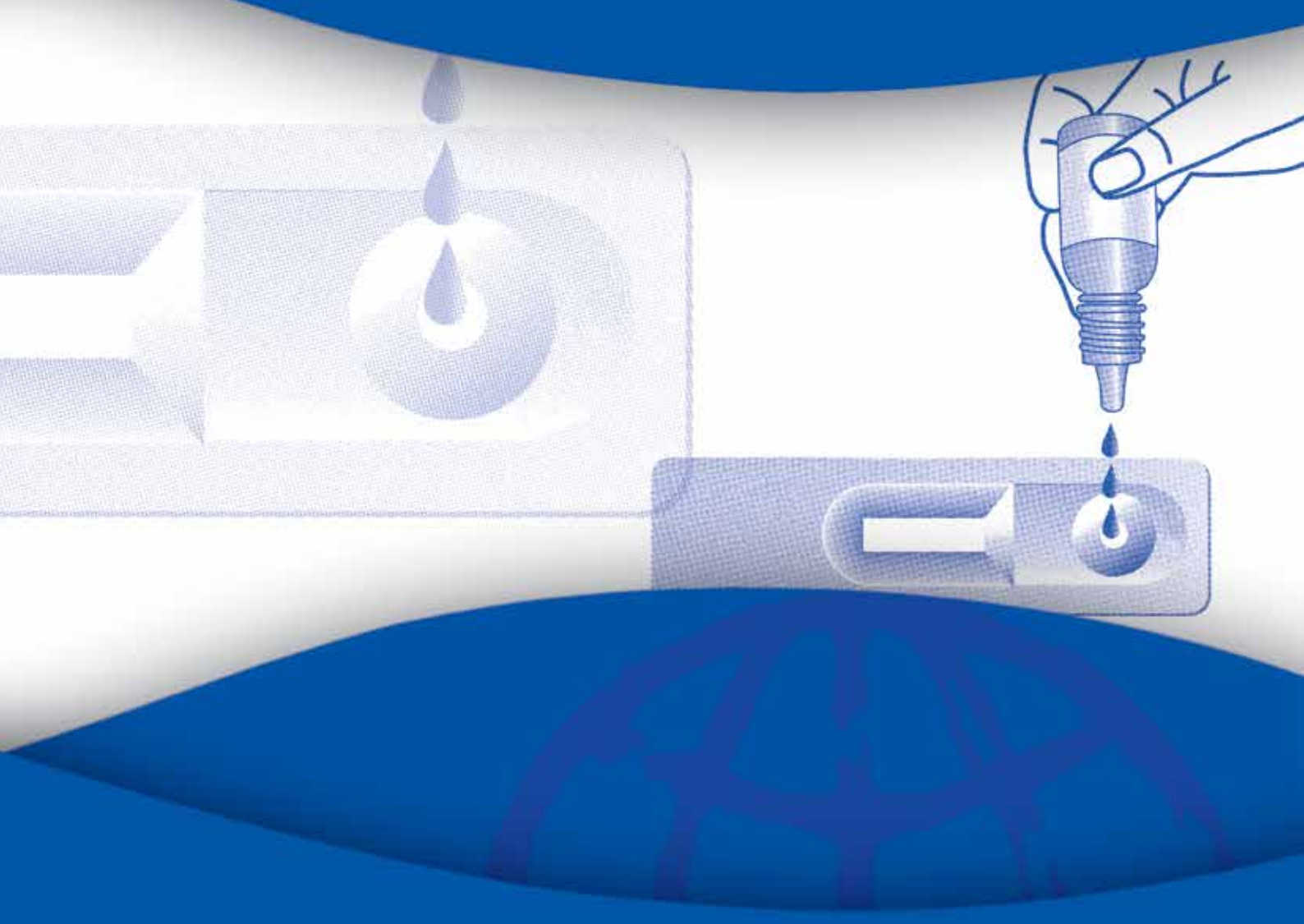
World Health Organization

HIV ASSAYS

LABORATORY PERFORMANCE AND OTHER OPERATIONAL CHARACTERISTICS

RAPID DIAGNOSTIC TESTS
(Combined detection of HIV-1/2 antibodies and discriminatory detection of HIV-1 and HIV-2 antibodies)

REPORT 18



Prequalification Team-Diagnostics

HIV ASSAYS: OPERATIONAL CHARACTERISTICS

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1. SUMMARY

Report 18 summarizes the assessment of the laboratory performance and major operational characteristics of commercially available assays to detect HIV-1/2 antibodies. The data that is presented was obtained in the evaluation of the following eight immunochromatographic (lateral flow) rapid diagnostic tests (RDTs), carried out between 2013 and 2014:

Immunochromatographic RDTs (detection of HIV-1 and HIV-2 antibodies)

- ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) (ABON Biopharm (Hangzhou) Co.,Ltd)
- SD BIOLINE HIV-1/2 3.0 (Standard Diagnostics, Inc.)
- First Response® HIV 1-2-O Card test (Premier Medical Corporation Ltd)

Immunochromatographic RDTs
(combined detection of HIV-1/2 antibodies)

- ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test (InTec PRODUCTS, INC) [1]
- DoubleCheckGold™ Ultra HIV 1&2 (Orgenics Ltd.)[2]
- Diagnostic Kit for HIV(1+2) Antibody (Colloidal Gold) (Shanghai Kehua Bioengineering Co., Ltd.)
- DPP® HIV 1/2 Assay (Chembio Diagnostic Systems, Inc.)
- VIKIA® HIV 1/2 (bioMérieux SA)

Section 2 of this report provides background information on the WHO Assays: Operational Characteristics series and the WHO Prequalification of In Vitro Diagnostics Programme. Sections 3 and 4 provide an overview of the laboratory diagnosis of HIV and comments on assay selection. Section 5 outlines how the assessments were carried out. Details of the evaluations are contained in the tables in section 6. Cumulative lists of the assays already assessed under the programme and the addresses of manufacturers are given in Annexes 1-3.

2. BACKGROUND INFORMATION

In 1988, World Health Organization (WHO), conscious of the need to advise WHO Member States on the laboratory diagnosis of HIV, initiated the WHO HIV Test Kit Evaluation programme to provide objective assessments of commercially available assays for detecting antibodies to HIV-1 and HIV-2. In 2010, this programme was superseded by the WHO Prequalification of In Vitro Diagnostics Programme. The WHO prequalification assessment is a more robust assessment based on regulatory principles that considers the performance, quality and safety of the assay. It achieves this through dossier assessment (part of technical file), on-site inspection of manufacturing facilities and the quality system under which the products are manufactured, and independent laboratory evaluation of performance and operational characteristics. The laboratory (product) testing for this continuing programme is carried out by the WHO Collaborating Centre for HIV/AIDS Diagnostics and Laboratory Support in the Department of Clinical Sciences, HIV/STI Reference Laboratory, Institute of Tropical Medicine, Belgium and coordinated by the Department of Essential Medicines and Health Products, WHO.

The laboratory evaluations continue to focus on the operational characteristics of these assays, such as ease of use and the performance characteristics; including diagnostic sensitivity and specificity and analytical aspects including lot-to-lot variation. The testing utilizes a panel of well-characterized specimens of diverse geographical origins, commercially sourced seroconversion panels and mixed titer panels, and a dilution series for assessing lot variability.

The evaluations are also designed to assess an assay's suitability for use in facilities such as small laboratories and non-facility based testing services including stand-alone HIV testing and counselling sites (HTC) and community settings. This includes all testing conducted in the context of provider-initiated testing and counselling and client-initiated testing and counselling, and in blood transfusion centres in resource-limited settings.

A minimum performance criteria is set for each format of HIV serology assay. **This report contains the results of all evaluations, including those products meeting the acceptance criteria for WHO prequalification and those products that did not.**

Disclaimer: Please note that the status of WHO prequalification is only assigned to products that meet the WHO acceptance criteria for laboratory evaluations, **in addition to** meeting the WHO prequalification requirements for dossier assessment and inspection of site of manufacture(s). All products must satisfactorily meet the WHO requirements for all three components, before they will be WHO prequalified, and therefore eligible for WHO procurement.

INTENDED AUDIENCE

The outcomes of the laboratory evaluations are published in the form of technical reports which are intended for use

1 Product later withdrawn from WHO Prequalification of In Vitro Diagnostics Programme

2 Product later withdrawn from WHO Prequalification of In Vitro Diagnostics Programme

by health policymakers, directors of blood banks, managers of national HIV/AIDS programmes, end users in testing services and laboratories, and procurement agencies. The comparative data contained in these reports may be used to help select HIV assays that are appropriate for local needs, by applying country relevant selection criteria, in conjunction with other considerations such as prior experience with a given assay, availability in-country, cost, customer service and technical support from manufacturers.

REPORT DISSEMINATION

The first report was issued in March 1989, and subsequent reports have been issued on a regular basis, details of which are given in Annexes 1 and 2. Recent reports are also published on the WHO website at the following web address: http://www.who.int/diagnostics_laboratory/en/.

Further copies of this and earlier reports are available by written request to the Department of Essential Medicines and Health Products, World Health Organization, 1211 Geneva 27, Switzerland or by e-mail to diagnostics@who.int Reports containing information on assays which are currently no longer available are taken out of distribution.

3. LABORATORY DIAGNOSIS OF HIV INFECTION

3.1 A BRIEF OVERVIEW

The laboratory diagnosis of HIV infection is usually made on the basis of serology, i.e. the detection of HIV-1/2 antibodies or simultaneous detection of HIV-1/2 antibodies and HIV-1 p24 antigen. Serological assays for detection of HIV-1/2 antibodies or detection of HIV-1/2 antibodies and HIV-1 p24 antigen are generally classified as either first-line assays (sometimes referred to as screening assays) or second- or third-line assays (sometimes referred to as supplemental assays, or confirmatory assays). First-line assays can provide the presumptive identification of reactive specimens and thus should have superior sensitivity, and second-line and third-line assays are used to confirm whether specimens found reactive with a particular first-line assay contain antibodies specific to HIV-1/2 and/or HIV-1 p24 antigen. These assays should have a superior specificity. Simple assays, rapid diagnostic tests (RDTs) and enzyme immunoassays (EIAs) may all serve as first-line assays. These same formats of assay may also be used as second- and third-line assays. There are some formats that may only be used as second- and third-line assays. Further discussion on choice of assay format for screening and confirming HIV infection follows.

3.2 FORMATS OF DIAGNOSTICS

3.2.1 RAPID DIAGNOSTIC TESTS

Rapid diagnostic tests for HIV infection include immunochromatographic (lateral-flow), and immunofiltration (flow-through) test formats that detect the presence of HIV-1/2 antibodies and/or HIV-1 p24 antigen. Other analytes may also be added to an HIV RDT such as antibodies to hepatitis C, hepatitis B surface antigen, antibodies to *Treponema pallidum* (syphilis) to create a multiplex RDT. In brief, specimen (fingerstick/capillary whole blood, venous whole blood, serum, plasma or oral fluid) is added to the test device by a specimen transfer device or pipette. A small volume of buffer is usually added, mostly for whole blood specimens. A reactive result is indicated by the appearance of a coloured band, line, spot or dot in the test region and in the control region. Immunochromatographic assays can be performed in less than 30 minutes and immunofiltration assays in less than 5 minutes and are referred to broadly as RDTs. Results for RDTs are read visually (subjectively read). In general, these assays are most suitable for use in both facility and non-facility based testing services such as stand-alone HIV testing and counselling centres and laboratories with limited facilities that process low numbers of specimens daily and other community-based testing services.

Due to their simplicity, cost and rapid turn-around time, WHO recommends the use of quality[3] RDTs for resource-limited settings, rather than conventional laboratory-based diagnostics such as enzyme immunoassay (EIA) and Western blots. RDTs enable quicker provision of test results. In addition, RDTs can be performed with simple capillary blood collected by a simple fingerstick procedure and therefore do not require venipuncture specimen collection. With adequate training, health workers and other non-laboratory staff or lay persons can perform HIV testing with high accuracy and reliability. The use of RDTs may lower the reliance on laboratory-based techniques; these are assays that use cold chain reagents and equipment requiring maintenance and skilled staff. However, in instances where there are many tests being carried out per day and patients are retained, testing by laboratory-based methods such as EIA may be more cost-effective and appropriate.

3.2.1.1 SIMPLE ASSAYS

Simple instrument-free assays for HIV include: combo immunoassays and particle or latex agglutination assays that detect the presence of HIV-1/2 antibodies and/or HIV-1 p24 antigen. These types of assays are more suited to laboratory or facility-based testing as cool storage of

3 For technical information on quality HIV RDTs, please refer to the list of WHO prequalified diagnostics, accessed 23 November 2014 http://www.who.int/diagnostics_laboratory/evaluations/en/

test kits and use of precision pipettes are usually required. Generally, simple assays are not suitable for use with capillary/fingerstick whole blood, venous whole blood, or oral fluid and thus require phlebotomy to collect an appropriate specimen. Simple assays are less rapid than RDTs and require between 30 minutes to two hours to be performed. As for RDTs, simple assays are read visually by the user/operator.

3.2.2 ENZYME IMMUNOASSAYS

Enzyme immunoassays (EIA) for HIV are a laboratory-based methods to detect the presence of HIV-1/2 antibodies and/or HIV-1 p24 antigen. Generally, EIAs are more objective and most cost-effective to perform in a laboratory setting with high specimen through-put (greater than 40 specimens per day). EIAs require equipment(s) and an experienced and proficient technician to perform the technique.

EIAs range in format and requirements. For example, EIAs may require the use of EIA plate incubators, EIA plate washers, and EIA plate readers and varying degrees of hands-on time by the laboratory technician for loading the specimens into the wells, reconstitution and addition of solutions and buffers, and plate washing and reading. Simple immunoanalyzers automate a number of these steps and as such require less hands-on time. Random access immunoanalyzers are fully automated and specimens can be placed onto the instrument at any time during the running of the instrument, eliminating the need to wait for testing cycle to end.

Serology assays for HIV are categorised by generation, being classified on the basis of the antigens and/or conjugate used. First generation EIAs were constructed using viral lysate as antigen, which were relatively sensitive but lacked specificity and thus were highly prone to producing false-reactive results. In order to improve sensitivity and specificity, second generation assays were developed that used recombinant proteins and synthetic peptides as antigen instead of lysate. Third generation assays utilize labelled antigen as conjugate, which further refines sensitivity and specificity. The latest generation of assays; fourth generation detects both antigen and antibody and successfully increases diagnostic sensitivity.

3.2.3 SUPPLEMENTAL ASSAYS

A combination of RDTs, simple assays and EIAs can be used as second- and third-line assays to confirm an initial reactive test result. In addition to these assays, line immunoassays (LIAs), based on recombinant proteins and/or synthetic peptides capable of detecting antibodies to specific HIV-1 and/or HIV-2 proteins, have been widely used to confirm HIV infection. Line immunoassays have replaced Western blotting in many settings and serve a similar purpose, i.e. to give additional information on the pattern of sero-reactivity. However, given the cost and relative difficulty to interpret the results, the use of line immunoassays and/or Western blotting to confirm HIV seropositivity is generally not required.

Studies have shown that testing algorithms consisting of combinations of EIA or simple assays or RDTs are just as reliable as EIA/Western blot testing algorithm combinations. WHO, therefore, recommends that national programmes consider to use testing algorithms for HIV diagnosis that use combinations of RDTs, simple assays or EIAs, rather than EIA/Western blot (Sato et al, 1994; WHO/UNAIDS, 1997).

3.2.4 FOURTH GENERATION ASSAYS FOR DISCRIMINATORY OR COMBINED DETECTION OF HIV-1 ANTIGEN AND HIV-1/2 ANTIBODIES

Fourth generation assays for the detection of HIV-1 p24 antigen and HIV-1/2 antibodies have the potential to identify infected individuals earlier in the disease course, including individuals in the seroconversion phase (window period characterised by presence of HIV-1 p24 antigen and incomplete HIV-1/2 antibodies) and acute infection (characterised by presence of HIV nucleic acid and/or HIV-1 p24 antigen but not HIV-1/2 antibodies). These assays are generally of superior seroconversion sensitivity to assays of earlier generations. Therefore, they should be considered as the first-line (screening) assay where feasible. However, recent data show that the HIV-1 antigen detection component of some fourth generation assays may be lacking in sensitivity.

Certain 4th generation assays can produce a result that indicates if the specimen is reactive for antigen or for antibody rather than combined detection of these markers. When these discriminatory 4th generation assays are used as the first-line assay and are followed with antibody-detection only assays for second-line and third-line assays, due care should be taken to confirm any initial HIV-1 antigen reactivity by an alternate pathway. This may be done through re-testing of a second specimen taken 14 days later to ascertain seroconversion (antibody positive) or referral of a specimen for HIV-1 antigen testing at a higher level laboratory.

Circulating p24 antigen that appears early in the course of HIV infection, is detectable for 1-2 weeks, and then disappears or falls to very low levels until the onset of clinical illness. Rising titers of HIV p24 antigen late in the illness are correlated with a poor prognosis. The presence of circulating p24 antigen is also associated with increased levels of infectious virus particles, as the probability of isolating HIV from an infected person is highest when p24 antigen can be detected.

3.3 DIAGNOSIS OF HIV-2 INFECTION

In order to identify infection with HIV-2, an assay with discriminatory capabilities (separate detection of HIV-1 and HIV-2 antibodies) may be used. However, the data generated by the WHO Prequalification of In Vitro Diagnostics Programme shows that the amount of cross reactivity between HIV-1 and HIV-2 may be significant. Dual infection of HIV-1 and HIV-2 within one individual is quite rare. Dual reactivity observed in any given discriminatory assay is more likely to be caused by cross-reactivity given certain homology in the amino acid sequences of HIV-1 and HIV-2. To determine the virus type or diagnose a co-infection, appropriate supplemental testing must be performed.

3.4 USE OF MOLECULAR TECHNOLOGIES

Molecular techniques may be used qualitatively to assist the diagnosis of HIV infection in adults and in children and quantitatively to monitor the progression of HIV infection and the response to anti-retroviral therapy (ART). These include molecular techniques that detect the presence of HIV viral nucleic acid i.e. RNA or DNA by means of nucleic acid amplification or signal amplification techniques. Molecular techniques are commonly used for early infant diagnosis in infants under 18 months of age, given the influence of passively transferred maternal antibody on serological methods.

Technologies based on the amplification of viral nucleic acids, such as polymerase chain reaction (PCR) and nucleic acid sequence-based amplification (NASBA) or amplification of the bound probe signal as in branched-DNA (bDNA) assays have made it possible to detect very low quantities of viral material. In theory, as little as a single viral genome can be detected. The detection limit for most assays is about 50 copies/ml but in practice, the technique can have limited specificity. These techniques are suited for early infant diagnosis in the context of mother-to-child transmission and for monitoring the HIV viral load of individuals who are taking ART to determine treatment, or virologic failure. Although prices have decreased recently, molecular assays remain expensive, they require sophisticated equipment, rigorous laboratory conditions and highly trained and proficient staff. Many of the assays need further refinement since not all HIV-1 subtypes are equally well detected, nor is HIV-2. Therefore, as with serology, it would be unwise to base a diagnosis of HIV infection on a single reactive/positive test result, in the absence of any other detectable marker.

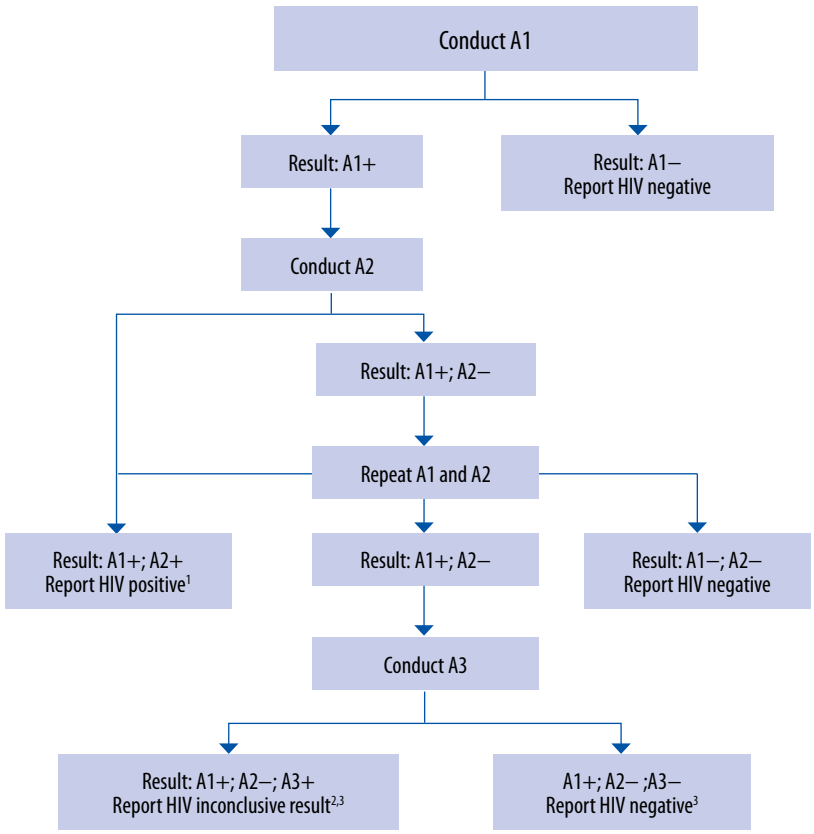
3.5 WHO TESTING STRATEGIES

3.5.1 WHO TESTING STRATEGY FOR DIAGNOSIS IN HIGH HIV PREVALENCE SETTINGS

The following testing strategy applies in high prevalence settings, i.e. prevalence above 5% in the population to be tested. Firstly, all specimens should be tested with the first-line assay. Specimens that are non-reactive (A1-) are considered and reported HIV-negative. Any specimens that are reactive on the first-line assay (A1+) should be tested again using a second-line assay which is different from the first. For specimens that are reactive on both first- and second-line assays (A1+; A2+), the result should be reported as HIV-positive. These individuals should be referred for assessment of eligibility for treatment and entry to care, if these services are not available at the testing site. Specimens that are reactive on the first-line assay but non-reactive on the second-line assay (A1+; A2-) **should be repeated** using the same specimen (in case of serum/plasma) with the same two assays. [When using capillary/finger-stick whole blood, a new specimen will have to be taken.] Repeating the assays is the best practice; it may eliminate discrepant results that are due to technical or clerical error or errors inherent to the test device itself. If the repeat test results are concordant (either A1+; A2+ or A1-; A2-), they may be reported as positive or negative, respectively. If the test results remain discrepant (A1+; A2-), the specimen should be further tested using a third-line assay. If the third-line assay is non-reactive (A1+; A2-; A3-), the test result is considered negative and reported as HIV-negative.

If the third-line assay is reactive (A1+; A2-; A3+), the test result is reported as HIV-inconclusive. The individual should be asked to return in 14 days for further testing. This situation is often rare. If the rate of HIV-inconclusive results is high, additional efforts to assure quality should be made, and the selection of assays might be reconsidered. If A1 is an antigen/antibody detection assay and A2 or A3 is an antibody-detection-only assay, re-testing should be performed with a second specimen taken after 14 days.

Figure 1.HIV testing strategy for diagnosis in **high prevalence** settings
(Figure 6, p.37 of Service delivery approaches to HTC: a strategic HTC programme framework)



Note:
"Assay A1", "A2" and "A3" represent three different assays (of any test format). "Report" = result may be reported.
1 For newly diagnosed individuals, a positive result should be confirmed on a second specimen to rule out laboratory error.
2 Re-testing should be performed on a second specimen taken after 14 days to rule out seroconversion.
3 If A1 is an antigen/antibody detection assay and A2 or A3 are antibody-detection-only assays, re-testing should be performed with a second specimen taken after 14 days.

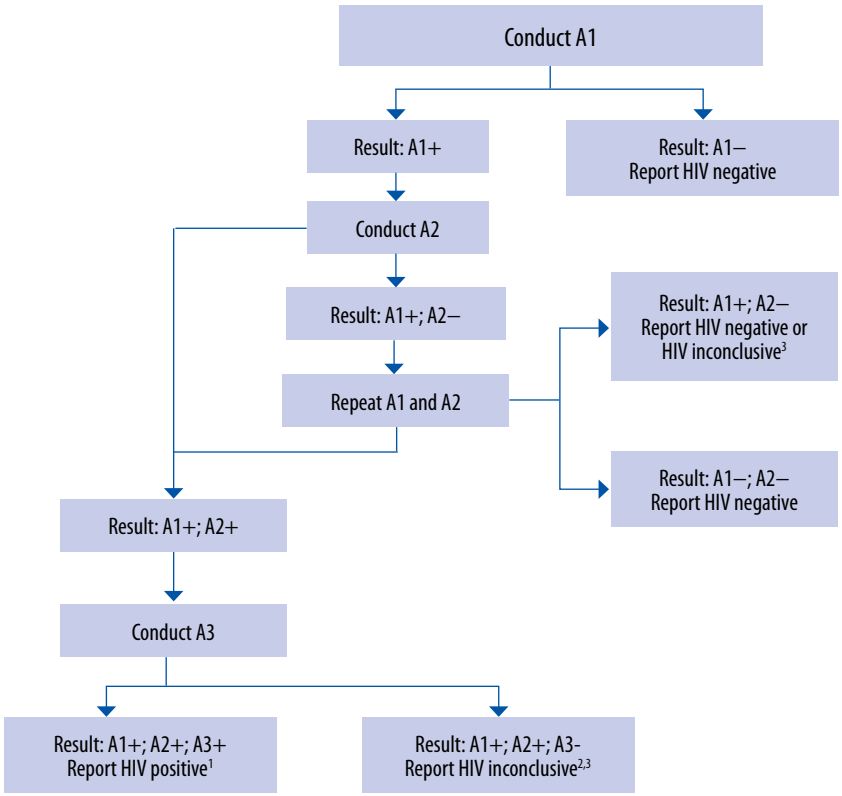
3.5.2 WHO TESTING STRATEGY FOR DIAGNOSIS IN LOW HIV PREVALENCE SETTINGS

The following testing strategy applies in low prevalence settings, i.e. prevalence below 5% in the population to be tested. Firstly, all specimens are tested with the first-line assay, and specimens that are non-reactive (A1-) are considered and reported HIV-negative. Any specimens that are reactive on the first-line assay (A+) should be retested using a second-line assay which is different from the first-line.

