HIV ASSAYS:
OPERATIONAL CHARACTERISTICS
(PHASE 1)

REPORT 14
SIMPLE/RAPID TESTS

World Health
Organization

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HIV ASSAYS: OPERATIONAL CHARACTERISTICS (*Phase I*)
REPORT 14
SIMPLE/RAPID

CONTENTS

1. Summary

Report 14 summarises the assessment of the major operational characteristics of commercially available assays to detect antibodies to HIV1 and HIV 2. The data that is presented was obtained in the Phase I evaluation of the following 10 simple/rapid assays carried out between December 2001 and August 2003. The kits are separated, at random, into two groups to allow ease of presentation and perusal of the extensive data.

Group 1: Tables 1 - 6

- *Instant*CHEK™ HIV 1+2 (EY Laboratories Inc)
- GENIE II HIV-1/HIV-2 (Bio-Rad)
- Efoora HIV Rapid (Efoora Inc.)
- OraQuick HIV-1/2 Rapid HIV-1/2 antibody (OraSure Technologies Inc)
- SD Bioline HIV 1/2 3.0 (Standard Diagnostics Inc)[1]

Group 2: Tables 8 – 12

- Hema • Strip® HIV 1/2 (Chembio Diagnostics)
- HIV 1/2 STAT-PAK (Chembio Diagnostics)
- HIV (1+2) Antibody (Colloidal Gold) (KHB Shanghai Kehua Bio-engineering Co Ltd)
- GENEDIA® HIV 1/2 Rapid 3.0 (Green Cross Life Science Corp.)
- DoubleCheckGold™ HIV 1&2 (Orgenics Ltd)

Section 2 of this report provides background information on the series. 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 assay evaluations themselves 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, the World Health Organization (WHO) Global Programme on AIDS (GPA), conscious of the need to advise Member States on the laboratory diagnosis of HIV, initiated a programme to provide objective assessments of commercially available assays for detecting antibody to both types of HIV, HIV-1 and HIV-2. The laboratory aspects of this continuing programme is carried out by the WHO Collaborating Centre for HIV/AIDS Diagnostic and Laboratory Support in the Department of Microbiology, Institute of Tropical Medicine, Antwerp, Belgium and coordinated by the Department of Essential Health Technologies of WHO in conjunction with UNAIDS.

[1] This kit is also available under the name of Hexagon HIV from Human GmbH, Germany under an Original Equipment Manufacturer (OEM) agreement between Human GmbH and Standard Diagnostics.

The assessments focus on the operational characteristics of these assays, such as ease of performance and their sensitivity and specificity on a panel of well-characterized sera of diverse geographical origins, and indicate their suitability for use in small laboratories, eg many blood-collection centres in developing countries. Additionally the sensitivity of the assays on 8 seroconversion panels is assessed.

The assessments are published in the form of reports which are intended for use by health policy-makers, directors of blood banks, and managers of national AIDS prevention programmes**.** They may be used in conjunction with consideration of other factors, such as experience with a given test, availability, cost, service and trouble-shooting provided locally by manufacturers, etc., to help select HIV antibody assays appropriate to local needs.

The first report was issued in March 1989, and subsequent reports have been issued on a regular basis; details are given in Annexes 1 and 2. Recent reports are also published on the WHO website and can be found on the Department of Essential Health Technologies site as follows: http://www.who.int/eht .
Further copies of this and earlier reports are available by written request to the Department of Essential Health Technologies, World Health Organization, 1211 Geneva 27, Switzerland or by e-mail to diagnostics@who.int . Reports containing information of assays which are currently no longer available are taken out of distribution.

3. Laboratory diagnosis of HIV infection

3.1 A brief overview

The diagnosis of HIV infection is usually made on the basis of the detection of antibodies to HIV. Serological tests for detecting antibodies to HIV are generally classified as **screening tests** (sometimes referred to as **initial** tests) or **confirmatory tests** (sometimes referred to as **supplemental** tests). Initial tests provide the presumptive identification of antibody-positive specimens, and supplemental tests are used to confirm whether specimens found reactive with a particular screening test contain antibodies specific to HIV.

The most widely used screening tests are **ELISAs** as they are the most appropriate for screening large numbers of specimens on a daily basis, e.g. blood donations. The earliest assays used purified HIV lysates (1st generation), and often lacked sensitivity and specificity. Improved assays based on recombinant proteins and/or synthetic peptides, which also enabled the production of combined HIV-1/HIV-2 assays became rapidly available (2nd generation). The so-called 3rd generation or sandwich ELISAs, which use labeled antigen as conjugate, are extremely sensitive and have reduced the window period considerably. To further reduce the window period, enhanced ELISA assays have been developed that detect both HIV antibody and antigen (4th generation assays).

A variety of simple, instrument-free initial tests are now available, including agglutination, immunofiltration (flow through tests), immunochromatographic (lateral flow tests) and dipstick tests. Specimens and reagents are often added by means of a dropper to the test device. A positive result is indicated by the appearance of a coloured dot or line, or shows an agglutination pattern. Most of these tests can be performed in less than 20 minutes, and are therefore called **simple/rapid (S/R) assays**. Other simple tests are less rapid and their procedures require 30 minutes to 2 hours. The results are read visually. In general, these tests

are most suitable for use in testing and counseling centres and laboratories that have limited facilities and process low numbers of specimens daily.

When a single screening assay is used for testing in a population with a very low prevalence of HIV infection, the probability that a person is infected when a positive test result is obtained (i.e., the positive predictive value) is very low, since the majority of people with positive results are not infected.

This problem occurs even when a test with high specificity is used. Accuracy can be improved if a second supplemental test is used to retest all those samples found positive by the first test. Those found negative by the test are considered negative for antibodies to HIV.

Until recently, the most commonly used confirmatory test was the Western blot (WB). However, its use has proven to be very expensive and can, under some conditions, produce a relatively large number of indeterminate results. Similar assays, generically called Line immuno-assays (LIAs), based on recombinant proteins and/or synthetic peptides capable of detecting antibodies to specific HIV-1 and/or HIV-2 proteins, have been developed. Examples of this technology include the INNOLIA, Pepti-Lav, and RIBA assays. In general, these assays produce fewer indeterminate results as compared to WB, but are equally expensive. Studies have shown that combinations of ELISAs or S/R assays can provide results as reliable as the WB at a much lower cost. WHO and UNAIDS therefore recommend that countries consider testing strategies which use a combination of ELISAs and/or S/R assays rather than ELISA/WB for HIV antibody detection.

3.2 HIV testing strategies

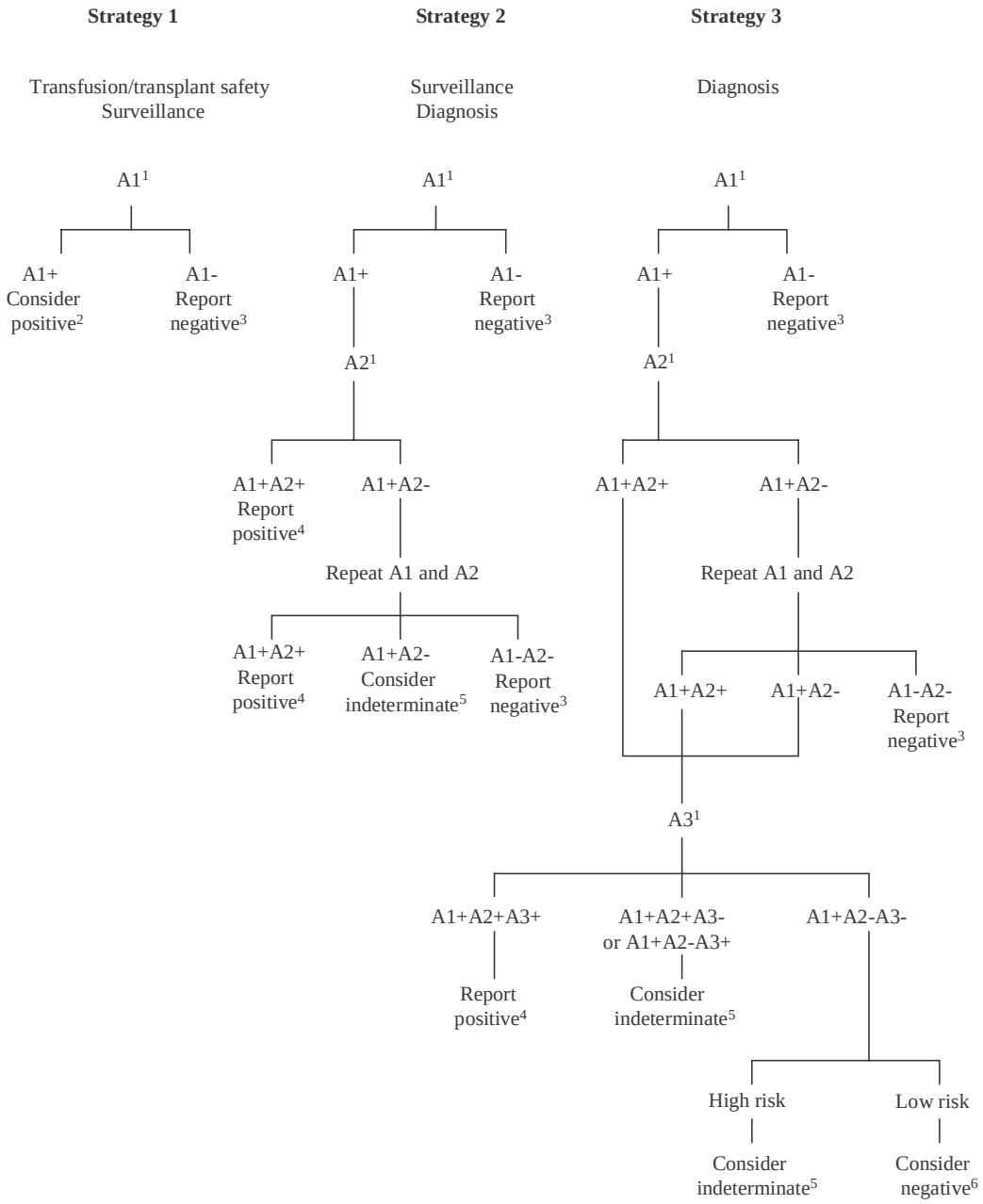
UNAIDS and WHO recommend three testing strategies, which have been recently updated, to maximize accuracy while minimizing cost. Which strategy is most appropriate will depend on the objective of the test and the prevalence of HIV in the population, as shown in *Table A* and *Figure 1*.

Table A. UNAIDS and WHO recommendations for HIV testing strategies according to test objective and prevalence of infection in the sample population

Objective of testing		Prevalences of infection	Testing strategy
Transfusion/transplant safety		All prevalences	I
Surveillance		>10%	I
		≤10%	II
Diagnosis	Clinical signs/ symptoms of HIV infection[2]	>30%	I
		≤30%	II
	Asymptomatic	>10%	II
		≤10%	III

[2] World Health Organization. Interim proposal for a WHO staging system for HIV infection and disease. Weekly Epidemiological Record 1990, 65:221-228.

Figure 1: Schematic representation of the UNAIDS and WHO HIV testing strategies.



[1] Assay A1, A2, A3 represent 3 different assays.
[2] Such a result is not adequate for diagnostic purposes; use strategies II or III. Whatever the final diagnosis, donations which were initially reactive should not be used for transfusions or transplants.
[3] Report: result may be reported.
[4] For newly diagnosed individuals, a positive result should be confirmed on a second sample.
[5] Testing should be repeated on a second sample taken after 14 days.
[6] Result is considered negative in the absence of any risk of HIV infection.

Strategy I

Each serum/plasma specimen is tested with one ELISA or simple/rapid assay. Serum that is reactive is considered HIV antibody positive. Serum that is non-reactive is considered HIV antibody negative.

Transfusion/transplant safety

When the objective is safeguarding the blood supply, the test selected for this strategy should preferably be a **combined HIV-1/HIV-2 assay** which is **highly sensitive**. Units of donated blood yielding **reactive** or **indeterminate** test results must be considered as probably infected with HIV and should be discarded according to universal safety instructions.[3] Strategy I is meant for testing the donations, but **must not be used for notifying donors of a positive test result**. If a blood or tissue donor is to be notified of a positive test result, testing strategies II or III for diagnosis must be applied (*Table A, Figure 1*). In situations where the blood centre does not have the capacity or facilities for further testing, the donor should be referred to their physician or to appropriate referral health services. Whatever the final diagnosis, donations which were initially reactive should not be used for transfusion or transplants. Several studies have shown that careful selection of donors is more efficient than HIV antigen testing in minimizing the risk of transfusion related infections. To prevent further spread of HIV, it is recommended that systems are put in place to notify donors of their HIV status. Such systems should include referral for counseling and confirmation of HIV status where these facilities are not available on site.

Surveillance

Sensitivity is less crucial for surveillance purposes; however, for this and the above application the assay chosen should have a specificity of at least 98%. It is recommended that the same assay(s) be used over time to monitor fluctuations in HIV prevalence.

Diagnosis (see below)

Strategy II

All serum/plasma is first tested with one ELISA or simple/rapid assay. Any serum found reactive on the first assay is retested with a second ELISA or simple/rapid assay based on a different antigen preparation and/or different test principle (e.g., indirect versus competitive). Serum that is reactive on both tests is considered HIV antibody positive. Serum that is non-reactive on the first test is considered HIV antibody negative. Any serum that is reactive on the first test but non-reactive on the second test, should be retested with the two assays. Concordant results after repeat testing will indicate a positive or negative result. If the results of the two assays remain discordant the serum is considered indeterminate.

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[3] See WHO AIDS SERIES 9, *Biosafety guidelines for diagnostic and research laboratories working with HIV*.

Surveillance

When testing low HIV prevalence populations for surveillance purposes, even if one uses a test of high specificity, the PPV will be very low. Therefore, an additional test is necessary in order not to overestimate the HIV prevalence in such regions. All samples remaining discordant after repeat testing with the two assays are considered indeterminate; unlike for diagnosis, no further testing is needed. The indeterminate results should be reported and analysed separately in the annual surveillance overviews.

Diagnosis (see below)

Strategy III

As in strategy II, all serum is first tested with one ELISA or simple/rapid assay, and any reactive samples are retested using a different assay. Serum that is non-reactive on the first test is considered HIV antibody negative. Serum that is reactive in the first test but non-reactive in the second assay, should be repeated with both tests. Strategy III, however, requires a third test if serum is found reactive on the second assay or is reactive on the repeated first assay. The three tests in this strategy should be based on different antigen preparations and/or different test principles. Serum reactive on all three tests is considered HIV antibody positive. Serum that remains discordant in the second assay, or is reactive in
the first and second tests but non-reactive in the third test, is considered to be indeterminate. Serum that is reactive on the first assay and non-reactive on the second and third assays is considered indeterminate for individuals who may have been exposed to HIV in the last three months and negative for those who have not been exposed to any risk for HIV infection.

Diagnosis (Strategies I, II and III)

Newly diagnosed HIV seropositives

An additional blood sample should be obtained and tested from all persons newly diagnosed as seropositive on the basis of their first sample. This will help eliminate any possible technical or clerical error.

Uncertain diagnosis: indeterminate result

Serum from people with clinical signs meeting the WHO criteria[4], stages III or IV, may have an indeterminate result due to a decrease in antibodies. In this case serum does not normally need to be retested.

