubes	Generic	Plastic, non-sterile, pre-defined volume capillary tube	N/A	N/A	N/A
251	Capillary tubes (EDTA) (50)	Generic	Plastic, non-sterile, pre-defined volume capillary tube containing EDTA, for collection of whole blood for RDT assays, 50 µl	Box	50	N/A
252	Alere Capillary Tubes (EDTA)	7D2227	EDTA-coated capillary tubes for blood collection from fingerstick sample	Pack	100	N/A
436	COBAS® AmpliPrep K-tips	03287343001	Racks of K-tips (12 x 36)	N/A	432	N/A
437	COBAS® AmpliPrep K-tubes	N/A	K-tubes, rack (12 x 96)	N/A	1152	N/A
378	COBAS® AmpliPrep sample input tubes (S-tubes)	P/N 03137040001	Input S-tube barcode clips hold sample input tubes in the COBAS® AmpliPrep Instrument sample racks and have a barcode to identify the sample	N/A	288	N/A
382	COBAS® AmpliPrep specimen-processing units	03137066001	Specimen-processing unit for pre-amplification	Unit	288	N/A
262	Cotton wool	Generic	Cotton wool	N/A	N/A	N/A
263	Dressing/adhesive plaster/ band aid strip	Generic	Roll of adhesive dressing for attaching gauze after blood draw	N/A	1	N/A
331	EIA microtitre plate (U-shaped)	Generic	N/A	N/A	N/A	N/A
265	Filter paper	N/A	N/A	N/A	N/A	N/A
266	Fine-tip marker pen (black)	Generic	N/A	N/A	1	N/A
	Finger Stick Collection Kit	260400199	Finger stick sample collection kit. Kit contains: 4x units of safety lancets (x28) (260400101); 4x units of gauze swabs (x25) (260400104), 1x unit of alcoholic swabs (x100) (260400103), 4x units of plasters (x26) (260400102)	N/A	100	N/A

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Comment
267	Forceps, non-metallic	Generic	Forceps, plastic, disposable, flat end	Unit	N/A	N/A
268	Gauze pad	Generic	Sterile approx. 5 cm x 5 cm	Box	100	N/A
505	Gloves – multiple sizes, powder-free	Generic	Vinyl/nitrile gloves, non-latex, powder-free designed for laboratory procedures and hospital ward use. Packed in dispenser box	Box	100	N/A
269	Gloves, large	Generic	Large vinyl/nitrile gloves (non-latex), powdered or powder-free designed for laboratory procedures and hospital ward use. Packed in dispenser box	Box	100	N/A
270	Gloves, medium	Generic	Medium vinyl/nitrile gloves (non-latex), powdered or powder-free designed for laboratory procedures and hospital ward use. Packed in dispenser box	Box	100	N/A
271	Gloves, small	Generic	Small vinyl/nitrile gloves (non-latex), powdered or powder-free designed for laboratory procedures and hospital ward use. Packed in dispenser box	Box	100	N/A
332	Humidity indicator card	Generic	Small visual humidity indicator cards, colour change indicator	Pack	100	N/A
333	Immersion oil	Generic	Immersion oil, ISO or DIN specifications 58-884 compliant	N/A	N/A	N/A
334	Inoculation loop, sterile, plastic (5 µl)	Generic	Plastic, disposable, sterile inoculating loop, 5 µl	N/A	100	N/A
	1.4 ml Internal Control Vial	03N19-01	Vial for internal control for Abbott m24 instrument	N/A	N/A	N/A
	1.4 ml Internal control Vial Cap	03N20-01	Vial cap for internal control for Abbott m24 instrument	N/A	N/A	N/A
335	Labels, adhesive (for labelling tubes/containers)	Generic	Adhesive specimen labels, approx. 30 mm x 60 mm	Roll	100	N/A
336	Lancet, 21G	Generic	Contact-activated, single-use lancet, 21G, incision depth approx. 2.0 mm	Pack	100	N/A
337	Lancet, 30G	Generic	Contact-activated, single-use lancet, 30G, incision depth approx. 2.0 mm	Pack	100	N/A
338	Lancet, infant	Generic	Contact-activated, single-use lancet for infant heelstick	Box	100	N/A