Specimens that are reactive on the first-line assay but non-reactive on the second-line assay (A1+; A2-) **should be repeated** using the same specimen (when serum/plasma) with the same two assays. [When using capillary/finger-stick whole blood, a new specimen will have to be taken.] Repeating the assays is best practice; as it may eliminate discrepant results that are due to technical or clerical errors or errors inherent to the test device itself. **Any specimens that are reactive on the first-line assay but non-reactive on the second-line assay (A1+; A2-) are considered HIV-negative**, and results are reported as such. For these specimens, the positive predictive value will be low for the first-line result, however, the negative predictive value for the second-line result will be high. If A1 is an antigen/antibody detection assay and A2 is an antibody-detection-only assay, the result is inconclusive and re-testing should be performed with a second specimen taken after 14 days. In a low HIV prevalence population, the positive predictive value based on two test results remains too low. Therefore, for specimens that are reactive on both first-line and second-

line assays (A1+; A2+), a third-line assay should be used to confirm HIV-reactive specimens. If the third test result is also reactive (A1+; A2+; A3+), the result can be reported as HIV-positive. Such individuals should be referred for assessment of their eligibility for treatment and entry to care, if these services are not available at the testing site. If the result of the third-line assay is non-reactive, (A1+; A2+; A3-), then the result is considered HIV-inconclusive. The individual should be asked to return in 14 days for further testing. This situation is often rare. If the rate of HIV-inconclusive results is high, additional efforts to assure quality should be made, and the selection of assays might be re-considered.

Figure 2. HIV testing strategy for diagnosis in **low prevalence** settings
(Figure 7, p.39 of Service delivery approaches to HTC: a strategic HTC programme framework)



Note:
"Assay A1", "A2", "A3" represent three different assays (of any test format). "Report" = result may be reported.
1 For newly diagnosed individuals, a positive result should be confirmed on a second specimen to rule out laboratory error.
2 Re-testing should be performed with a second specimen taken after 14 days to rule out potential seroconversion.
3 If A1 is an antigen/antibody detection assay and A2 or A3 are antibody-detection-only assay, re-testing should be performed with a second specimen taken after 14 days.

3.6 FOLLOW UP AFTER DIAGNOSIS

It is usual best practice to obtain an additional specimen after a time interval (i.e. not the same day) to retest all newly diagnosed individuals. Retesting is usually performed as part of the clinical and laboratory-based assessment of treatment eligibility and entry to care, for example at the time of CD4 count for ART initiation. This procedure aims to rule out possible technical or clerical errors including specimen mislabelling and transcription errors. Further guidance on retesting is available in specific WHO guidance "*Delivering HIV test results and messages for re-testing and counselling in adults*, World Health Organization, Geneva, 2010, ISBN 978 92 4 159911 5"[4]

3.6.1 INCONCLUSIVE HIV SERO STATUS

Individuals with overall inconclusive HIV sero status should be asked to return for re-testing after 14 days. In particular, if there has been a specific incident of HIV exposure within the preceding three months, the discrepancy in the test results may be due to seroconversion, and thus testing a second specimen is advisable. If re-testing results are subsequently concordantly reactive (A1+; A2+), true seroconversion may be highly likely, as the antibody response will have matured and positive status can be reported. If re-testing results remain either discrepant (A1+; A2-) or resolve to both non-reactive (A1-; A2-), false reactivity is likely to have been the cause, and negative status can be reported.

Care should be taken when interpreting the results from 4th generation assays, see previous section 3.1.

Specimens from individuals with clinical signs and symptoms meeting WHO criteria for HIV stage III or IV may show discrepant testing results due to a decrease in the levels of HIV-1/2 antibodies with advanced disease progression and impaired immune function. These instances should not be common; if observed, retesting for HIV diagnosis may not be required, but instead additional testing such as CD4+ T lymphocyte enumeration (and HIV virological testing, where available) may be carried out to guide clinical decisions.

3.7 QUALITY ASSURANCE

All laboratories and testing sites carrying out HIV testing should have a well-functioning quality management programme following the twelve quality system essentials (QSEs):

1. Organization
2. Personnel
3. Equipment
4. Purchasing and inventory
5. Process control
6. Information management
7. Documents and records
8. Occurrence management
9. Assessment
10. Process improvement
11. Customer service
12. Facilities and safety

These twelve QSEs can be implemented in varying degrees but the basic principles will still apply to any service providing HIV testing results. Further guidance on quality management systems is available in specific WHO guidance "*Laboratory quality management system: handbook*, World Health Organization, Geneva, 2011, ISBN 978 92 4 154827 4".[5] Other guidelines have been developed for application of quality aspects to HIV testing with an emphasis on rapid testing in resource-limited settings. For further details, see the *Joint CDC/WHO Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach*, World Health Organization, Geneva, 2005[6].

1. Organization – ensure there is an organization chart that describes the roles and responsibilities of all staff in the testing facility, this includes those who may collect specimens, who may issue reports, who may double-check test results and final reports, etc.

2. Personnel – ensure staff are adequately qualified and trained for the position they are assigned to, including an understanding of quality system essentials. Competency-based pre-service training is preferred, along with on-going in-service training as new tests are introduced, etc.

3. Equipment – maintain an inventory of equipment, and ensure preventive and corrective maintenance is performed, as appropriate. Standard operating procedures (SOPs) should exist for all equipment.

4. Purchasing and inventory – ensure adequate system is in place to track test kits/reagents and consumables (i.e. venous and fingerstick blood collection equipment) that are ordered/received. Then, track consumption and requirements for replenishing stock as this data is important for national quantification of supplies. Take special note

4 Delivering HIV test results and messages for re-testing and counselling in adults, World Health Organization, Geneva, 2010. Accessed on 23 November 2014 at http://whqlibdoc.who.int/publications/2010/9789241599115_eng.pdf

5 Laboratory quality management system: handbook, World Health Organization, Geneva, 2011. Accessed on 23 November 2014 at http://whqlibdoc.who.int/publications/2011/9789241548274_eng.pdf

6 Joint CDC/WHO Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach, World Health Organization, Geneva, 2005. Accessed 23 November 2014 http://whqlibdoc.who.int/publications/2005/9241593563_eng.pdf

of expiry dates and ensure adequate time is allowed for delivery.

5. Process control – ensure systems are in place to control pre-analytical, analytical, and post-analytical steps of the testing procedure, including criteria for specimen acceptance/rejection, specimen storage/retention/disposal/referral, quality control (QC) for both qualitative and quantitative tests using test kit controls or external QC with established limits of acceptability, verification of subjectively read tests by a second reader (especially important for RDTs), etc.

6. Information management – ensure a system for recording all test results, lot numbers, expiry dates, as well as the overall results given to each individual tested. Standardised laboratory logbooks and/or electronic data capture systems may be useful in this regard. Each specimen should be assigned a unique identifying number, and each individual who enters the service should be assigned their own patient identifier so that all results for all specimens tested from one individual may be tracked.

7. Documents and recordkeeping – ensure SOPs for all procedures undertaken including: specimen collection and processing requirements, testing algorithms, all test procedures with QC, final reporting (in accordance with validated testing algorithms), etc. Equipment maintenance records and temperature records for fridges, freezers and the testing rooms should be kept. Laboratory notebooks and forms used for recording testing should be kept.

8. Occurrence management – ensure a system to immediately capture quality issues/problems, then to identify the root cause and implement a corrective action. Indicators such as turn-around times for each test and for an overall testing report, rate of discrepant results, rate of invalid results, rate of specimen rejection may be used.

9. Assessment – ensure some form of internal and external quality assessment is undertaken. An internal audit of certain tasks may also be performed by another staff member not usually performing the task. External assessment may be undertaken in the form of participation in an external quality assessment scheme (EQAS) also known as proficiency testing, or supervisory visits from another facility. WHO, US CDC, UKNEQAS, RARS Senegal, NICD South Africa, NRL Australia are some of the EQA providers[7] that are able to ship EQAS panels to resource-limited settings. National reference laboratories should participate in an international EQAS at least twice per year, with the concurrent aim towards implementation of a national EQAS for all testing services using locally derived specimens. The dried tube specimen (DTS) approach developed by US CDC provides a practical means to prepare specimens for distribution to outlying laboratories and testing services. (Parekh et al, 2013)[8]

10. Process improvement – proactively identify opportunities for improvement of services, then relay to higher level management for implementation of better working practices. This may link closely to activities associated with number 8 – occurrence management.

11. Customer service – ensure internal (doctors, nurses, other healthcare workers) and external (clients, accreditation agencies, professional associations, regulatory agencies) customer satisfaction with the testing services provided.

12. Facilities and safety – ensure a person is assigned as safety officer and receives appropriate training on safety. Maintain a safe working environment for all staff with necessary procedures in place (universal precautions, how to prevent and/or respond to needle-stick injuries or other occupation exposures, chemical and biological safety, spill containment, waste disposal, personal protective equipment, etc.)

4. ASSAY SELECTION

There are various operational factors that influence the selection and use of assays in addition to their performance characteristics. WHO performance evaluations take these factors into account in assessing suitability for use in both non-facility based testing such as community testing and testing campaigns, and facility-based testing such as in stand-alone HIV testing and counselling sites, and small or lesser-equipped laboratories. The results of the laboratory evaluations demonstrate that certain RDTs are more suitable than EIAs in small centres where there are only a limited number of specimens to be tested for HIV (<40 specimens per day) and infrastructure such as electricity, cool storage and clean water are lacking. For testing large numbers of specimens, EIAs are still the most rapid and appropriate assay type where infrastructure and available skilled staff permit.

The choice of the most appropriate HIV assay also depends on the HIV variants (genotypes) present in a particular geographical region (e.g., HIV-1 group O). It is clear, for example, that in areas such as West Africa where HIV-2

7 Inventory of EQA Programmes. Accessed 23 November 2014 http://wwwn.cdc.gov/mlp/eqa.aspx

8 Parekh, B.S., et al., Dried tube specimens: A simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings. J. Virol. Methods (2009), doi:10.1016/j.jviromet.2009.10.013

is prevalent, an assay capable of detecting antibodies to HIV-2 as well as HIV-1 may be desirable. Furthermore, other factors such as concomitant infections and the underlying prevalence of exogenous and endogenous infections/ substances may affect the performance of certain assays. These factors will likely vary from region to region and country to country. Therefore, testing algorithms should always be validated in the context in which they will be used before large-scale implementation.

HIV assays found to meet minimum quality, safety, and performance standards for WHO prequalification are then eligible for WHO, and therefore United Nations (UN), procurement[8]. The UN Bulk Procurement Scheme provides UN agencies and national programmes with access to appropriate diagnostics of good quality at reduced cost. HIV assays other than those purchased by the pooled procurement programme but meeting the WHO minimum standards in terms of sensitivity and specificity can also be considered for use with the WHO testing strategies.

In general, for the selection and use of HIV assays to be used within the WHO HIV testing strategies in Figures 1 and 2, the first-line assay should have the highest sensitivity, whereas the second- and third-line assays should have a similar or higher specificity than the first-line. As assay development has resulted in an improvement in terms of performance, it is now frequently the case that many assays have both high sensitivity and specificity.

When validating a potential testing algorithm, six to ten assays should be selected, taking into account the considerations outlined in Table 1. One validated testing algorithm with two additional algorithms as back-up options is preferable, in case of stock-outs or product failures. In total, three assays will be required, irrespective of the testing strategy and one back-up assay is preferable to ensure that sufficient alternate testing algorithms can be utilised. In addition to acceptable performance characteristics, the positive and negative predictive value of the overall testing algorithm should be considered. WHO is currently developing more specific guidance on this topic.

Table 1: Specific considerations for selection of HIV diagnostics

Parameter	Considerations
Performance characteristics	
Clinical sensitivity	Set the minimum acceptable criteria for 1st line and for 2nd/3rd line assays e.g. ≥99% for RDTs, 100% for EIAs
Clinical specificity	Set the minimum acceptable criteria for 1st line and for 2nd/3rd line assays e.g. ≥98% for RDTs and EIAs
Seroconversion sensitivity	Important for blood screening and high incident populations
Inter-reader variability, if subjectively read format	Set the minimum acceptable criteria e.g. ≤5%
Invalid rate (devices/test results)	Set the minimum acceptable criteria e.g. ≤5% or ≤1% depending on assay format
Operational characteristics	
Test format	RDTs (immunochromatographic, immunofiltration) Simple (comb formats, agglutination assays) EIAs (manual plate-based EIAs, immunoanalysers) Supplemental assays (Western blot, line immunoassays) NAT (qualitative)
Specimen type	Serum/plasma, venous or capillary whole blood, oral fluid, venous or capillary whole blood dried blood spots
Detection type	Discriminatory detection of HIV-1 and HIV-2 antibodies or combined detection of HIV-1/2 antibodies Discriminatory or combined detection of HIV-1 antigen and HIV-1/2 antibodies
Subtype detection	M, N, O subtypes
Time to result	Immunochromatographic: Less than 30 minutes with fewer steps Immunofiltration: Less than 5 minutes with more steps
Endpoint stability	How long is the result stable? Is longer reading time or shorter reading time desirable? (depends on service delivery model)
Ease of use	Depends on a combination of: • nature of specimen collection (fingerstick whole blood by lancet or venous whole blood by venipuncture) • number of steps in the test procedure • ease of reading of the test band, line, spot • ease of interpretation of testing results • addition of procedural quality control (band appears when human specimen is added versus band appears when running buffer is added)
Degree of laboratory infrastructure required	Refrigeration for storage of test kits and/or reconstituted reagents Temperature controlled work space Electricity/generator
Equipment/consumables required but not provided in the test kit	Lancets, alcohol swabs for fingerstick whole blood Blood collection equipment for venous whole blood Other general laboratory consumables
Specimen through-put and individual testing service delivery models	RDTs if ≤40 specimens per day per operator with limited laboratory infrastructure EIAs if ≥40 specimens per day per operator with laboratory infrastructure
Technical skill of staff conducting testing	Including both laboratory and phlebotomy skills
Availability of test kit controls and compatibility with quality control materials	Some are available but separate from test kit See also note above on procedural in-built quality control
Shelf-life of test kits	Must be negotiated as part of the procurement contract
Access to referral laboratory	Particularly important when 4th generation assays are used

5. MATERIALS AND METHODS OF ASSESSMENT

5.1 ASSAYS

Kits for the commercial assays listed in Section 5.1 were kindly provided free of charge by the manufacturers to WHO for assessments. The manufacturers and distributors were informed that the assessments were to be carried out and that they were free to visit the assessment site and to demonstrate their assays at their own expense.

ABON™ HIV 1/2/O TRI-LINE HUMAN IMMUNODEFICIENCY VIRUS RAPID TEST DEVICE (ABON BIOPHARM (HANGZHOU) CO., LTD).

ABON™ HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is an immunochromatographic rapid diagnostic test for the qualitative detection of HIV-1 and HIV-2 antibodies in human serum/plasma and capillary/venous whole blood specimens.

KEY INFORMATION:

Shelf life: 24 months
Storage conditions: 2-30 °C
Volume of specimen needed: 25µL (serum/plasma); 50µL (whole blood)
Time to test one specimen: 11 minutes

EQUIPMENT REQUIRED BUT NOT SUPPLIED:

- personal protection equipment such as gloves, lab coat or gown
- timer
- appropriate biohazard waste containers
- for capillary whole blood: heparinised capillary tubes with 50µl fill line
- for capillary blood collection: lancet, cotton wool, alcohol swab
- for venous blood collection: venipuncture apparatus and appropriate blood collection tubes.

Non-reactive HIV-1 & 2 antibodies

Reactive for HIV-1 antibodies

Disclaimer: These instructions were prepared based on the instructions for use submitted as part of the WHO Prequalification of In Vitro Diagnostics assessment. These may change over time and so it is recommended to always refer to the most current instructions for use when developing standard operating procedures and/or job aids.

TEST PROCEDURE:

1) Remove the device from protective foil pouch, use within 1 hour.
2) Label the test with patient or specimen ID number
3) For serum or plasma specimens:
   a. Using the dropper provided within the test kit, apply 1 drop (25µl) of specimen to the specimen well (S).
   b. Add 1 drop (40µl) of buffer to the same specimen well (S).
   c. Read results at 10 minutes, do not read after 20 minutes.
4) For venous whole blood (venipuncture) specimens:
   a. Using the dropper provided within the test kit, apply 2 drops (50µl) of specimen to the specimen well (S).
   b. Add 2 drops (80µl) of buffer to the same specimen well (S).
   c. Read results at 10 minutes, do not read after 20 minutes.
5) For capillary whole blood (finger stick) specimens:
   a. Clean fingertip with alcohol swab, place lancet off-centre and puncture the finger tip. Wipe away first drop of blood with cotton wool.
   b. Using capillary tube, take specimen until the fill line. Apply 50µl of specimen to the specimen well (S).
   c. Add 2 drops (80µl) of buffer to the same specimen well (S).
   d. Read results at 10 minutes, do not read after 20 minutes.
6) **Interpret results as follows:**

Non-reactive for HIV-1 & HIV-2 antibodies: One coloured line appears in the control region C and no apparent coloured lines in the test line regions T1 and T2.

Reactive for HIV-1 & HIV-2 antibodies: Two or three distinct coloured lines appear, one on the control line 'C' and other one or two coloured lines in the test line region(s) **T1** and or **T2**

Reactive for HIV-1 antibodies: Two distinct coloured lines appear, one in the control line 'C' and one other coloured line in the test region T1.

Reactive for HIV-2 antibodies: Two distinct coloured lines appear, one in the control line 'C' and one other coloured line in the test region T2.

Invalid: Control line fails to appear in control region, even if coloured lines appear in any of the test regions T1 or T2.

SD BIOLINE HIV-1/2-3.0
(STANDARD DIAGNOSTICS, INC).

SD BIOLINE HIV-1/2 3.0 is an immunochromatographic rapid diagnostic test for the qualitative detection of HIV-1 and HIV-2 antibodies in human serum/plasma and capillary/venous whole blood specimens.

KEY INFORMATION:

Shelf life: 24 months
Storage conditions: 1-30 °C
Volume of specimen needed: 10µL (serum/plasma); 20 µL (whole blood)
Time to test one specimen: 10 minutes

EQUIPMENT REQUIRED BUT NOT SUPPLIED:

- personal protection equipment such as gloves, lab coat or gown
- timer
- appropriate biohazard waste containers
- precision pipette + tips, when using serum/ plasma
- for capillary blood collection: cotton wool.
  Certain kit configurations require capillary pipettes, lancets, alcohol swabs
- for venous blood collection: venipuncture apparatus and appropriate blood collection tubes.

Non-reactive for HIV-1&HIV

Reactive for HIV-1 antibodies

Reactive for HIV- 2 antibodies

Reactive for HIV- 1+2 antibodies

TEST PROCEDURE:

1) Remove the test device from its pouch and place it on a flat surface.
2) Label the test device with patient or specimen ID number.
3) For serum or plasma specimens:
   a. Using a precision pipette, apply 10µl of specimen to the specimen well (S).
4) For venous whole blood (venipuncture) specimens:
   a. Using a precision pipette, apply 20µl of specimen to the specimen well (S).
5) For capillary whole blood (finger stick) specimens:
   a. Clean fingertip with alcohol swab, place lancet off-centre and puncture the finger tip. Wipe away first drop of blood with cotton wool.
   b. Using capillary tube provided within the test kit, draw specimen. Apply 20µl of specimen to the specimen well (S).
6) For all specimen types, add 4 drops (120µl) of buffer to the same specimen well (S).
7) Read results at 10 minutes after adding the assay diluent, but no later than 20 minutes.
8) Interpret results as follows:

Non-reactive for HIV-1 & HIV-2: Presence of only control line (C) within the result window.

Reactive for HIV-1 antibodies: Presence of two lines as control line (C) and test line 1 (T) within the result window

Reactive for HIV- 2 antibodies: Presence of two lines as control line (C) and test line 2 (T) within the result window

Reactive for HIV- 1 and 2 antibodies: Presence of three lines as control line (C), test line 1 (T) and test line 2 (T) within the result window

Invalid: No presence of control line (C) within the result window

Disclaimer: These instructions were prepared based on the instructions for use submitted as part of the WHO Prequalification of In Vitro Diagnostics assessment. These may change over time and so it is recommended to always refer to the most current instructions for use when developing standard operating procedures and/or job aids.

FIRST RESPONSE® HIV 1-2.0 CARD TEST (PREMIER MEDICAL CORPORATION LTD)

FIRST RESPONSE® HIV 1-2.O CARD TEST is an immunochromatographic rapid diagnostic test for the qualitative discriminatory detection of HIV-1 and HIV-2 antibodies in human serum, plasma or venous/capillary whole blood specimens.

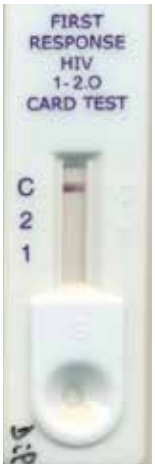
KEY INFORMATION:

Shelf life: 22 months
Storage conditions: 4-30 ˚C
Volume of specimen needed: 10 µL(serum/plasma); 20 µL (whole blood)
Time to test one specimen: 16 minutes

EQUIPMENT REQUIRED BUT NOT SUPPLIED:

- personal protection equipment such as gloves, lab coat or gown
- timer
- appropriate biohazard waste containers
- for capillary blood collection: lancet, cotton wool, alcohol swab
- for venous blood collection: venipuncture apparatus and appropriate blood collection tubes.

Non-reactive for HIV antibodies



Reactive for HIV-1 antibodies

TEST PROCEDURE:

1) Bring the FIRST RESPONSE HIV 1-2.0 card test kit component to room temperature prior to testing.
2) Remove the Test Device and the sample pipette from the foil and place it on a flat, dry surface.
3) Label the test device with patient or specimen ID number.
4) For serum/plasma specimens:
   a. Slowly add 10µl (one drop) of specimen to the sample well (S) using the sample pipette provided within the test kit.
5) For venous whole blood specimens:
   a. Slowly add 20µl (two drops) of specimen to the sample well (S) using the sample pipette provided within the test kit.
6) For capillary whole blood specimens:
   a. Clean fingertip with alcohol swab, place lancet off-centre and puncture the finger tip. Wipe away the first drop of blood with cotton wool.
   b. Using capillary tube provided within the test kit, draw specimen. Apply 2 drops (20µl) of specimen to the specimen well (S).
7) For all specimen types, add 35 µL (one drop) of the assay diluent to the sample well (S)
8) Interpret test results 15 minutes after addition of assay diluent. Do not interpret after 15 minutes.
9) Interpret the results as follows:

Non-reactive: If only one colour band appears at control line C.

Reactive for HIV-1 antibodies: Two colour bands appear, one on the control line 'C' and other at test line 1.

Reactive for HIV-2 antibodies: Two colour bands appear , one on the control line 'C' and other at test line 2.

Reactive for HIV-1 & 2 antibodies: Three colour bands appear , one on the control line 'C' and other two at test line 1 and 2.

Invalid: If no colour band appears at the control line 'C' within the stipulated time.

Disclaimer: These instructions were prepared based on the instructions for use submitted as part of the WHO Prequalification of In Vitro Diagnostics assessment. These may change over time and so it is recommended to always refer to the most current instructions for use when developing standard operating procedures and/or job aids.

ADVANCED QUALITY™ ONE STEP ANTI-HIV (1&2) TEST (INTEC PRODUCTS, INC)

ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test is an immunochromatographic rapid diagnostic test for the combined detection of HIV-1/2 antibodies in human serum, plasma and venous/capillary whole blood specimens.

KEY INFORMATION:

Shelf life: 24 months
Storage conditions: 2-30 ˚C
Volume of specimen needed: 30 µL
Time to test one specimen: 16 minutes

EQUIPMENT REQUIRED BUT NOT SUPPLIED:

- personal protection equipment such as gloves, lab coat or gown
- timer
- appropriate biohazard waste containers
- for capillary blood collection: lancet, cotton wool, alcohol swab
- for venipuncture blood collection: venipuncture apparatus and appropriate blood collection tubes.