For diagnosis of HIV infection in asymptomatic individuals with an indeterminate result, a second blood sample should be obtained after a minimum of two weeks following the first sample and should be tested using the appropriate strategy. If the second serum sample also produces an indeterminate result, it should be tested with a confirmatory assay. However, if this result is also indeterminate longer follow-up may be required (3, 6, 12 months). If the

4 See footnote [2] on page 3

results remain indeterminate after 1 year, the person is considered to be HIV antibody negative.

General remarks about Strategies I-II-III

Strategy I can only be used to confirm the clinical diagnosis of individuals meeting the WHO criteria of stage III or IV of HIV infection and when the HIV prevalence in the sample population is above 30% (e.g. a sample of patients from a tuberculosis ward). In lower prevalence populations, strategy II should be used to diagnose persons with the above-mentioned clinical symptoms.

In the selection of HIV antibody tests for use in strategies II and III, the first test should have the highest sensitivity, whereas the second and third tests should have a similar or higher specificity than the first. As tests have continued to increase in quality, it is now frequently found, however, that the tests employed have both high sensitivity and specificity values. The number of initial discordant, indeterminate results should not exceed 5%. If it does, quality assurance procedures should be checked and/or a new test combination should be adopted.

3.3 Follow up after diagnosis

A number of other assays have been introduced in recent years which assist in the establishment of the diagnosis of HIV infection and may also be used to monitor the progress of the infection and the response to therapy. These include assays that detect virus particles e.g. the HIV p24 antigen ELISA, or the presence of HIV viral nucleic acid sequences (RNA or DNA) by means of nucleic acid amplification techniques. The first assays capable of detecting free circulating HIV particles were the HIV p24 antigen ELISAs.

Circulating p24 antigen 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.

New technologies based on the amplification of viral nucleic acids, such as PCR and NASBA or amplification of the probe binding signal as in branched-DNA tests, have made it possible to detect minute amounts of viral material. In theory, as little as a single viral genome can be detected - the detection limit for most assays is around 300 copies/ml. In practice the technique can have limited specificity. These sensitive procedures are well suited to early diagnosis of mother-to-child transmission and for monitoring the viral load of patients who are taking antiretroviral therapy. Although prices have recently decreased, the tests remain expensive (US$20-30), need sophisticated equipment, rigorous laboratory conditions and highly trained staff, and are still largely a research tool. Many of these tests need further refinement since not all HIV-1 subtypes are equally well detected, nor is HIV-2. Therefore, it would be unwise to base a diagnosis of HIV infection on a single positive PCR test result, in the absence of any other detectable marker.

3.4 Quality assurance

All laboratories and testing sites carrying out HIV tests, should have a well-functioning quality management programme. It is most important that quality control and assurance procedures be stringently complied with so as to maximize the accuracy of the laboratory results. Procedures for detecting both (technical) laboratory and clerical errors must be included in all protocols. For example, procedures that guarantee the correct identification of initially reactive units of donated blood, which must be discarded, are essential to the maintenance of a safe blood supply. It is recommended that laboratories submit to an external quality assessment at least once a year, but preferably more regularly.

3.5 Safety

The testing of all clinical specimens should be performed in such a manner as to minimize occupational risk. Guidelines for good laboratory practice have been developed that, if followed, will ensure safety and keep laboratory accidents to a minimum. For further details see the *Laboratory Biosafety Manual, second edition*, World Health Organization, Geneva, 1993 (ISBN 92 4 154450 3) and the Communicable Diseases Surveillance and Response section of the WHO website, www.who.int/csr , where information on laboratory biosafety and transport of infectious substances may be found.

4. Assay selection

In addition to the requirements indicated in section 3, there are various operational factors that influence the selection of assays, including:

- laboratory infrastructure
- access to a reference laboratory
- desired characteristics of the test (antigen, antibody)
- simplicity of test procedure
- equipment necessary to perform the test
- performance time
- shelf-life of the reagents
- price
- storage conditions
- technical skill of laboratory staff
- laboratory logistics (continuous supply of kits, stability of electrical source, maintenance of equipment, spare parts, availability of service, etc.).

For use in small blood-collection centres and hospitals in developing countries, assays are needed that have the following specific characteristics:

- high level of sensitivity and specificity
- long shelf life at ambient temperatures
- reasonable cost (generally not exceeding the per-test cost of the most readily available ELISA)
- ease of performance
- rapidity of performance

The WHO evaluations take these factors into account in assessing suitability for use in small centres. They show that some of the S/R assays now available, which need no or relatively simple equipment and can be read visually, are more suitable than ELISAs in small centres where there are only a limited number of sera to be screened (< 90 sera at a time). For testing large series of sera, ELISAs are still the most rapid and most appropriate assay type. However, they require expensive equipment which has to be well maintained.

The aim of the HIV assay assessment programme is to supply managers who will decide which tests to use, and the potential users of the tests, with enough comparative data to apply their own criteria and choose the best tests for their particular circumstances. The choice of the most appropriate HIV tests also depends on the HIV variants 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 is prevalent, a test capable of detecting antibodies to HIV-2 as well as HIV-1 will be required. Therefore, test combinations should always be evaluated in the context in which they will be used before large-scale implementation.

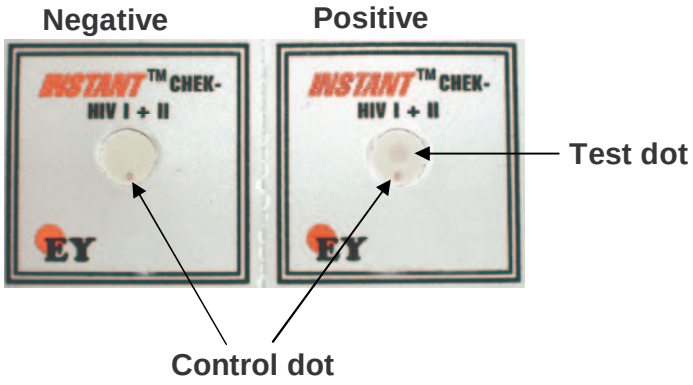
An HIV test kit bulk-purchase programme has been established by WHO in collaboration with UNAIDS in order to provide national AIDS control programmes with tests giving the most accurate results at the lowest possible cost. This list of HIV test kits is updated annually. The procurement procedure is outlined in Annex 4. Tests other than those bulk-purchased through WHO, but meeting the minimum standards in terms of sensitivity and specificity, are also suitable for use with the testing strategies shown in *Table A* and *Figure 1*.

5. Materials and methods of assessment

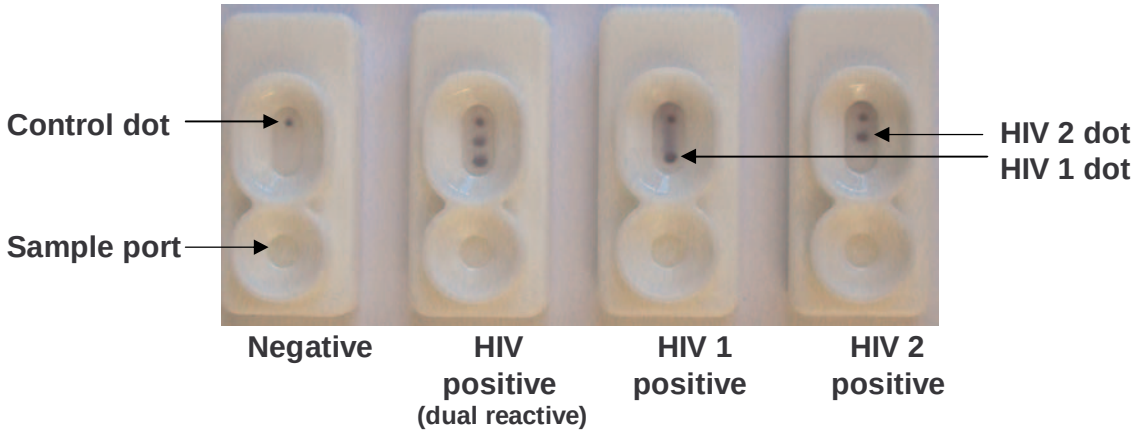
5.1 Assay kits

Kits for the 10 commercial assays listed in section 1 were kindly provided free of charge to WHO by the manufacturers for these 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.

***Instant*CHEK™-HIV 1+2 (EY Laboratories Inc)**
A Rapid Affinity Immunochromatographic Assay (AIA) for the detection of antibodies to the Human Immunodeficiency Virus Type 1 and Type 2

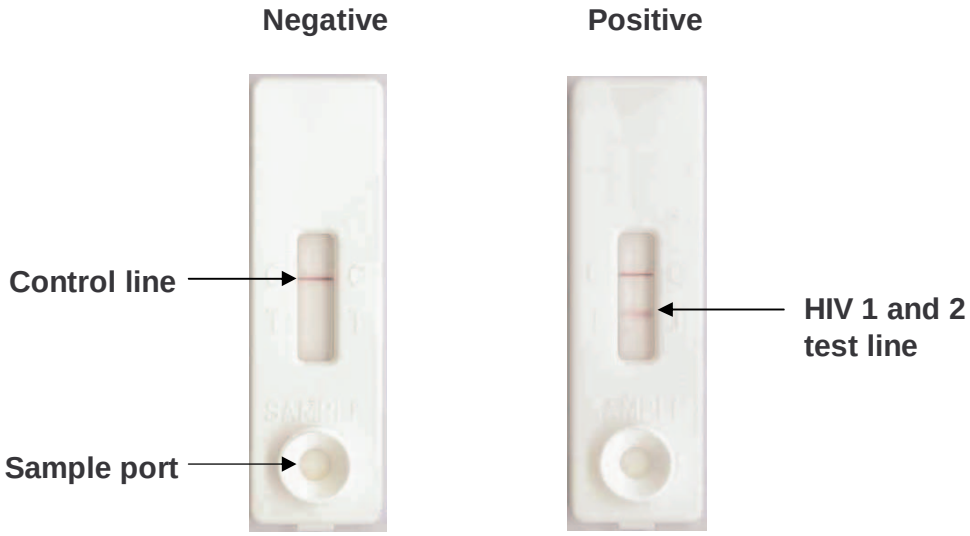


GENIE II HIV-1/HIV-2 (Bio-Rad)
A rapid enzyme immunoassay for the qualitative detection of antibodies to human immunodeficiency virus types 1 and 2 in human serum or plasma.

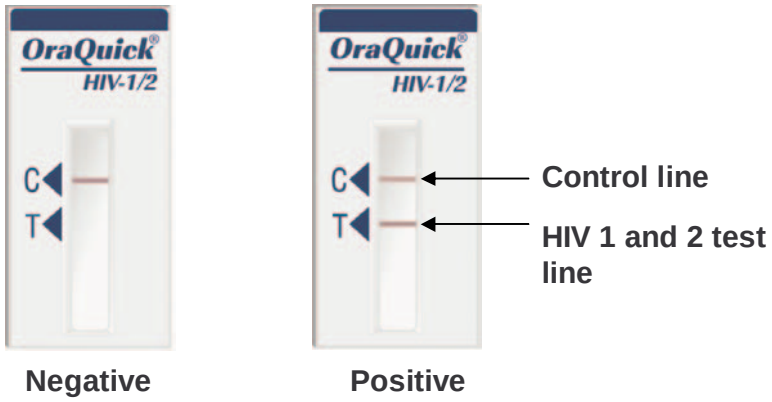


Efoora HIV Rapid (Efoora Inc.)

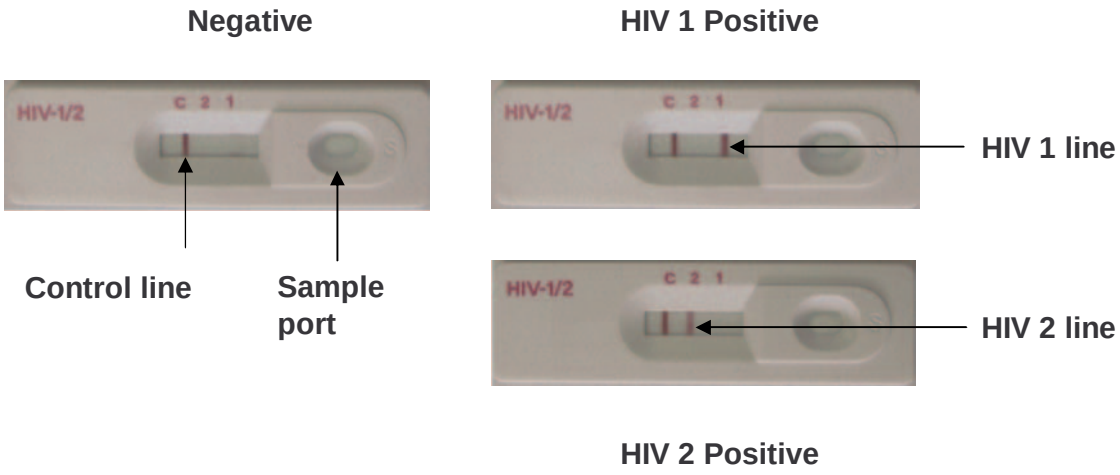
A rapid test for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood.



OraQuick HIV-1/2 Rapid HIV-1/2 antibody (OraSure Technologies Inc)
A qualitative assay for the detection of antibodies to HIV-1 and HIV-2 in human oral fluid, whole blood, serum or plasma.

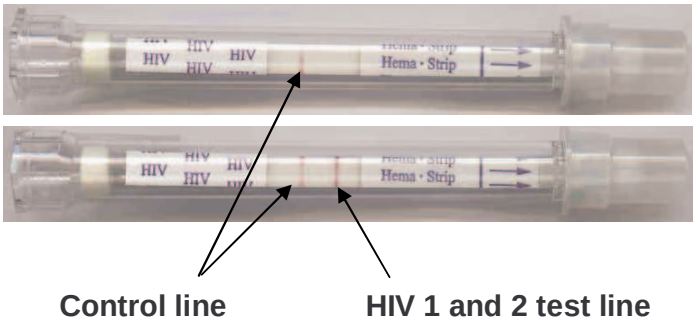


SD Bioline HIV 1/2 3.0 (Standard Diagnostics Inc)
One step, rapid, immunochromatographic test for the detection of anti-HIV 1/2 in human serum, plasma or whole blood.



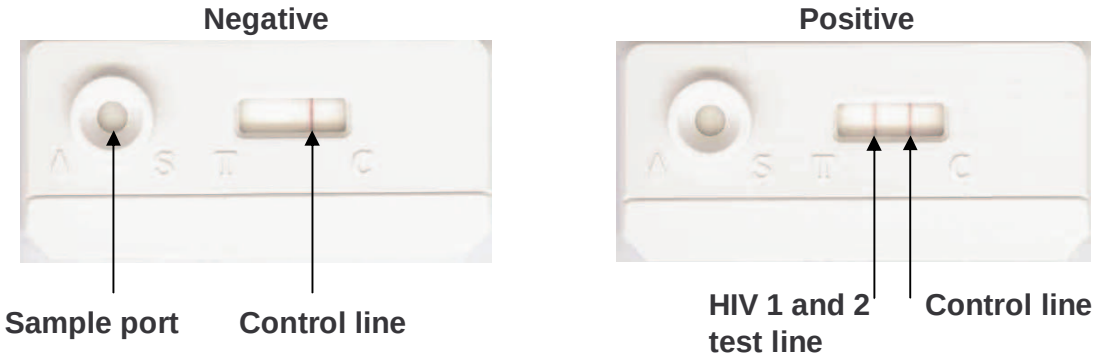
Hema • Strip(R) HIV 1/2 (Chembio Diagnostics)

A rapid test for the detection of antibodies to Human Immunodeficiency Virus (HIV-1 and HIV-2) in whole blood, serum or plasma.