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Comment
339	Microscope slides, with frosted edge	Generic	Microscope slides, cut/frosted edge, made of soda-lime glass, 76 × 26 mm, 1 mm thick, washed and packed lint free, frosted edge of approx. 20 mm width	N/A	N/A	N/A
256	Millipore Guava® Sample Acquisition Tubes	N/A	1.5-ml microcentrifuge tubes with screw caps	Pack	100	N/A
240	Needle Holder	Generic	Blood collection needle holder (for blood collection tubes)	Pack	250	N/A
340	Normal blood (EDTA)	Generic	Pooled blood for use in quality control	N/A	N/A	N/A
342	Paper Towels, 2-ply, 3-part Fanfold	2016604	Paper towels, 2-ply, 3-part fanfold	Pack	N/A	N/A
343	Paper wipes, small	Generic	N/A	Pack	N/A	N/A
257	Partec CyFlow, Thermal Printer Paper	04-4000	Thermal paper for printer	Roll	5	N/A
522	Partec CyFlow®, Tube, Caps	04-4000	Caps for 3.5-ml Partec CyFlow® tubes	Pack	1000	N/A
258	Partec CyFlow®, Tubes, 3.5 ml	04-2000	Partec CyFlow® 3.5-ml tubes	Pack	500	N/A
478	Petri dish with cover	Generic	Use with BD FACSCount™ and BD FACSCalibur™	Unit	1	N/A
330	Pipette dropper, 25 µl	Generic	Pipette dropper, calibrated to 25 µl	Unit	1	N/A
347	Pipette tip, 100–1000 µl	Generic	Non-sterile, autoclavable, pipette tips, translucent, specific for brand of 100–1000-µl adjustable volume pipette	Box	96	N/A
348	Pipette tip, 100–1000 µl filter/aerosol barrier	Generic	Sterile, filter-tip, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 100–1000 µl adjustable volume pipette	Box	96	N/A
351	Pipette tip, 10–200 µl	Generic	Non-sterile, autoclavable pipette tips, translucent, specific for brand of 10–100/200 µl adjustable volume pipette	Box	96	N/A
	Pipette tip, 200 µl disposable	4J71-17	200 µl Disposable tips for m2000sp instrument automatic sample preparation to perform Abbott RealTime HIV-1 Qualitative assay	case	96 tips/box, 12 boxes/case	N/A
	Pipette tip, 1000 µl disposable	4J71-10	1000 µl Disposable tips for m2000sp instrument automatic sample preparation to perform Abbott RealTime HIV-1 Qualitative assay	case	96 tips/box, 12 boxes/case	N/A
352	Pipette tip, 10–200 µl filter/aerosol barrier	Generic	Sterile, filter-tip, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 10–100/20 µl adjustable volume pipette	Box	96	N/A

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Comment
501	Pipette tip, 1–5 ml	Generic	Non-sterile, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 1–5 ml adjustable volume pipette	Box	96	N/A
500	Pipette tip, 1–5 ml filter/aerosol barrier	Generic	Sterile, filter-tip, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 1–5 ml adjustable volume pipette	Box	96	N/A
353	Pipette tip 1–5 µl	Generic	Non-sterile, autoclavable pipette tips, translucent, specific for brand of 1–5 µl adjustable volume pipette	Box	96	N/A
354	Pipette tip, 1–5 µl filter/aerosol barrier	Generic	Sterile, filter-tip, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 1–5 µl adjustable volume pipette	Box	96	N/A
349	Pipette tip, 5–20 µl	Generic	Non-sterile, autoclavable pipette tips, translucent, specific for brand of 10–20 µl adjustable volume pipette	Box	96	N/A
350	Pipette tip, 5–20 µl filter/aerosol barrier	Generic	Sterile, filter-tip, DNase-, RNase-, ATP- and pyrogen-free, autoclavable pipette tips, translucent, specific for brand of 10–20 µl adjustable volume pipette	Box	96	N/A
355	Pipette tip, repeater/dispenser 1.0 ml	Generic	Non-sterile, autoclavable, or sterile, pipette tips, translucent, specific for brand of 50-µl adjustable repeat pipettor	Box	Varies	N/A
356	Pipette tip, repeater/dispenser 1.25 ml	Generic	1.0 ml must be appropriate brand to fit pipettor	Pack	N/A	N/A
357	Pipette, disposable micro-pipette/dropper 25 µl	Generic	1.25 ml must be appropriate brand to fit pipettor	Pack	N/A	N/A
358	Pipette, serological, 1.0 ml	Generic	Disposable glass micro-pipettes/dropper	Pack	N/A	N/A
359	Pipette, transfer disposable, 1000 µl	Generic	Polyethylene plastic pipettes suitable for blood banking, urinalysis, hematology, wet chemistry, microbiology, and serology.	case	Varies	N/A
358	Pipette, serological, 1.0 ml	Generic	Serological pipette, 1.0 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	N/A	N/A	N/A
359	Pipette, serological, 10.0 ml	Generic	Serological pipette, 10 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	N/A	N/A	N/A
359	Pipette, serological, 10.0 ml	Generic	Serological pipette, 10 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	N/A	N/A	N/A