Non-reactive for HIV-1/2 antibodies

Reactive for HIV-1/2 antibodies

TEST PROCEDURE:

1) Bring all reagents and specimens to room temperature
2) Remove the test card from the foil pouch and place it on a clean dry surface
3) Label the test device with patient or specimen ID number.
4) For serum/plasma specimens:
   a. Add 30µl (one drop) of specimen to the sample well (S) using the plastic dropper provided within the test kit.
5) For venous whole blood specimens:
   a. Add 30µl (one drop) of specimen to the sample well (S) using the plastic dropper provided within the test kit.
6) For capillary whole blood specimens:
   a. Clean fingertip with alcohol swab, place lancet off-centre and puncture the finger tip. Wipe away first drop of blood with cotton wool.
   b. Using plastic dropper provided within the test kit, draw specimen. Add one drop (30µl) of specimen to the specimen well (S).
7) For all specimen types, add 50µL (one drop) of the sample diluent to the sample well (S)
8) Interpret test results at 15-20 minutes.

Non-reactive: Only the purplish red test control band appear on the membrane.

Reactive for HIV-1/2 antibodies: Both purplish red test band and purplish red control band appear on the membrane.

Invalid: If control band is not seen on the membrane

Disclaimer: These instructions were prepared based on the instructions for use submitted as part of the WHO Prequalification of In Vitro Diagnostics assessment. These may change over time and so it is recommended to always refer to the most current instructions for use when developing standard operating procedures and/or job aids.

DOUBLECHECKGOLD™ ULTRA HIV 1&2 (ORGENICS LTD)

DoubleCheckGold™ Ultra HIV 1&2 is an immunochromatographic rapid diagnostic test for the detection of HIV-1/2 antibodies in human serum, plasma and venous/capilary whole blood specimens.

KEY INFORMATION:

Shelf life: 18 months
Storage conditions: 2-30 °C
Volume of specimen needed: 25 µL
Time to test one specimen: 16 minutes

EQUIPMENT REQUIRED BUT NOT SUPPLIED:

- personal protection equipment such as gloves, lab coat or gown
- timer
- appropriate biohazard waste containers
- precision pipette + tips, when using any specimen type
- for capillary blood collection: lancet, cotton wool, alcohol swab
- for venipuncture blood collection: venipuncture apparatus and appropriate blood collection tubes.

Non-reactive for HIV-1/2 antibodies

Reactive for HIV-1/2 antibodies

TEST PROCEDURE:

1) Remove the test cassette from the aluminium pouch.
2) Label the test cassette with patient or specimen ID number.
3) For serum/plasma specimens:
   a. Add 25µl of specimen to the sample port (S) using a precision pipette.
4) For venous whole blood specimens:
   a. Add 25µl of specimen to the sample port (S) using a precision pipette.
5) For capillary whole blood specimens:
   a. Clean fingertip with alcohol swab, place lancet off-centre and puncture the finger tip. Wipe away first drop of blood with cotton wool.
   b. Using a precision pipette, add 25µl of specimen to the specimen well (S).
6) For all specimen types, immediately add 50µL (two drops) of the wash reagent to the sample port.
7) The results should be read at the end of the 15 minutes incubation time.
8) The results are stable for an additional 10 minutes (25 minutes after the application of the sample/wash reagent).
9) Interpret results as follows:

Non-reactive: Coloured internal control line only

Reactive for HIV-1/2 antibodies: Coloured internal control and test lines.

Invalid: Absence on internal control line

Disclaimer: These instructions were prepared based on the instructions for use submitted as part of the WHO Prequalification of In Vitro Diagnostics assessment. These may change over time and so it is recommended to always refer to the most current instructions for use when developing standard operating procedures and/or job aids.

DIAGNOSTIC KIT FOR HIV (1+2) ANTIBODY (COLLOIDAL GOLD) (SHANGHAI KEHUA BIO-ENGINEERING CO. LTD.)

Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) is an immunochromatographic rapid diagnostic test for combined detection of HIV-1/2 antibodies in human serum, plasma and venous/capillary whole blood specimens.

KEY INFORMATION:

Shelf life: 18 months
Storage conditions: 4-30 °C
Volume of specimen needed: 40 µL
Time to test one specimen: 31 minutes

EQUIPMENT REQUIRED BUT NOT SUPPLIED:

- personal protection equipment such as gloves, lab coat or gown
- timer
- appropriate biohazard waste containers
- precision pipette and tips, if serum/plasma
- capillary tube if whole blood
- for capillary blood collection: cotton wool, alcohol swab
- for venipuncture blood collection: venipuncture apparatus and appropriate blood collection tubes.

Non-reactive for HIV-1/2 antibodies

Reactive for HIV-1/2 antibodies

TEST PROCEDURE:

1) Equilibrate all samples and the device to room temperature before testing
2) Take out a test cassette from the foil pouch and place it on a horizontal surface
3) Label the test cassette with patient or specimen ID number
4) For serum/plasma specimens:
a. Add 40µl of specimen to the sample area using a precision pipette.
5) For venous whole blood specimens:
a. Add 40µl of specimen to the sample area using a capillary tube.
6) For capillary whole blood specimens:
   a. Clean fingertip with alcohol swab, place lancet off-centre and puncture the finger tip. Wipe away first drop of blood with cotton wool.
   b. Using a capillary tube, add 40µl of specimen to the specimen well (S).
7) For all specimen types, add 1 drop of the sample diluent to the sample area.
8) Wait for 30 minutes and interpret the results as follows:

Non-reactive for HIV-1/2 antibodies: A reddish-purple band appears at the control line 'C' of the cassette.

Reactive for HIV-1/2 antibodies: A clear visible reddish-purple band appears at both the control line 'C' and the test line 'T' of the cassette.

Invalid: If reddish-purple band appears neither at the control line 'C' nor the test 'T' of the cassette.

Disclaimer: These instructions were prepared based on the instructions for use submitted as part of the WHO Prequalification of In Vitro Diagnostics assessment. These may change over time and so it is recommended to always refer to the most current instructions for use when developing standard operating procedures and/or job aids.

DPP® HIV 1/2 ASSAY (CHEMBIO DIAGNOSTIC SYSTEMS, INC)

DPP ® HIV 1/2 assay is immunochromatographic rapid diagnostic test for the detection of HIV-1/2 antibodies in venous and capillary whole blood, serum, plasma and oral fluid specimens.

KEY INFORMATION:

Shelf life: 24 months
Storage conditions: 2-30 °C
Volume of specimen needed: 10 µL
Time to test one specimen: 15 minutes

EQUIPMENT REQUIRED BUT NOT SUPPLIED:

- personal protection equipment such as gloves, lab coat or gown
- appropriate biohazard waste containers
- Pipette + tips, optional for serum/plasma and for venous whole blood
- for capillary blood collection: lancet, cotton wool, alcohol swab
- for venipuncture blood collection: venipuncture apparatus and appropriate blood collection tubes.

Non-reactive for HIV-1/2 antibodies

Reactive for HIV-1/2 antibodies

TEST PROCEDURE:

1) Remove the test device from the pouch and place it on a flat surface.
2) Label the test device with patient identification number
3) If the test device has no a blue line (Test) and green line discard and don't use the device.
4) For serum/plasma specimens:
   a. Dip specimen loop provided into serum/plasma and allow to fill or draw 10µl using a precision pipette.
   b. Insert specimen loop or pipette specimen into SampleTainer (black cap). If specimen loop, snap and twist to break at notch and replace lid.
5) For venous whole blood specimens:
   a. Dip specimen loop provided into serum/plasma and allow to fill or draw 10µl using a precision pipette.
   b. Insert specimen loop or pipette specimen into SampleTainer (black cap). If specimen loop, snap and twist to break at notch and replace lid.
6) For capillary whole blood specimens:
   a. Clean fingertip with alcohol swab, place lancet off-centre and puncture the finger tip. Wipe away first drop of blood with cotton wool.
   b. Using specimen loop, touch to blood drop and allow to fill.
   c. Insert specimen loop into SampleTainer (black cap). Snap and twist to break at notch and replace lid.
7) For all specimen types, add 2 drops (~65 µL) of specimen buffer from the SampleTainer slowly into the Sample and Buffer well 1.
8) Wait 5 minutes. The blue and green colour lines should have disappeared from the rectangular TEST and Control window. If not discard test device.
9) Add 4 drops (~135 µL) of buffer into the Buffer well 2
10) For finger stick, venous blood, serum or plasma, read the test results not earlier that 10 minutes after addition of the running buffer to Buffer well 2. Do not read results after 25 minutes.
11) For oral fluid, read results 25 minutes after addition of buffer to Buffer well 2. Do not read results after 25 minutes
12) Interpret results as follows:

Non-reactive for HIV-1/2 antibodies: A pink-purple line in the Control (C) area with no line in the Test (T) area

Reactive for HIV-1/2 antibodies: Two pink-purple lines, one in the test (T) area and one in the Control (C) area

Invalid: No distinct pink-purple line on the Control (C) line

Disclaimer: These instructions were prepared based on the instructions for use submitted as part of the WHO Prequalification of In Vitro Diagnostics assessment. These may change over time and so it is recommended to always refer to the most current instructions for use when developing standard operating procedures and/or job aids.

VIKIA® HIV 1/2
(BIOMÉRIEUX SA)

VIKIA® HIV 1/2 is a lateral flow immunochromatographic rapid diagnostic test for the combined detection of HIV-1/2 antibodies in human serum/plasma and capillary/venous whole blood specimens.

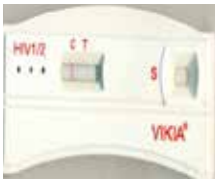
KEY INFORMATION:

Shelf life: 21 months
Storage conditions: 4-30 °C
Volume of specimen needed: 75 µl
Time to test one specimen: 31 minutes

EQUIPMENT REQUIRED BUT NOT SUPPLIED:

- personal protection equipment such as gloves, lab coat or gown
- appropriate biohazard waste containers
- for capillary blood collection: lancet, cotton wool, alcohol swab, EDTA capillary tubes
- for venipuncture blood collection: venipuncture apparatus and appropriate blood collection tubes.

Non-reactive for HIV-1/2 antibodies



Reactive for HIV-1/2 antibodies

TEST PROCEDURE:

1) Remove the test device from the sealed pouch and place on flat surface.
2) Label the test cassette with patient or specimen ID number.
3) For serum/plasma specimens:
   a. Add 3 drops (75µl) of specimen to the sample well (S) using the sample dropper provided.
4) For venous whole blood specimens:
   a. Add 3 drops (75µl) of specimen to the sample well (S) using sample dropper provided.
   b. Add 1 drop (40µl) of buffer to the sample well (S).
5) For capillary whole blood specimens:
   a. Clean fingertip with alcohol swab, place lancet off-centre and puncture the finger tip. Wipe away first drop of blood with cotton wool.
   b. Using capillary tube, draw specimen, add 3 drops (75µl) of specimen to the specimen well (S).
   c. Add 1 drop (40µl) of buffer to the sample well (S).
6) For all specimen types, read results 30 minutes after addition of buffer or specimen if serum/plasma.
7) Interpret results as follows:

Non-reactive for HIV-1/2 antibodies: The line in the control region (C) changes from blue to pinkish/red and no line appears in the test region (T).

Reactive for HIV-1/2 antibodies: The line in the control region (C) changes from blue to pinkish/red and a blue line appears in the test region (T) .

Invalid: The line in the control region (C) does not change colour from blue to pinkish-red.

Disclaimer: These instructions were prepared based on the instructions for use submitted as part of the WHO Prequalification of In Vitro Diagnostics assessment. These may change over time and so it is recommended to always refer to the most current instructions for use when developing standard operating procedures and/or job aids.

5.2 EVALUATION PANELS

5.2.1 WHO HIV PANEL

The WHO HIV Specimen Reference Panel consisted of approximately 1118 clinically derived serum/plasma specimens of European, African, Latin America and Asian origin. There were 460 anti-HIV positive specimens, of which 16 were anti-HIV-2 positive, and 658 anti-HIV negative specimens.

5.2.2 COMMERCIALLY ACQUIRED PANELS

5.2.2.1 SEROCONVERSION PANELS

Eight anti-HIV 1 seroconversion panels: PRB914, PRB925, PRB926, PRB930, PRB935, PRB965, PRB968 and PRB969 (sourced from SeraCare Life Science Inc) were tested to determine the sensitivity of the assay during the seroconversion period.

5.2.2.2 HIV MIXED TITER PANELS

One anti-HIV mixed titer performance panel containing 25 members: PRB205 (sourced from SeraCare Life Science Inc) was tested to determine the sensitivity of the assay in specimens with low antibody titer, including from early seroconversion specimens.

For 4th generation assays only: one HIV p24 antigen mixed titer performance panel containing 25 members: PRA204 (sourced from SeraCare Life Science Inc) was tested to determine sensitivity of p24 antigen detection.

5.2.3 LOT-TO-LOT VARIATION PANEL

A panel of ten anti-HIV positive specimens was diluted 2-fold in normal human serum until the antibody endpoint titer to make 16 member dilutions series (n=160). These were tested to determine lot-to-lot variability in two production lots.

5.2.4 WHO REFERENCE PREPARATIONS

The WHO international biological reference panel with the catalogue number 02/210 (Anti-HIV antibodies [HIV-1 subtypes A, B, C, CRF01_AE, group O and HIV-2] were tested to determine subtype sensitivity.

For 4th generation assays only: the WHO international standard for HIV-14 p24 antigen with the NIBSC catalogue number 90/636 was tested in doubling dilutions beginning at 1:10 to determine analytical sensitivity for HIV-1 p24 antigen detection.

5.2.5 HIV CULTURE SUPERNATANT PANEL

For 4th generation assays only: a panel consisting of ten commonly occurring HIV-1 subtypes and HIV-2 derived from culture supernatant studies was tested to determine subtype sensitivity.

Table 2 WHO Specimen Reference Panel for antibody detection and Antibody/antigen detection assays

Panel name	Number of specimens
WHO HIV specimen reference panel	460 HIV positive, 658 HIV negative
Lot-to-lot variation panel	16 member dilution series of 10 specimens (160 in total)
Commercial HIV seroconversion panels	8 panels comprising 52 specimens
Commercial HIV performance panels	2 panels comprising 50 specimens
HIV culture supernatant panel	1 panel comprising 10 specimens (6 member dilutions)
WHO international biological reference preparations	1 panel comprising 7 specimens 1 panel comprising 1 specimen (12 member dilution)

5.3 TEST PERFORMANCE

The assays were performed according to the instructions for use (IFU) supplied within the test kit. One laboratory technician carried out all the testing for any one particular assay. Due to the subjective, visual nature of the reading of RDTs, they were read independently by three technicians. Two out of three reading results determined the final outcome, see section 5.5.2 on inter-reader variability.

5.4 REFERENCE ASSAYS

Initially, each specimen was tested on the following two EIAs: Vironostika HIV Ag/Ab (bioMérieux) EIA and Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics), in parallel. (Figure 3)

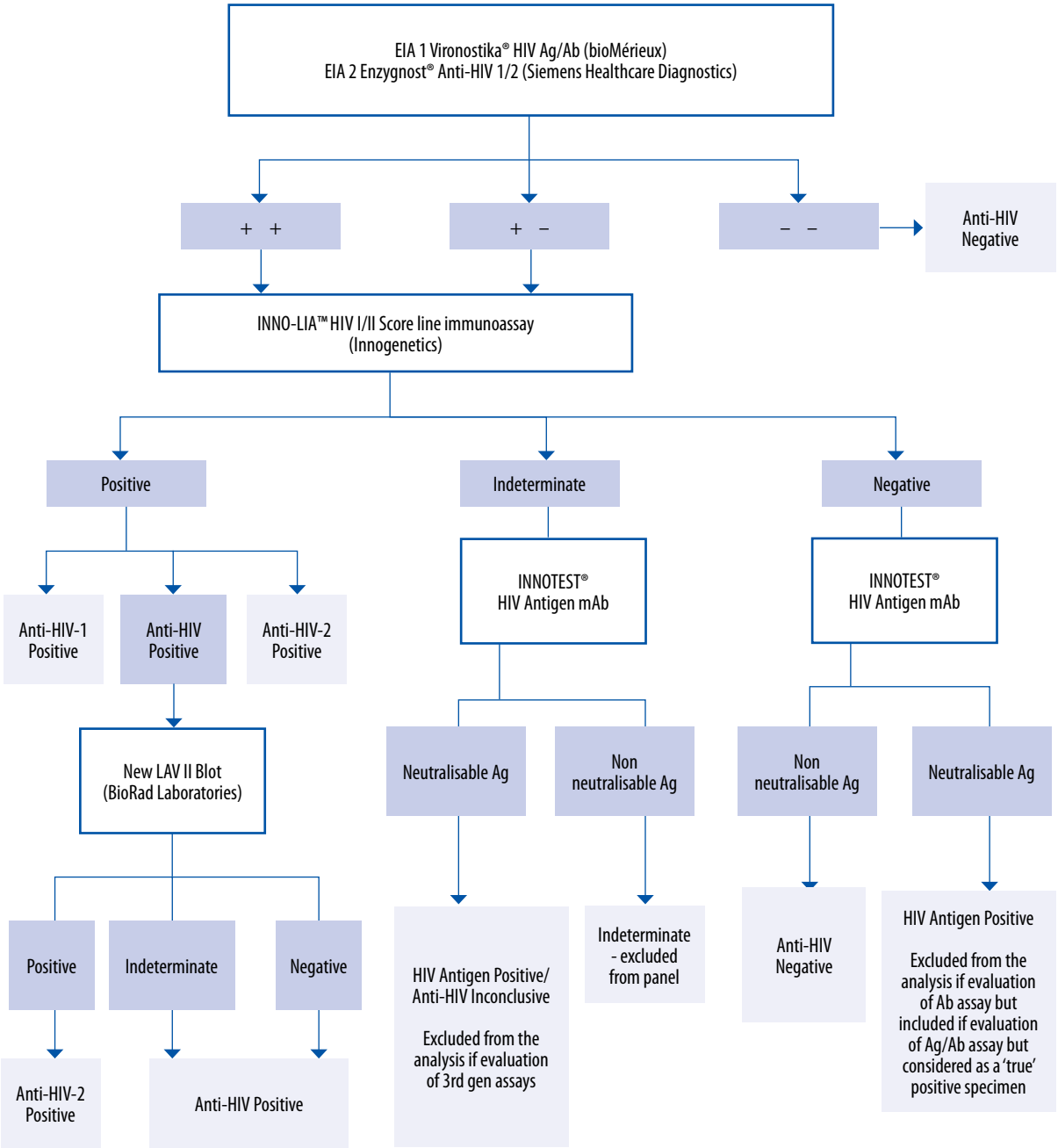
Specimens that were non-reactive on both EIAs were assigned anti-HIV negative.

Specimens with discrepant EIA results AND with dually reactive results on both EIAs were tested on the INNO-LIA™ HIV I/II Score (Innogenetics) line immunoassay. Specimens that were negative by line immunoassay were further tested on Innotest® HIV Antigen mAb (Innogenetics) EIA, and if found non-reactive then were assigned anti-HIV negative. If found to be neutralisable for HIV-1 antigen, the specimen was considered HIV-1 antigen positive and anti-HIV negative and was retained for the evaluation of antigen/antibody detection (4th generation) assays **but not** for antibody detection (2nd and 3rd generation) assays.

Specimens that are indeterminate by line immunoassay were further tested on Innotest® HIV Antigen mAb (Innogenetics) EIA, and if found non-reactive then were excluded from the panel. Specimens that were reactive for antigen (and were neutralisable) were assigned as HIV-1 antigen positive and anti-HIV inconclusive. These

specimens were retained for the evaluation of antigen/antibody detection (4th generation) assay **but not** for antibody detection (2nd and 3rd generation) assays.
Specimens that were positive by line immunoassay were assigned as anti-HIV-1 positive or anti-HIV-2 positive. Those specimens that could not be discriminated (i.e. anti-HIV positive) were further tested on the NEW LAV II Blot (BioRad Laboratories). Specimens that were indeterminate or negative by the NEW LAV II Blot were assigned as anti-HIV-1 positive. Specimens that were positive by the NEW LAV II Blot were assigned as anti-HIV positive.
All reference assays were interpreted according to IFU as given by the manufacturer. The data obtained with each assay were compared to the reference testing results.

Figure 3 – Characterisation testing algorithm for the WHO Specimen reference panel



5.5 ANALYSIS OF THE RESULTS OF THE ASSAYS UNDER EVALUATION

5.5.1 SENSITIVITY, SPECIFICITY AND PREDICTIVE VALUES OF HIV ASSAYS

The following methods were used to calculate the performance characteristics, see Table 3.

Table 3. CALCULATION OF PERFORMANCE CHARACTERISTICS

		Reference testing results		
		Positive	Negative	Total
Results of assay under evaluation	Reactive	a true positives	b false positives	a + b
	Non-reactive	c false negatives	d true negatives	**c** + d
	Total	**a** + c	**b** + d	**a** + b + c + d

SENSITIVITY

Sensitivity is the ability of the assay under evaluation to detect correctly specimens that contain HIV-1/2 antibodies and/or HIV-1 p24 antigen (reference assays positive). Thus sensitivity is the number of true positive specimens identified by the assay under evaluation as positive (a), divided by the number of specimens identified by the reference assays as positive (a+c), expressed as a percentage.

$$\text{Sensitivity} = \frac{a}{a+c}$$

SPECIFICITY

Specificity is the ability of the assay under evaluation to detect correctly specimens that do not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen (reference assays negative). Thus specificity is the number of true negative specimens identified by the assay under evaluation as negative (d), divided by the number of specimens identified by the reference assays as negative (b+d), expressed as a percentage.

$$\text{Specificity} = \frac{d}{b+d}$$

CONFIDENCE INTERVALS

The 95% confidence intervals were calculated for values in order to assess the level of uncertainty introduced by sample size, etc. Exact 95% confidence intervals for binomial proportions were calculated from the F-distribution (Armitage, 2002; Kirkwood, 2003).

PREDICTIVE VALUES

The positive predictive value (PPV) is the probability that when the test is reactive that the specimen does contain HIV-1/2 antibodies and/or HIV-1 p24 antigen. PPVs were calculated using the formula.

$$\text{PPV} = \frac{(prevalence)(sensitivity)}{(prevalence)(sensitivity)+(1-prevalence)(1-specificity)}$$

The negative predictive value (NPV) is the probability that when the test is negative that a specimen does not contain HIV-1/2 antibodies and/or HIV-1 p24 antigen. NPVs were calculated using the formula.

$$\text{NPV} = \frac{(1-prevalence)(specificity)}{(1-prevalence)(specificity)+(prevalence)(1-sensitivity)}$$

The probability that a test result will accurately determine the true infection status of a person being tested varies with the prevalence of HIV infection in the population from which the person comes. In general, the higher the prevalence of HIV infection in the population, the greater the probability that a person testing positive is truly infected (i.e., the greater the positive predictive value [PPV]). Thus, with increasing prevalence, the proportion of individuals testing false-positive decreases; conversely, the likelihood that a person whose test result is negative is truly uninfected (i.e., the negative predictive value [NPV]), decreases as prevalence increases. Therefore, as prevalence increases, the proportion of individuals testing false negative decreases.

The PPV and NPV are calculated at a prevalence of 0.1%, 1% and 5%.

5.5.2 INTER-READER VARIABILITY

For subjectively read assays, three individuals independently interpreted each test result. The inter-reader variability was expressed as the percentage of specimens for which initial test results were differently interpreted (i.e. reactive, non-reactive, indeterminate) by the independent readers for the WHO HIV specimen reference panel (clinical specimens) only.

5.5.3 SENSITIVITY IN SEROCONVERSION PANELS

The results obtained with seroconversion panels using the assays under evaluation were compared with those obtained using Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics), the assay arbitrarily designated the reference for determination of relative sensitivity in these panels i.e. the benchmark assay. For each seroconversion series (panel), the first specimen in the sample sequence to become reactive with Enzygnost Anti-HIV 1/2 was assigned the value "0". Results from the assays under evaluation were

compared with Enzygnost Anti-HIV 1/2 Plus by determining the difference between the specimen assigned value "0" and the relative position in the sample sequence of the first specimen which showed a reactive result with each of the assays under evaluation. For example, if an assay became reactive two specimens earlier in a series than Enzygnost Anti-HIV 1/2 Plus, the value assigned for that series in that assay was -2. Similarly, if an assay became reactive one specimen later than Enzygnost Anti-HIV 1/2 Plus, the value assigned was +1. The assigned values over the eight seroconversion series were averaged to determine a mean relative seroconversion sensitivity index for each assay and the 95% confidence limits were determined. These estimates should be interpreted with caution as only eight panels were tested.