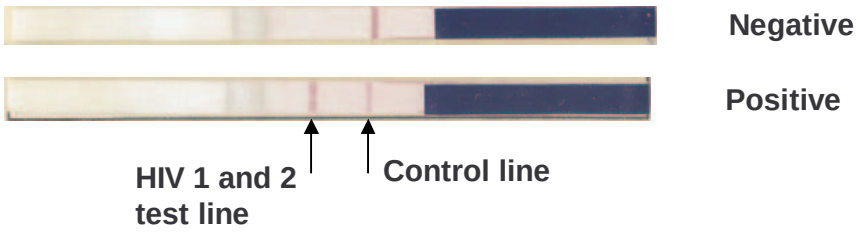


HIV 1/2 STAT-PAK (Chembio Diagnostics)

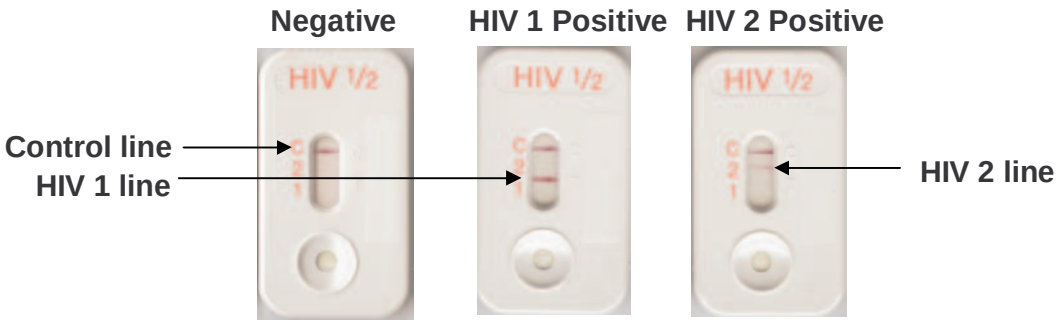
A qualitative screening test kit for the detection of antibodies to HIV1/2 in human sera, plasma or whole blood.



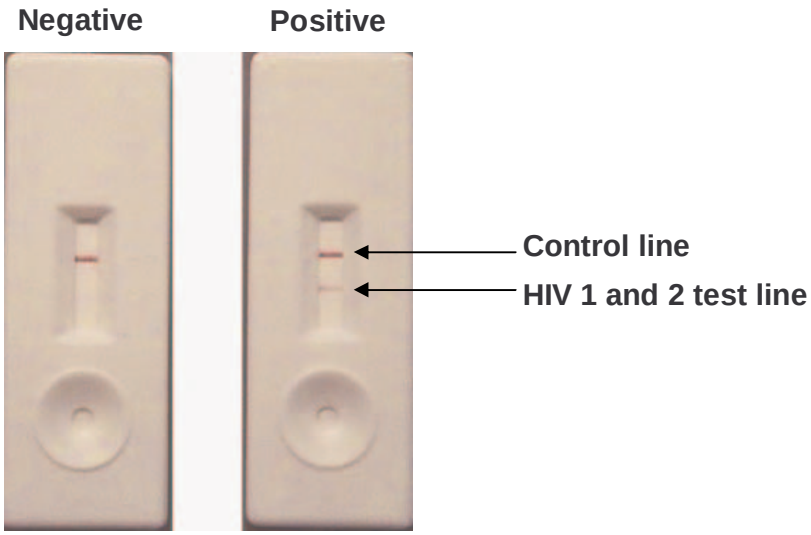
HIV (1+2) Antibody (Colloidal Gold) (KHB Shanghai Kehua Bio-engineering Co. Ltd)
A visually read rapid test for the qualitative determination of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood.



GENEDIA(R) HIV 1/2 Rapid 3.0 (Green Cross Life Science Corp.)
An immunochromatographic assay for the detection of antibodies for HIV1 and HIV2 in Human serum, plasma or whole blood.



DoubleCheckGold™ HIV 1&2 (ORGENICS)
A single reagent immunoassay for the qualitative detection of antibodies to human immunodeficiency virus types 1 and 2 (HIV-1 and HIV-2) in human serum or plasma.



5.2 Evaluation panels

5.2.1 WHO HIV Panel

The Phase I evaluations reported here were carried out using a panel of 453 sera (as shown in *Table B*), of which 100 were from Africa, 1 from Asia, 315 from Europe and 37 from South America. The panel contained 136 sera positive for HIV-1 and 21 positive for HIV-2. All samples were stored in aliquots and thawed at least once but not more than twice.

Table B WHO Evaluation Panel

Origin	Positive sera		Negative sera	Total Number
	HIV 1	HIV 2		
Africa	24	21	55	100
Asia	0	0	1	1
Europe	86	0	229	315
Latin America	26	0	11	37
Total	136	21	296	453

5.2.2 Seroconversion panels

Additionally eight anti-HIV 1 seroconversion panels: PRB910, PRB912, PRB914, PRB917, PRB927, PRB928, PRB930 and PRB944 from Boston Biomedica (BBI) were tested. Western blot and HIV antigen data as provided by BBI are given in Tables 6 and 12.

5.2.3 Test performance

The assays were performed according to the manufacturers' instructions. Usually, one person carried out all the tests. The tests on initially reactive samples were repeated. Sera with discrepant results were repeated twice. Two out of three results determined the overall test outcome. Because of their extreme value, samples belonging to the eight seroconversion panels were tested once only with each assay under evaluation.

Due to the subjective, visual nature of the reading of the S/R assays, they were read independently by three people. Two out of three reading results determined the final outcome.

5.4 Reference tests

The HIV 1 positive specimens and the HIV negative specimens included in the evaluation panel were tested by the Enzygnost Anti-HIV 1/2 Plus and Vironostika HIV Uniform II plus O ELISA tests and the Inno-LIA HIV Confirmation assay. The HIV 2 positive specimens

included in the evaluation panel were tested by Western blot HIV-1 (WB HIV-1) (Genelabs Diagnostics, HIV blot (version 1.2)), NEW LAV BLOT II (WB HIV-2) (Sanofi Diagnostics Pasteur) and Pepti-Lav 1+2 (Sanofi Diagnostics Pasteur) - which is designed to differentiate between HIV-1 and/or HIV-2 infections. All samples dually reactive or indeterminate with WB were tested with the Pepti-Lav 1+2. Following testing with the reference tests, 136 sera were considered to be HIV-1 positive, 21 samples were HIV-2 positive and 296 were HIV negative.

A WB HIV-1 result or WB HIV-2 result was considered positive when 2 of 3 env bands (env precursor, external and transmembrane glycoproteins) with or without gag and/or pol bands, were present (*WHO Weekly Epidemiological Record* (1990); 65: pp 281-283.) A WB result was considered negative when no HIV specific band was present; indeterminate when it showed any band pattern not considered positive or negative. The results of the Pepti-Lav 1+2 and Inno-LIA HIV Confirmation were interpreted according to the instruction manual. The evaluation panel did not include any samples that gave an indeterminate result by WB.

The data obtained with the HIV antibody assays under evaluation were compared to the outcome of the results obtained by the above reference assays.

5.5 Analysis of the results of the assays under evaluation

5.5.1 Sensitivity, specificity and predictive value of HIV serological tests

		True HIV status		
		+	–	
Results of assay under evaluation	+	**a** **True-positives**	b False positives	a+b
	–	c False-negatives	**d** **True-negatives**	c+d
		a+c	b+d	

Sensitivity = a/(a+c) Positive predictive value = a/(a+b)
Specificity = d/(b+d) Negative predictive value = d/(c+d)

Sensitivity : Is the ability of the assay under evaluation to detect correctly sera that contain antibody to HIV (reference assays positive). Thus sensitivity is the number of true positive sera identified by the assay under evaluation as positive (a), divided by the number of sera identified by the reference assays as positive (a+c), expressed as a percentage.

Specificity : Is the ability of the assay under evaluation to detect correctly sera that do not contain antibody to HIV (reference assays negative). Thus specificity is the number of true negative sera identified by the assay under evaluation as negative (d), divided by the number of sera identified by the reference assays as negative (b+d), expressed as a percentage.

NOTE: Indeterminate results, obtained with the assays under evaluation, were included in the calculation of sensitivities and specificities.

Positive Predictive Value (PPV) : The probability that when the test is reactive, the specimen does contain antibody to HIV. This may be calculated in two ways:

1. using the simple formula a/(a+b) which will give an approximate value.

2. using the more precise formula which takes the prevalence of HIV in the population into account:

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

Negative Predictive Value (NPV) : The probability that when the test is negative, a specimen does not have antibody to HIV. This may be calculated using:

1. the simple formula d/(c+d) which will give an approximate value.

2. the more precise formula which takes the prevalence of HIV in the population into account:

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

The probability that a test 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 serum samples testing false-positive decreases; conversely, the likelihood that a person showing negative test results is truly uninfected (i.e., the negative predictive value [NPV]), decreases as prevalence increases. Therefore, as prevalence increases, so does the proportion of samples testing false-negative.

Confidence limits (CL):

95 % CL of the calculated sensitivity and specificity are given in parenthesis. CL's were calculated using the formula:

$$p \pm 1.96 \sqrt{\frac{P(1 - P)}{n}}$$

where P is the sensitivity or specificity
where N is the number of sera analyzed

95% confidence limits are a means of determining whether observed differences in sensitivity or specificity between assays are significant or not.

5.5.2 Reproducibility

All initially reactive samples were repeated at least once. Reproducibility, expressed as a percentage, is calculated by dividing the number of concordant results by the total number of samples retested.

5.5.3 Inter-reader variability

The reader variability is indicated in the table when readings are performed without any equipment. Three persons independently interpret each test result. The reader variability is expressed as the percentage of sera for which initial test results are differently interpreted by different readers.

5.5.4 Sensitivity in seroconversion panels

The results obtained with early seroconversion panels using the assays under evaluation were compared with those obtained using Enzygnost Anti-HIV 1/2 Plus (Dade Behring), the assay arbitrarily designated the reference for determination of relative sensitivity in these panels. For each seroconversion series (panel) the first specimen in the sample sequence to become reactive with Enzygnost Anti-HIV 1/2 Plus (Dade Behring) was assigned the value "0". Results from the assays under evaluation were compared with Enzygnost Anti-HIV 1/2 Plus (Dade Behring) 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 (Dade Behring), 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 (Dade Behring), the value assigned was +1. The assigned values over the 8 seroconversion series were averaged to determine a mean relative seroconversion sensitivity index for each assay and the 95% confidence limits were determined. These limits should be interpreted with caution as only 8 panels were tested.

5.5.5 Additional analyses

The technical aspects of the assays under evaluation were assessed by the technician who performed the testing. These assessments, along with other selected assay characteristics, contributed to an overall appraisal of each assay's suitability for use in small laboratories. To enable comparison between assays, an arbitrary scoring system was used to rate specified assay characteristics.

6. Assay evaluations

Tables 1 and 7 summarise the general characteristics of the assays. Results of the assays evaluated as compared to the reference tests are given in Tables 2 and 8. Tables 3 and 9 provide 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 and 10, and Tables 5 and 11 respectively. Performance of the assays evaluated on early

seroconversion panels is given in Tables 6 and 12, and the relative performance of the evaluated assays as compared to the reference test is given in Figure 2. Explanatory notes are provided at the end of the assay evaluation tables.

ASSAY EVALUATIONS

GROUP 1

Table 1. General characteristics and operational aspects

NAME	*Instant*CHEK™ HIV 1+2	GENIE II HIV-1/HIV-2	Efoora HIV Rapid	OraQuick HIV-1/2 Rapid HIV-1/2 Antibody	SD BIOLINE HIV 1/2 3.0*
Company	EY Laboratories, Inc. San Mateo, CA USA	Bio-Rad, Marnes La Coquette, France	Efoora, Inc, Buffalo Grove, Ill, USA	OraSure Technologies Inc., Bethlehem, PA, USA	Standard Diagnostics Inc. Kyonggi-do, Korea
Assay type	Immunochromatographic assay, flow-through	Immunochromatographic assay, lateral flow	Immunochromatographic assay, lateral flow	Immunochromatographic assay, lateral flow	Immunochromatographic assay, lateral flow
Antigen type	HIV-1 and HIV-2	Recombinant and peptide HIV-1 and HIV-2	gp41 and gp120 of HIV-1 and gp36 of HIV-2	Synthetic HIV-1 and HIV-2	Recombinant HIV1 (gp41, p24) and HIV2 (gp36)
Individual/combined HIV 1 & HIV 2 reactivity	Combined	Individual	Combined	Combined	Individual
Solid phase	Immunochromatographic membrane	Immunochromatographic membrane	Immunochromatographic membrane	Immunochromatographic membrane	Immunochromatographic membrane
Specimen type	serum/plasma/whole blood	serum/plasma	serum/plasma/whole blood	serum/plasma/whole blood/oral fluid	serum/plasma/whole blood
Number of tests per kit (product code)	40 (8-1003-40) 100 (8-1003-100)	40 (72323)	60 (5000019) 1 (5000021) 60 (5000060)	500 (5X4-0012) 100 (5X4-0010) 25 (5X4-0011)	30 (03FK10)
Lot numbers evaluated (expiry date)	2BL101(10/12/02) 2BL102 (10/12/02)	010709 (02/10/02) 010812 (12/11/02) 011119 (13/02/03) 011127 (27/02/03)	22695 (8/02) 22687 (8/02)	HIVCO-1071 (3/02) HIVCO-1155 (9/02)	023009 (17/4/02) 023010 (19/05/03)
Shelf life (at °C)	9 months (22-28)	15 months (2-8)	12 months (15-30)	7 months (2-27)	18 months (15-30)
Volume of sample needed (µ) Final dilution of sample	80µl none	50µl none	5µl none	5µl none	10µl (serum) 20µl (whole blood) none
Total time to perform the assay: h. min. (number of sera)	0.02 (1)	0.13 (1)	0.21 (1)	0.21 (1)	0.06-0.21 (1)
Reading	Visual	Visual	Visual	Visual	Visual
Indicative price/test US$	0.60-1.50	2.55	0.75 - 2.60	4.00-12.00	1.10

***** This kit is also available under the name of Hexagon HIV from Human GmbH, Germany under an Original Equipment Manufacturer (OEM) agreement between Human GmbH and Standard Diagnostics.