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Comment
530	Pipette, serological, 25.0 ml	Generic	Serological pipette, 25 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	N/A	N/A	N/A
360	Pipette, serological, 5.0 ml	Generic	Serological pipette, 5.0 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	N/A	N/A	N/A
360	Pipette, serological, 5.0 ml	Generic	Serological pipette, 5.0 ml, sterile, disposable, transparent plastic construction, graduated markings, non-pyrogenic, filter-plugged	N/A	N/A	N/A
	Plate, 96 well polypropylene	Generic	Polypropylene plates suitable for liquid phase assays.	N/A	N/A	N/A
361	Reagent reservoirs for ELISA	Generic	Reservoirs for multi-channel pipetting solutions into microtitre plates during ELISA	Pack	N/A	N/A
361	Reagent reservoirs for ELISA	Generic	Reservoirs for multi-channel pipetting solutions into microtitre plates during ELISA	N/A	N/A	N/A
362	Resealable specimen bags	Generic	Resealable specimen bag, clear, attached external document pocket	N/A	N/A	N/A
363	Sharps container, large	Generic	Robust, durable sharps container conforming to international safety standards, large, approx. 15 litres	N/A	N/A	N/A
364	Sharps container, medium	Generic	Robust, durable sharps container conforming to international safety standards, medium, approx. 5 litres	N/A	N/A	N/A
365	Sharps container, small	Generic	Robust, durable sharps container conforming to international safety standards, small, approx. 2 litres	N/A	N/A	N/A
524	Siemens VERSANT® 1000 µl pipette tips	US: 06635759	Pipette tips supplied for VERSANT	N/A	N/A	N/A
525	Siemens VERSANT® 300 µl pipette tips	US: 06635767	Pipette tips supplied for VERSANT	N/A	N/A	N/A
526	Siemens VERSANT® 96-well, 2-ml nuclease-free, sterile deep-well plates	US: 06691055	Microtitre plates supplied for VERSANT	N/A	N/A	N/A
529	Siemens VERSANT® Barcoded 96-well Semi-skirted Polypropylene Plates for PCR	US: 06653412	Siemens VERSANT® Barcoded 96-well semi-skirted polypropylene plates for PCR	N/A	N/A	N/A
523	Siemens VERSANT® Large and Small Reagent Troughs	US: 10489008	Siemens large and small reagent troughs	N/A	N/A	N/A