5.5.4 INTERPRETATION OF RESULTS FROM HIV MIXED TITER PANELS

The number of specimens detected by the assays on the HIV mixed titer performance panel was determined by comparison with the expected results following interpretation of the combined reference testing results generated by the following assays: Enzgnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics) EIA, Vironostika® HIV Ag/Ab (bioMérieux) EIA, INNO-LIA™ HIV I/II Score (Innogenetics) line immunoassay, and INNOTEST® HIV Antigen mAb (Innogenetics) EIA.

5.5.5 INTERPRETATION OF RESULTS FROM LOT-TO-LOT VARIATION PANEL

The results of the lot-to-lot variation panel on the two lots were compared and a variation of +/- one 2-fold dilution series was considered acceptable.

5.5.6 INTERPRETATION OF WHO REFERENCE PREPARATIONS

The results of the WHO reference preparations were compared for each subtype with the status assigned in the instructions for use that accompanied the preparations.

6. ASSAY EVALUATIONS

6.1 RESULTS OF INDIVIDUAL ASSAYS

ABON™ HIV 1/2/O TRI-LINE RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA) (ABON BIOPHARM (HANGZHOU) CO., LTD.)

In this limited evaluation on a panel of 1118 clinically-derived serum/plasma specimens, we observed an initial sensitivity (95% CI) of 100% (99.2 - 100%) and an initial specificity (95% CI) of 99.7% (98.9 - 100%) compared to the reference assay results. The final sensitivity (95% CI) was 100% (99.2 - 100.0%) and the final specificity (95% CI) was 99.7% (98.9% - 100%) compared to the reference assay results. Lot to lot variation was acceptable. ABON™ HIV 1/2/O Tri-Line HIV Rapid Test Device was unable to discriminate between HIV-1 and HIV-2 for 150 specimens (2 HIV-2 positives and 148 HIV-1 positives). Twelve HIV-2 positive specimens showed a false reactive HIV-1 antibody band and would have been assigned as HIV reactive or HIV-1 and HIV-2 reactive (according to instructions for use at the time of the evaluation). One hundred forty eight HIV-1 positive specimens showed a false reactive HIV-2 antibody band and would have been assigned as HIV reactive or HIV-1 and HIV-2 reactive (according to instructions for use at the time of the evaluation).

For eight seroconversion panels, ABON™ HIV 1/2/O Tri-Line HIV Rapid Test Device detected on average 0.5 specimens later than the benchmark assay (Enzygnost Anti-HIV 1/2 Plus [Siemens Healthcare Diagnostics]). For the mixed titer panel, ABON™ HIV 1/2/O Tri-Line HIV Rapid Test Device correctly classified all specimens. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], ABON™ HIV 1/2/O Tri-Line HIV Rapid Test Device detected all subtypes tested (HIV-1 A, HIV-1 B, HIV-C, HIV-1 CRF01_AE, HIV-1 O and HIV-2). In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 3.9% (0.1% for HIV-1 band and 3.8% for HIV-2 band). The invalid rate was 0.9%.

SD BIOLINE HIV-1/2 3.0 (STANDARD DIAGNOSTICS, INC.)

In this limited evaluation on a panel of 1118 clinically-derived serum/plasma specimens, we found an initial sensitivity (95% CI) of 99.8% (98.8% - 100.0%) and an initial specificity (95% CI) of 99.9% (99.2% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.2% - 100%) and the final specificity (95% CI) was 99.9% (99.2% - 100%) compared to the reference assays. Lot to lot variation observed was within the acceptance criteria. SD BIOLINE HIV-1/2 3.0 was unable to discriminate between HIV-1 and HIV-2 for seven HIV-2 specimens, and 22 HIV-1 specimens (6.3% of 460 HIV positive specimens), as two test bands of equal intensity were observed.

For eight seroconversion panels, SD BIOLINE HIV-1/2 3.0 detected on average 0.125 specimens later than the benchmark assay (Enzygnost Anti-HIV 1/2 Plus [Siemens Healthcare Diagnostics]). For the mixed titer panel, SD BIOLINE HIV-1/2 3.0 correctly classified all specimens. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], SD BIOLINE HIV-1/2 3.0 detected all HIV-1 subtypes tested (HIV-1 A, HIV-1 B, HIV-C, HIV-1 CRF01_AE, and HIV-2). In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently

by three technicians; the overall inter-reader variability was 1.9% (0.2% for HIV- 1 band, 1.8% for HIV-2 band). The invalid rate was 0%.

FIRST RESPONSE® HIV 1-2.0 CARD TEST (PREMIER MEDICAL CORPORATION LTD)

In this limited evaluation on a panel of 1079 clinically-derived serum/plasma specimens, we found an initial sensitivity (95% CI) of 100% (99.1% - 100%) and an initial specificity (95% CI) of 98.9% (97.8% - 99.6%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.1% - 100%) and the final specificity (95% CI) was 99.4% (98.5% - 99.8%) compared to the reference assays. Lot to lot variation observed was within the acceptance criteria for all but one dilution series. Seventeen HIV-1 positive specimens showed reaction with both the HIV-1 and HIV-2 test lines. Fourteen out of 31 HIV-2 positive specimens were correctly identified, 17 other specimens showed reaction with both the HIV-1 and the HIV-2 test line.

For eight seroconversion panels, FIRST RESPONSE® HIV 1-2.O CARD TEST detected on average 0.25 specimens earlier than the benchmark assay (Enzygnost Anti-HIV 1/2 Plus [Siemens Healthcare Diagnostics]). For the mixed titer panel, FIRST RESPONSE® HIV 1-2.O CARD TEST correctly classified all specimens. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], FIRST RESPONSE® HIV 1-2.O CARD TEST detected all HIV-1 subtypes tested (HIV-1 A, HIV-1 B, HIV-C, HIV-1 CRF01_AE, and HIV-2) with the exception of HIV-1 type O. In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the overall inter-reader variability was 2.1% (0.8% for HIV-1 band, 1.2% for HIV-2 band). The invalid rate was 0%.

ADVANCED QUALITY™ ONE STEP ANTI-HIV (1&2) TEST (INTEC PRODUCTS, INC)

In a limited laboratory evaluation of ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test on a panel of 1118 clinically-derived serum/plasma specimens, the initial sensitivity (95% CI) was 100% (99.2% - 100%) while the initial specificity (95% CI) was 100% (99.4% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.2% - 100%) and the final specificity (95% CI) was 100% (99.4% - 100%) compared to the reference assays. Lot to lot variation was within the acceptable range.

For eight seroconversion panels, ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test detected on average 0.125 specimens earlier than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics). For the mixed titer panel, ADVANCED QUALITY™ One Step Anti-HIV (1&2) Test correctly classified 24 out of the 25 specimens. One anti-HIV negative/HIV-1 antigen positive specimen was not detected. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test correctly classified five out of the six specimens, one HIV-1 subtype O specimen was not detected. In the study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 0%. The invalid rate was 0%.

DOUBLECHECKGOLD™ ULTRA HIV 1&2 (ORGENICS LTD)

In this limited evaluation on a panel of 1079 clinically-derived serum/plasma specimens, we found an initial sensitivity (95% CI) of 100% (99.1% - 100%) and an initial specificity (95% CI) of 99.9% (99.2% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.1% - 100%) and the final specificity (95% CI) was 99.9% (99.2% - 100%) compared to the reference assays. Lot to lot variation was within the acceptable range.

For eight seroconversion panels DoubleCheckGold™ Ultra HIV 1&2 detected on average, 0.125 specimens later than the reference assay (Enzygnost Anti-HIV 1/2 Plus [Siemens Healthcare Diagnostics]). For the mixed titer panel DoubleCheckGold™ Ultra HIV 1&2 test correctly classified 22 out of 25 specimens. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], DoubleCheckGold™ Ultra HIV 1&2 correctly classified 5 of 6 specimens, however HIV subtype O was not detected. In this study, 0 % of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 0.3%. The invalid rate was 0%.

DIAGNOSTIC KIT FOR HIV (1+2) ANTIBODY (COLLOIDAL GOLD) (SHANGHAI KEHUA BIO-ENGINEERING CO. LTD.)

In this limited evaluation on a panel of 1118 clinically-derived serum/plasma specimens, we found an initial sensitivity (95% CI) of 100% (99.2% - 100%) and an initial specificity (95% CI) of 98.9% (97.8% - 99.6%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.2% - 100%) and the final specificity (95% CI) was 99.1% (98.0% - 99.7%) compared to the reference assays. Lot to lot variation was acceptable.

For eight seroconversion panels, Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) detected on average 0.125 specimens earlier than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics). For the mixed titer panel, Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) correctly classified all specimens. For the

1st International Reference Panel for anti-HIV [NIBSC code 02/210], Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) correctly classified all specimens. In this study, 0.1% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 0.4%. The invalid rate was 0.1%.

DPP® HIV 1/2 ASSAY (PLEASE NOTE THESE RESULTS DO NOT REFLECT PERFORMANCE OF THE ASSAY WITH ORAL FLUID SPECIMENS) (CHEMBIO DIAGNOSTIC SYSTEMS, INC.)

In this limited evaluation on a panel of 1118 clinically-derived serum/plasma specimens, we found an initial sensitivity (95% CI) of 99.8% (98.8% - 100%) and an initial specificity (95% CI) of 99.9% (99.2% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.2% - 100%) and the final specificity (95% CI) was 99.9% (99.2% - 100%) compared to the reference assays. Lot to lot variation was acceptable.

For eight seroconversion panels, DPP® HIV 1/2 Assay detected on average 0.5 specimens later than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics). For the mixed titer panel, DPP® HIV 1/2 Assay correctly classified all anti-HIV positive and anti-HIV negative specimens. Six out of the seven anti-HIV indeterminate/HIV-1 antigen positive specimens were not detected. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], DPP® HIV 1/2 Assay correctly classified all specimens. In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 0.2%. The invalid rate was 0%

VIKIA® HIV 1/2 (BIOMÉRIEUX)

In this limited evaluation on a panel of 1118 clinically-derived serum/plasma specimens, we found an initial sensitivity (95% CI) of 99.4% (98.1% - 99.9%) and an initial specificity (95% CI) of 99.9% (99.2% - 100%) compared to the reference assays. The final sensitivity (95% CI) was 100% (99.2% - 100%) and the final specificity (95% CI) was 99.9% (99.2% - 100%) compared to the reference assays. Lot to lot variation was acceptable for seven of the ten dilution series, the remaining three dilution series showed +/- 2 dilution series.

For eight seroconversion panels, VIKIA® HIV 1/2 detected on average 0.125 specimens earlier than the benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics). For the mixed titer panel, VIKIA® HIV 1/2 correctly classified all anti-HIV positive and anti-HIV negative specimens. Two of the six anti-HIV indeterminate/HIV-1 antigen positive specimens were not detected. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], VIKIA® HIV 1/2 correctly classified all specimens. In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 0.18%. The invalid rate was 0%.

6.2 TABLES OF COMPARATIVE PERFORMANCE DATA

The assays are grouped into two for ease of reading. Table 1 summarize the general characteristics of each of the assays. The performance characteristics (i.e. the results of the assays evaluated as compared to the reference tests) are given in Table 2. Table 3 provides further details of operational aspects. Factors taken into account in the calculation of ease of performance and suitability for use in small laboratories are listed in Tables 4-6. Performance of the assays evaluated on commercial seroconversion panels and the relative performance of the evaluated assays as compared to the benchmark assay are given in Table 7 and Figure 4. Performance on commercial anti-HIV 1 mixed titer panels is given in Table 8. Performance on lot-to-lot variation panels is given in Table 9. Performance on WHO reference preparations is given in Table 10. Explanatory notes are provided at the end of each of the assay evaluation tables.

Table 1. General characteristics and operational aspects

PARAMETER	ABON™ Tri-line HIV Rapid Test Device	SD BIOLINE HIV-1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	DoubleCheckGold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
Manufacturer (Address)	ABON Biopharm (Hangzhou) Co., Ltd. (Hangzhou, PR China)	Standard Diagnostics, Inc. (Giheung-gu, Yongin-si, Kyonggi-do Korea)	Premier Medical Corporation Ltd. (Daman, India)	InTec PRODUCTS, INC (Xiamen, PR China)	Orgenics Ltd (Yavne, Israel)	Shanghai Kehua Bio-engineering Co. Ltd. (Shanghai, PR China)	Chembio Diagnostics Systems, Inc (NY, United States)	bioMérieux (Marcy-L'Etoile, France)
Assay type	Lateral flow (immu-nochromatographic) rapid diagnostic test	Lateral flow (immu-nochromatographic) rapid diagnostic test	Lateral flow (immu-nochromatographic) rapid diagnostic test	Lateral flow (immu-nochromatographic) rapid diagnostic test	Lateral flow (immu-nochromatographic) rapid diagnostic test	Lateral flow (immu-nochromatographic) rapid diagnostic test	Dual path platform lateral flow (immu-nochromatographic) rapid diagnostic test	Lateral flow (immu-nochromatographic) rapid diagnostic test
Antigen type	Recombinant HIV-1 (gp41, p24) and HIV-2 (gp36)	Recombinant HIV-1 (gp41, p24) and HIV-2 (gp36)	Recombinant HIV-1 (gp41, p24) and HIV-2 (gp36)	Recombinant HIV-1(gp41, gp120) and HIV-2 gp36	Recombinant HIV-1 gag and envelope proteins and HIV-2 (gp36)	Recombinant protein for HIV-1 (gp41, gp160) and HIV-2 (gp 36)	Synthetic peptides for HIV-1 and HIV-2	Synthetic peptide for HIV-1 gp41 (group M and group O) and HIV-2 (gp36).
Detection type	Discriminatory (separate detection of HIV-1 and HIV-2 antibodies)	Discriminatory (separate detection of HIV 1 and HIV-2 antibodies)	Discriminatory (separate detection of HIV-1 and HIV-2 antibodies)	Non-discriminatory (combined HIV 1/2 antibodies)	Non-discriminatory (combined HIV 1/2 antibodies)	Non-discriminatory (combined HIV 1/2 antibodies)	Non-discriminatory (combined HIV 1/2 antibodies)	Non-discriminatory (combined HIV 1/2 antibodies)
Solid phase	Nitrocellulose membrane strip	Nitrocellulose membrane strip	Nitrocellulose membrane strip	Nitrocellulose membrane strip	Nitrocellulose membrane strip	Nitrocellulose membrane strip	Two nitrocellulose membrane strips	Nitrocellulose membrane strip
Specimen type	Serum/plasma, venous/capillary whole blood	Serum/plasma, venous/capillary whole blood	Serum/plasma, venous/capillary whole blood	Serum/plasma, venous/capillary whole blood	Serum/plasma, venous/capillary whole blood	Serum/plasma, venous/capillary whole blood	Serum/plasma, venous/capillary whole blood, oral fluid	Serum/plasma, venous/capillary whole blood
Number of tests per kit (product code)	40 (IHI-T402)	25(03FK16) 30(03FK10)	1 (105FRC01) 5 (105FRC05) 30 (105FRC30) 60 (105FRC60) 100 (105FRC100)	40 (ITP02006TC40)	20 (70635020) 100 (70635100)	50 (KH-R-02)	20 (65-9506-0) Available by separate order: Chembio DPP HIV 1/2 Assay Controls	25 (31112)
Lot numbers evaluated (expiry date)	2090023 (08/2014) 2090089 (08/2014)	023450 (22/10/2014) 023452 (04/11/2014)	38J1511 (08/2013) 38J1411 (08/2013)	2013032725 (03/2015) 2013032726 (03/2015)	110524 (25/01/2013) 1105171A (18/12/2012)	201202017 (02/12/2013) 201202016 (01/12/2013)	55061912 (02/04/2014) 55102312/2 (29/08/2014)	1001934410 (15/09/2014) 1001829090 29/07/2014)
Shelf life upon manufacture	24 months	24 months	22 months	24 months	18 months	18 months	24 months	21 months
Storage conditions	2 to 30 °C	1 to 30 °C	4 to 30 °C	2 to 30 °C	2 to 30 °C	4 to 30 °C	2 to 30 °C	4 to 30 °C
Volume of specimen needed	25µl (for S/P); 50 µl (for WB)	10µl (S/P); 20µl (for WB)	10µl (for S/P); 20µl (for WB)	30 µl	25µl	40 µl	10 µl	75 µl

Table 1. (continued) General characteristics and operational aspects

PARAMETER	ABON™ Tri-line HIV Rapid Test Device	SD BIOLINE HIV-1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	DoubleCheckGold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
Time to test 1 specimen Time to test 1 run (h:min)	0:11 0:13	0:06 (revised to 0:10) 0:10	0:16 0:20	0:16 0:18	0:16 0:20	0:31 0:33	0:15 0:35	0:31 0:34
Reading	Visual	Visual	Visual	Visual	Visual	Visual	Visual	Visual
Indicative price/test	US$ 0.32	US$ 0.80-0.81	US$ 0.45- 1.05	US$ 0.35	US$ 0.9-1.6	US$ 0.58	US$ 2.75	US$ 1.15

Notes for Table1	General characteristics and operational aspects of the assays
Specimen type	The nature of specimen(s) that may be used in the assay but note that these laboratory evaluations were carried out using serum/plasma specimens, see section 5.2.1.
Non-discriminatory HIV-1/2 or discriminatory HIV-1 & HIV-2 reactivity	Non-discriminatory: No ability to differentiate between HIV-1 and HIV-2 reactivity i.e. one combined test line/band/spot/dot. Discriminatory: Ability to differentiate between HIV-1 and HIV-2 reactivity i.e. two separate test lines/bands/spots/dots.
Total time to perform the assay	Reflects the time needed to carry out 1 specimen and 1 test run, i.e. the most economical use of the technique
Indicative price/test in US$	As given at the time of the evaluation by the manufacturer, or converted to USD using the currency conversion rate at the time (2014/2015). The prices stated are meant to be indicative only.

Table 2. Comparison of the assays under evaluation with reference assays

	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)	SD BIOLINE HIV-1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	DoubleCheckGold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
Initial Sensitivity % (95% CI)	100 (99.2-100) (n=460)	99.8 (98.8-100) (n=460)	100 (99.1-100) (n=421)	100 (99.2-100) (n=460)	100 (99.1-100) (n=421)	100 (99.2-100) (n=460)	99.8(98.8-100) (n=460)	99.4 (98.1-99.9) (n=460
Final Sensitivity % (95% CI)	100 (99.2-100) (n=460)	100 (99.2-100) (n=460)	100 (99.1-100) (n=421)	100 (99.2-100) (n=460)	100 (99.1-100) (n=421)	100 (99.2-100) (n=460	100 (99.2-100) (n=460)	100 (99.2-100) (n=460
Initial Specificity % (95% CI)	99.7 (98.9-100) (n=657)	99.9 (99.2-100) (n=658)	98.9 (97.8-99.6) (n=658)	100 (99.4-100) (n=658)	99.9 (99.2-100) (n=658)	98.9 (97.8 – 99.6) (n=657)	99.8 (99.2-100) (n=658)	99.9 (99.2-100) (n=658)
Final Specificity % (95% CI)	99.7 (98.9-100) (n=658)	99.9 (99.2-100) (n=658)	99.4 (98.5-99.8) (n=658)	100 (99.4-100) (n=658)	99.9 (99.2-100) (n=658)	99.1 (98.0 – 99.7%) (n=658)	99.9 (99.2-100) (n=658)	99.9 (99.2-100) (n=658)
Initial indeterminate results %	0	0	0	0	0	0.1	0	0
Final indeterminate results %	0	0	0	0	0	0	0	0
Initial invalid rate %	0.1	0	0	0	0	0.1	0	0
Final invalid rate %	0.1	0	0	0	0	0.1	0	0
Initial inter-reader variability %	3.9 (0.1% for HIV-1; 3.8% for HIV-2)	1.9 (0.2% for HIV-1; 1.8% for HIV-2)	2.0 (0.8% for HIV-1; 1.2% for HIV-2)	0	0.3	0.4	0.2	0.2
PPV								
0.1% prevalence	24.8	39.7	14.1	100	40.0	8.6	39.7	39.6
1% prevalence	76.8	86.9	62.3	100	87.1	48.7	86.9	86.9
5% prevalence	94.5	97.2	89.6	100	97.2	83.2	97.2	97.2
PPV								
0.1% prevalence	100	100	100	100	100	100	100	99.9
1% prevalence	100	100	100	100	100	100	100	99.9
5% prevalence	100	100	100	100	100	100	100	99.9

Notes for Table 2	Comparison of the results of the assays with reference assays
Sensitivity	Calculated as described on section 5.5.1 of this document
Specificity	Calculated as described on section 5.5.1 of this document.
95% Confidence intervals (CI)	Calculated as described on section 5.5.1 of this document.
Indeterminate results	Rapid diagnostic tests - test results which could not be interpreted as clearly reactive or non-reactive were considered indeterminate.
Inter-reader variability	Calculated as described on section 5.5.3 of this document.
PPV and NPV	Calculated as described on section 5.5.1 of this document.

Table 3. Detailed operational aspects

PARAMETER	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)	SD BIOLINE HIV1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	DoubleCheckGold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
Dimension (cm) of kit: w-l-h	26 - 12 – 7	18-12.5-7	19- 12-7.5	18 - 13 -9	26 - 19 - 14	21 – 13.5 - 12	24 - 16 – 9.5	18.5 - 13 – 8.5
Incubation temperature	15 to 30 °C	1 to 30 °C	15 to 30 °C	10 to 30 °C	18 to 26 °C	20 °C	18-30 °C	18 to 25 °C
Minimum incubation time (minutes)	10 minutes after addition of buffer	5 minutes after addition of assay diluent (revised to 10 minutes after addition of assay diluent)	5 minutes after addition of assay diluent (revised to 15 minutes)	15 minutes (after addition of buffer, or specimen)	15 minutes	30 (revised to 15 minutes)	15 minutes	30 minutes (after addition of buffer, or specimen)
Maximum incubation time [reading endpoint stability] (minutes)	No more than 20 minutes after addition of buffer	No more than 20 minutes after addition of assay diluent	No more than 15 minutes after addition of assay diluent	No more than 20 minutes after addition of sample diluent	No more than 25 minutes after additional of wash reagent	No more than 30 minutes after addition of sample diluent	No more than 25 minutes after addition of running buffer to Buffer well 2	No more than 30 minutes after addition of specimen or buffer (revised to 60 minutes after addition of specimen or buffer)
Stability after dilution/ opening								
- test device	Test kit expiry date (2 to 30°C)	Test kit expiry date (1 to 30°C)	Test kit expiry date (4 to 30°C)	Test kit expiry date (2 to 30°C)	Test kit expiry date (2 to 30°C)	Test kit expiry date (4 to 30°C)	Test kit expiry date (2 to 30°C)	Test kit expiry date (4 to 30°C)
- controls	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- sample diluent/ running buffer	Not stated	Test kit expiry date (1 to 30°C)	Test kit expiry date (4 to 30°C)	8 weeks (2 to 30°C)	Test kit expiry date (2 to 30°C)	Three months (4 to 30°C)	Test kit expiry date (2 to 30°C)	Test kit expiry date (4 to 30°C)
- conjugate	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- substrate	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
- wash buffer	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
No. of sera per run, min–max	1 - 10	1 - 10	1 - 10	1 - 10	1 - 10	1 - 10	1 - 10	1 - 10

Table 3. (continued) Detailed operational aspects

PARAMETER	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)	SD BIOLINE HIV1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	DoubleCheckGold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
Number of controls per run	Control samples not available from the manufacturer.	Control samples not available from manufacturer.	Control samples not available from manufacturer.	Control samples not available from the manufacturer.	Control samples not available from the manufacturer.	Control samples not available from the manufacturer.	Control samples not supplied within the kit but available on order from manufacturer.	Control samples not available from the manufacturer.
- negative	N/A	N/A	N/A	N/A	N/A	N/A	1 (0.5ml)	N/A
- positive	N/A	N/A	N/A	N/A	N/A	N/A	1x HIV-1 (0.5ml), 1x HIV-2 (0.5ml)	N/A
internal controls :								
- reagent addition control	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
- specimen addition control	No	No	No	No	No	No	Yes	No
Equipment/items required but not provided in the kit:								
- washer	-	-	-	-	-	-	-	-
- incubator (water-bath)	-	-	-	-	-	-	-	-
- spectrophotometric reader	-	-	-	-	-	-	-	-
- refrigerator (storage)	+	+	+	+	+	+	+	+
- agitator, rocker	-	-	-	-	-	-	-	-
- aspiration device	-	-	-	-	-	-	-	-
- precision pipette (µl)	-	+(if serum/plasma, 20µL)	-	-	+	+ (if serum/plasma, 40 µl)	+ (optional for serum/ plasma and venous whole blood)	-
- multichannel pipette (µl)	-	-	-	-	-	-	-	-