Table 2. Comparison of the assays with reference tests

NAME	*Instant*CHEK™ HIV 1+2	GENIE II HIV-1/HIV-2	Efoora HIV Rapid	OraQuick HIV-1/2 Rapid HIV-1/2 Antibody	SD BIOLINE HIV 1/2 3.0
Final Sensitivity % (95 CL)* n = 157	99.4 (96.5-100.0)	100 (97.7-100)	96.2 (91.9-98.6)	98.1 (94.5-99.6)	100.0 (97.7-100.0)
Initial Specificity % (95 CL)*	96.3 (93.4-98.1)	99.3 (97.6-99.9)	97.0 (94.3 - 98.6)	99.3 (97.6-99.9)	99.0 (97.1-99.8)
Final Specificity % (95 CL)* n = 296	97.6 (95.2-99.0)	99.7 (98.1-100)	98.0 (95.6 - 99.3)	100 (98.8-100.0)	99.3 (97.6-99.9)
Indeterminate results %	0.0	0.2	0.4	0.2	0.0
Initial inter-reader variability %	4.6	0.7	3.8	2.4	3.5
PPV 0.1%	4.1	3.20	0.48	100.0	1.41
6.0%	72.6	95.50	75.40	100.0	90.12
NPV 0.1%	99.99	100.0	100.0	99.99	100.0
6.0%	99.96	100.0	99.75	99.88	100.0

* 95 % Confidence Limits

Note: evaluations carried out using serum specimens, see section 5.2

Table 3. Detailed operational aspects

NAME	*Instant*CHEK™ HIV 1+2	GENIE II HIV-1/HIV-2	Efoora HIV Rapid	OraQuick HIV-1/2 Rapid HIV-1/2 Antibody	SD BIOLINE HIV 1/2 3.0
Dimension (cm) of kit: w-l-h	24-9-10 (40 tests) 26.5-12.5-10.5 (100 tests)	26-19-14	36-13-8	16.5-19-7.5	23-13-7.5
Storage conditions (°C)	22-28	2-8	15-30	2-30	2-30
Incubation temperature (°C)	22-28	22-26	15-30	Room temperature	15-30
Reading endpoint stability (h.min)	0.00	0.00	0.10	0.40	0.15
Stability after dilution/ reconstitution/ opening at (°C)					
- antigen (device)	use immediately	use immediately	use immediately	use immediately	use immediately
- controls	3 weeks (22-28), 6 mths (2-8)	expiry date (2-8)	not applicable	not applicable	not applicable
- sample diluent	not applicable	expiry date (2-8)	not applicable	use immediately	not applicable
- conjugate	10 days (2-8)	expiry date (2-8)	not applicable	not applicable	not applicable
- substrate	not applicable	expiry date (2-8)	not applicable	not applicable	not applicable
- wash buffer	expiry date (22-28)	expiry date (2-8)	expiry date (15-30)	not applicable	expiry date (15-30)
Number of sera per run minimum – maximum	1 – 4	1 – 5	1 - 10	1-10	1-10
Number of controls per test run	Control samples included in kit.	Control samples included in kit.	Control samples not included in kit.	Control samples not included in kit. Available as separate item.	Control samples not included in kit.
- negative	1	1	1	1	1
- cut-off/weak positive	0	0	0	0	0
- positive	1	1	1	1	1
- blank	0	0	0	0	0
internal control :					
reagent control	yes	yes	yes	yes	yes
sample addition control	yes	no	no	yes	no

Table 3. (continued) Detailed operational aspects

NAME	*Instant*CHEK™ HIV 1+2	GENIE II HIV-1/HIV-2	Efoora HIV Rapid	OraQuick HIV-1/2 Rapid HIV-1/2 Antibody	SD BIOLINE HIV 1/2 3.0
Estimated time to perform one run: h. min (number of sera)	0:03 (5)	0:15 (5)	0.25 (10)	0.25 (10)	0.20 (10)
Equipment needed but not provided in the kit:[1]					
- washer	-	-	-	-	-
- incubator (water-bath)	-	-	-	-	-
- spectrophotometric reader	-	-	-	-	-
- refrigerator (storage)	±	+	-	±	-
- agitator , rocker	-	-	-	-	-
- aspiration device	-	-	-	-	-
- automatic pipette (µl)	-	+ (50)	-	-	+ (10-20)
- multichannel (µl)	-	-	-	-	-
- disposable tips	-	+	-	-	+
- dilution tubes/rack,	-	-	-	-	-
- microtiterplate	-	-	-	-	-
- distilled or deionised water	-	-	-	-	-
- plate covers	-	-	-	-	-
- graduated pipette; cylinder (ml)	+ (1)	-	-	-	-
- sulfuric acid/sodium hydroxide	-	-	-	-	-
- absorbent paper	-	-	-	-	-
- disinfectant	-	-	-	-	-
- gloves	+	+	+	+	+
- reagent trough	-	-	-	-	-
- timer	+	+	+	+	+
Definition of positive results	Clearly defined pink/red spot in both test and control areas	Appearance of grey/blue HIV1 and/or HIV 2 and control spots	Appearance of line in both test and control areas	Appearance of line in both test and control areas	Appearance of HIV 1 and/or HIV 2 lines and control line
Definition of grey zone or invalid result	No control spot present. High or uneven background with control spot present	Absence of control spot	Absence of control line	Absence of control line	Absence of control line

[1] + : 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.

Table 4a. Technician's appraisal of the test kit

NAME	Score	*Instant*CHEK™ HIV 1+2	GENIE II HIV-1/HIV-2	Efoora HIV Rapid	OraQuick HIV-1/2 Rapid HIV-1/2 Antibody	SD BIOLINE HIV 1/2 3.0
Number of steps in the test procedure: -1-2 steps -3-5 steps - >5 steps	 6 3 1	3	3	6	6	6
Clarity of kit instructions: - good - needs improvement	 2 1	2	2	2	2	2
Kit and reagent packaging and labelling: - good - needs improvement	 2 1	2	2	2	2	2
Total (out of possible 10)	10	7	7	10	10	10
Comments on the test kit		none	none	One device could not be used as the plastic sheet from the test area covered the sample well	One device could not be used as the plastic sheet from the test area covered the sample well In kit insert, one illustration did not match the text	none

Table 4b. Calculation of ease of performance

NAME	*Instant*CHEK™-HIV 1+2	GENIE II HIV-1/HIV-2	Efoora HIV Rapid	OraQuick HIV-1/2 Rapid HIV-1/2 Antibody	SD BIOLINE HIV 1/2 3.0
Need to prepare:					
-antigen	1[1]	1	1	1	1
-substrate	1	1	1	1	1
-wash solution	0[2]	1	1	1	1
-conjugate	0	1	1	1	1
-predilution of serum	1	0	1	1	1
Stability after dilution/opening: (expiry date = 1; less = 0)					
-antigen	1	1	1	1	1
-controls	0	1	1	1	1
-sample diluent	1	1	1	1	1
-conjugate	0	1	1	1	1
-substrate	1	1	1	1	1
-wash buffer	1	1	1	1	1
-sufficient reagents	1	1	1	1	1
-wash (yes =1; no = 0)	1	1	1	1	1
Item needed but not provided in the kit:					
-reagent trough	1	1	1	1	1
-automatic /multichannel pipette	1	0	1	1	0
-dilution – tubes, rack/microtiter plate	1	1	1	1	1
-distilled or deionised water	1	1	1	1	1
-plate covers	1	1	1	1	1
-graduated pipette, cylinder	0	1	1	1	1
-sulfuric acid/sodium hydroxide	1	1	1	1	1
Technician's appraisal of the test kit[3] (rating out of 10)	7	7	10	10	10
Total (out of possible 30)	22	25	30	30	29
Ease of performance: -less easy < 20 -easy $20 \leq x \leq 25$ -very easy > 25	easy	easy	very easy	very easy	very easy

[1] 1 : positive rating: reagent needs no preparation; item provided in the kit

[2] 0 : negative rating: reagent needs preparation; item not provided in the kit

[3] see table 4a

Table 5. Technical suitability for use in small laboratories

NAME	Score	*Instant*CHEK™-HIV 1+2	GENIE II HIV-1/HIV-2	Efoora HIV Rapid	OraQuick HIV-1/2 Rapid HIV-1/2 Antibody	SD BIOLINE HIV 1/2 3.0
Sensitivity						
- 100%	5					
- 98 – 100%	3	3	5	0	3	5
- <98%	0					
Specificity (final)						
- >98%	5					
- 95 – 98%	3	3	5	3	5	5
- <95%	0					
Incubation temperature						
- room t°	3	3	3	3	3	3
- other than room t°	1					
Shelf-life						
- >1 year	3					
- ≥ 6 months ≤ 1 year	2	2	3	2	2	3
- < 6 months	1					
Storage at						
- room t° possible (opened kit)	5					
- room t° possible (unopened kit)	2	5	1	5	5	5
- 2-8 °C required	1					
Price per test (US$)						
- ≤ 1.0	3					
- >1.0 ≤ 2.0	2	3	1	1	1	2
- > 2.0	1					
Ease of performance						
- very easy	5					
- easy	3	3	3	5	5	5
- less easy	1					
Rapidity of performance:1 serum						
- < 10 min	3					
- 10 – 30 min	2	3	2	2	2	2
- > 30 min	1					
Washer/agitator						
- not needed	3					
- needed	1	3	3	3	3	3
Reading						
- visual: inter-reader variability ≤ 3%	5					
: inter-reader variability > 3%	3	3	5	3	5	3
- reading equipment	1					
Total (out of possible 40)		31	31	27	34	36
Suitability for use in small laboratories: - less suitable < 23 - suitable 23 ≤ x ≤ 30 - very suitable > 30		very suitable	very suitable	suitable	very suitable	very suitable

Table 6 . Results on commercial seroconversion panels

Panel	Days since 1st bleed	HIV Ag[1] S/CO	Assays under evaluation					Enzygnost Anti-HIV1/2 Plus[2] OD/CO	Vironostika HIV Uniform II Plus O[2] OD/CO	INNO-LIA HIV Confirmation[2]							
			SR 1	SR 2[3]	SR 3	SR 4	SR 5[3]			Result	Sgp120	gp41	p31	p24	p17	sgp105	gp36
PRB910-01	0	0.4	neg	neg	neg	neg	neg	0.1	0.4	neg	-	-	-	-	-	-	-
PRB910-02	14	5.7	neg	neg	neg	neg	neg	0.1	0.4	neg	-	-	-	-	-	-	-
PRB910-03	26	06	**pos**	**pos**	**pos**	**pos**	**pos**	**>6,7**	**8.9**	**HIV-1**	2+	3+	-	2+	2+	-	-
PRB910-04	28	0.5	pos	pos	pos	pos	pos	>6,7	8.9	HIV-1	2+	3+	-	2+	2+	-	-
PRB910-05	32	0.4	pos	pos	pos	pos	pos	>6,7	8.3	HIV-1	2+	3+	-	2+	2+	-	-
PRB910-06	35	0.4	pos	pos	pos	pos	pos	>6,7	8.4	HIV-1	2+	3+	-	2+	2+	-	-
PRB910-07	40	0.4	pos	pos	pos	pos	pos	>6,7	8.6	HIV-1	2+	3+	-	2+	2+	-	-
PRB912-01	0	10.2	neg	neg	neg	neg	**pos**	**1.8**	0.9	neg	-	-	-	-	-	-	-
PRB912-02	9	24.9	**pos**	**pos**	**pos**	**pos**	pos	>6,7	**5.4**	**HIV-1**	-	3+	-	2+	2+	-	-
PRB912-03	14	10.6	pos	pos	pos	pos	pos	>6,7	6.8	HIV-1	-	3+	-	2+	2+	-	-
PRB912-04	16	3.2	pos	pos	pos	pos	pos	>6,7	7.7	HIV-1	-	3+	-	2+	2+	-	-
PRB912-05	28	0.5	pos	pos	pos	pos	pos	>6,7	10.7	HIV-1	-	3+	-	2+	2+	-	-
PRB912-06	30	0.5	pos	pos	pos	pos	pos	>6,7	11.9	HIV-1	-	3+	-	2+	2+	-	-
PRB914-01	0	0.4	**pos**	**pos**	neg	neg	**pos**	**>6,7**	**4.9**	**HIV-1**	1+	2+	-	+/-	-	-	-
PRB914-02	4	0.5	pos	pos	neg	neg	pos	>6,7	6.5	HIV-1	1+	2+	-	1+	-	-	-
PRB914-03	7	0.5	pos	pos	neg	neg	pos	>6,7	7.8	HIV-1	1+	2+	-	2+	1+	-	-
PRB914-04	25	0.4	pos	pos	neg	neg	pos	>6,7	13.8	HIV-1	2+	2+	-	2+	2+	-	-
PRB914-05	31	0.4	pos	pos	**pos**	**pos**	pos	>6,7	14.0	HIV-1	2+	2+	-	2+	2+	-	-
PRB917-01	0	0.4	neg	neg	neg	neg	neg	0.6	0.7	neg	-	-	-	-	-	-	-
PRB917-02	53	3.9	neg	neg	neg	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB917-03	57	21.6	neg	neg	neg	neg	neg	0.2	0.4	neg	-	-	-	-	-	-	-
PRB917-05	65	2.4	**pos**	**pos**	**pos**	**pos**	**pos**	**>6,7**	**5.7**	**HIV-1**	1+	2+	-	+/-	-	-	-
PRB917-06	67	1.6	pos	pos	pos	pos	pos	>6,7	6.8	HIV-1	1+	2+	-	1+	-	-	-
PRB927-01	0	0.6	neg	neg	neg	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB927-02	28	>22.7	neg	neg	neg	neg	neg	**2.2**	**1.8**	neg	-	-	-	-	-	-	-
PRB927-03	33	10.2	**pos**	**pos**	**pos**	neg	**pos**	>6,7	8.3	ind	-	2+	-	-	-	-	-
PRB927-04	35	2.6	pos	pos	pos	**pos**	pos	>6,7	5.5	**HIV-1**	1+	2+	-	-	-	-	-
PRB927-05	40	1.3	pos	pos	pos	pos	pos	>6,7	6.2	HIV-1	2+	3+	-	2+	2+	-	-

Table 6 cont. Results on commercial seroconversion panels

Panel	Days since 1st bleed	HIV Ag[1] S/CO	Assays under evaluation					Enzygnost Anti-HIV1/2 Plus[2] OD/CO	Vironostika HIV Uniform II Plus O[2] OD/CO	INNO-LIA HIV Confirmation[2]							
			SR 1	SR 2[3]	SR 3	SR 4	SR 5[3]			Result	Sgp120	gp41	p31	p24	p17	sgp105	gp36
PRB928-01	0	0.6	neg	neg	neg	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB928-02	111	>22.7	**pos**	neg	neg	neg	**pos**	**4.8**	**1.5**	ind	-	1+	-	-	-	-	-
PRB928-03	120	2.2	pos	**pos**	**pos**	**pos**	pos	>6.7	4.0	**HIV-1**	-	3+	-	2+	-	-	-
PRB928-04	125	1.8	pos	pos	pos	pos	pos	>6.7	3.7	HIV -1	1+	2+	-	2+	1+	-	-
PRB928-05	130	1.0	pos	pos	pos	pos	pos	>6.7	5.6	HIV -1	2+	3+	-	2+	2+	-	-
PRB930-01	0	0.9	neg	neg	neg	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB930-02	3	2.7	neg	neg	neg	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB930-03	7	4.2	neg	**pos**	neg	neg	**pos**	**4.5**	**2.2**	ind	-	1+	-	-	-	-	-
PRB930-04	10	12.8	**pos**	pos	neg	neg	pos	>6.7	8.6	**HIV -1**	-	2+	-	2+	-	-	-
PRB944-01	0	0.5	neg	neg	**pos**	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB944-02	2	1.0	neg	neg	pos	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB944-03	7	6.6	neg	neg	pos	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB944-04	9	7.0	neg	neg	pos	neg	neg	0.2	0.3	neg	-	-	-	-	-	-	-
PRB944-05	14	5.8	**pos**	**pos**	pos	**pos**	**pos**	**5.0**	**1.8**	**HIV -1**	-	2+	-	1+	-	-	-
PRB944-06	16	3.2	pos	pos	pos	pos	pos	>6.7	3.1	HIV -1	-	2+	-	2+	-	-	-

Notes: [1] Results obtained from Boston Biomedica Inc.