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Comment
527	Siemens VERSANT® Optical Caps (8 × strip)	US: 06653439	Siemens VERSANT® optical caps, 8 × strip	N/A	N/A	N/A
366	Silica gel packs	Generic	Silica gel packs, small, individual packs, with indicator	Box	100	N/A
367	Slide cover slips 75 mm × 25 mm	N/A	N/A	N/A	N/A	N/A
368	Swab, 70% alcohol	Generic	N/A	Box	100	N/A
369	Swab, dry	Generic	N/A	N/A	N/A	N/A
370	Thermal Paper	322839	Thermal paper roll	Pack	1	N/A
371	Tissues, wipes	Generic	Tissues, wipes	N/A	N/A	N/A
372	Tourniquet, adult	Generic	Rubber tourniquet with closure, adult	N/A	N/A	N/A
373	Tourniquet, child	Generic	Rubber tourniquet with closure, child	N/A	N/A	N/A
503	Tube strips, PCR, 0.2 ml, RNase-free with caps	Generic	0.2-ml PCR tubes in strips with caps, thin-walled, polyethylene	Pack	100	Alternate to item 502
374	PE Biosystems MicroAmp® Reaction Tube with Cap, 0.2 ml, Autoclaved	N801-0533	0.2-ml tube with cap	Pack	1000	N/A
375	Tube, 1.0 ml, microcentrifuge, cap	Generic	1.0-ml tube with cap	Pack	N/A	N/A
243	Tube, blood collection, plain, red top	Generic	Clot-activator, red top for serum determinations in chemistry, preferably plastic. May be used for routine blood donor screening and diagnostic testing of serum for infectious disease. Volume depends upon standard operating procedures and availability	Pack	N/A	N/A
375	Tube, microcentrifuge, 1.0 ml, with cap	Generic	Tube, microcentrifuge, 1.0 ml, with cap	Pack	N/A	N/A
244	Tubes, blood collection, sodium citrate, blue top	Generic	Sodium citrate blue top for coagulation determinations, preferably plastic, volume depends upon standard operating procedures and availability	Pack	100	N/A
245	Tubes, blood collection, sodium fluoride, grey top	Generic	Sodium fluoride grey top for glucose determinations, volume depends upon standard operating procedures and availability	Pack	100	N/A
246	Tubes, Blood Collection, Sodium/Lithium Heparin, Green Top	Generic	Sodium/lithium heparin green top for plasma determinations in chemistry, volume depends upon and availability	Pack	100	N/A



Item no.	Item name	Catalogue no.	Description/specification	Pack type	Quantity/pack	Comment
477	Tubes, Centrifuge, 50 ml	Generic	50-ml Falcon tubes	Pack	N/A	N/A
376	Tubes, microcentrifuge, 1.5 ml, screw cap	Generic	1.5-ml microcentrifuge tubes with screw caps	Pack	N/A	N/A
502	Tubes, microcentrifuge, 1.5 ml, RNase-free	Generic	1.5-ml microcentrifuge tubes with caps	Pack	N/A	N/A
376	Tubes, microcentrifuge, 1.5 ml, screw cap	Generic	1.5 ml microcentrifuge tubes with screw caps	Pack	N/A	N/A
475	Tubes, microcentrifuge, 1.7 ml, RNase-free	Generic	1.5-ml microcentrifuge tubes with screw caps	Pack	100	N/A
377	Tubes, test, 12 mm x 75 mm, capped	Generic	Test tubes, 12 mm x 75 mm, with caps	Pack	100	N/A
467	Tubes, test, 13 mm x 75 mm	Generic	Test tubes, 13 mm x 75 mm	Pack	N/A	N/A
466	Tubes, Test, 16 mm x 75 mm	Generic	Test tubes, 16 mm x 75 mm	Pack	100	N/A
378	Viral load, COBAS® AMPLICOR®, Racks of D-cups	P/N 21045644001 (US: 1045644)	Racks of D-cups	N/A	N/A	N/A
379	Viral load, COBAS® AMPLICOR®, Racks of K-tips	03287343001	Racks of K-tips for pre-amplification	N/A	N/A	N/A
380	Viral load, COBAS® AMPLICOR®, Racks of Output Tubes	03137058001	Racks of output tubes for pre-amplification	N/A	N/A	N/A
381	Viral load, COBAS® AMPLICOR®, Specimen Input Tubes	03137040001	Specimen input tubes (5-tubes) with barcode clips for pre-amplification	N/A	N/A	N/A
382	Viral load, COBAS® AMPLICOR®, Specimen Processing Units	03137066001	Specimen processing units for pre-amplification	N/A	N/A	N/A
494	Waste container – with cap	Generic	Waste container – with cap for proper disposal of PCR products	Unit	1	N/A
383	Wooden applicator sticks	N/A	Wooden applicator sticks	N/A	N/A	N/A