Table 3. (continued) Detailed operational aspects

PARAMETER	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)	SD BIOLINE HIV1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	DoubleCheckGold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
- disposable tips	-	+ (if serum/plasma, 20µL)	-	-	+	+(if serum/plasma, 40 µl)	+ (optional for serum/ plasma and venous whole blood)	-
- dilution tubes/rack	-	-	-	-	-	-	-	-
- microtiter plate	-	-	-	-	-	-	-	-
- distilled or deionized water	-	-	-	-	-	-	-	-
- plate covers	-	-	-	-	-	-	-	-
- graduated pipette; cylinder (ml)	-	-	-	-	-	-	-	-
- sulphuric acid/sodium hydroxide	-	-	-	-	-	-	-	-
- absorbent paper	-	-	-	-	-	-	-	-
- disinfectant	-	-	-	-	-	-	-	-
- gloves	+	+	+	+	+	+	+	+
- reagent trough	-	-	-	-	-	-	-	-
- timer	+	+	+	+	+	+	+	+
- centrifuge	+ (if serum/plasma)	+ (if serum/plasma)	+ (if serum/plasma)	+ (if serum/plasma)	+ (if serum/plasma)	+ (if serum/plasma)	+ (if serum/plasma)	+ (if serum/plasma)
- alcohol swabs / cotton wool	+ (if capillary whole blood)	+ (if capillary whole blood for certain kit configurations)	-	+ (if capillary whole blood)	+ (if capillary whole blood)	+ (if capillary whole blood)	+ (if capillary whole blood)	+ (if capillary whole blood)
- lancets	+ (if capillary whole blood)	+ (if capillary whole blood for certain kit configurations)	-	+ (if capillary whole blood)	+ (if capillary whole blood)	+ (if capillary whole blood)	+ (if capillary whole blood)	+ (if capillary whole blood)

Table 3. (continued) Detailed operational aspects

PARAMETER	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)	SD BIOLINE HIV1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	DoubleCheckGold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
- specimen transfer devices	+ (if capillary whole blood, requires heparinised with 50µl fill line)	+ (if capillary whole blood, for certain kit configurations)	-	-	+	+(if capillary whole blood)	-	+(if capillary whole blood, EDTA capillary tube)
- venous blood collection equipment	+ (if serum/plasma, venous whole blood)	+ (if serum/plasma, venous whole blood)	+ (if serum/plasma, venous whole blood)	+ (if serum/plasma, venous whole blood)	+ (if serum/plasma, venous whole blood)	+ (if serum/plasma, venous whole blood)	+ (if serum/plasma, venous whole blood)	+ (if serum/plasma, venous whole blood)
Definition of reactive result	Distinct coloured line appears in the CONTROL region C and one or more coloured lines appear in the TEST regions T1 and or T2	Distinct coloured 2 or 3 line appears one in the CONTROL region C and one or more coloured lines appear in the TEST regions T1 and or T2	Distinct coloured 2 or 3 line appears one in the CONTROL region C and one or more coloured lines appear in the TEST regions 1 and or 2	Purplish-red band appears in the TEST and CONTROL areas	Distinct band appears in the TEST and CONTROL areas	Reddish-purple band appears in the TEST and CONTROL lines	Two Pink/purple line appears in the TEST and CONTROL areas	Blue line appears in the TEST region and blue line changes to pink/ red line in the CONTROL region
Definition of non-reactive result	One coloured line appears in the CONTROL region but no coloured line appears in either of the TEST regions T1 and T2	One coloured line appears in the CONTROL area but no line in the TEST areas	One coloured line appears in the CONTROL area but no line in the TEST area	Purplish-red band appears in the CONTROL area but no band in the TEST area	One coloured band appears in the CONTROL area but no band in the TEST area	Reddish-purple band appears in the CONTROL line but no band in the TEST area	One Pink/purple line appears in the CONTROL area but no band in the TEST area	Blue line changes to pink/red line in the CONTROL region but no band in the TEST region
Definition of invalid result	No distinct coloured line in the CONTROL region	No distinct coloured line in the CONTROL area	No distinct coloured line in the CONTROL area	No purplish-red band in the CONTROL area	No distinct band in the CONTROL area	No distinct reddish-purple band in the CONTROL line	No distinct pink/ purple band in the CONTROL area	No change of colour from blue to pink/red band in the CONTROL region

Notes for Table 3	Detailed operational aspects of the assays
Reading endpoint stability	The time period after the completion of the test procedure, including any stated incubation period, within which the result may be read. Assays which show a time period of 0 must be read immediately upon completion of the test procedure.
Minimum - maximum number of sera	Minimum number = one specimen, in addition to the required controls. Maximum number = the maximum number of specimens in addition to the required controls which can be simultaneously tested within the limits of the test procedure.
Number of controls per test run	The number of controls shows the number of replicates of each control required for each test run.
Internal control: - specimen addition control - reagent addition control	The following assays have a control line that shows both that the specimen has been added and the reagents functioned correctly : None The following assay has a control line that shows that the reagents have been added: ABONTM Tri-line HIV Rapid Test Device (Whole Blood/Serum/Plasma), SD BIOLINE HIV1/2 3.0, FIRST RESPONSE® HIV 1-2.0 CARD TEST, ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test, DoubleCheckGoldTM Ultra HIV 1&2, Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold), DPP® HIV 1/2 Assay, VIKIA® HIV 1/2
Definition of reactive, nonreactive, invalid results	A specimen is interpreted as reactive, non-reactive or invalid according to the criteria set by the manufacturer and summarized in the table + : not provided in the kit but necessary to perform the test; - :provided in the kit or not necessary to perform the test; ± : use is optional; * comes with some kit configurations

Table 4. Technician's appraisal of the test kit

PARAM-ETER	Score	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/Serum/ Plasma)	SD BIOLINE HIV-1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	Double Check Gold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
Number of steps in the test procedure:									
- 1-2 steps	6	6	6	6	6	6	6	6	6
- 3-5 steps	3								
- >5 steps	1								
Clarity of kit instructions:									
Good	2	2	2	2	2	2		2	1
- Needs improve-ment	1						1 (later revised)		
Kit and reagent packaging and label-ling:									
- Good	2	2	2	2	2	2	2	2	2
- Needs improve-ment	1								
Total (out of 10)	10	10	10	10	10	10	9	10	9

Table 4. (continued) Technician's appraisal of the test kit

PARAMETER	Score	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/Serum/Plasma)	SD BIOLINE HIV-1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	Double Check Gold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
Comments on the test kit		IFU at time of evaluation specified that when finger stick whole blood is used, two "hanging" drops should fall into the centre of the specimen well or the drop should touch the membrane. If this procedure is used, there is no apparent control over the volume of specimen that is added. Many specimens showed cross-reactivity. The IFU is not clear on interpretation of such results where two test bands are observed, it states that "any shade of colour in the test line region (T1 and/or T2) should be considered positive.	Not all positive specimens could be interpreted 5 minutes after buffer addition due to faint or no bands and visible weak pink background. Generally, this disappeared after 10-15 minutes to make reading easier. A subsequent version of the IFU was revised to state the reading time as 10 minutes after addition of assay diluent.	IFU at the time of the evaluation stated that the test result may be interpreted 5 minutes after the specimen and assay diluent and up to 15 minutes. In this evaluation, the colloidal gold conjugate/specimen mixture did not always completely migrate within 5 minutes i.e. control band was observed but background coloration of the membrane was visible which resolved later after 15 minutes. A subsequent version of the IFU was revised to state the reading time as 15 minutes after addition of assay diluent. For the interpretation of the test results, the IFU states that if all three bands appear, the specimen is reactive for antibodies to HIV-1 and HIV-2. It would be advisable for the IFU to further note that dual reactivity should not be interpreted as dual infection unless confirmed by supplemental testing.	None stated.	None stated	IFU should more clearly state that for reading time for the final test result, one should wait until 30 minutes after the specimen and buffer have been added to avoid misinterpretation (high background and faint lines visible earlier). IFU was then revised to state reading time as "Wait minimum of 15 minutes (up to 30 minutes)".	None stated	IFU is in a small font size. The control line took on average +/- 1 minute to change colour, the test line usually appeared within 2 to 3 minutes.

Table 5. Calculation of ease of performance

PARAMETER	ABON™ Tri-line HIV Rapid Test Device		SD BIOLINE HIV1/2 3.0		FIRST RESPONSE® HIV 1-2.0 CARD TEST		ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2	
	Serum/ plasma	Capillary WB	Serum/ plasma	Capillary WB	Serum/ plasma	Capillary WB	Serum/ plasma	Capillary WB	Serum/ plasma	Capillary WB	Serum/ plasma	Capillary WB	Serum/ plasma	Capillary WB	Serum/ plasma	Capillary WB
Need to prepare:																
1 = reagent needs no preparation																
0 = reagent needs preparation																
- antigen	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- substrate	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- wash solution	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- conjugate	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- pre-dilution of serum/plasma	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Stability after dilution opening :																
1 = expiry date or N/A																
0 = less than kit expiry date																
- test device	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- controls	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- sample diluent/ running buffer	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1
- conjugate	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- substrate	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- wash buffer	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- sufficient reagents	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- wash (yes=1; no =0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 5. (continued) Calculation of ease of performance

PARAMETER	ABON™ Tri-line HIV Rapid Test Device		SD BIOLINE HIV1/2 3.0		FIRST RESPONSE® HIV 1-2.0 CARD TEST		ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2	
Items required but not provided in the kit: 1 = item provided in kit or N/A 0 = item not provided in kit																
- reagent trough	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- precision pipette	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1
- dilution tubes, rack/ microtiter plate	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- distilled or deionised water	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- plate covers	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- graduated pipette, cylinder	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- sulphuric acid/ sodium hydroxide	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
- lancets, alcohol swabs, cotton wool	1	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0
- specimen transfer devices, running buffer	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	0
Technician's appraisal of the test kit – see Table 4A (rating out of 10)	10	10	10	9	10	10	10	10	10	10	10	10	10	10	10	8
Total (out of possible 30)	31	29	30	29	31	31	29	29	29	29	29	29	30	30	30	28
Ease of performance: -less easy < 20 -easy 20 ≤ x < 25 -very easy > 25	very easy	very easy	very easy	very easy	very easy	very easy	very easy	very easy	very easy	very easy	very easy	very easy	very easy	very easy	very easy	very easy

Notes for Table 5 Technician's appraisal and calculation of ease of performance of the assays

Table 6. Technical suitability for use in small laboratories or non-laboratory testing services

PARAMETER	Score	ABON™ Tri-line HIV Rapid Test Device	SD BIOLINE HIV-1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	DoubleCheckGold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
Sensitivity (final)									
- 100%	5	5	5	5	5	5	5	5	5
- 98 – 100%	3								
- <98%	0								
Specificity (final)									
- >98%	5	5	5	5	5	5	5	5	5
- 95 – 98%	3								
- <95%	0								
Incubation temperature									
- room temp °C	3	3	3	3	3	3	3	3	3
- other than room temp °C	1								
Shelf-life									
- >1 year	3	3	3	3	3	3	3	3	3
- > 6 months < 1 year	2								
- < 6 months	1								
Storage at									
- room temp °C possible (opened kit)	5	5	5	5	5	5	5	5	5
- room temp °C possible (unopened kit)	2								
- 2-8 °C required	1								
Price per test (US$)									
- < 1.0	3	3	3	3	3	3	3	2.75	
- >1.0 < 2.0	2								2
- > 2.0	1								

Table 6. (continued) Technical suitability for use in small laboratories or non-laboratory testing services

PARAMETER	Score	ABON™ Tri-line HIV Rapid Test Device	SD BIOLINE HIV-1/2 3.0	FIRST RESPONSE® HIV 1-2.0 CARD TEST	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test	DoubleCheckGold™ Ultra HIV 1&2	Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP ® HIV 1/2 Assay	VIKIA® HIV 1/2
Ease of performance									
- very easy	5	5	5	5	5	5	5	5	5
- easy	3								
- less easy	1								
Rapidity of performance: 1 specimen									
- < 10 min	3								
- 10 – 30 min	2	2	2	2	2	2	2	2	
- > 30 min	1								1
Washer/agitator									
- not needed	3	3	3	3	3	3	3	3	3
- needed	1								
Reading									
- visual:									
inter-reader variability ≤ 3%	5		5	5	5	5	5	5	5
inter-reader variability > 3%	3	3							
- reading equipment	1								
Total (out of possible 40)		37	39	39	39	39	39	39	37
Suitability for use in small labs and non-lab testing services									
less suitable < 23									
suitable 23 ≤ x ≤ 30									
very suitable > 30		very suitable	very suitable	very suitable	very suitable	very suitable	very suitable	very suitable	very suitable

Table 7. Results on commercial seroconversion panels

Panel	Days since 1st bleed	Assays under evaluation											Reference Results										
		ABON™ Tri-HIV line Rapid test Device		SD BIOLINE HIV1/2 3.0		FIRST RESPONSE® HIV-1 TEST 2.0		AD-VANCED QUAL-ITY™ ONE STEP Anti-HIV (1&2) Test	Double Check Gold™ Ultra HIV 1&2	Diag-nostic Kit for HIV (1+2) ùanti-boby (Col-loidal Gold)	DPP® HIV 1/2 Assay	VIKIA® HIV 1/2	IN-NOTEST HIV Antigen mAb[1]	Enzyg-nost Anti-HIV1/2 Plus[1]	Viro-nostika HIV Ag/ Ab[1]	INNO-LIA HIV Confirmation[1]							
		HIV 1	HIV 2	HIV 1	HIV 2	HIV 1	HIV 2	HIV 1/2	HIV 1/2	HIV 1/2	HIV 1/2	HIV 1/2	OD/CO	OD/CO	OD/CO	Sgp 120	gp41	p31	p24	p17	sgp 105	gp 36	Re-sult
PRB914-01	0	NR	NR	R	NR	R	NR	R	R	R	R	R	0.43	4.49	4.68	-	2+	-	1+	-	-	-	HIV-1
PRB914-02	4	NR	NR	R	NR	R	NR	R	R	R	R	R	0.41	4.16	7.63	-	2+	-	2+	-	-	-	HIV-1
PRB914-03	7	R	NR	R	NR	R	NR	R	R	R	R	R	0.39	4.71	8.23	-	2+	-	2+	-	-	-	HIV-1
PRB914-04	25	R	NR	R	NR	R	NR	R	R	R	R	R	0.46	6.47	18.29	1+	2+	-	2+	1+	-	-	HIV-1
PRB914-05	31	R	NR	R	NR	R	NR	R	R	R	R	R	0.44	6.61	18.29	2+	2+	-	3+	1+	-	-	HIV-1
PRB925-01	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.43	0.10	0.37	-	-	-	-	-	-	-	Neg
PRB925-02	10	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.41	0.08	0.38	-	-	-	-	-	-	-	Neg
PRB925-03	18	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.37	0.08	0.35	-	-	-	-	-	-	-	Neg
PRB925-04	22	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.41	0.09	0.35	-	-	-	-	-	-	-	Neg
PRB925-05	44	R	NR	R	NR	R	NR	R	R	R	R	R	10.57	6.61	3.88	-	2+	-	-	-	-	-	IND
PRB925-06	49	R	NR	R	NR	R	NR	R	R	R	R	R	5.62	6.61	6.13	-	3+	-	2+	-	-	-	HIV-1
PRB926-01	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.45	0.07	0.37	-	-	-	-	-	-	-	Neg
PRB926-02	2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.43	0.08	0.37	-	-	-	-	-	-	-	Neg
PRB926-03	7	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	9.14	0.08	0.77	-	-	-	-	-	-	-	Neg
PRB926-04	9	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	21.74	0.07	5.42	-	-	-	-	-	-	-	Neg
PRB926-05	27	R	NR	R	NR	R	NR	R	R	R	R	R	2.26	6.6	10.93	-	3+		2		-	-	HIV-1
PRB926-06	32	R	NR	R	NR	R	NR	R	R	R	R	R	2.66	661	16.84	-	3+	-	2+	1+	-	-	HIV-1
PRB930-01	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	2.29	0.09	0.59	-	-	-	-	-	-	-	Neg
PRB930-02	3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	9.01	0.12	1.05	-	-	-	-	-	-	-	Neg

Table 7. (continued) Results on commercial seroconversion panels

Panel	Days since 1st bleed	Assays under evaluation											Reference Results										
		ABON™ Tri-HIV line Rapid test Device		SD BIOLINE HIV1/2 3.0		FIRST RESPONSE® HIV-1 TEST 2.0		AD-VANCED QUAL-ITY™ ONE STEP Anti-HIV (1&2) Test	Double Check Gold™ Ultra HIV 1&2	Diag-nostic Kit for HIV (1+2) ùanti-boby (Col-loidal Gold)	DPP® HIV 1/2 Assay	VIKIA® HIV 1/2	IN-NOTEST HIV Antigen mAb[1]	Enzyg-nost Anti-HIV1/2 Plus[1]	Viro-nostika HIV Ag/ Ab[1]	INNO-LIA HIV Confirmation[1]							
		HIV 1	HIV 2	HIV 1	HIV 2	HIV 1	HIV 2	HIV 1/2	HIV 1/2	HIV 1/2	HIV 1/2	HIV 1/2	OD/CO	OD/CO	OD/CO	Sgp 120	gp41	p31	p24	p17	sgp 105	gp 36	Re-sult
PRB930-03	7	R	NR	R	NR	R	NR	R	R	R	NR	R	15.48	4.57	3.46	-	1+	-	-	-	-	-	IND
PRB930-04	10	R	NR	R	NR	R	NR	R	R	R	R	R	19.40	6.61	7.32	-	2+	-	2+	-	-	-	HIV-1
PRB955-01	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.49	0.08	0.38	-	-	-	-	-	-	-	Neg
PRB955-02	3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.95	0.07	0.51	-	-	-	-	-	-	-	Neg
PRB955-03	7	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	14.95	0.11	1.66	-	-	-	-	-	-	-	Neg
PRB955-04	12	NR	NR	NR	NR	R	NR	R	NR	R	NR	R	18.59	1.19	2.41	-	-	-	-	-	-	-	Neg
PRB955-05	14	NR	NR	R	NR	R	NR	R	R	R	R	R	17.88	6.61	6.70	-	1+	-	1+	-	-	-	HIV-1
PRB965-01	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.46	0.09	0.37	-	-	-	-	-	-	-	Neg
PRB965-02	5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.49	0.08	0.52	-	-	-	-	-	-	-	Neg
PRB965-03	7	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.51	0.16	0.63	-	-	-	-	-	-	-	Neg
PRB965-04	12	R	NR	R	NR	R	NR	R	R	R	NR	R	0.49	6.61	3.45	-	+	-	-	-	-	-	Neg
PRB965-05	14	R	NR	R	NR	R	NR	R	R	R	R	R	0.50	6.61	6.32	-	2+	-	-	-	-	-	IND
PRB965-06	21	R	NR	R	NR	R	NR	R	R	R	R	R	0.49	6.61	6.93	-	2+	-	1+	-	-	-	HIV-1
PRB968-01	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.41	0.08	0.32	-	-	-	-	-	-	-	Neg
PRB968-02	3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.38	0.08	0.30	-	-	-	-	-	-	-	Neg
PRB968-03	8	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.42	0.10	0.35	-	-	-	-	-	-	-	Neg
PRB968-04	10	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.42	0.08	0.36	-	-	-	-	-	-	-	Neg
PRB968-05	15	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.45	0.08	0.34	-	-	-	-	-	-	-	Neg
PRB968-06	17	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.52	0.08	0.37	-	-	-	-	-	-	-	Neg

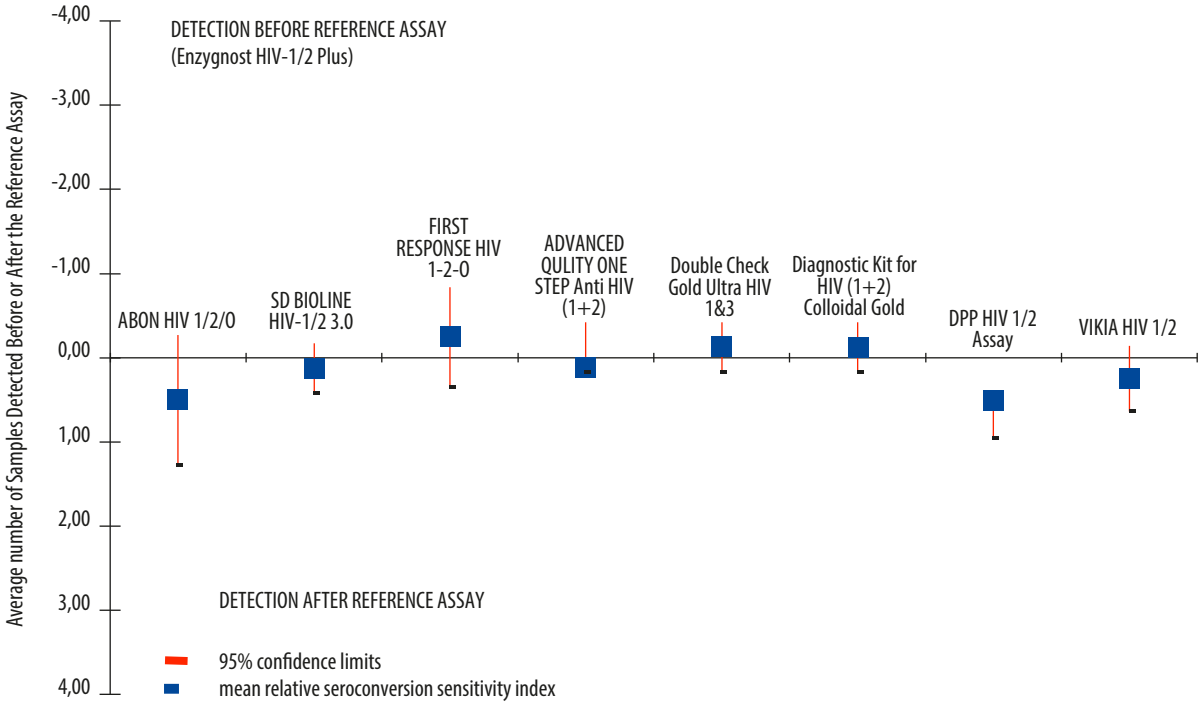
Table 7. (continued) Results on commercial seroconversion panels

Panel	Days since 1st bleed	Assays under evaluation											Reference Results										
		ABON™ Tri-HIV line Rapid test Device		SD BIOLINE HIV1/2 3.0		FIRST RESPONSE® HIV-1 TEST 2.0		AD-VANCED QUAL-ITY™ ONE STEP Anti-HIV (1&2) Test	Double Check Gold™ Ultra HIV 1&2	Diag-nostic Kit for HIV (1+2) ùanti-boby (Col-loidal Gold)	DPP® HIV 1/2 Assay	VIKIA® HIV 1/2	IN-NOTEST HIV Antigen mAb[1]	Enzyg-nost Anti-HIV1/2 Plus[1]	Viro-nostika HIV Ag/ Ab[1]	INNO-LIA HIV Confirmation[1]							
		HIV 1	HIV 2	HIV 1	HIV 2	HIV 1	HIV 2	HIV 1/2	HIV 1/2	HIV 1/2	HIV 1/2	HIV 1/2	OD/CO	OD/CO	OD/CO	Sgp 120	gp41	p31	p24	p17	sgp 105	gp 36	Re-sult
PRB968-07	26	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	21.74	0.26	3.46	-	-	-	-	-	-	-	Neg
PRB968-08	28	NR	NR	NR	NR	R	NR	R	NR	R	NR	R	21.74	0.78	6.75	-	-	-	-	-	-	-	Neg
PRB968-09	33	R	NR	R	NR	R	NR	R	R	R	R	R	11.56	6.61	5.07	-	2+	-	2+	-	-	-	HIV-1
PRB968-10	35	R	NR	R	NR	R	NR	R	R	R	R	R	2.12	6.55	4.50	-	2+	-	2+	1+	-	-	HIV-1
PRB969-01	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.41	0.09	0.38	-	-	-	-	-	-	-	Neg
PRB969-02	29	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.41	0.08	0.33	-	-	-	-	-	-	-	Neg
PRB969-03	48	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.44	0.08	0.35	-	-	-	-	-	-	-	Neg
PRB969-04	53	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.45	0.08	0.39	-	-	-	-	-	-	-	Neg
PRB969-05	55	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.44	0.07	0.54	-	-	-	-	-	-	-	Neg
PRB969-06	61	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.64	0.08	0.35	-	-	-	-	-	-	-	Neg
PRB969-07	63	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.02	0.07	0.38	-	-	-	-	-	-	-	Neg
PRB969-08	70	R	NR	R	NR	R	NR	R	R	R	NR	R	2.49	5.96	4.49	-	2+	-	2+	2+	-	-	HIV-1
PRB969-09	72	R	NR	R	NR	R	NR	R	R	R	R	R	1.86	5.75	8.94	-	2+	-	2+	2+	-	-	HIV-1
PRB969-10	77	R	NR	R	NR	R	NR	R	R	R	R	R	0.57	2.58	6.15	-	2+	-	2+	2+	-	-	HIV-1

Notes for Table 7 An assay's performance on the seroconversion panels should be viewed against both the sensitivity and specificity of the assay. Caution should be taken when reviewing seroconversion performance of assays tested only in eight seroconversion panels.