[2] Results obtained from ITM, Antwerp.

[3] Results are shown of HIV 1 detection only. No cross-reactivity was observed with HIV 2.

SR1*: Instant*CHEK™-HIV 1+2 *RAPID TEST.*

SR2: Genie II HIV-1/HIV-2.

SR3: Efoora HIV Rapid.

SR4: OraQuick HIV 1/2 Rapid.

SR5: SD BIOLINE HIV 1/2 3.0

ASSAY EVALUATIONS

GROUP 2

Table 7. General characteristics and operational aspects

NAME	Hema ● Strip® HIV 1/2	HIV 1/2 STAT-PAK	HIV (1+2) Antibody (Colloidal Gold)	GENEDIA(R)HIV 1/2 Rapid 3.0	DoubleCheckGold™ HIV 1&2
Company	Chembio Diagnostic System Inc. Medford, NY USA	Chembio Diagnostic System Inc. Medford, NY USA	KHB Shanghai Kehua Bio-enginerring Co. Ltd. Shanghai People's Republic of China	Green Cross Life Science Corp. Kyunggi-do Korea	Orgenics Ltd Yavne Israel
Assay type	Immunochromatographic assay, lateral flow	Immunochromatographic assay, lateral flow	Immunochromatographic assay, lateral flow	Immunochromatographic assay, lateral flow	Immunochromatographic assay, lateral flow
Antigen type	HIV-1 and HIV-2	HIV-1 and HIV-2	HIV-1 and HIV-2	Recombinant HIV-1 gp41 and p24 and HIV-2 gp36	Recombinant envelope and gag proteins of HIV-1 and HIV-2
Individual/combined HIV 1 and HIV 2 reactivity	Combined	Combined	Combined	Individual	Combined
Solid phase	Immunochromatographic membrane	Immunochromatographic membrane	Nitrocellulose membrane	Nitrocellulose membrane	Nitrocellulose strip
Specimen type	serum/plasma/whole blood	serum/plasma/whole blood	serum/plasma/whole blood	serum/plasma/whole blood	serum/plasma
Number of tests per kit (product code)	25 (HH-0200)	20 (HIV 101)	50 (KH-R-02)	20 (F7171020) 50 (F7171050) 100 (F7171100)	20 (70632020) 100 (70632100)
Lot numbers evaluated (expiry date)	2301080 (9/11/02) 2201078 (9/11/02) 2701092 (18/5/03) 2701095 (06/05/03)	102501 (9/11/02) 110801 (9/11/02) 072502 (1/10/02)	20021203 (03/06/04) 20021219 (19/06/04)	X0002 (04/11/03) X0003 (11/11/03)	6210G081 (4/11/03) 628G223 (22/08/03)
Shelf life at (°C)	15 months (2-33)	15 months (8-30)	18 months (4-30)	18 months (2-30)	12 months (2-30)
Volume of sample needed (µ) Final dilution of sample	2.5µl none	5µl none	40µl none	20µl serum/plasma 40µl whole blood none	10µl none
Total time to perform the assay: h. min. (number of sera)	0:16 (1)	0:11 (1)	0:04-0:30 (1)	0.11 (1)	0:16 (1)
Reading	Visual	Visual	Visual	Visual	Visual
Indicative price/test US$	1.85 – 2.50	0.75 – 1.40	1.50	0.93 – 1.15	0.65 - 0.70

Table 8. Comparison of the assays with reference tests

NAME	Hema ● Strip® HIV 1/2	HIV 1/2 STAT-PAK	HIV (1+2) Antibody (Colloidal Gold)	GENEDIA® HIV 1/2 Rapid 3.0	DoubleCheckGold™ HIV 1&2
Final Sensitivity % (95 CL)* n = 157	98.1 (94.5-99.6)	97.5 (93.6-99.3)	100.0 (97.7-100.0)	100.0 (97.7-100.0)	99.4 (96.5-100.0) Lot A 100 (97.7-100.0) Lot B
Initial Specificity % (95 CL)*	100.0 (98.8-100.0)	100.0 (98.8-100.0)	100.0 (98.8-100.0)	99.3 (97.6-99.9)	95.6 (92.6-97.6) Lot A 94.6 (91.4-96.9) Lot B
Final Specificity % (95 CL)* n = 296	100.0 (98.8-100.0)	100.0 (98.8-100.0)	100.0 (98.8-100.0)	99.7 (98.1-100.0)	95.6 (92.6-97.6) Lot A 94.6 (91.4-96.9) Lot B
Indeterminate results %	0.0	0.0	0.0	0.0	0.9 Lot A 2.0 Lot B
Initial inter-reader variability %	3.3	0.7	0.2	1.8	2.4
PPV 0.1%	100	100	100	3.23	0.23 Lot A / 0.18 Lot B
6.0%	100	100	100	95.51	59.1 Lot A / 54.2 Lot B
NPV 0.1%	100	100	100	100	100.0 Lot A / 100.0 Lot B
6.0%	99.80	99.84	100	100	100.0 Lot A / 100.0 Lot B

* 95 % Confidence Limits

Note: evaluations carried out using serum specimens, see section 5.2

Table 9. Detailed operational aspects

NAME	Hema ● Strip® HIV 1/2	HIV 1/2 STAT-PAK	HIV (1+2) Antibody (Colloidal Gold)	GENEDIA® HIV 1/2 Rapid 3.0	DoubleCheckGold™ HIV 1&2
Dimension (cm) of kit: w-l-h	24-16-9.5	16.5-12.5-9	13.5-10-8	21-6.5-8.5 (20) 17-12.5-9 (50) 20-12.5-15 (100)	18-13-5.5 (20) 26-19-14 (100)
Storage conditions (°C)	20-33	8-30	4-30	2-30	2-30
Incubation temperature (°C)	Room temperature	Room temperature	Room temperature	Room temperature	Room temperature
Reading endpoint stability (h.min)	0.00	0.00	0.27	0.10	0.10
Stability after dilution/ reconstitution/ opening at °C					
- antigen	not applicable	not applicable	not applicable	not applicable	not applicable
- controls	not applicable	not applicable	not applicable	not applicable	not applicable
- sample diluent	not applicable	not applicable	expiry date (4-30)	not applicable	not applicable
- conjugate	not applicable	not applicable	not applicable	not applicable	not applicable
- substrate	not applicable	not applicable	not applicable	not applicable	not applicable
- wash buffer	not applicable	expiry date (8-30)	not applicable	expiry date (2-30)	expiry date (2-30)
Number of sera per run minimum – maximum	1-10	1-10	1-10	1-10	1-10
Number of controls per test run	Control samples not included in kit.	Control samples not included in kit.	Control samples not included in kit.	Control samples not included in kit.	Control samples not included in kit.
- negative	1	1	1	1	1
- cut-off/weak positive	0	0	0	0	0
- positive	1	1	1	1	1
- blank	0	0	0	0	0
internal control :					
reagent control	Yes	Yes	Yes	Yes	Yes
sample addition control	No	No	No	No	No

Table 9 cont. Detailed operational aspects

NAME	Hema ● Strip® HIV 1/2	HIV 1/2 STAT-PAK	HIV (1+2) Antibody (Colloidal Gold)	GENEDIA® HIV 1/2 Rapid 3.0	DoubleCheckGold™ HIV 1&2
Estimated time to perform one run: h. min (number of sera)	0.20 (10)	0.13 (10)	0.05 – 0.32 (10)	0.13 (10)	0.18 (10)
Equipment needed but not provided in the kit:[1]					
- washer	-	-	-	-	-
- incubator (water-bath)	-	-	-	-	-
- spectrophotometric reader	-	-	-	-	-
- refrigerator (storage)	-	±	±	±	±
- agitator , rocker	-	-	-	-	-
- aspiration device	-	-	-	-	-
- automatic pipette (µl)	+ (2.5)	-	+ (40)	± (20/40)	+ (10)
- multichannel (µl)	-	-	-	-	-
- disposable tips	+	-	+	±	+
- dilution tubes/rack,	-	-	-	-	-
- microtiterplate	-	-	-	-	-
- distilled or deionised water	-	-	-	-	-
- plate covers	-	-	-	-	-
- graduated pipette; cylinder	-	-	-	-	-
- sulfuric acid/sodium hydroxide	-	-	-	-	-
- absorbent paper	-	-	-	-	-
- disinfectant	-	-	-	-	-
- gloves	+	+	+	+	+
- reagent trough	-	-	-	-	-
- timer	+	+	+	+	+
Definition of positive results	Both test and control indicator lines visible	Appearance of pink/purple lines in each of test and control area	Appearance of a purple/red band at both the test and control line position	Appearance of a coloured band at the HIV 1 and/or HIV 2 line and at the control line	Appearance of a coloured test line and a control line
Definition of grey zone or indeterminate result	Absence of control line	Absence of control line	Absence of control line	Absence of control line	Absence of control line

[1] + : 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.

Table 10a. Technician's appraisal of the test kit

NAME	Score	Hema ● Strip® HIV 1/2	HIV 1/2 STAT-PAK	HIV (1+2) Antibody (Colloidal Gold)	GENEDIA® HIV 1/2 Rapid 3.0	DoubleCheckGold™ HIV 1&2
Number of steps in the test procedure: -1-2 steps -3-5 steps - >5 steps	 6 3 1	 6	 6	 6	 6	 6
Clarity of kit instructions: - good - needs improvement	 2 1	 2	 2	 2	 2	 2
Kit and reagent packaging and labelling: - good - needs improvement	 2 1	 2	 2	 2	 2	 2
Total (out of possible 10)	10	10	10	10	10	10
Comments on the test kit		None	None	None	None	None

Table 10b. Calculation of ease of performance

NAME	Hema ● Strip® HIV 1/2	HIV 1/2 STAT-PAK	HIV (1+2) Antibody (Colloidal Gold)	GENEDIA® HIV 1/2 Rapid 3.0	DoubleCheckGold™ HIV 1&2
Need to prepare:					
-antigen	1[1]	1	1	1	1
-substrate	1	1	1	1	1
-wash solution	1	1	1	1	1
-conjugate	1	1	1	1	1
-predilution of serum	1	1	1	1	1
Stability after dilution/opening: (expiry date = 1; less = 0)					
-antigen	1	1	1	1	1
-controls	1	1	1	1	1
-sample diluent	1	1	1	1	1
-conjugate	1	1	1	1	1
-substrate	1	1	1	1	1
-wash buffer	1	1	1	1	1
-sufficient reagents	1	1	1	1	1
-wash (yes =0; no = 1)	1	1	1	1	1
Item needed but not provided in the kit:					
-reagent trough	1	1	1	1	1
-automatic /multichannel pipette	0[2]	1	0	0	0
-dilution – tubes, rack/microtiter plate	1	1	1	1	1
-distilled or deionised water	1	1	1	1	1
-plate covers	1	1	1	1	1
-graduated pipette, cylinder	1	1	1	1	1
-sulfuric acid/sodium hydroxide	1	1	1	1	1
Technician's appraisal of the test kit[3] (rating out of 10)	10	10	10	10	10
Total (out of possible 30)	29	30	29	29	29
Ease of performance: -less easy < 20 -easy 20 ≤ x ≤ 25 -very easy > 25	Very easy	Very easy	Very easy	Very easy	Very easy

[1] 1 : positive rating: reagent needs no preparation; item provided in the kit
[2] 0 : negative rating: reagent needs preparation; item not provided in the kit
[3] see table 4a

Table 11. Technical suitability for use in small laboratories

NAME	Score	Hema ● Strip® HIV 1/2	HIV 1/2 STAT-PAK	HIV (1+2) Antibody (Colloidal Gold)	GENEDIA® HIV 1/2 Rapid 3.0	DoubleCheckGold™ HIV 1&2
Sensitivity						
- 100%	5					
- 98 – 100%	3	3	0	5	5	3
- <98%	0					
Specificity						
- >98%	5					
- 95 – 98%	3	5	5	5	5	3
- <95%	0					
Incubation temperature						
- room t°	3	3	3	3	3	3
- other than room t°	1					
Shelf-life						
- >1 year	3					
- ≥ 6 months ≤ 1 year	2	3	3	3	3	3
- < 6 months	1					
Storage at						
- ambient t° possible (opened kit)	5					
- ambient t° possible (unopened kit)	2	5	5	5	5	5
- 2-8 °C required	1					
Price per test (US$)						
- ≤ 1.0	3					
- ≤ 2.0	2	2	3	2	2	3
- > 2.0	1					
Ease of performance						
- very easy	5					
- easy	3	5	5	5	5	5
- less easy	1					
Rapidity of performance:1 serum						
- < 10 min	3					
- 10 – 30 min	2	2	2	2	2	2
- > 30 min	1					
Washer/agitator						
- not needed	3	3	3	3	3	3
- needed	1					
Reading						
- visual: inter-reader variability ≤ 3%	5					
: inter-reader variability > 3%	3	3	3	5	5	5
- reading equipment	1					
Total (out of possible 40)		34	32	38	38	35
Suitability for use in small laboratories:						
- less suitable < 23						
- suitable 23 ≤ x ≤ 30		Very suitable	Very suitable	Very suitable	Very suitable	Very suitable
- very suitable > 30						