## SECTION III: DURABLES

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Required accessory
59	Apogee Reagent Tubes	Unknown	Apogee reagent tubes	Pack	N/A
384	Beaker, 500 ml	Generic	Durable glass or plastic beaker with spout	Unit	N/A
385	Biohazardous waste container, large	Generic	Capacity of approx. 50 litres, made of high-density polypropylene, at least 40 µm thick, cleanable, meeting the country's standards for environmental and hygiene considerations	Unit	N/A
386	Biohazardous waste container, medium	Generic	Capacity of approx. 25 litres, made of high-density polypropylene, at least 40 µm thick, autoclavable up to 134°C, meeting the country's standards for environmental and hygiene considerations	Unit	N/A
387	Biohazardous waste container, small	Generic	Capacity of approx. 3–5 litres, made of high-density polypropylene, at least 40 µm thick, autoclavable up to 134°C, meeting the country's standards for environmental and hygiene considerations	Unit	N/A
388	Blood collection tray (for phlebotomy supplies)	Generic	Phlebotomy tray, lightweight, easy to clean and disinfect, built-in test tube rack for 16-mm tubes, swing-out or pull-out compartmentalized draws for supplies	Unit	N/A
516	Blu-O™ Instrument Waste Container	N000111542	Blu-O™ 10-litre waste containers	Unit	N/A
389	Bottle, dispensing/wash, 500 ml	Generic	500-ml dispensing/wash bottle, plastic, vented with cap	Unit	N/A
461	Bottle/tube, 25 ml	N/A	25-ml bottle/tube for Cavidl ExaVir™ system	Unit	N/A
442	COBAS® Ampliprep K-carrier	28150397001	K-carrier	Unit	N/A
444	COBAS® Ampliprep K-carrier rack	P/N 03286436001	K-carrier rack	Unit	N/A
443	COBAS® Ampliprep K-carrier transporter	P/N 03517519001	K-carrier transporter	Unit	N/A
439	COBAS® Ampliprep reagent rack	P/N 28122199001	Reagent rack	Unit	N/A
438	COBAS® Ampliprep sample rack	P/N 28122172001	Sample rack (SK 24 rack)	Unit	N/A
440	COBAS® Ampliprep specimen-processing unit rack	P/N 28122199001	Specimen-processing unit rack	Unit	N/A

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Required accessory
391	Coplin jars	Generic	Coplin jar/staining dish, clear soda lime glass, glass cover and a wide, flat, round base (Coplin) or rectangular dish with lid, able to hold minimum of 10 slides back to back	N/A	N/A
392	Dried blood spot card drying rack	Generic	Sturdy, easy-to-clean and disinfect dried blood spot card drying rack with capacity for a minimum of 20 cards at a time	Unit	N/A
393	Eppendorf PCR Cooler or StrataCooler 96 benchtop cooler	Generic	Stand for protection of temperature-sensitive samples at the bench. It is a superior replacement for an ice bath.	Unit	N/A
394	Goggles/eye protection	Generic	Safety goggles, curved lens, impact-resistant, adjustable headband, offers chemical splash and ultraviolet protection, ventilated	Unit	N/A
395	Graduated cylinder, 1000 ml	Generic	1000-ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing	Unit	N/A
396	Graduated cylinder, 100 ml	Generic	100-ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing	Unit	N/A
397	Graduated cylinder, 2000 ml	Generic	200-ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing	Unit	N/A
398	Graduated cylinder, 50 ml, glass	Generic	500-ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing	Unit	N/A
399	Graduated cylinder, 50 ml, non-glass	Generic	50-ml graduated cylinder, hexagon base and spout, class B, short line graduation with durable graduation and printing, glass	Unit	N/A
400	Haemocytometer/counting chamber	Generic	50-ml graduated cylinder, hexagon base and spout, polypropylene (or similar material), short line graduation with durable graduation and printing, non-glass	Unit	N/A
401	Laboratory coat, large	Generic	Haemocytometer, complete set in case, consisting of: 1 counting chamber DIN 12 847 without clamps with double net ruling and two cover glasses, one blood diluting pipette Thoma for red and white blood cells, two silicone tubing of approx. 16 cm length and carrying case	Unit	N/A
402	Laboratory coat, medium	Generic	Laboratory coat, large, made from strong, lightweight, liquid resistant, breathable material. Long sleeves, elasticated cuffs and high neck closure. Material must be autoclavable	Unit	N/A
403	Laboratory coat, small	Generic	Laboratory coat, medium, made from strong, lightweight, liquid resistant, breathable material. Long sleeves, elasticated cuffs and high neck closure. Material must be autoclavable	Unit	N/A
404	Microtitre plate lid	Generic	Laboratory coat, medium, made from strong, lightweight, liquid resistant, breathable material. Long sleeves, elasticated cuffs and high neck closure. Material must be autoclavable	Pack	N/A