Reference results 1 Reference results obtained from ITM, Belgium. INNOTEST HIV Antigen mAb (HIV-1 p24 antigen EIA), Enzygnost Anti-HIV1/2 Plus (HIV-1/2 antibody EIA), Vironostika HIV Ag/Ab combo (HIV-1/2 antibody and HIV-1 p24 antigen EIA), and INNO-LIA HIV Confirmation (HIV line immunoassay)

Figure 4. Relative seroconversion sensitivity compared to antibody-detection immunoassays (Enzygnost Anti-HIV-1/2 plus (Siemens healthcare Diagnostics)



	ABON™ HIV 1/2/O Tri-Line	SD BIOLINE HIV-1/2 3.0	First Response® HIV 1-2-0 Card test	ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2)	Double CheckGold™ Ultra HIV 1&2	Diagnostic kit for HIV(1+2) Antibody (Colloidal Gold)	DPP® HIV 1/2 Assay	VIKIA® HIV 1/2
Lower 95%	-0.274	-0.1706	-0.8412	-0.4206	-0.4206	-0.4206	0.531	-0.137
mean	0.5	0.125	-0.25	-0.125	0.125	-0.125	0.5	0.25
- Upper 95%	1.274	0.4206	0.3412	0.1706	0.1706	0.1706	0.9469	0.637

Table 8. Results on commercial anti-HIV 1 mixed titer performance panel

Panels	Assays under evaluation											Reference Assays										Reference result
	ABON™ Tri-line HIV Rapid Test Device		SD BIOLINE HIV1/2 3.0		FIRST RESPONSE® HIV 1-2.0 CARD TEST		AD-VANCED QUALI-TYTM ONE STEP Anti-HIV (1&2) Test	Double Check-Gold™ Ultra HIV 1&2	Diagnos-tic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP® HIV 1/2 Assay	VIKIA® HIV 1/2	IN-NOTEST HIV Antigen mAb[1]	Enzyg-nost ANTI-HIV1/2 Plus[1]	Viro-nostika HIV Ag/ Ab[1]	INNO-LIA HIV I/II Score Confirmation[1]								
	HIV 1	HIV 2	HIV 1	HIV 2	HIV 1	HIV 2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	OD/CO	OD/CO	OD/CO	gp 120	gp 41	p 31	p 24	p 17	gp 105	gp 36	Result	
PRB205-01	R	NR	R	NR	R	NR	R	R	R	R	R	0.43	3.90	5.94	-					-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-02	R	R	R	NR	R	NR	R	R	R	R	R	15.49	6.68	20.13	3+	3+	2+	3+	2+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen positive
PRB205-03	R	NR	R	NR	R	NR	R	R	R	NR	R	26.32	6.68	9.74	-	-	-	-	-	-	-	Neg	Anti-HIV indeterminate HIV-1 antigen positive
PRB205-04	R	R	R	R	R	NR	R	R	R	R	R	0.65	6.68	20.13	2+	3+	2+	2+	-	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-05	R	R	R	NR	R	NR	R	R	R	R	R	0.39	6.68	20.13	3+	3+	2+	3+	3+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-06	R	NR	R	NR	R	NR	R	R	R	NR	NR	1.81	4.82	3.42	-	-	-	-	-	-	-	Neg	Anti-HIV indeterminate HIV-1 antigen positive
PRB205-07	R	NR	R	NR	R	NR	R	R	R	NR	R	9.18	5.80	2.49	-	-	-	-	-	-	-	Neg	Anti-HIV indeterminate HIV-1 antigen positive
PRB205-08	R	NR	R	NR	R	NR	R	R	R	NR	R	26.32	3.90	20.13	-	2+	-	-	-	-	-	IND	Anti-HIV indeterminate HIV-1 antigen positive
PRB205-09	R	R	R	NR	R	NR	R	R	R	R	R	0.45	6.68	20.13	2+	2+	2+	2+	3+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-10	R	NR	R	NR	R	NR	R	R	R	R	R	0.41	6.68	20.13	3+	3+	-	3+	2+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-11	R	R	R	NR	R	NR	R	R	R	R	R	4.42	6.68	20.13	3+	2+	2+	2+	2+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen positive

Table 8. (continued) Results on commercial anti-HIV 1 mixed titer performance panel

Panels	Assays under evaluation											Reference Assays										Reference result
	ABON™ Tri-line HIV Rapid Test Device		SD BIOLINE HIV1/2 3.0		FIRST RESPONSE® HIV 1-2.0 CARD TEST		AD-VANCED QUALI-TYTM ONE STEP Anti-HIV (1&2) Test	Double Check-Gold™ Ultra HIV 1&2	Diagnos-tic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP® HIV 1/2 Assay	VIKIA® HIV 1/2	IN-NOTEST HIV Antigen mAb[1]	Enzyg-nost ANTI-HIV1/2 Plus[1]	Viro-nostika HIV Ag/ Ab[1]	INNO-LIA HIV I/II Score Confirmation[1]								
	HIV 1	HIV 2	HIV 1	HIV 2	HIV 1	HIV 2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	OD/CO	OD/CO	OD/CO	gp 120	gp 41	p 31	p 24	p 17	gp 105	gp 36	Result	
PRB205-12	R	NR	R	NR	R	NR	R	R	R	NR	NR	12.85	2.87	1.93	-	-	-	-	-	-	-	Neg	Anti-HIV indeterminate HIV-1 antigen positive
PRB205-13	R	R	R	NR	R	NR	R	R	R	R	R	0.39	6.68	20.13	2+	4+	2+	3+	3+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-14	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.39	0.08	0.38	-	-	-	-	-	-	-	Neg	Anti-HIV negative HIV-1 antigen negative
PRB205-15	R	NR	R	NR	R	NR	R	R	R	R	R	3.53	3.21	13.78	1+	2+	-	2+	2+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen positive
PRB205-16	R	R	R	NR	R	NR	R	R	R	R	R	0.42	6.68	20.13	3+	3+	2+	3+	3+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-17	R	NR	R	NR	R	NR	R	R	R	R	R	1.07	4.78	17.20	1+	2+	-	2+	2+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen positive
PRB205-18	R	NR	R	NR	R	NR	R	R	R	R	R	4.68	6.68	4.01	-	2+	-	-	-	-	-	IND	Anti-HIV indeterminate HIV-1 antigen positive
PRB205-19	R	NR	R	NR	R	NR	R	R	R	R	R	0.46	5.26	20.13	2+	3+	-	2+	1+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-20	R	R	R	NR	R	NR	R	R	R	R	R	0.42	6.68	20.13	3+	3+	2+	3+	3+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-21	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.41	0.09	0.43	-	-	-	-	-	-	-	Neg	Anti-HIV negative HIV-1 antigen negative
PRB205-22	R	R	R	NR	R	NR	R	R	R	R	R	2.48	6.68	20.13	3+	3+	2+	2+	2+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen positive

Table 8. (continued) Results on commercial anti-HIV 1 mixed titer performance panel

Panels	Assays under evaluation											Reference Assays											Reference result
	ABON™ Tri-line HIV Rapid Test Device		SD BIOLINE HIV1/2 3.0		FIRST RESPONSE® HIV 1-2.0 CARD TEST		AD-VANCED QUALI-TYTM ONE STEP Anti-HIV (1&2) Test	Double Check-Gold™ Ultra HIV 1&2	Diagnos-tic Kit for HIV (1+2) Antibody (Colloidal Gold)	DPP® HIV 1/2 Assay	VIKIA® HIV 1/2	IN-NOTEST HIV Antigen mAb[1]	Enzyg-nost ANTI-HIV1/2 Plus[1]	Viro-nostika HIV Ag/Ab[1]	INNO-LIA HIV I/II Score Confirmation[1]								
	HIV 1	HIV 2	HIV 1	HIV 2	HIV 1	HIV 2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	OD/CO	OD/CO	OD/CO	gp 120	gp 41	p 31	p 24	p 17	gp 105	gp 36	Result	
PRB205-23	R	R	R	NR	R	NR	R	R	R	R	R	0.40	6.68	18.22	2+	3+	-	2+	2+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative
PRB205-24	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	9.10	0.89	0.82	-	-	-	-	-	-	-	Neg	Anti-HIV negative HIV-1 antigen positive
PRB205-25	R	NR	R	NR	R	NR	R	R	R	R	R	0.38	6.68	20.13	**3+**	4+	-	1+	1+	-	-	HIV-1	Anti-HIV positive HIV-1 antigen negative

Notes for Table 8 Performance on mixed HIV-1 antibody titer specimens

Reference results [1]Reference results obtained from ITM, Belgium. INNOTEST HIV Antigen mAb (HIV-1 p24 antigen EIA), Enzygnost Anti-HIV1/2 Plus (HIV-1/2 antibody EIA), Vironostika HIV Ag/Ab combo (HIV-1/2 antibody and HIV-1 p24 antigen EIA), and INNO-LIA HIV Confirmation (HIV line immunoassay).

Table 9. Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
Neat	WHO3-0690	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/2	WHO3-0690	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/4	WHO3-0690	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/8	WHO3-0690	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/16	WHO3-0690	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/32	WHO3-0690	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/64	WHO3-0690	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/128	WHO3-0690	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/256	WHO3-0690	R	NR	NR	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	NR	R	R	R	R	R	R	15.63
1/512	WHO3-0690	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	R	R	NR	NR	R	R	R	R	R	R	9.75
1/1024	WHO3-0690	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	R	R	NR	NR	R	R	7.20
1/2048	WHO3-0690	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	R	R	4.41
1/4096	WHO3-0690	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	R	NR	1.89

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/8192	WHO3-0690	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	1.59
1/16384	WHO3-0690	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.91
1/32768	WHO3-0690	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		1				0				0				1		1		1		0		2		
Neat	WHO3-0736	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/2	WHO3-0736	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/4	WHO3-0736	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/8	WHO3-0736	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/16	WHO3-0736	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/32	WHO3-0736	R	NR	R	NR	NR	NR	NR	NR	R	NR	R	NR	R	R	NR	NR	R	R	NR	NR	R	NR	> 17.8
1/64	WHO3-0736	R	NR	R	NR	NR	NR	NR	NR	R	NR	NR	NR	R	R	NR	NR	R	R	NR	NR	R	NR	> 17.8
1/128	WHO3-0736	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	> 17.8
1/256	WHO3-0736	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	15.63

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/512	WHO3-0736	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	9.75
1/1024	WHO3-0736	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	7.20
1/2048	WHO3-0736	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	4.41
1/4096	WHO3-0736	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.89
1/8192	WHO3-0736	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.59
1/16384	WHO3-0736	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.91
1/32768	WHO3-0736	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		1				0				1				1		0				0		2		
Neat	WHO3-0789	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/2	WHO3-0789	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/4	WHO3-0789	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/8	WHO3-0789	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/16	WHO3-0789	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/32	WHO3-0789	NR	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	NR	R	R	R	R	R	R	> 17.8
1/64	WHO3-0789	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	R	R	NR	NR	R	R	NR	NR	R	NR	> 17.8
1/128	WHO3-0789	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	R	R	NR	NR	R	NR	> 17.8
1/256	WHO3-0789	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	15.63
1/512	WHO3-0789	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	9.75
1/1024	WHO3-0789	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	7.20
1/2048	WHO3-0789	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	4.41
1/4096	WHO3-0789	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.89
1/8192	WHO3-0789	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.59
1/16384	WHO3-0789	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.91
1/32768	WHO3-0789	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		1				0				0				0		1		0		0		2		
Neat	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/2	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/4	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/8	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/16	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/32	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/64	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/128	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/256	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	15.63
1/512	WHO3-0634	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	9.75
1/1024	WHO3-0634	NR	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	NR	R	R	R	R	NR	R	R	7.20
1/2048	WHO3-0634	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	R	R	NR	NR	R	R	NR	NR	R	R	4.41
1/4096	WHO3-0634	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	R	NR	NR	R	R	NR	NR	R	R	1.89
1/8192	WHO3-0634	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	R	NR	1.59

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/16384	WHO3-0634	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	NR	NR	0.91
1/32768	WHO3-0634	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		1				0				1				1		1		0		1		1		
Neat	WHO3-0577	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/2	WHO3-0577	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/4	WHO3-0577	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/8	WHO3-0577	R	NR	R	NR	NR	NR	NR	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/16	WHO3-0577	R	NR	R	NR	NR	NR	NR	NR	R	NR	NR	NR	R	R	NR	NR	R	R	R	R	R	R	> 17.8
1/32	WHO3-0577	R	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	R	R	R	R	R	R	> 17.8
1/64	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	> 17.8
1/128	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	> 17.8
1/256	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	15.63
1/512	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	9.75

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/1024	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	7.20
1/2048	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	4.41
1/4096	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.89
1/8192	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.59
1/16384	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.91
1/32768	WHO3-0577	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		1				0				2				0		0		0		0		1		
Neat	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/2	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/4	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/8	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/16	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/32	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/64	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/128	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/256	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	15.63
1/512	WHO3-0584	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	NR	NR	R	R	R	R	R	R	9.75
1/1024	WHO3-0584	R	NR	R	NR	NR	NR	R	NR	R	NR	R	NR	R	R	NR	NR	R	R	R	NR	R	R	7.20
1/2048	WHO3-0584	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	R	NR	NR	R	R	NR	NR	R	R	4.41
1/4096	WHO3-0584	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	R	R	1.89
1/8192	WHO3-0584	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	R	R	1.59
1/16384	WHO3-0584	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.91
1/32768	WHO3-0584	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		0				1				1				0		0		1		1		0		
Neat	990885	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/2	990885	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/4	990885	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/8	990885	NR	NR	R	NR	NR	NR	NR	NR	R	NR	R	NR	R	R	R	NR	R	R	R	R	R	R	> 17.8

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/16	990885	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	R	R	NR	NR	R	R	NR	NR	R	R	> 17.8
1/32	990885	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	R	NR	R	R	NR	NR	R	R	NR	NR	R	R	> 17.8
1/64	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	R	NR	> 17.8
1/128	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	> 17.8
1/256	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	15.63
1/512	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	9.75
1/1024	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	7.20
1/2048	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	4.41
1/4096	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.89
1/8192	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.59
1/16384	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.91
1/32768	990885	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		1				0				0				0		1		0		0		0		
Neat	990814	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/2	990814	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	NR	R	R	> 17.8
1/4	990814	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	NR	NR	R	NR	> 17.8
1/8	990814	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	NR	NR	NR	NR	> 17.8
1/16	990814	NR	NR	NR	NR	R	NR	R	NR	R	NR	R	NR	R	R	NR	NR	R	R	NR	NR	NR	NR	> 17.8
1/32	990814	NR	NR	NR	NR	R	NR	R	NR	R	NR	R	NR	R	R	NR	NR	R	R	NR	NR	NR	NR	> 17.8
1/64	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	R	R	NR	NR	NR	NR	> 17.8
1/128	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	NR	NR	> 17.8

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/256	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	NR	NR	15.63
1/512	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	9.75
1/1024	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	7.20
1/2048	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	4.41
1/4096	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.89
1/8192	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.59
1/16384	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.91
1/32768	990814	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		0				0				0				1		0		0		1		1		
Neat	990831	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/2	990831	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/4	990831	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/8	990831	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/16	990831	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/32	990831	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	R	R	R	NR	R	R	R	R	R	R	> 17.8
1/64	990831	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	R	R	R	R	> 17.8
1/128	990831	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	R	R	R	R	> 17.8
1/256	990831	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	R	R	15.63
1/512	990831	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	9.75
1/1024	990831	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	7.20
1/2048	990831	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	4.41

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/4096	990831	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	1.89
1/8192	990831	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.59
1/16384	990831	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.91
1/32768	990831	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		0				1				0				0		1		0		0		1		
Neat	WHO3-0788	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/2	WHO3-0788	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/4	WHO3-0788	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/8	WHO3-0788	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/16	WHO3-0788	R	NR	R	NR	R	NR	R	NR	R	NR	R	NR	R	R	R	R	R	R	R	R	R	R	> 17.8
1/32	WHO3-0788	R	NR	R	NR	NR	NR	R	NR	NR	NR	R	NR	R	R	R	NR	R	R	R	NR	R	NR	> 17.8
1/64	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	R	R	NR	NR	NR	NR	> 17.8
1/128	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	R	NR	NR	NR	NR	> 17.8
1/256	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	NR	NR	NR	15.63
1/512	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	9.75

Table 9. (continued) Results on lot-to-lot variation panel

Dilution	Specimen ID	ABON™ Tri-line HIV Rapid Test Device (Whole Blood/ Serum/Plasma)				SD BIOLINE HIV-1/2 3.0				FIRST RESPONSE® HIV 1-2.0 CARD TEST				ADVANCED QUALITY™ ONE STEP Anti-HIV (1&2) Test		DoubleCheckGold™ Ultra HIV 1&2		Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold		DPP ® HIV 1/2 Assay		VIKIA® HIV 1/2		Reference Results
		Lot 209 0023	Lot 209 0023	Lot 209 0089	Lot 209 0089	Lot 023450	Lot 023450	Lot 023452	Lot 023452	Lot 38J1511	Lot 38J1511	Lot 38J1411	Lot 38J1411	Lot 201 3032725	Lot 201 3032726	Lot 110524	Lot 110 5171A	Lot 110524	Lot 110 5171A	Lot 550 61912	Lot 551 02312/2	Lot 100 1934410	Lot 100 1829090	Vironostika HIV Ag/Ab
		HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	HIV1/2	
1/1024	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	7.20
1/2048	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	4.41
1/4096	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.89
1/8192	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	1.59
1/16384	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	0.91
1/32768	WHO3-0788	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	NR	NR	NR	NR	NR	NR	NR	0.66
Difference		0				1				1				0		1		0		1		1		

Table 10 RESULTS ON WHO REFERENCE PREPARATIONS

Subtype	Assays under evaluation											Reference Results									
	ABONTM Tri-line HIV Rapid Test Device (Whole Blood/ Serum/ Plasma		SD BIOLINE HIV-1/2 3.0		FIRST RESPONSE® HIV 1-2.0 CARD TEST		AD-VANCED QUAL-ITY™ ONE STEP Anti-HIV (1&2) Test	Double Check-Gold™ Ultra HIV 1&	Diag-nostic Kit for HIV (1+2) Anti-body (Col-loidal Gold)	DPP ® HIV 1/2 Assay	VI-KIA® HIV 1/2	INNOTEST HIV Anti-gen mAb[1] OD/CO	Enzygnost Anti-HIV1/2 Plus[1] OD/CO	Vironosti-ka HIV Ag/ Ab[1] OD/CO	Sgp120	gp41	p31	p17	sgp105	gp36	Result
	HIV-1	HIV-2	HIV-1	HIV-2	HIV-1	HIV-2	HIV 1/2	HIV 1/2	HIV 1/2	HIV 1/2	HIV 1/2										
HIV-1 A	R	NR	R	NR	R	NR	R	R	R	R	R	> 17.1	> 6.7	0.4	4+	2+	3+	4+	-	-	HIV-1
HIV-1 B	R	NR	R	NR	R	NR	R	R	R	R	R	> 17.1	> 6.7	0.4	3+	2+	2+	-	-	-	HIV-1
HIV-1 C	R	NR	R	NR	R	NR	R	R	R	R	R	> 17.1	> 6.7	0.4	2+	1+	2+	2+	-	-	HIV-1
HIV-1 CRF01_AE	R	NR	R	NR	R	NR	R	R	R	R	R	> 17.1	> 6.7	0.4	2+	2+	2+	2+	-	-	HIV-1
HIV-1 O	R	NR	R	NR	NR	NR	NR	NR	R	R	R	> 17.1	> 6.7	0.6	2+	1+	-	-	-	-	HIV-1
HIV-2	R	NR	R	R	NR	R	R	R	R	R	R	> 17.1	> 6.7	0.4	-	1+	3+	1+	2+	2+	HIV-2

Notes for Table 10 — Performance of assays on WHO reference preparations

Reference results — [1] Reference results obtained from ITM, Belgium. INNOTEST HIV Antigen mAb (HIV-1 p24 antigen EIA), Enzygnost Anti-HIV1/2 Plus (HIV-1/2 antibody EIA), Vironostika HIV Ag/Ab combo (HIV-1/2 antibody and HIV-1 p24 antigen EIA), and INNO-LIA HIV Confirmation (HIV line immunoassay).

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8. ANNEXES

ANNEX 1 - CUMULATIVE LIST OF ASSAYS EVALUATED WHOSE PRODUCTION HAS BEEN DISCONTINUED

The names (and manufacturers) of the assays evaluated to date under the WHO Test Kit Evaluation programme are listed in the table below. The number of the report in which each assay is covered is given, as well as sensitivity and specificity with 95% confidence intervals, δ values for HIV antibody-positive and antibody-negative specimen populations, cost per test, ease of performance and suitability for use in small blood collection centers.

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values		Cost per test (US$) /year	nm[h]	Ease of performance	Suitability	Indeterminate results (%)
				Pos	Neg					
Enzyme immunoassays										
For the detection of antibody to HIV-1										
Detect-HIV™ (Biochem Immunosystemes now Adaltis)	3	100.0	97.4	12.65	-2.21	2.5/'90	450	LE	LS	N/A
		(98.6-100.0)	(94.0-99.2)				600-650			
Abbott Recombinant HIV-1/HIV-2 3rd Generation (Abbott)	7	100.0	100.0	11.5	-4.3	1.7/1.8'93	492	LE	LS	N/A
		(98.5-100.0)	(98.5-100.0)							
IMx HIV-1/HIV-2 3rd generation Plus (Abbott GmbH Diagnostika)	11	99.6	97.9	9.1	-2.1	3-4'95	Imx system	VE	S	0.3
		(98.9 -100.0)	(96.4-99.4)							
Enzygnost HIV Integral II (Dade Behring)	15	100	100	N/A	N/A	NA/'04	450	LE	LS	0.0
		(97.7-100)	(98.7-100)				650			
Vironostika® HIV UniForm II Ag/Ab	15	100	99.0	N/A	1.48-1.95/'04		450 620-700	LE	LS	0.0
		(97.7-100)	(97.1-99.8)							
Dupont HIV-1 Recombinant ELISA (Dupont de Nemours)	1	100.0	97.0	N/A	N/A	0.9/'88	450/410	LE	LS	N/A
		(98.7-100.0)	(92.7-98.8)							
Enzygnost Anti-HIV Micro (Behringwerke)	1	100.0	100.0	N/A	N/A	1.8/'88	450	LE	LS	0.0
		(97.8-100.0)	(98.1-100.0)				450/630			
HIV-TEK G (Sorin Biomedica)	1	100.0	86.5	N/A	N/A	1.0/'88	450	LE	LS	N/A
		(96.0-100.0)	(79.5-91.8)							
Vironostika Anti-HIV Uni-Form (Organon Teknika)	1	100.0	99.5	N/A	N/A	2.2/'88	492	LE	LS	N/A
		(97.6-100.0)	(97.3-100.0)				492/630			

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values		Cost per test (US$) /year	nm[h]	Ease of performance	Suitability	Indeterminate results (%)
				Pos	Neg					
Ortho HIV ELISA System (Ortho Diagn. Systems)	1	100.0	98.0	N/A	N/A	1.8/'88	490	LE	LS	N/A
		(97.8-100.0)	(95.0-99.4)							
HIV-1 env Peptide EIA (Labsystems)	2	96.0	97.0	N/A	N/A	3.9/'89	405	LE	LS	N/A
		(90.8-98.7)	(93.5-98.9)				405/630			
Wellcozyme HIV Recombinant (Wellcome Diagnostics)	2	100.0	99.1	N/A	N/A	1.5/'89	450	LE	LS	N/A
		(98.2-100.0)	(96.8-99.9)							
REC VIH-KCOI (Heber Biotec)	3	97.0	100.0	2.1	-4.14	N/A	492	LE	LS	N/A
		(93.5-98.9)	(98.3-100.0)							
UBI HIV-1 EIA (United Biomedical)	6	100.0	88.2	7.5	-1.12	1.0/'92	492/620-690	LE	S	N/A
		(99.9-100.0)	(87.1-89.3)							
Peptide HIV-1 ELISA Test System (Sero-Immuno Diagnostics)	6	82.1	94.1	N/A	N/A	0.6/'92	visual	E	VS	0.0
		(76.5-87.6)	(91.0-97.2)							
Peptide HIV-2 ELISA Test (Sero-Immuno Dianostics)	6	97.1	98.1	N/A	N/A	0.6/'92	visual	E	VS	N/A
		(93.0-100.0)	(96.3-99.9)							
UBI HIV-2 EIA (United Biomedical)	7	100.0	96.1	10.5	-1.7	1.2/'93	492/620-630	LE	S	N/A
		(97.4-100.0)	(93.4-98.8)							
Enzygnost Anti-HIV-1 (Behringwerke)	7	100.0	100.0	7.4	-3.3	N/A	450/615-690	LE	LS	0.0
		(98.1-100.0)	(98.8-100.0)							
Enzygnost Anti-HIV-2 (Behringwerke)	8	100.0	99.5	23.8	-3.5	6.2/'93	450/630	LE	LS	
		(96.7-100.0)	(98.5-100.0)							
For the detection of antibody to HIV-1 and HIV-2										
Enzygnost Anti-HIV -1+2 (Behringwerke)	2	100.0	97.4	11.3	-2.15	2.3/'89	450	LE	LS	0.0
		(98.4-100.0)	(94.0-99.2)				450/615-690			
Biochrom HIV-1/ HIV-2 ELISA Modul-test (Biochrom)	3	100.0	96.3	6.20	-1.69	0.9/'89	405	LE	LS	1.0
		(98.6-100.0)	(92.5-98.5)							
DuPont HIV-1/ HIV-2 ELISA (DuPont de Nemours)	3	100.0	85.6	9.34	-0.96	1.3/'90	405 or 410			
		(98.7-100.0)	(79.8-90.2)	N/A	N/A	N/A	405 or 410/ 620 or 630	LE	LS	N/A
Vironostika HIV MIXT (Organon Teknika)	3	100.0	100.0	10.10	-2.94	1.8/'90	492	LE	LS	N/A
		(98.7-100.0)	(98.1-100.0)							
Elavia Mixt (Diagnostics Pasteur)	4	100.0	95.1	54.33	-2.31	2.1/'90	492	LE	LS	0.0
		(98.7-100.0)	(91.3-97.8)				492/620			