Table 12. Results on commercial seroconversion panels

Panel	Days since 1st bleed	HIV Ag[1] S/CO	Assays under evaluation					Enzygnost Anti-HIV1/2 Plus[2] OD/CO	Vironostika HIV Uniform II Plus O[2] OD/CO	INNO-LIA HIV Confirmation[2]							
			SR 6	SR 7	SR 8	SR 9[3]	SR 10			Result	sgp120	gp41	p31	p24	p17	sgp105	gp36
PRB910-01	0	0.4	neg	neg	neg	neg	neg	0.1	0.4	neg	-	-	-	-	-	-	-
PRB910-02	14	5.7	neg	neg	neg	neg	neg	0.1	0.4	neg	-	-	-	-	-	-	-
PRB910-03	26	06	**pos**	**pos**	**pos**	**pos**	**pos**	**>6,7**	**8.9**	**HIV-1**	2+	3+	-	2+	2+	-	-
PRB910-04	28	0.5	pos	pos	pos	pos	pos	>6,7	8.9	HIV-1	2+	3+	-	2+	2+	-	-
PRB910-05	32	0.4	pos	pos	pos	pos	pos	>6,7	8.3	HIV-1	2+	3+	-	2+	2+	-	-
PRB910-06	35	0.4	pos	pos	pos	pos	pos	>6,7	8.4	HIV-1	2+	3+	-	2+	2+	-	-
PRB910-07	40	0.4	pos	pos	pos	pos	pos	>6,7	8.6	HIV-1	2+	3+	-	2+	2+	-	-
PRB912-01	0	10.2	neg	neg	neg	neg	**pos**	**1.8**	0.9	neg	-	-	-	-	-	-	-
PRB912-02	9	24.9	**pos**	**pos**	**pos**	**pos**	pos	>6,7	**5.4**	**HIV-1**	-	3+	-	2+	2+	-	-
PRB912-03	14	10.6	pos	pos	pos	pos	pos	>6,7	6.8	HIV-1	-	3+	-	2+	2+	-	-
PRB912-04	16	3.2	pos	pos	pos	pos	pos	>6,7	7.7	HIV-1	-	3+	-	2+	2+	-	-
PRB912-05	28	0.5	pos	pos	pos	pos	pos	>6,7	10.7	HIV-1	-	3+	-	2+	2+	-	-
PRB912-06	30	0.5	pos	pos	pos	pos	pos	>6,7	11.9	HIV-1	-	3+	-	2+	2+	-	-
PRB914-01	0	0.4	**pos**	neg	**pos**	**pos**	**pos**	**>6,7**	**4.9**	**HIV-1**	1+	2+	-	+/-	-	-	-
PRB914-02	4	0.5	pos	neg	pos	pos	pos	>6,7	6.5	HIV-1	1+	2+	-	1+	-	-	-
PRB914-03	7	0.5	neg	**pos**	pos	pos	pos	>6,7	7.8	HIV-1	1+	2+	-	2+	1+	-	-
PRB914-04	25	0.4	neg	pos	pos	pos	pos	>6,7	13.8	HIV-1	2+	2+	-	2+	2+	-	-
PRB914-05	31	0.4	pos	pos	pos	pos	pos	>6,7	14.0	HIV-1	2+	2+	-	2+	2+	-	-
PRB917-01	0	0.4	neg	neg	neg	neg	neg	0.6	0.7	neg	-	-	-	-	-	-	-
PRB917-02	53	3.9	neg	neg	neg	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB917-03	57	21.6	neg	neg	neg	neg	neg	0.2	0.4	neg	-	-	-	-	-	-	-
PRB917-05	65	2.4	neg	neg	**pos**	**pos**	**pos**	**>6,7**	**5.7**	**HIV-1**	1+	2+	-	+/-	-	-	-
PRB917-06	67	1.6	**pos**	**pos**	pos	pos	pos	>6,7	6.8	HIV-1	1+	2+	-	1+	-	-	-
PRB927-01	0	0.6	neg	neg	neg	neg	neg	0.1	0.3	neg	-	-	-	-	-	-	-
PRB927-02	28	>22.7	neg	neg	neg	neg	neg	**2.2**	**1.8**	neg	-	-	-	-	-	-	-
PRB927-03	33	10.2	**pos**	**pos**	**pos**	**pos**	**pos**	>6,7	8.3	ind	-	2+	-	-	-	-	-
PRB927-04	35	2.6	pos	pos	pos	pos	pos	>6,7	5.5	**HIV-1**	1+	2+	-	-	-	-	-
PRB927-05	40	1.3	pos	pos	pos	pos	pos	>6,7	6.2	HIV-1	2+	3+	-	2+	2+	-	-

Table 12 cont. Results on commercial seroconversion panels

Panel	Days since 1st bleed	HIV Ag[1]	Assays under evaluation					Enzygnost Anti-HIV 1/2 Plus[2]	Vironostika HIV Uniform II Plus O[2]	INNO-LIA HIV Confirmation[2]							
			SR 6	SR 7	SR 8	SR 9[3]	SR 10	OD/CO	OD/CO	result	sgp120	gp41	p31	p24	p17	sgp105	gp36
PRB928-01	0	0.6	neg	neg	neg	neg	neg	0.1	0.3	NEG	-	-	-	-	-	-	-
PRB928-02	111	>22.7	neg	neg	**pos**	neg	pos	**4.8**	**1.5**	IND	-	1+	-	-	-	-	-
PRB928-03	120	2.2	**pos**	**pos**	pos	**pos**	**pos**	>6,7	4.0	**HIV-1**	-	3+	-	2+	-	-	-
PRB928-04	125	1.8	pos	pos	pos	pos	pos	>6,7	3.7	HIV-1	1+	2+	-	2+	1+	-	-
PRB928-05	130	1.0	pos	pos	pos	pos	pos	>6,7	5.6	HIV-1	2+	3+	-	2+	2+	-	-
PRB930-01	0	0.9	neg	neg	neg	neg	neg	0.1	0.3	NEG	-	-	-	-	-	-	-
PRB930-02	3	2.7	neg	neg	neg	neg	neg	0.1	0.3	NEG	-	-	-	-	-	-	-
PRB930-03	7	4.2	neg	neg	**pos**	**pos**	**pos**	**4.5**	**2.2**	IND	-	1+	-	-	-	-	-
PRB930-04	10	12.8	neg	neg	pos	pos	pos	>6,7	8.6	**HIV-1**	-	2+	-	2+	-	-	-
PRB944-01	0	0.5	neg	neg	neg	neg	neg	0.1	0.3	NEG	-	-	-	-	-	-	-
PRB944-02	2	1.0	neg	neg	neg	neg	neg	0.1	0.3	NEG	-	-	-	-	-	-	-
PRB944-03	7	6.6	neg	neg	neg	neg	neg	0.1	0.3	NEG	-	-	-	-	-	-	-
PRB944-04	9	7.0	neg	neg	neg	neg	neg	0.2	0.3	NEG	-	-	-	-	-	-	-
PRB944-05	14	5.8	**pos**	neg	**pos**	**pos**	**pos**	**5.0**	**1.8**	**HIV-1**	-	2+	-	1+	-	-	-
PRB944-06	16	3.2	pos	**pos**	pos	pos	pos	>6,7	3.1	HIV-1	-	2+	-	2+	-	-	-

Notes:

[1]Results obtained from Boston Biomedica Inc.

[2]Results obtained from ITM, Antwerp.

[3]Results are shown of HIV 1 detection only. No cross-reactivity was observed with HIV 2.

SR6: Hema● Strip® HIV 1/2.

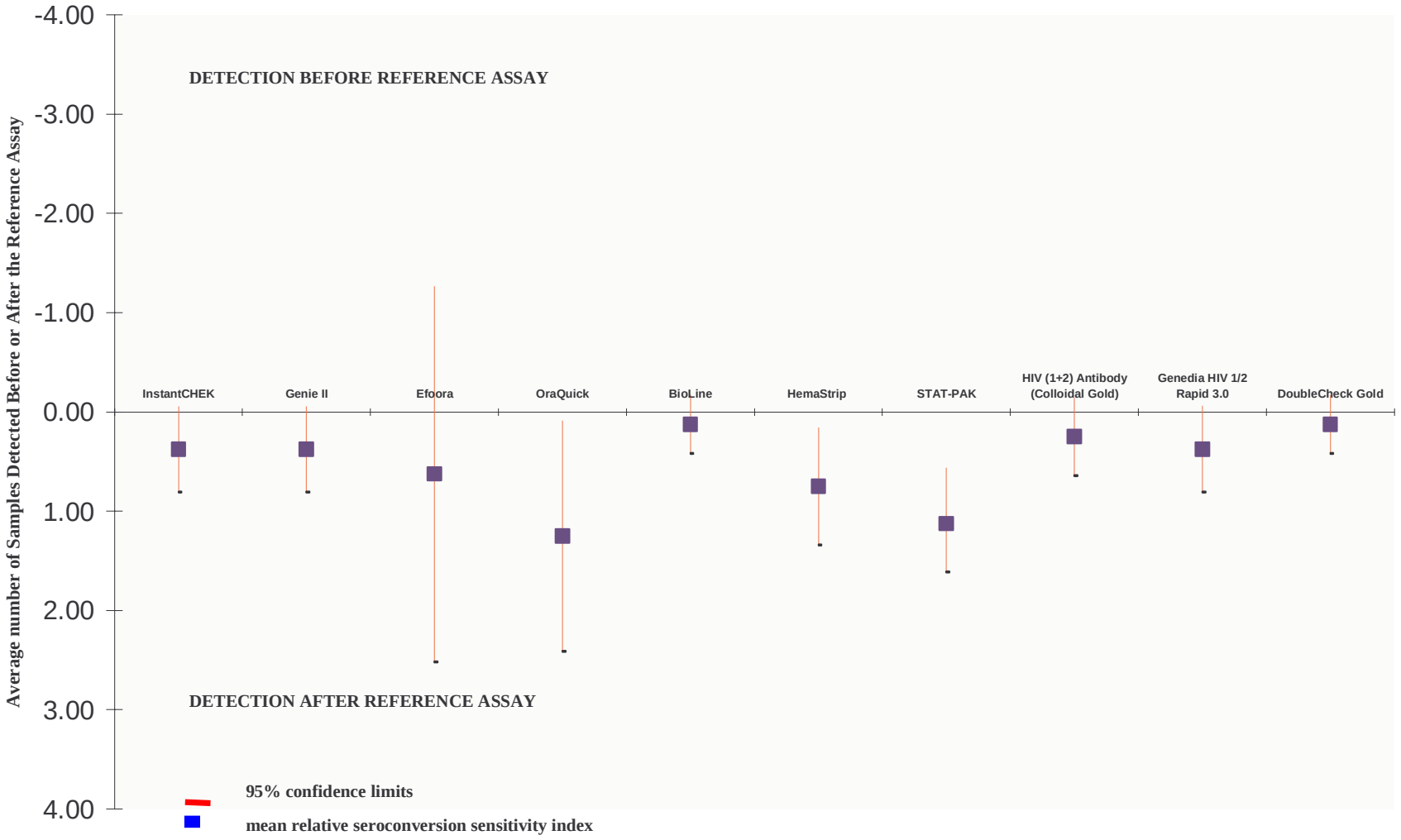
SR7: HIV 1/2 STAT-PAK .

SR8: Kehua Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold).

SR9: Genedia® HIV 1/2 Rapid 3.0

SR10: DoubleCheckGold™ HIV 1&2

Figure 2: Relative performance on seroconversion panels as compared to the reference assay (Enzygnost HIV 1/2 Plus)



Explanatory notes for Tables 1-12 and Figure 2

Tables 1 and 7	**General characteristics and operational aspects of the assays**.
Specimen type	the nature of specimen(s) that may be used in the assay. *Instant*CHEK HIV 1+2: when using whole blood samples, the sample must be passed through a filter unit as supplied by the company.
Individual/combined HIV 1 & HIV 2 reactivity	Individual: Genie II HIV-1/HIV-2, SD Bioline HIV 1/2 3.0 and Genedia HIV 1/2 Rapid 3.0 are able to differentiate between HIV 1 and HIV 2 reactivity. Combined: The remaining assays do not distinguish between HIV 1 and HIV 2 reactivity.
Shelf life (at °C)	the maximum shelf life of the product if stored within the given temperature range.
Final dilution of the serum	the dilution of the serum in the test format, e.g. 10µl serum added to 200µl diluent gives a final dilution of 1/21.
Total time to perform the assay	reflects the time needed to carry out 1 test run, i.e. the most economical use of the technique. A range is stated for the HIV (1+2) Antibody (Colloidal Gold) as strong positives may be read after 2-3 minutes incubation but for negative results an incubation time of 30 minutes is required.
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. The prices stated are catalogue prices and therefore indicative only.
Tables 2 and 8	**Comparison of the results of the assays with reference tests**
Sensitivity	calculated as described on page 15 of this document.
Specificity	calculated as described on page 15 of this document.
PPV and NPV	calculated as described on page 16 of this document
95% Confidence limits (CL)	calculated as described on page 16 of this document
Indeterminate results	simple/rapid assays - test results which could not be interpreted as clearly positive or negative were considered indeterminate.
Inter-reader variability	calculated as described on page 17 of this document.

Explanatory notes for Tables 1-12 and Figure 2

Tables 3 and 9	**Detailed operational aspects of the assays**
Reading endpoint	The time period after the completion of the test procedure, including any stated incubation period, within which the result may be read. Kits which show a time period of 0.00 must be read immediately upon completion of the assay.
Minimum - maximum number of sera	- minimum number = 1 sample in addition to the required controls. - maximum number = the maximum number of samples in addition to the required controls which can be simultaneously tested within the limits of the assay procedure.
Number of controls per test run	Two assays supplied HIV positive and negative control samples as part of the kit: *Instant*CHEK HIV 1+2 and Genie II HIV-1/HIV-2. One assay supplied HIV positive and negative controls as a separate item. The remaining 7 assays' manufacturers do not supply control samples. The number of controls shows the number of replicates of each control required for each assay run.
Internal control: - sample addition control	The following assays have a control spot or line on the test devices which shows both that the sample has been added and the reagents functioned correctly: *Instant*CHEK HIV 1+2 and OraQuick HIV-1/2.
- reagent addition control	The following assays have a control spot or line that which shows that the reagents have been added correctly: Genie II HIV-1/HIV-2, Efoora HIV Rapid, SD BIOLINE HIV 1/2 3.0, Hema • Strip HIV 1/2, HIV 1/2 STAT-PAK, HIV (1+2) Antibody (Colloidal Gold), Genedia HIV 1/2 Rapid 3.0 and DoubleCheckGold HIV 1&2.
Definition of positive results	A sample is interpreted as positive according to the criteria set by the manufacturer and summarised in the table
Tables 4a, 4b, 10a and 10b	**Technician's appraisal and Calculation of ease of performance of the assays** The criteria for this calculation are given in the respective tables.
Tables 5 and 11	**Technical suitability of the assays for use in small laboratories** The criteria for this calculation are given in the respective table.
Note	These criteria are primarily technical and while an assay may be regarded as "technically" suitable for use in laboratories with limited facilities or where small numbers of samples are routinely tested, the sensitivity and specificity of the assay are over-riding factors in determining the suitability of an assay for use in any laboratory.

Explanatory notes for Tables 1-12 and Figure 2

Tables 6 and 12.

Performance of the assay on seroconversion panels

An assay's performance on the seroconversion panels should be viewed against both the sensitivity and specificity of the assay. Assays of relatively low specificity may appear to detect antibody to HIV earlier than other assays of higher specificity. Caution should be taken when reviewing seroconversion performance of assays tested only in 8 panels.

Figure 2.

Relative performance on seroconversion panels

Eight seroconversion panels (BBI), each containing several samples taken at different time intervals early in the infection period (window period), were tested with the simple and/or rapid anti-HIV test kits. The results obtained with these assays were compared to those of the combined outcome of the Enzygnost HIV 1/2 Plus reference test (see page 17 of this report). The mean of the difference in time period for a test to become positive as compared to the reference test was calculated and plotted on a yardstick. The 95% confidence limits of the mean were also calculated.

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 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 serum populations, cost per test, ease of performance and suitability for use in small blood collection centres.