Item no.	Item name	Catalogue no.	Description/specification	Pack type	Required accessory
405	Phlebotomy chair, with arm rest	Generic	Phlebotomy/blood draw chair, steel frame, height-adjustable swing-out arms, easy to clean and disinfect, weight capacity at least 136 kg	Unit	N/A
406	Phlebotomy grips (for patients to squeeze)	Generic	Phlebotomy grips, rubber, used to encourage firm squeeze	Pack	N/A
407	Rack, test tubes, 0.5 ml, 1.5 ml, 2.0 ml centrifuge	Generic	Polypropylene (or similar material) or epoxy-coated wire rack for 14-mm diameter test tubes	Unit	N/A
	Rack, reaction vessels, 5 ml	Generic	Polypropylene (or similar material) or epoxy-coated wire rack for 5ml reaction vessels	Unit	N/A
	13 mm Sample racks	4J72-82	Sample racks to hold controls and patient specimens during automatic sample preparation in the Abbott m2000sp instrument. Supplied with the Abbott m2000sp instrument.	Pack	N/A
408	Graduated cylinder, 2000 ml	Generic	Polypropylene (or similar material) or epoxy-coated wire rack for 14 mm diameter test tubes	Unit	N/A
409	Scissors	Generic	Metal scissors, plastic handle, approx. 15–30 cm in length	Unit	N/A
410	Slide staining rack	Generic	Slide staining rack, plastic/stainless steel, horizontal type, flexible length to fit different sized sinks, must hold minimum of 12 slides	Unit	N/A
411	Slide storage box	Generic	Slide storage box to hold a minimum of 100 slides, must be easy to clean and disinfect	Unit	N/A
507	Stand, magnetic separator for 1.5-ml tubes	Generic	Stand for magnetic separation protocols using 1.5-ml tubes	Unit	N/A
	Stand, magnetic separator for 5-ml reaction vessels	Generic	Stand for magnetic separation protocols using 5-ml tubes	Unit	N/A
412	Thermometer, digital	Generic	Digital thermometer, must conform to ASTM standards	Unit	N/A
413	Thermometer – non-digital	Generic	Non-mercury thermometer, must conform to ASTM standards	Unit	N/A
414	Tourniquet, adult	Generic	Rubber tourniquet with closure, adult	Unit	N/A
48	Transport box/potentially infectious sample	Generic	Triple package transportation system for potentially infected substances consisting of primary, secondary and outer packaging. Must comply with international standards for construction and labelling	Unit	N/A
49	Transport box/sample/blood/vaccine battery-powered	Generic	Transport box (extended cold life). WHO specification reference B4/BC2. Capacity: 15–27 litres (approx. 20 blood bags). Max weight: 45 kg	Unit	N/A
50	Transport box/sample/blood/vaccine transport container with ice packs	Generic	Transport boxes (extended cold life). WHO specification reference B4/BC2. Capacity: 15–27 litres (approx. 20 blood bags). Max weight: 45 kg. Maintains < 10°C for minimum of 130 h in ambient temp of 43°C. Max. ice melting rate: > 10 h/kg ice at + 43°C	Unit	Must include sufficient numbers of ice packs (E5/IP2 or 2)



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