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values		Cost per test (US$) /year	nm[h]	Ease of performance	Suitability	Indeterminate results (%)
				Pos	Neg					
Anti-HIV-1/HIV-2 EIA <Roche> (F. Hoffman-LaRoche)	4	100.0	96.9	11.30	-2.37	1.7/'90	492	LE	LS	N/A
		(98.7-100.0)	(93.4-98.9)							
Clonatec HIV (1+2) Ab EIA (Clonatec)	6	99.6	95.9	7.47	-1.68	2.7'91	492	LE	S	0.0
		(98.8-100.0)	(93.1-98.7)							
Enzymun-Test Anti-HIV-1+2 (Boehringer Mannheim)	6	100.0	100.0	5.50	-2.48	3.0'92	405	LE	S	0.0
		(98.7-100.0)	(98.6-100.0)							
UBI HIV-1/2 EIA (United Biomedical)	6	100.0	88.7	7.18	-1.24	1.2/'92	492	LE	S	N/A
		(99.9-100.0)	(84.2-93.1)				492/620-690			
Enzygnost Anti-HIV-1/HIV-2 (Behringwerke)	6	100.0	99.5	26.53	-3.50	2.6'92	450	LE	LS	0.0
		(99.9-100.0)	(98.5-100.0)				450/615-690			
Cobas Core Anti-HIV-1/HIV-2 EIA <Roche> (Hoffmann-La Roche)	7	100.0	89.2	10.8	-1.0	2.2'93	450	LE	LS	0.0
		(98.6-100.0)	(84.6-93.8)							
Biochrom HIV-1/HIV-2 ELISA Version 2 (Biochrom)	7	99.5	100.0	7.5	-7.3	1.0/'93	450	LE	LS	0.0
		(99.0-100.0)	(98.6-100.0)							
Wellcozyme HIV-1 + 2 (Wellcome Diagnostics)	4	100.0	96.9	38.51	-1.99	1.5/'90	492	LE	LS	N/A
		(98.7-100.0)	(93.3-98.9)							
Peptide HIV ELISA (Cal-Tech Diagnostics)	5	72.6	95.4	N/A	N/A	0.9/'91	visual	E	S	0.2
		(69.4-77.6)	(91.3-97.9)							
Genelavia Mixt (Sanofi Diagnostics Pasteur)	5	100.0	98.5	16.77	-2.10	1.5/'91	492	LE	LS	0.0
		(98.6-100.0)	(95.6-99.8)				492/620			
Biotest Anti-HIV-1/-2 Recombinant (Biotest)	5	100.0	97.9	50.47	-3.08	1.2/'91	492	LE	LS	0.0
		(98.6-100.0)	(94.9-99.4)				492/570-650			
Innotest HIV-1/HIV-2 Ab (Innogenetics)	6	100.0	97.9	7.22	-2.30	1.9'91	450	LE	LS	N/A
		(98.8-100.0)	(95.9-99.9)				450/620-690			
Peptide HIV-1 & HIV-2 ELISA Test (Sero-Immuno Dianostics)	6	97.6	98.5	N/A	N/A	0.6'92	visual	E	VS	N/A
		(95.7-99.5)	(96.7-100.0)							
UBI HIV-1/2 EIA 2nd (United Biomedical)	7	99.5	92.4	4.8	-1.5	1.2'93	492/620,630	LE	S	N/A
		(98.6 -100.0)	(88.6 - 96.2)							
VIDAS HIV-1+2 (Bio Merieux)	8	100.0	97.8	N/A	N/A	3.6/'93	450	VE	S	0.3
		(98.5-100.0)	(95.6-100.0)							

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values		Cost per test (US$) /year	nm[h]	Ease of performance	Suitability	Indeterminate results (%)
				Pos	Neg					
HIV 1+2 env Peptide EIA (Labsystems OY)	8	100.0	76.2	N/A	N/A	08/2.8/'93	450	LE	LS	0.0
		(98.6-100.0)	(70.0-82.4)							
Enzygnost Anti-HIV 1/-HIV 2 (Behringwerke)	9	100.0	99.5	24.8	-2.55	2.6'92	450	LE	LS	0.0
		(99.6-100.0)	(98.7-100.0)				450/615-690			
VIRONOSTIKA HIV Uni-Form II (Organon Teknika)	9	100.0	98.8	7.4	-3.0	1.7/'94	450/660 ± 40	LE	LS	N/A
		(99.6-100.0)	(97.6-100.0)							
BIOTEST Anti-HIV-1/-2 recombinant (Biotest AG)	9	100.0	99.1	74.9	-3.3	1.2/'94	492/570-650	LE	LS	0.0
		(99.6-100.0)	(98.1-100.0)							
INNOTEST HIV-1/ HIV-2 Ab s.p. (Innogenetics n.v.)	9	100.0	98.8	14.0	-3.8	1.5/'94	450	LE	LS	N/A
		(99.6-100.0)	(97.6-100.0)				450/620-690			
Genelabs Diagnostics HIV-1/HIV-2 ELISA (Genelabs Diagnostics)	10	100	97.3	72.2	-2.7	0.9'94	492	LE	LS	N/A
		(99.6 -100.0)	(95.6-99.0)							
HIV SCREEN (Labsystems OY)	10	100.0	99.7	21.51	-4.11	0.6'95	450	LE	LS	N/A
		(99.6 -100.0)	(99.1-100.0)							
HIVvisual 1 & 2 (Immuno Diagnostics Inc.)	10	90.9	94.5	1.88	-1.15	N/A	450	LE	LS	N/A
		(87.4 - 94.4)	(92.5 -97.3)							
ETI-AB-HIV-1/2 K (Sorin Biomedica)	10	100.0	98.8	10.4	-2.5	1.5/'94	450/630	LE	LS	N/A
		(99.6-100.0)	(97.6-100.0)							
ICE * HIV-1.0.2 (Murex Biotech Ltd.)	11	100.0	99.4	16.8	-4.3	0.6'95	450	LE	LS	N/A
		(99.6 -100.0)	(98.6 100.0)				450/620-690			
GENSCREEN HIV 1/2 (Sanofi Diagnostics Pasteur)	11	100.0	98.5	22.8	-2.7	1.5'95	450/620	LE	LS	0.0
		(99.6 -100.0)	(97.2-99.8)							
HIVA TEST (Lupin Laboratories Ltd)	11	100.0	93.7	12.2	-1.1	0.6'98	450	LE	LS	1.5
		(99.5 -100.0)	(91.0-96.4)							
HIV-1 and/or HIV-2 Recombigen EIA (Trinity Biotech plc)	7	100.0	100.0	10.4	-5.0	1.7/'93	490/630	LE	LS	N/A
		(98.6-100.0)	(98.6-100.0)							
For the detection of antibody to HIV-1 and HIV-2 and HIV-1 p24 antigen										
Genscreen® Plus HIV Ag/Ab (Bio-Rad Laboratories)	15	100	98.3	N/A	N/A	N/A	0.62-0.68 /'04	LE	LS	0.0
		(97.7-100)	(96.1-99.4)							

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values		Cost per test (US$) /year	nm[h]	Ease of performance	Suitability	Indeterminate results (%)
				Pos	Neg					
EIA and Western blot - Evaluations on urine specimens										
For the detection of HIV-1										
Calypte™HIV-1 Urine EIA, Fc (Calypte™ Biomedical Corporation)	13	97.8	100.0	2.4	-4.4	3.00-4.25/'02	405	E	LS	
		(92.4-99.7)	(98.2-100)			405/630				
Calypte™ HIV-1 Urine EIA (Recombinant) (Calypte™ Biomedical Corporation)	13	98.9	98.6	2.28	-2.42	3.00-4.25/'02	405	E	LS	
		(94.2-100)	(95.8-99.7)			405/630				
Cambridge Biotech HIV-1 Urine Western Blot Kit (Calypte™ Biomedical Corporation)	13	98.9	N/A	N/A	26.00/'02	Visual	E	LS/S		
		(94.2-100)								

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Inter-reader variability %	Cost per test (US$) /year	Ease of performance	Suitability	Indeterminate results (%)
Simple/Rapid assays								
For the detection of antibody to HIV-1								
HIV CHEK/HIVSPOT (Genelabs Diagnostics)	1	94.5	99.0	12.3	2.5/'88	VE	VS	
		(89.7- 97.4)	(96.4-99.9)					
Recombigen HIV-LA (Cambridge BioScience)	1	95.2	96.1	6.0	3.0/'88	VE	S	
		(88.3-98.7)	(92.6-98.2)					
Immunocomb (PBS Orgenics)	1	98.8	98.9	2.8	2.5/'89	VE	VS	
		(95.7- 99.9)	(96.0-99.9)					
Serion Immuno Tab HIV-1 (Serion Immunodiagnostica)	2	98.9	100.0	7.1	2.5/'90	LE	LS	1.2
		(96.9- 99.9)	(98.3-100.0)					
Genie HIV-1 (Genetic Systems)	4	99.5	99.1	1.1	3.5/'90	VE	VS	0.2
		(97.4-100.0)	(96.7-99.9)					
SimpliRed HIV-1 Ab (Agen Biomedical)	5	97.5	91.2	10.5	7.8/1.5/'91	VE	S	0.7
		(94.2-99.2)	(86.6-94.7)					
Healthtest HIV-1 Assay (Akers Research Corp.)	6	58.7	89.4	7.0	1.4/2.3/'92	VE	S	0.2
		(49.2-68.2)	(84.9-93.9)					
Entebe HIV Dipstick (Hepatika Laboratories)	6	97.0	99.1	N/A	N/A	E	VS	N/A
		(94.4-99.6)	(97.8-100.0)					

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Inter-reader variability %	Cost per test (US$) /year	Ease of performance	Suitability	Indeterminate results (%)
Abbott Retrocell HIV 1 (Abbott GmbH)	9	100.0	100.0	2.2	1.45/'94	VE	S	0.6
		(99.6 -100.0)	(99.7-100.0)					
PATH HIV Dipstick (PATH)	4	99.5	98.2	1.3	<1.5'91	E	VS	0.0
		(97.3-100.0)	(97.1.99.1)					
SUDS Murex HIV-1 Ab test (Murex Corporation)	5	100.0	75.1	22.9	4.5/'91	VE	S	11.7
		(98.5-100.0)	(69.3-80.9)					
Serodia-HIV (Fujirebio)	1	100.0	96.9	0.8	1.1/'88	E	S	0.0
		(97.6-100.0)	(93.4-99.0)					
For the detection of antibody to HIV-1/HIV-2								
SPAN COMBAIDS VISUAL (Span Diagnostics.)	8	96.5	100.0	0.8	0.4/'93	E	VS	0.0
		(93.5-99.5)	(98.3-100.0)					
SPAN COMBAIDS VISUAL (Span Diagnostics Ltd.)	10	100.0	88.0	6.3	0.5'94	E	S	3.2
		(99.6-100.0)	(84.5-91.5)					
ADVANCED QUALITY™ HIV Rapid Test (InTec Products)	16	99.7	99.8	0.8	0.80-0.90/'05	VE	VS	0.0
		(98.2 - 99.8)	(98.8 - 100)					
Retrocheck HIV WB / Core HIV 1&2 (Qualpro Diagnostics / Core Diagnostics)	16	100	99.1	0.4	0.70-0.85/"05	VE	VS	0.1
		(98.8 - 100)	(97.8 - 99.8)					
Test Pack HIV-1/HIV-2 Ab (Abbott)	2	100.0	95.9	1.4	4.8/'89	VE	VS	0.0
		(98.5-100.0)	(92.0-98.2)					
Immunocomb Bi-Spot (PBS Orgenics)	3	98.5	100.0	7.6	4.0/'90	VE	VS	0.9
		(96.3-99.6)	(98.1-100.0)					
HIV CHEK 1+2/HIVSPOT 1+2 (DuPont de Nemours)/ (Genelabs Diagnostics)	3	99.3	100.0	7.2	4.0/'90	E	VS	1.0
		(97.4-99.9)	(98.1-100.0)					
Recodot (Waldheim Pharmazeutika)	4	98.9	88.6	31.7	2.0/'90	LE	LS	12.3
		(97.0-99.8)	(82.2-93.3)					
Genie HIV-1 and HIV-2 (Genetic Systems)	4	99.3	99.5	11.8	3.5/'90	VE	VS	0.0
		(97.5-99.9)	(97.2-100.0)					
Clonatec rapid HIV 1-HIV 2 Ab (Clonatec)	5	98.9	99.5	15.9	4.3/'91	E	VS	0.4
		(96.8-99.8)	(97.2-99.8)					
Recobead LA Assay (Waldheim Pharmazeutika)	6	59.8	94.8	22.3	1.7/2.2/'91	VE	S	0.4
		(53.9 -65.7)	(91.7 - 97.9)					
Recombigen HIV-1/HIV-2 Rapid Test Device (Trinity Biotech plc)	7	100.0	94.5	11.4	4.0/'93	E	VS	2.8
		(98.7-100.0)	(91.2-97.8)					
MicroRed HIV-1/HIV-2 Ab Test (Agen Biomedical)	9	98.5	95.5	1.5	1.5/1.0/'94	VE	S	0.5
		(97.0-100.0)	(93.2-97.7)					

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Inter-reader variability %	Cost per test (US$) /year	Ease of performance	Suitability	Indeterminate results (%)
SimpliRed HIV-1 /HIV-2Ab Test (Agen Biomedical)	9	99.2	87.3	9.5	4.0/3.0/'94	VE	S	0.3
		(98.2 -100.0)	(83.7-90.9)					
HIV (Sav) 1&2 Rapid Sero Test (Diatech (Savyon) Diagnostica Ltd.)	10	97.7	96.7	5.1	1.9'94	VE	S	0.2
		(95.9 -99.5)	(94.8-98.6)					
ENTEBE HIV Dipstick (Hepatika Laboratories)	10	100.0	96.4	5.0	0.8'94	VE	VS	1.3
		(99.6 -100.0)	(94.4-98.4)					
Dipstick-HIV 1 + 2 (Pacific Biotech Co., Ltd.)	10	100.0	98.2	1.0	0.5'94	E	VS	0.3
		(99.6- 100.0)	(96.8 -99.6)					
DIA (Dot Immuno Assay) HIV 1 + 2 (Weiner Lab.)	10	99.6	99.4	0.8	<1.0'94	VE	VS	0.2
		(98.8-100.0)	(98.6-100.0)					
SERO-STRIP HIV-1/2 (Saliva Diagnostic Systems)	11	98.9	100.0	1.5	1.5'95	VE	VS	0.0
		(97.6 -100.0)	(99.7-100.0)					
RED-DOT HIV 1&2	11	100.0	94.9	9.5	2.9'94	VE	S	1.9
(Cal-Test Diagnostics Inc.)		(99.6 -100.0)	(92.5-97.3)					
HIVCHEK System 3 Test Kit	11	99.6	99.7	1.0	4.35'95	E	VS	0.2
(Ortho Diagnostic Systems)		(98.9 -100.0)	(99.1-100.0)					
AccuSpot HIV-1 and 2 (Specialty BioSystems Inc.)	11	100.0	86.3	10.8	2.5'95	VE	S	5.0
		(99.6 -100.0)	(82.5-90.1)					
SEROCARD HIV (Trinity Biotech plc)	11	100.0	97.9	1.5	4.0/'94	VE	VS	0.2
		(99.6 -100.0)	(96.4-99.1)					
EasiDot HIV/EasiSpot HIV (Nubenco Diagnostics)	11	95.3	71.3	23.7	N/A	VE	S	12.5
		(92.7-97.9)	(66.4-76.2)					
CAPILLUS HIV-1/HIV-2 (Trinity Biotech plc)	9	100.0	98.8	0.0	2.2/'94	VE	VS	0.0
		(99.6-100.0)	(97.6-100.0)					
HIV 1 & 2 DoubleCheck (Orgenics)	11	100	99.4	0.8	2.0/'96	VE	VS	0.2
		(99.6 -100.0)	(98.6-100.0)					
GENIE II HIV-1/HIV-2 (Bio-Rad)	14	100	99.7	0.7	2.55/'03	E	VS	0.2
		(97.7 - 100)	(98.1-100)					
Efoora HIV Rapid (Efoora Inc)	14	96.2	98.9	3.8	0.75-2.60/'03	VE	S	0.4
		(91.9 - 98.6)	(95.6-99.3)					
Hema · Strip(R) HIV 1/2 (Chembio Diagnostics Inc)	14	98.1	100.0	3.3	1.85-2.5/'03	VE	VS	0.0
		(94.5 - 99.6)	(98.8-100.0)					
DoubleCheckGold™ HIV 1&2 (Orgenics Ltd)	14	Lot A 99.4 (96.5 - 100.0)	Lot A 95.6 (92.6-97.6)	2.4	0.65-0.70/'03	VE	VS	Lot A 0.9 Lot B 2.0
		Lot B 100.0 (97.7 - 100.0)	Lot B 94.6 (91.4-96.9)					

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Inter-reader variability %	Cost per test (US$) /year	Ease of performance	Suitability	Indeterminate results (%)
DoubleCheckGold™ HIV 1&2 Whole Blood (Orgenics Ltd)	16	100	99.3	0.13	1.20-1.32/"05	VE	VS	0.0
		(98.8 - 100)	(98.1 - 99.9)					
InstantScreen™ HIV-1/2 (Gen 2) (Gaifar GmbH)	12	100.0	100.0	0.7	8.00-12.00/'01	VE	VS	0.0
		(90.0-100.0)	(97.0-100.0)					
CAPILLUS™ HIV-1/HIV-2 (Trinity Biotech PLC)	12	100.0	100.0	0.0	2.20/'01	VE	VS	0.0
		(95.5-100.0)	(97.9-100.0)					
SMLX Technologies Diagnostic test (SMLX Technologies)	13	62.7	74.8	22.5	NA	E	S	7.7
		(51.0-74.0)	(67.0-82.0)					
OraScreen HIV Rapid Test (Beacon Diagnostics Inc)	13	56.0	98.6	11.3	NA	E	S	4.1
		(44.0-68.0)	(95.0-100.0)					
Salivax™-HIV (ImmunoScience Inc)	13	79.4	96.0	8.5	NA	E	S	2.7
		(67.0-89.0)	(91.0-99.)					
Wellcozyme HIV 1+2 GACELISA (Murex Biotech Ltd)	13	100	99.0	NA	NA	LE	LS	0.0
		(95.2-100.0)	(95.0-100.0)					
Supplemental assays								
For the detection of antibody to HIV-1 or HIV-2								
New Lav-Blot-I (Sanofi Diagnostics Pasteur)	5	100.0	100.0	N/A	11.6/'91	E	S	30.6
		(98.1-100.0)	(96.8-100.0)					
Pepti-Lav 1-2 (Sanofi Diagnostics Pasteur)	4	99.3	100.0	N/A	21.5/'90	LE	S	0.7
		(96.4-99.9)	(98.1/100.0)					
RIBA HIV-1 (Chiron)	1	99.4	100.0	N/A	27.6/'88	E	S	N/A
		(96.6-100.0)	(97.9-100.0)					
HIV Western Blot Kit (Organon Teknika)	3	100.0	100.0	N/A	21.0/'90	LE	S	10.5
		(98.2-100.0)	(98.0-100.0					
Wespage HIV-1 Western blot Kit (Bio Genex)	6	100.0	100.0	N/A	21.6/'92	LE	VS	12.8
		(99.9-100.0)	(99.9-100.0)					
Wespage HIV-1 Western blot Kit II (Bio Genex)	7	100.0	100.0	N/A	17.7/'93	LE	S	12.4
		(98.5 -100.0)	(98.7 -100.0)					
CBC HIV-2 Western blot kit (Cambridge Biotech)	7	100.0	100.0	N/A	16/'93	LE	S	13.9
		(97.0-100.0)	(98.5-100.0)					
INNO-LIA HIV-1/HIV-2 Ab (Innogenetics)	2	100.0	100.0	NA	18.4/'89	LE	S	4.3
		(98.6-100.0)	(98.0-100.0)					
Ancoscreen (Ancos)	2	100.0	90.4	NA	10.8/21.5/'89	LE	LS	31.4
		(97.8-100.0)	(82.6-95.5)					

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Inter-reader variability %	Cost per test (US$) /year	Ease of performance	Suitability	Indeterminate results (%)
IFA anti-HIV-1 (Waldheim Pharmazeutika)	5	98.9	100.0	13.8	5.6/'91	LE	LS	0.7
		(96.9-99.8)	(98.3-100.0)					
IFA anti-HIV-2 (Waldheim Pharmazeutika)	5	98.7	100.0	11.0	6.0/'91	LE	LS	1.8
		(93.1-99.7)	(98.2-100.0)					
HIV-1 Western Blot Kit (Open Tray Procedure) (Bio Genex)	7	100.0	100.0	NA	17.7/'93	LE	S	6.7
		(98.5-100.0)	(98.7-100.0)					
Speedscreen HIV (British Bio-Technology)	4	100.0	66.4	NA	17.0/'90	LE	S	16.9
		(99.4-100.0)	(57.9-74.1)					

ANNEX 2 - CUMULATIVE LIST OF ASSAYS EVALUATED; CURRENTLY COMMERCIALLY AVAILABLE

The names (and manufacturers) of the assays evaluated to date under the WHO Test Kit Evaluation programme are listed in the table below. The number of the report in which each assay is covered is given, as well as sensitivity and specificity with 95% confidence intervals, δ values for HIV antibody-positive and antibody-negative specimen populations, cost per test, ease of performance and suitability for use in small blood collection centers.