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values[e]		Cost per test (US$) /year[g]	nm[h]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
				WB pos sera	WB neg sera					
Enzyme linked immunosorbent assays										
<u>For the detection of antibody to HIV-1</u>										
Dupont HIV-1 Recombinant ELISA (Dupont de Nemours)	1	100.0 (98.7-100.0)	97.0 (92.7-98.8)			0.9/'88	450/410	LE	LS	NA
Enzygnost Anti-HIV Micro (Behringwerke)	1	100.0 (97.8-100.0)	100.0 (98.1-100.0)			1.8/'88	450 450/630	LE	LS	0.0
HIV-TEK G (Sorin Biomedica)	1	100.0 (96.0-100.0)	86.5 (79.5-91.8)			1.0/'88	450	LE	LS	NA
Vironostika Anti-HIV Uni-Form (Organon Teknika)	1	100.0 (97.6-100.0)	99.5 (97.3-100.0)			2.2/'88	492 492/630	LE	LS	NA
Ortho HIV ELISA System (Ortho Diagn. Systems)	1	100.0 (97.8-100.0)	98.0 (95.0-99.4)			1.8/'88	490	LE	LS	NA
HIV-1 env Peptide EIA (Labsystems)	2	96.0 (90.8-98.7)	97.0 (93.5-98.9)			3.9/'89	405 405/630	LE	LS	NA
Wellcozyme HIV Recombinant (Wellcome Diagnostics)	2	100.0 (98.2-100.0)	99.1 (96.8-99.9)			1.5/'89	450	LE	LS	NA
Genetic Systems LAV EIA (Genetic Systems)	3	100.0 (98.2-100.0)	96.3 (92.9-98.4)	9.2	-2.13	1.0/'90	450 450/615-630	LE	LS	NA

Annex 1 (continued)

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values[e] WB pos sera	δ Values[e] WB neg sera	Cost per test (US$) /year[g]	nm[h]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
REC VIH-KCOI (Heber Biotec)	3	97.0 (93.5-98.9)	100.0 (98.3-100.0)	2.1	-4.14		492	LE	LS	NA
UBI HIV-1 EIA (United Biomedical)	6	100.0 (99.9-100.0)	88.2 (87.1-89.3)	7.5	-1.12	1.0/'92	492/620-690	LE	S	NA
Peptide HIV-1 ELISA Test System (Sero-Immuno Diagnostics)	6	82.1 (76.5-87.6)	94.1 (91.0-97.2)			0.6/'92	visual	E	VS	0.0
Peptide HIV-2 ELISA Test (Sero-Immuno Dianostics)	6	97.1 (93.0-100.0)	98.1 (96.3-99.9)			0.6/'92	visual	E	VS	NA
UBI HIV-2 EIA (United Biomedical)	7	100.0 (97.4-100.0)	96.1 (93.4-98.8)	10.5	-1.7	1.2/'93	492/620-630	LE	S	NA
Enzygnost Anti-HIV-1 (Behringwerke)	7	100.0 (98.1-100.0)	100.0 (98.8-100.0)	7.4	-3.3		450/615-690	LE	LS	0.0
Enzygnost Anti-HIV-2 (Behringwerke)	8	100.0 (96.7-100.0)	99.5 (98.5-100.0)	23.8	-3.5	6.2/'93	450/630	LE	LS	0.0
<u>For the detection of antibody to HIV-1 and HIV-2</u>										
Enzygnost Anti-HIV -1+2 (Behringwerke)	2	100.0 (98.4-100.0)	97.4 (94.0-99.2)	11.3	-2.15	2.3/'89	450 450/615-690	LE	LS	0.0
Biochrom HIV-1/HIV-2 ELISA Modul-test (Biochrom)	3	100.0 (98.6-100.0)	96.3 (92.5-98.5)	6.20	-1.69	0.9/'89	405	LE	LS	1.0
DuPont HIV-1/HIV-2 ELISA (DuPont de Nemours)	3	100.0 (98.7-100.0)	85.6 (79.8-90.2)	9.34	-0.96	1.3/'90	405 or 410 405 or 410/ 620 or 630	LE	LS	NA

Annex 1 (continued)

Assay (manufacturer)	Report No [a]	Sensitivity (%) [b,c]	Specificity (%) [c,d]	δ Values [e] WB pos sera	δ Values [e] WB neg sera	Cost per test (US$) /year [g]	nm [h]	Ease of performance [i]	Suitability [j]	Indeterminate results [k] (%)
Vironostika HIV MIXT (Organon Teknika)	3	100.0 (98.7-100.0)	100.0 (98.1-100.0)	10.10	-2.94	1.8/'90	492	LE	LS	NA
Elavia Mixt (Diagnostics Pasteur)	4	100.0 (98.7-100.0)	95.1 (91.3-97.8)	54.33	-2.31	2.1/'90	492 492/620	LE	LS	0.0
Anti-HIV-1/HIV-2 EIA <Roche> (F. Hoffman-LaRoche)	4	100.0 (98.7-100.0)	96.9 (93.4-98.9)	11.30	-2.37	1.7/'90	492	LE	LS	NA
Clonatec HIV (1+2) Ab EIA (Clonatec)	6	99.6 (98.8-100.0)	95.9 (93.1-98.7)	7.47	-1.68	2.7'91	492	LE	S	0.0
Enzymun-Test Anti-HIV-1+2 (Boehringer Mannheim)	6	100.0 (98.7-100.0)	100.0 (98.6-100.0)	5.50	-2.48	3.0'92	405	LE	S	0.0
UBI HIV-1/2 EIA (United Biomedical)	6	100.0 (99.9-100.0)	88.7 (84.2-93.1)	7.18	-1.24	1.2/'92	492 492/620-690	LE	S	NA
Enzygnost Anti-HIV-1/HIV-2 (Behringwerke)	6	100.0 (99.9-100.0)	99.5 (98.5-100.0)	26.53	-3.50	2.6'92	450 450/615-690	LE	LS	0.0
Cobas Core Anti-HIV-1/HIV-2 EIA <Roche> (Hoffmann-La Roche)	7	100.0 (98.6-100.0)	89.2 (84.6-93.8)	10.8	-1.0	2.2'93	450	LE	LS	0.0
Biochrom HIV-1/HIV-2 ELISA Version 2 (Biochrom)	7	99.5 (99.0-100.0)	100.0 (98.6-100.0)	7.5	-7.3	1.0/'93	450	LE	LS	0.0
Detect-HIV™ (Biochem Immunosystemes)	3	100.0 (98.6-100.0)	97.4 (94.0-99.2)	12.65	-2.21	2.5/'90	450 450/600-650	LE	LS	NA
Wellcozyme HIV-1 + 2 (Wellcome Diagnostics)	4	100.0 (98.7-100.0)	96.9 (93.3-98.9)	38.51	-1.99	1.5/'90	492	LE	LS	NA

Annex 1 (continued)

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values [e]		Cost per test (US$) /year[g]	nm[h]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
				WB pos sera	WB neg sera					
Peptide HIV ELISA (Cal-Tech Diagnostics)	5	72.6 (69.4-77.6)	95.4 (91.3-97.9)			0.9/'91	visual	E	S	0.2
Genelavia Mixt (Sanofi Diagnostics Pasteur)	5	100.0 (98.6-100.0)	98.5 (95.6-99.8)	16.77	-2.10	1.5/'91	492 492/620	LE	LS	0.0
Biotest Anti-HIV-1/-2 Recombinant (Biotest)	5	100.0 (98.6-100.0)	97.9 (94.9-99.4)	50.47	-3.08	1.2/'91	492 492/570-650	LE	LS	0.0
Innotest HIV-1/HIV-2 Ab (Innogenetics)	6	100.0 (98.8-100.0)	97.9 (95.9-99.9)	7.22	-2.30	1.9'91	450 450/620-690	LE	LS	NA
Peptide HIV-1 & HIV-2 ELISA Test (Sero-Immuno Dianostics)	6	97.6 (95.7-99.5)	98.5 (96.7-100.0)			0.6'92	visual	E	VS	NA
UBI HIV-1/2 EIA 2nd (United Biomedical)	7	99.5 (98.6 -100.0)	92.4 (88.6 - 96.2)	4.8	-1.5	1.2'93	492/620 or 630	LE	S	NA
VIDAS HIV-1+2 (Bio Merieux)	8	100.0 (98.5-100.0)	97.8 (95.6-100.0)			3.6/'93	450	VE	S	0.3
HIV 1+2 env Peptide EIA (Labsystems OY)	8	100.0 (98.6-100.0)	76.2 (70.0-82.4)			08/2.8/'93	450	LE	LS	0.0
Enzygnost Anti-HIV 1/-HIV 2 (Behringwerke)	9	100.0 (99.6-100.0)	99.5 (98.7-100.0)	24.8	-2.55	2.6'92	450 450/615-690	LE	LS	0.0
VIRONOSTIKA HIV Uni-Form II (Organon Teknika)	9	100.0 (99.6-100.0)	98.8 (97.6-100.0)	7.4	-3.0	1.7/'94	450/660 ± 40	LE	LS	NA
BIOTEST Anti-HIV-1/-2 recombinant (Biotest AG)	9	100.0 (99.6-100.0)	99.1 (98.1-100.0)	74.9	-3.3	1.2/'94	492/570-650	LE	LS	0.0
INNOTEST HIV-1/HIV-2 Ab s.p. (Innogenetics n.v.)	9	100.0 (99.6-100.0)	98.8 (97.6-100.0)	14.0	-3.8	1.5/'94	450 450/620-690	LE	LS	NA

Annex 1 (continued)

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values [e]		Cost per test (US$) /year[g]	nm[h]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
				WB pos sera	WB neg sera					
Genelabs Diagnostics HIV-1/HIV-2 ELISA (Genelabs Diagnostics)	10	100 (99.6 -100.0)	97.3 (95.6 - 99.0)	72.2	-2.7	0.9'94	492	LE	LS	NA
HIV SCREEN (Labsystems OY)	10	100.0 (99.6 -100.0)	99.7 (99.1 -100.0)	21.51	-4.11	0.6'95	450	LE	LS	NA
HIVvisual 1 & 2 (Immuno Diagnostics Inc.)	10	90.9 (87.4 - 94.4)	94.5 (92.5 -97.3)	1.88	-1.15		450	LE	LS	NA
ETI-AB-HIV-1/2 K (Sorin Biomedica)	10	100.0 (99.6-100.0)	98.8 (97.6-100.0)	10.4	-2.5	1.5/'94	450/630	LE	LS	NA
ICE * HIV-1.O.2 (Murex Biotech Ltd.)	11	100.0 (99.6 -100.0)	99.4 (98.6 -100.0)	16.8	-4.3	0.6'95	450 450/620-690	LE	LS	NA
GENSCREEN HIV 1/2 (Sanofi Diagnostics Pasteur)	11	100.0 (99.6 -100.0)	98.5 (97.2 - 99.8)	22.8	-2.7	1.5'95	450/620	LE	LS	0.0
HIVA TEST (Lupin Laboratories Ltd)	11	100.0 (99.5 -100.0)	93.7 (91.0 - 96.4)	12.2	-1.1	0.6'98	450	LE	LS	1.5

Annex 1 (continued)

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Initial inter-reader[f] variability (%)	Cost per test (US$) /year[g]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
Simple/Rapid assays								
For the detection of antibody to HIV-1								
HIV CHEK/HIVSPOT (Genelabs Diagnostics)	1	94.5 (89.7- 97.4)	99.0 (96.4-99.9)	12.3	2.5/'88	VE	VS	
Recombigen HIV-LA (Cambridge BioScience)	1	95.2 (88.3-98.7)	96.1 (92.6-98.2)	6.0	3.0/'88	VE	S	
Immunocomb (PBS Orgenics)	1	98.8 (95.7- 99.9)	98.9 (96.0-99.9)	2.8	2.5/'89	VE	VS	
Serion Immuno Tab HIV-1 (Serion Immunodiagnostica)	2	98.9 (96.9- 99.9)	100.0 (98.3-100.0)	7.1	2.5/'90	LE	LS	1.2
Genie HIV-1 (Genetic Systems)	4	99.5 (97.4-100.0)	99.1 (96.7-99.9)	1.1	3.5/'90	VE	VS	0.2
SimpliRed HIV-1 Ab (Agen Biomedical)	5	97.5 (94.2-99.2)	91.2 (86.6-94.7)	10.5	7.8/1.5/'91	VE	S	0.7
Healthtest HIV-1 Assay (Akers Research Corp.)	6	58.7 (49.2-68.2)	89.4 (84.9-93.9)	7.0	1.4/2.3/'92	VE	S	0.2
Entebe HIV Dipstick (Hepatika Laboratories)	6	97.0 (94.4-99.6)	99.1 (97.8-100.0)			E	VS	
Abbott Retrocell HIV 1 (Abbott GmbH)	9	100.0 (99.6 -100.0)	100.0 (99.7-100.0)	2.2	1.45/'94	VE	S	0.6
For the detection of antibody to HIV-1 and HIV-2								
Test Pack HIV-1/HIV-2 Ab (Abbott)	2	100.0 (98.5-100.0)	95.9 (92.0-98.2)	1.4	4.8/'89	VE	VS	0.0
Immunocomb Bi-Spot	3	98.5	100.0	7.6	4.0/'90	VE	VS	0.9

(PBS Orgenics)	(96.3-99.6)	(98.1-100.0)

Annex 1 (continued)

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Initial inter-reader[f] variability (%)	Cost per test (US$) /year[g]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
HIV CHEK 1+2/HIVSPOT 1+2 (DuPont de Nemours)/(Genelabs Diagnostics)	3	99.3 (97.4-99.9)	100.0 (98.1-100.0)	7.2	4.0/'90	E	VS	1.0
Recodot (Waldheim Pharmazeutika)	4	98.9 (97.0-99.8)	88.6 (82.2-93.3)	31.7	2.0/'90	LE	LS	12.3
Genie HIV-1 and HIV-2 (Genetic Systems)	4	99.3 (97.5-99.9)	99.5 (97.2-100.0)	11.8	3.5/'90	VE	VS	0.0
Clonatec rapid HIV 1-HIV 2 Ab (Clonatec)	5	98.9 (96.8-99.8)	99.5 (97.2-99.8)	15.9	4.3/'91	E	VS	0.4
Recobead LA Assay (Waldheim Pharmazeutika)	6	59.8 (53.9 -65.7)	94.8 (91.7 - 97.9)	22.3	1.7/2.2/'91	VE	S	0.4
Recombigen HIV-1/HIV-2 Rapid Test Device (Trinity Biotech plc)	7	100.0 (98.7-100.0)	94.5 (91.2-97.8)	11.4	4.0/'93	E	VS	2.8
MicroRed HIV-1/HIV-2 Ab Test (Agen Biomedical)	9	98.5 (97.0-100.0)	95.5 (93.2-97.7)	1.5	1.5/1.0/'94	VE	S	0.5
SimpliRed HIV-1 /HIV-2Ab Test (Agen Biomedical)	9	99.2 (98.2 -100.0)	87.3 (83.7 -90.9)	9.5	4.0/3.0/'94	VE	S	0.3
HIV (Sav) 1&2 Rapid Sero Test (Diatech (Savyon) Diagnostica Ltd.)	10	97.7 (95.9 -99.5)	96.7 (94.8 -98.6)	5.1	1.9'94	VE	S	0.2
ENTEBE HIV Dipstick (Hepatika Laboratories)	10	100.0 (99.6 -100.0)	96.4 (94.4 -98.4)	5.0	0.8'94	VE	VS	1.3
Dipstick-HIV 1 + 2 (Pacific Biotech Co., Ltd.)	10	100.0 (99.6- 100.0)	98.2 (96.8 -99.6)	1.0	0.5'94	E	VS	0.3
DIA (Dot Immuno Assay) HIV 1 + 2 (Weiner Lab.)	10	99.6 (98.8-100.0)	99.4 (98.6-100.0)	0.8	<1.0'94	VE	VS	0.2

Annex 1 (continued)

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Initial inter-reader[f] variability (%)	Cost per test (US$) /year[g]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
SERO•STRIP HIV-1/2 (Saliva Diagnostic Systems)	11	98.9 (97.6 -100.0)	100.0 (99.7 -100.0)	1.5	1.5'95	VE	VS	0.0
RED-DOT HIV 1&2 (Cal-Test Diagnostics Inc.)	11	100.0 (99.6 -100.0)	94.9 (92.5 - 97.3)	9.5	2.9'94	VE	S	1.9
HIVCHEK System 3 Test Kit (Ortho Diagnostic Systems)	11	99.6 (98.9 -100.0)	99.7 (99.1 -100.0)	1.0	4.35'95	E	VS	0.2
Supplemental assays								
For the detection of antibody to HIV-1 or HIV-2								
RIBA HIV-1 (Chiron)	1	99.4 (96.6-100.0)	100.0 (97.9-100.0)	NA	27.6/'88	E	S	
HIV Western Blot Kit (Organon Teknika)	3	100.0 (98.2-100.0)	100.0 (98.0-100.0	NA	21.0/'90	LE	S	10.5
Wespage HIV-1 Western blot Kit (Bio Genex)	6	100.0 (99.9-100.0)	100.0 (99.9-100.0)	NA	21.6/'92	LE	VS	12.8
Wespage HIV-1 Western blot Kit II (Bio Genex)	7	100.0 (98.5 -100.0)	100.0 (98.7 -100.0)	NA	17.7/'93	LE	S	12.4
CBC HIV-2 Western blot kit (Cambridge Biotech)	7	100.0 (97.0-100.0)	100.0 (98.5-100.0)	NA	16/'93	LE	S	13.9

Annex 2

Cumulative list of assays evaluated; currently commercially available

The names (and manufacturers) of the assays evaluated to date under the WHO 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 serum populations, cost per test, ease of performance and suitability for use in small blood collection centres.