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values [e]	Cost per test (US$) /year		nm[h]	Ease of performance	Suitability	Indeterminate results (%)
					Pos	Neg				
Enzyme immunoassays - Evaluations on serum/plasma										
For the detection of antibodies to HIV-1 and HIV-2										
UBI HIV 1/2 EIA (United Biomedical Inc.)	9	100.0	100.0	10.8	-3.2	1.0/'94	492	LE	LS	N/A
		(99.6-100.0)	(99.7-100.0)				492/620-690			
HIV EIA (Labsystems OY now Anilabsystems)	10	100	99.4	14.20	-3.85	0.6'95	450	LE	LS	N/A
		(99.6 -100.0)	(98.6 -100.0)							
Enzygnost Anti-HIV 1/2 Plus (Behringwerke AG now Dade Behring)	11	100.0	99.7	19.1	-6.6	1.0'95	450	LE	LS	0.0
		(99.6 -100.0)	(99.1 -100.0)				450/615-690			
Vironostika Uni-Form II plus O (Organon Teknika nv now bioMérieux)	11	100.0	100.0	17.2	-4.1	1.5'97	450	LE	LS	N/A
		(99.6 -100.0)	(99.7 -100.0)				450/620-700			

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Inter-reader variability %	Cost per test (US$) /year	Ease of performance	Suitability	Indeterminate results (%)
Rapid diagnostic tests - Evaluations on serum/plasma								
For the detection of antibody to HIV-1 and HIV-2								
Serodia-HIV-1/2 (Fujirebio)	8	100	100	6.3	2.8/'93	LE	S	0.0
		(98.5-100.0)	(98.5-100.0)					
Immunocomb II BiSpot HIV 1&2 (PBS Orgenics)	9	100.0	99.7	4.5	1.7/'94	VE	VS	0.2
		(99.6-100.0)	(99.1-100.0))					
HIV TRI-DOT (J. Mitra & Co. Ltd.)	11	99.6	99.7	3.2	2.0'96	VE	VS	0.2
		(98.9 -100.0)	(99.1 -100.0)					
BIONOR HIV-1&2 (Bionor A/S)	11	100.0	98.8	1.0	2.5/'95	VE	S	0.2
		(99.6 -100.0)	(97.6 -100.0)					
InstantCHEK™-HIV 1+2 (EY Laboratories Inc)	14	99.4	97.6	4.6	1.0'03	E	S	0.0
		(96.5 - 110.0)	(95.2 - 99.0)					
OraQuick HIV-1/2 Rapid HIV-1/2 (OraSure Technologies Inc)	14	98.1	100.0	2.4	NA	VE	VS	0.4
		(94.5 - 99.6)	(98.8 - 100)					

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Inter-reader variability %	Cost per test (US$) /year	Ease of perfor-mance	Suitability	Indeterminate results (%)
SD Bioline HIV 1/2 3.0 (Standard Diagnostics)	14	100.0	99.3	3.5	1.10/'03	VE	VS	0.0
		(97.7 - 100.0)	(97.6 - 99.9)					
HIV 1/2 STAT-PAK (Chembio Diagnostics Inc)	14	97.6	100.0	0.7	0.75-1.25/'03	VE	VS	0.0
		(93.6 - 99.3)	(98.8 - 100.0)					
HIV (1+2) Antibody (Colloidal Gold) (KHB Shanghai Kehua Bioengineering Co. Ltd)	14	100	100.0	0.2	1.50/'03	VE	VS	0.0
		(97.7 - 100.0	(98.8 - 100.0)					
GENEDIA(R) HIV 1/2 Rapid 3.0 (Green Cross Life Science Corp)	14	100	99.7	1.8	0.93-1.15/'03	VE	VS	0.0
		(97.7 - 100.0)	(98.1 - 100.0)					
HIV 1/2 Stat-Pak (Chembio Diagnostics Systems)	16	100	99.3	1.7	1.10-1.35/'05	VE	VS	0.0
		(98.8 - 100)	(98.1 - 99.9)					
HIV 1/2 Stat-Pak Dipstick (Chembio Diagnostic Systems)	16	99.4	100	0.3	0.80-0.95/'05	VE	VS	0.0
		(97.7 - 99.9)	(99.2 - 100)					
Alere Determine™ HIV-1/2 (Alere Medical Co. Ltd)	17	100	98.9	1.4	0.80-1.25/'11	VE	VS	0.0
		(99.1 - 100)	(97.8 - 99.6)					
HIV 1/2 STAT-PAK® (Chembio Diagnostic Systems, Inc.)	17	99.5	100	0.2	1.50/'12	VE	VS	0.0
		(98.3 - 99.9)	(99.4 - 100)					
HIV 1/2 STAT-PAK® Dipstick (Chembio Diagnostic Systems, Inc.)	17	100	99.7	0.1	0.85-.090/'11	VE	VS	0.0
		(99.1 – 100)	(98.9 - 99.9)					
One Step HIV 1/2 Whole Blood/Serum/Plasma Test (Guangzhou Wondfo Biotech Co., Ltd)	17	100	99.9	0.2	0.42-0.65/'12	VE	VS	0.1
		(99.1 - 100)	(99.2 - 100)					
Uni-Gold™ HIV (Trinity Biotech Manufacturing Ltd)	17	99.8	99.9	0.1	1.60-2.80/'12	VE	VS	0.0
		(98.7 - 100)	(99.2 - 100)					
Anti-human immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold) (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd)	17	100	98.5	0.1	0.35-0.60/'12	VE	VS	0
		(99.1 - 100)	(97.2 - 99.3)					
INSTI HIV-1/HIV-2 Antibody Test (bioLytical Laboratories)	17	100	99.7	0.0	1.50-2.50/'13	E	VS	0
		(99.1 - 100)	(98.9 - 100)					
Reveal Rapid HIV Antibody Test (MedMira Laboratories Inc)	17	99.8	99.9	1.6	2.40-4.00/'12	E	VS	0.3
		(98.6 - 100)	(99.2 - 100)					
ABON™ HIV 1/2/O Tri-Line HIV RDT (WBSP) (ABON Biopharm (Hangzhou) Co.,Ltd)	18	100	99.7	3.9	0.32/'13	VE	VS	0.1
		(99.2-100)	(98.9-100)					

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Inter-reader variability %	Cost per test (US$) /year	Ease of performance	Suitability	Indeterminate results (%)
First Response® HIV 1-2-0 Card test (Premier Medical Corporation Ltd)	18	99.8	98.9%	2.0	0.45-1.05/'13	VE	VS	0.0
		(99.2-100)	(97.8%-99.6%)					
SD BIOLINE HIV-1/2 3.0 (Standard Diagnostics, Inc.)	18	99.8	99.8	1.9	0.80-0.81/'13	VE	VS	0.0
		(98.8-100)	(99.2-100)					
Advanced Quality™ One Step Anti-HIV (1&2) Test (InTec PRODUCTS, INC)	18	100	100	0.0	0.35/'13	VE	VS	0.0
		(99.2-100)	(99.4-100)					
DoubleCheckGold Ultra HIV 1&2 (Orgenics Ltd.)	18	100	99.8	0.28	0.9-1.6/'13	VE	VS	0.0
		(99.1-100)	(99.2-100)					
Diagnostic kit for HIV(1+2) Antibody (Colloidal Gold) (Shanghai Kehua Bioengineering Co., Ltd.)	18	100	98.9	0.4	0.34-0.65/'13	VE	VS	0.1
		(99.2-100)	(97.8 – 99.6)					
DPP® HIV 1/2 Assay (Chembio Diagnostic Systems, Inc.	18	99.8	99.8	0.2	2.75/'13	VE	VS	0.0
		(98.8-100)	(99.2-100)					
VIKIA HIV 1/2 (bioMérieux SA)	18	99.4	99.9	0.2	1.15/'13	VE	VS	0.0
		(98.1-99.9)	(99.2-100)					
For the detection of antibody to HIV-1 and HIV-2 and HIV-1 p24 antigen								
Genedia® HIV Ag-Ab ELISA (Green Cross)	15	100	99.7	N/A	0.40-0.45/'04	LE	LS	0.0
		(97.7-100)	(98.1-100)					
Murex HIV Ag/Ab Combination (Abbott Diagnostics)	15	100	99.3	N/A	0.80-1.20/'04	LE	LS	0.0
		(97.7-100)	(97.6-99.9)					
Rapid diagnostic tests - Evaluations on whole blood specimens								
For the detection of antibody to HIV-1 and HIV-2								
Determine™ HIV-1/2 (Abbott Laboratories Dainabot Co. Ltd)	12	100.0	99.4	1.6	1.20/'01	VE	VS	0.0
		(95.5-100.0)	(96.7-100.0)					
ADVANCED QUALITY™ Rapid HIV Test (InTec Products Inc.)	12	98.8	100.0	2.0	0.80-1.20/'01	VE	VS	0.8
		(93.2-100.0)	(97.9-100.0)					
MedMira Rapid HIV Test (MedMira Laboratories Inc.)	12	100.0	97.6	14.4	3.00/'00	E	VS	0.8
		(95.5-100.0)	(94.1-99.6)					
First Response™ HIV-1/ HIV-2 WB (PMC Premier Medical Corporation)	12	100.0	98.8	0.4	1.15/'01	VE	VS	0.0
		(95.5-100)	(95.8-99.9)					
Uni-Gold™ HIV (Trinity Biotech PLC)	12	100.0	100.0	0.4	2.34/'01	VE	VS	0.0
		(95.5-100.0)	(97.9-100.0)					

Legend for Annexes 1 and 2

a: Operational characteristics of commercially available assays to detect antibodies to HIV-1 and/or HIV-2 in human sera:
Report 1-GPA/RES/BMR/89.4
Report 2-GPA/RES/BMR/90.1
Report 3-GPA/RES/BMR/91.1
Report 4-GPA/RES/DIA/91.6
Report 5-GPA/RES/DIA/92.8
Report 6-GPA/RES/DIA/93.4
Report 7-GPA/RES/DIA/93.6
Report 8-GPA/RES/DIA/94.4
Report 9,10-WHO/BLS/98.1
Report 11-WHO/BTS/99.1
Report 14-ISBN 92 4 159216 8
Report 15-ISBN 92 4 159237 0
Report 16-ISBN 978 92 4 159769 2
Report 16-ISBN 978 92 4 150647 2
Report 17-ISBN 978 92 4 150647 2

b,c,d: Sensitivity, specificity and 95% confidence intervals were calculated as described section 5.5.1 of this document.
e: d-values were calculated as described in previous documents , see above.
f: Inter-reader variability was calculated as described section 5.5.3 of this document.
g: Prices quoted are those in effect at the time of the evaluation.
h: The wavelength(s) of the spectrophotometer (single and/or double) is specified by the manufacturer.
i: Ease of performance is defined on table 4b.
j: Suitability for use in small laboratories is defined on table 5.
k: Indeterminate results.

ANNEX 3 - CUMULATIVE LIST OF ASSAY MANUFACTURERS' ADDRESSES

Name	Address
Abbott GmbH, Diagnostika	Max-Planck-Ring 2, 65205 Wiesbaden, Germany. Tel: +49 6122 58 16 23; Telex: 4182555; Fax: +49 6122 58 16 12
Abon Biopharm (Hangzhou) Co., Ltd.	198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, PR China Tel: + 86-571-8163 8128, Fax: + 86-571-8163 8030
Adaltis	10900 rue Hamon, Montréal (Québec), Canada H3M 3A2. Tel: +1 514 335 9922; Telex: 058-27642 IAF BCM MTL; Fax: +1 514 335 9919
Agen Biomedical Ltd	11 Durbell Street, P.O. Box 391, Acacia Ridge, Queensland 4110, Australia. Tel: +61 7 173 6266; Fax: +61 7 273 6224
Akers Laboratories Inc.	201 Grove Road, Thorofare, New Jersey 08086, USA. Tel: +1 609 848 8698; Fax: +1 609 848 0269
Ancos Denmark ApS	Tengslemarkvej 4, 4573, Hfjby, Denmark. Tel: +45 59 30 65 55; Telex: 42580 ancos dk; Fax: +45 59 30 60 45
Anilabsystems	Pulttitie 8, P. O. Box 8, 00881 Helsinki, Finland. Tel: +358 0 75821; Telex: 123569 Labsy sf; Fax: +358 0 7557610
Biochem Immunosystèmes	See Adaltis
Biochrom KG	Leonorenstrasse 2-6, 12247 Berlin, Germany. Tel: +49 30 77 99 06 00; Telex: 185 821 bio d; Fax: +49 30 771 0012
Bio Genex	4600 Norris Canyon Road, San Ramon, CA 94583, USA. Tel: +1 510 275 0550, Fax: +1 510 276 0580
BioMérieux S.A.,	69280 Marcy-l'Etoile, France. Tel: +33 78 87 20 00; Fax: +33 78 87 20 90
BIONOR A/S	P.O. Box 1868, N-3705 Skien, Norway Tel: +47 35 53 84 88; Fax: +47 35 53 71 30
Bio-Rad Laboratories	3, boulevard Raymond Poincaré, 92430 Marnes-la-Coquette, France Tel: +33 1 47 95 60 00; Fax: +33 1 47 41 91 33
Biotest AG	Landsteiner Str. 5, 63303 Dreieich, Germany. Tel: +49 6103 80 10; Telex: 4185429; Fax: +49 6103 80 11 30
Boehringer Mannheim GmbH	Sandhofer Strasse 116, 68298 Mannheim, Germany. Tel: +49 621 759 8838; Telex: 463193 bmd/462420 bmd; Fax: +49 621 759 8842
British Bio-Technology Ltd	Watlington Road, Cowley, Oxford OX4 5LY, England. Tel: +44 865 748747; Telex: 838083 BIOTEC G; Fax: +44 865 717598
Cal-Tech Diagnostics	1580 A. West San Bernardino Road, Covina, CA 91722, USA. Tel: +1 818 331 9763, (1 818) 571 6826, (1 818) 369 3755; Fax: +1 818 331 1882, (1 818) 280 4846; Telex: 9102409630 Cal-Tech UQ.
CAL-TEST DIAGNOSTICS	13760 Mountain Avenue, Chino, CA 91710, USA Tel: +1 909 902 0550, Fax: +1 909 902 0044
Cambridge Diagnostics Ireland Ltd.	See Trinity Biotech plc
Catalina Bio-Diagnostic Consulting, Inc.	5595 E. 7th Street, Long Beach, CA 90804, USA. Tel: +1 310 983 8111; Fax: +1 310 987 0670
Chembio Diagnostic Systems Inc.	3661 Horseblock Road, Medford, BY 11763, USA Tel: +1 631 924 1135; Fax: +1 631 924 6033
Chiron Corporation	4560 Horton Street, Emeryville, CA 94608-2916, USA. Tel: +1 510 655 8730; Fax +1 510 655 9910
Clonatec Diagnostics S.A.	60 rue de Wattignies, 75580 Paris Cedex 12, France. Tel: +33 1 43 42 43 88; Telex: 214044F; Fax: +33 1 43 40 48 86
Core Diagnostics	Aspect Court, 4 Temple Row, Birmingham B2 5HG, United Kingdom. Tel: + 44 121 609 4720; Fax: + 44 121 609 4721
Dade Behring Marburg GmbH	Postfach 1149, 35001 Marburg, Germany. Tel: +49 6421 39 4478; Fax: +49 6421 66064
Efoora Inc.	900 Asbury Drive, Buffalo Grove, Illinois, USA 60089 Tel: +1 847 634 6400; Fax: +1 847 634 0476
EY Laboratories, Inc.	P.O. Box 1787, 107 N. Amphlett Blvd., San Mateo, CA 94401, USA Tel: +1 650 342 3296; Fax: +1 650 342

Name	Address
Fujirebio Inc.	19th floor, Shinjuku Daiichi Seimei Building, 7-1 Nishi-Shinjuku 2-Chome, Shinjuku-Ku, Tokyo 163-07, Japan. Tel: +81 3 3348 0947; Telex: J 28612; Fax: +81 3 3342 6220
Genelabs Diagnostics	See MP Biomedicals
Genetic Systems Corporation	3005 First Avenue, Seattle, WA 98121, USA. Tel: +1 206 728 4900; Telex: 532050 Genetic Systems; Fax: +1 206 728 495
Green Cross Life Science Corporation	227-3, Gugal-li, Giheung-eup, Yongin-shi, Kyonggi-do, Korea Tel: +82 31 260 9300; Fax: +82 31 260 9491
Heber Biotec S.A.	Calle 8, No. 306, Miramar, Havana, Cuba. Tel: +537 291187; Telex: 511269 cimex cu; Fax: +537 222261
Hepatika Laboratories	Yayasan Hati Sehat, Jalan Bung Hatta 3A, Mataram, Lombok, Indonesia, under license from the Concept Foundation Program for Appropriate Technology in Health (PATH), Seattle, WA, USA. Tel: +62 3 64 31 662; Fax: +62 3 64 35642
Hoffmann-La Roche F. AG	Grenzacherstr 124, 4058 Basel, Switzerland. Tel: +41 61 688 55 55; Fax: +41 61 681 98 67
Human GmbH	Max-Planck-Ring 21, D 65205, Wiesbaden, Germany. Tel: +49 6122 99880; Fax: +49 6122 9988 100/99
Immuno-Chemical Laboratories.	See Pacific Biotech Co.Ltd.
Immuno Diagnostics, Inc.	85 Great Arrow Avenue., Buffalo, New York 14216, USA. Tel: +1 716 873 9400; Fax: +1 716 876 7919
InTec Products Inc.	332 Xinguang Road, Xinyang Industry Area, Haicang, Xiamen, 361022 P R China. Tel: +86 5926 807 188; Fax: +86 592 651 9161
Innogenetics S.A.	Technologiepark 6, 9052 Ghent, Belgium Tel: +32 9 329 1329; Fax: +32 9 329 1911
J. Mitra & Co. Ltd	A-180, Okhla Industrial Area, Phase-1, New Delhi-110 020, India Tel: +91 11 681 8971, +91 11 681 8973, +91 11 681 3995, +91 11 681 3989; Fax: +91 11 681 0945, +91 11 681 8970
Johnson & Johnson International	Roissy Pole B.P. 10784, 1, Place de Londres, F-95727 Roissy CDG Cedex, France. Tel: +33 1 48 62 08 75; Fax: +33 1 48 62 00 54
KHB Shanghai Kehua Bio-engineering Co. Ltd.	1189 N Qinzhou Road, Shanghai, 200233, People's Republic of China Tel: +86 21 64851188 +86 21 64853370 +86 21 8203370; Fax: +86 21 64854051
Labsystems OY	See Anilabsystems
Lupin Laboratories Ltd.	159, CST Road, Kalina, Santacruz (E), Mumbai 400098, India. Tel: +91 22 611 3391; Fax: +91 22 611 4008
Murex Biotech Limited	Central Road, Temple Hill, Dartford, Kent DA1 5LR, England. Tel: +44 1322 27 77 11; Telex MUREX G 896113; Fax: +44 1322 27 32 88
MP Biomedicals	Halle de Frêt, P. O. Box 1015, 1215 Geneva 15 Airport, Switzerland. Tel: +41 22 788 1908; Fax +41 22 788 1986
Nubenco Enterprises, Inc.	One Kalisa Way, Suite 207 Paramus, New Jersey 07652-3508, USA. Tel: +1 201 967 9000; Fax +1 201 967 9444
OraSure Technologies, Inc.	150 Webster Street, Bethlehem, PA 18015, USA Tel: +1 610 882 1820
Organon Teknika N.V.	See bioMérieux
Orgenics Ltd.	P.O. Box 360, Yavne 70650, Israel Tel: +972 8 9429212; Fax: +972 8 9438758
Ortho Diagnostic Systems Inc.,	US Route 202, Raritan, N.J. 08869, USA. Tel: +1 201 218 1300; Telex: 833 425; Fax: +1 201 218 8582
Pacific Biotech Co., Ltd.	6 Ladprao 110 (Sonthiwattana 3), Ladprao Road, Bangkapi, Bangkok 10310, Thailand. Tel: +66 2 530 4608 or 530 2754; Fax: +66 2 530 4619
PBS Orgenics	Parc de l'Innovation, B.P. 209, 67405 Illkvich Cedex, Strasbourg, France. Tel: +33 88 67 08 30; Telex: 890665; Fax: +33 88 67 38 61 North Industrial Zone, P. O. Box 360, Yavne, 70650 Israel. Tel: +972 8 43 87 52-2; Fax: +972 8 43 87 58
Premier Medical Corporation Ltd.	32-35, Shree Ganesh Indl. Estate, Kachigam, Nani Daman, Daman 396215. India Tel: + 91-260-3298483-3266800, Fax: + 91-260-2242411

Name	Address
Program for Appropriate Technology in Health (PATH)	4 Nickerson Street, Seattle, WA 98109, USA. Tel: +1 206 285 3500; Telex: 47 100 49 PATH UI; Fax: +1 206 285 6619
Qualpro Diagnostics	Plot Nos. 88/89, Phase II C, Verna Industrial Estate, Verna, Goa, 403 722, India. Tel: + 91 832 2783140; Fax: + 91 832 2783139
Saliva Diagnostic Systems (SDS), SDS International Ltd.	11 Sovereign Close, Sovereign Court, London E1)HW, UK Tel: +44 171 415 0550; (Fax: +44 171 415 0553 Saliva Diagnostic Systems, (SDS), 11719 NE 95th Street, Vancouver, WA 98682, USA Tel: +1 360 696 4800; Fax: +1 360 254 7942
Sanofi Diagnostics Pasteur	See Bio-Rad Laboratories
Savyon Diagnostics, LTD	Kiryat Minrav, 3 Habosem, Ashdod 77101, Israel. 5870 Pacific Center Boulevard, Suite A, SanDiego,California 92121 USA. Tel: +1 619 457 9927; Fax: +1 619 457 2425
Serion Immunodiagnostica	Bronnbachergasse 18a, 8700 Würzburg, Germany. Tel: +49 931 14079; Telex: 68480 virion d; Fax: +49 931 52650
Sero-Immuno Diagnostics	P.O. Box 616, 2177-J Flintstone Drive, Tucker, GA 30084, USA. Tel: +1 404 496 1370; Telex: 750747 SERO UD; Fax: +1 404 938 7189
Shanghai Kehua Bio-engineering Co. Ltd.	1189 North Qinzhou Road, 200233 Shanghai, P.R. China Tel: + 86-21-64850088; Fax: + 86-21-64854051
Sorin Biomedica SpA	Divisione Diagnostici, 13040 Saluggia (Vercelli), Italy. Tel: +39 161 487243; Telex: 200064 I SORIN; Fax +39 161 487672
Span Diagnostics PVT-Ltd	173-B New Industrial Estate UDHNA-394210 (SURAT), India. Tel: +91 261 67 71 43; Telex: 0188284 span in; Fax: +91 261 66 57 57
Specialty BioSystems, Inc.	N/A
Standard Diagnostics, Inc.	575-34 Pajang-dong, Jangan-ku, Suwon-si, Kyonggi-do, Korea 440-290 Tel: +82 31 258 2994; Fax: +82 31 258 2995
Trinity Biotech plc,	IDA Business Park, Bray, Co. Wicklow, Ireland. Tel: +353 1276 9800; Fax: +353 1276 9888
United Biomedical Inc.	25, Davids Drive, Hauppauge, NY 11788, USA. Tel: +1 516 273 2828; Fax: +1 516 273 1717
Waldheim Pharmazeutika GmbH	Boltzmanngasse 11, 1091 Vienna, Austria. Tel: +43 1 319 1456; Telex: 116487 wamed a; Fax: +43 1 319 1456-44;
Wiener Laboratories	Riobama 2944, 2000 Rosario, Argentina. Tel: +54 41 39 01 73/8; Fax: +54 41 37 13 77
Wellcome Diagnostics	See Abbott GmbH Diagnostika Tel: +972 8 562920; Fax +972 8 563258

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This report was prepared by Dr Willy Urassa with the assistance of Ms Anita Sands, under the supervision of Ms Irena Prat.

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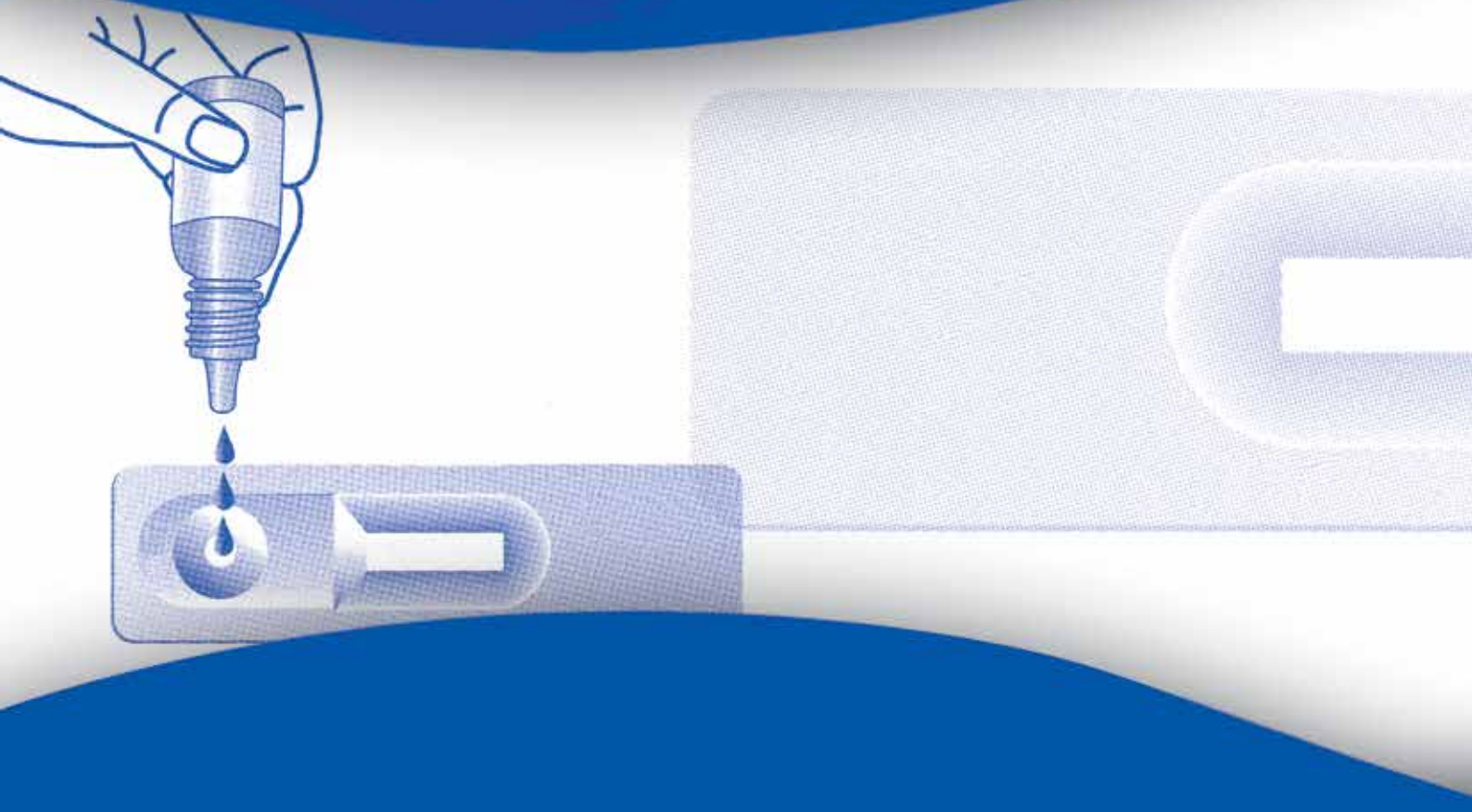

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