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	δ Values [e]		Cost per test (US$) /year[g]	nm[h]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
				WB pos sera	WB neg sera					
Enzyme-linked immunosorbent assays										
<u>For the detection of antibody to HIV-1 and HIV-2</u>										
Abbott Recombinant HIV-1/HIV-2 3rd Generation (Abbott)	7	100.0 (98.5-100.0)	100.0 (98.5-100.0)	11.5	-4.3	1.7/1.8'93	492	LE	LS	NA
HIV-1 and/or HIV-2 Recombigen EIA (Trinity Biotech plc)	7	100.0 (98.6-100.0)	100.0 (98.6-100.0)	10.4	-5.0	1.7/'93	490/630	LE	LS	NA
UBI HIV 1/2 EIA (United Biomedical Inc.)	9	100.0 (99.6-100.0)	100.0 (99.7-100.0)	10.8	-3.2	1.0/'94	492 492/620-690	LE	LS	NA
HIV EIA (Labsystems OY)	10	100 (99.6 -100.0)	99.4 (98.6 -100.0)	14.20	-3.85	0.6'95	450	LE	LS	NA
IMx HIV-1/HIV-2 3rd generation Plus (Abbott GmbH Diagnostika)	11	99.6 (98.9 -100.0)	97.9 (96.4- 99.4)	9.1	-2.1	3-4'95	Imx system	VE	S	0.3
Enzygnost Anti-HIV 1/2 Plus (Behringwerke AG)	11	100.0 (99.6 -100.0)	99.7 (99.1 -100.0)	19.1	-6.6	1.0'95	450 450/615-690	LE	LS	0.0
Vironostika Uni-Form II *plus* O (Organon Teknika nv)	11	100.0 (99.6 -100.0)	100.0 (99.7 -100.0)	17.2	-4.1	1.5'97	450 450/620-700	LE	LS	NA

Annex 2 (continued)

Assay (manufacturer)	Report No[a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Initial inter-reader variability[f] (%)	Cost per test (US$) /year[g]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
Simple/rapid assays								
For the detection of antibody to HIV-1								
Serodia-HIV (Fujirebio)	1	100.0 (97.6-100.0)	96.9 (93.4-99.0)	0.8	1.1/'88	E	S	
PATH HIV Dipstick (PATH)	4	99.5 (97.3-100.0)	98.2 (97.1.99.1)	1.3	<1.5'91	E	VS	0.0
SUDS Murex HIV-1 Ab test (Murex Corporation)	5	100.0 (98.5-100.0)	75.1 (69.3-80.9)	22.9	4.5/'91	VE	S	11.7
For the detection of antibody to HIV-1 and HIV-2								
Serodia-HIV-1/2 (Fujirebio)	8	100 (98.5-100.0)	100 (98.5-100.0)	6.3	2.8/'93	LE	S	0.0
SPAN COMBAIDS VISUAL (Span Diagnostics.)	8	96.5 (93.5-99.5)	100.0 (98.3-100.0)	0.8	0.4/'93	E	VS	0.0
CAPILLUS HIV-1/HIV-2 (Trinity Biotech plc)	9	100.0 (99.6-100.0)	98.8 (97.6-100.0)	0.0	2.2/'94	VE	VS	0.0
Immunocomb II BiSpot HIV 1&2 (PBS Orgenics)	9	100.0 (99.6-100.0)	99.7 (99.1-100.0))	4.5	1.7/'94	VE	VS	0.2
SPAN COMBAIDS VISUAL (Span Diagnostics Ltd.)	10	100.0 (99.6-100.0)	88.0 (84.5-91.5)	6.3	0.5'94	E	S	3.2
HIV TRI-DOT (J. Mitra & Co. Ltd.)	11	99.6 (98.9 -100.0)	99.7 (99.1 -100.0)	3.2	2.0'96	VE	VS	0.2

Annex 2 (continued)

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Initial inter-reader[f] variability (%)	Cost per test (US$) /year[g]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
AccuSpot HIV-1 and 2 (Specialty BioSystems Inc.)	11	100.0 (99.6 -100.0)	86.3 (82.5 - 90.1)	10.8	2.5'95	VE	S	5.0
BIONOR HIV-1&2 (Bionor A/S)	11	100.0 (99.6 -100.0)	98.8 (97.6 -100.0)	1.0	2.5'95	VE	S	0.2
SEROCARD HIV (Trinity Biotech plc)	11	100.0 (99.6 -100.0)	97.9 (96.4 - 99.1)	1.5	4.0'94	VE	VS	0.2
HIV 1 & 2 DoubleCheck (Orgenics)	11	100 (99.6 -100.0)	99.4 (98.6 -100.0)	0.8	2.0'96	VE	VS	0.2
EasiDot HIV/EasiSpot HIV (Nubenco Diagnostics)	11	95.3 (92.7 - 97.9)	71.3 (66.4 - 76.2)	23.7		VE	S	12.5
*Instant*CHEK™-HIV 1+2 (EY Laboratories Inc)	14	99.4 (96.5 - 110.0)	97.6 (95.2 - 99.0)	4.6	1.0'03	E	S	0.0
GENIE II HIV-1/HIV-2 (Bio-Rad)	14	100 (97.7 - 100)	99.7 (98.1 - 100)	0.7	2.55'03	E	VS	0.2
Efoora HIV Rapid (Efoora Inc)	14	96.2 (91.9 - 98.6)	98.9 (95.6 - 99.3)	3.8	0.75-2.60'03	VE	S	0.4
OraQuick HIV-1/2 Rapid HIV-1/2 (OraSure Technologies Inc)	14	98.1 (94.5 - 99.6)	100.0 (98.8 - 100)	2.4	NA	VE	VS	0.4
SD Bioline HIV 1/2 3.0 (Standard Diagnostics)	14	100.0 (97.7 - 100.0)	99.3 (97.6 - 99.9)	3.5	1.10'03	VE	VS	0
Hema • Strip(R) HIV 1/2 (Chembio Diagnostics Inc)	14	98.1 (94.5 - 99.6)	100.0 (98.8 - 100.0)	3.3	1.85-2.5'03	VE	VS	0.0

Annex 2 (continued)

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Initial inter-reader[f] variability (%)	Cost per test (US$) /year[g]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
HIV 1/2 STAT-PAK (Chembio Diagnostics Inc)	14	97.6 (93.6 - 99.3)	100.0 (98.8 - 100.0)	0.7	0.75-1.25'03	VE	VS	0.0
HIV (1+2) Antibody (Colloidal Gold) (KHB Shanghai Kehua Bioengineering Co. Ltd)	14	100 (97.7 - 100.0	100.0 (98.8 - 100.0)	0.2	1.50'03	VE	VS	0.0
GENEDIA(R) HIV 1/2 Rapid 3.0 Green Cross Life Science Corp)	14	100 (97.7 - 100.0)	99.7 (98.1 - 100.0)	1.8	0.93-1.15'03	VE	VS	0.0
DoubleCheckGold™ HIV 1&2 (Orgenics Ltd)	14	Lot A 99.4 (96.5 - 100.0) Lot B 100.0 (97.7 - 100.0)	Lot A 95.6 (92.6 - 97.6) Lot B 94.6 (91.4 - 96.9)	2.4	0.65-0.70'03	VE	VS	Lot A 0.9 Lot B 2.0
Supplemental assays								
For the detection of antibody to HIV-1								
Ancoscreen (Ancos)	2	100.0 (97.8-100.0)	90.4 (82.6-95.5)	NA	10.8/21.5/'89	LE	LS	31.4
IFA anti-HIV-1 (Waldheim Pharmazeutika)	5	98.9 (96.9-99.8)	100.0 (98.3-100.0)	13.8	5.6/'91	LE	LS	0.7
New Lav-Blot-I (Sanofi Diagnostics Pasteur)	5	100.0 (98,.1-100.0)	100.0 (96.8-100.0)	NA	11.6/'91	E	S	30.6
HIV-1 Western Blot Kit (Open Tray Procedure) (Bio Genex)	7	100.0 (98.5-100.0)	100.0 98.7-100.0)	NA	17.7/'93	LE	S	6.7

Annex 2 (continued)

Assay (manufacturer)	Report No [a]	Sensitivity (%)[b,c]	Specificity (%)[c,d]	Initial inter-reader[f] variability (%)	Cost per test (US$) /year[g]	Ease of performance[i]	Suitability[j]	Indeterminate results[k] (%)
For the detection of antibody to HIV-2								
IFA anti-HIV-2 (Waldheim Pharmazeutika)	5	98.7 (93.1-99.7)	100.0 (98.2-100.0)	11.0	6.0/'91	LE	LS	1.8
For the detection of antibody to HIV-1 and HIV-2								
INNO-LIA HIV-1/HIV-2 Ab (Innogenetics)	2	100.0 (98.6-100.0)	100.0 (98.0-100.0)	NA	18.4/'89	LE	S	4.3
Speedscreen HIV (British Bio-Technology)	4	100.0 (99.4-100.0)	66.4 (57.9-74.1)	NA	17.0/'90	LE	S	16.9
Pepti-Lav 1-2 (Sanofi Diagnostics Pasteur)	4	99.3 (96.4-99.9)	100.0 (98.1/100.0)	NA	21.5/'90	LE	S	0.7

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 - unpublished document GPA/RES/BMR/89.4
Report 2 - unpublished document GPA/RES/BMR/90.1
Report 3 - unpublished document GPA/RES/BMR/91.1
Report 4 - unpublished document GPA/RES/DIA/91.6
Report 5 - unpublished document GPA/RES/DIA/92.8
Report 6 - unpublished document GPA/RES/DIA/93.4
Report 7 - unpublished document GPA/RES/DIA/93.6
Report 8 - unpublished document GPA/RES/DIA/94.4
Report 9/10 - unpublished document WHO/BLS/98.1
Report 11 - unpublished document WHO/BTS/99.1

b,c,d: Sensitivity, specificity and 95% confidence limits were calculated as described on pp 15 - 17 of this document.

e: δ-values were calculated as described in previous documents , see above.

f: Inter-reader variability was calculated as described on page 17 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 tables 4b and 10b.

j: Suitability for use in small laboratories is defined on tables 5 and 11.

k: Indeterminate results were calculated as described in the explanatory notes on page 40.

Annex 3

Cumulative list of assay manufacturers' addresses

Abbott GmbH, Diagnostika, Max-Planck-Ring 2, 65205 Wiesbaden, Germany.
Tel: (49 6122) 58 16 23; Telex: 4182555; Fax: (49 6122) 58 16 12.

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, Hϕjby, Denmark.
Tel: (45 59) 30 65 55; Telex: 42580 ancos dk; Fax: (45 59) 30 60 45.

Biochem Immunosystèmes., 10900 rue Hamon, Montréal (Québec), Canada H3M 3A2. Tel: (1 514) 335 9922; Telex: 058-27642 IAF BCM MTL; Fax: (1 514) 335 9919.

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) 8-0 10; Telex: 4185429; Fax: (49 6103) 8-0 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.

Annex 3, continued

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: 0001 909 902-0550, Fax: 0001 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.

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 2648

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.
Fujirebio Europe BV, Takkebijsters 69c, 4817 BL Breda, The Netherlands
Tel: (31 76) 571 0440; Fax: (31 76) 587 2181

Genelabs Diagnostics, Halle de Frêt, P. O. Box 1015, 1215 Geneva 15 Airport, Switzerland.
Tel: (41 22) 788 1908; Fax (41 22) 788 1986.

Genetic Systems Corporation, 3005 First Avenue, Seattle, WA 98121, USA.
Tel: (1 206) 728 4900; Telex: 532050 Genetic Systems; Fax: (1 206) 728 4950.

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

Annex 3, continued

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) 9988-0; 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.

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, Pulttitie 8, P. O. Box 8, 00881 Helsinki, Finland.
Tel: (358 0) 75821; Telex: 123569 Labsy sf; Fax: (358 0) 7557610.

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

Nubenco Enterprises, Inc. One Kalisa Way, Suite 207 Paramus, New Jersey 07652-3508, USA. Tel: (1 201) 967 9000; Fax +1 201 967 9444

Annex 3, continued

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.

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.

Saliva Diagnostic Systems (SDS), SDS International Ltd., 11 Sovreign 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.
Tel: (972 8) 562920; Fax (972 8) 563258

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.

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.

Annex 3, continued

Specialty BioSystems, Inc. 5870 Pacific Center Boulevard, Suite A, San Diego, California 92121 USA. Tel: (1 619) 457 9927; Fax: (1 619) 457 2425

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;
email: 100302.2552@compuserve.com.

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

Annex 4

WHO HIV Test Kit Bulk Procurement Scheme

World Health Organization, Geneva

WHO HIV Test Kit — Bulk Procurement Scheme

"ensuring access to high quality, low cost HIV test kits"

The Issue

HIV test kits are essential for:

- ✓ Diagnosis of HIV infection
- ✓ Screening of donated blood
- ✓ Surveillance
- ✓ Voluntary counselling and testing
- ✓ Prevention of mother-to-child transmission

However…

- HIV test kits account for a substantial proportion of the budgets of most National AIDS Control Programmes.
- National and local blood transfusion services in many countries do not have the financial resources to purchase the required number of test kits.
- Many countries have interrupted supplies of test kits.
- Many countries require additional information to ensure that the kits they do purchase are of high quality and are suitable for their particular situation.

The Response

WHO established the HIV Test Kit Bulk Procurement Scheme in 1989. The goals of the scheme are to:

- Facilitate access to:
  - ✓ *high quality* test kits
  - ✓ at a *low cost*
  - ✓ through an *easy purchase procedure*
- Provide additional information and assistance to those selecting/purchasing test kits to ensure that the chosen kits will be appropriate for the conditions in which they will be used and will meet the overall testing objectives.

The Bulk Procurement Scheme is directed towards and assists:

- National AIDS Control Programmes
- Blood transfusion services
- UN agencies
- Nongovernmental organizations
- Donor supported HIV/AIDS projects
- Other recognized groups

High Quality

All HIV test kits available through the Bulk Procurement Scheme have been evaluated by WHO. These evaluations assess the operational characteristics of the tests i.e. sensitivity, specificity, ease of performance and storage conditions. To be eligible for inclusion in the Bulk Procurement Scheme, the evaluated test kits must meet current standards. All test kits included in the Bulk Procurement Scheme are reviewed annually.

The Bulk Procurement Scheme encompasses the main types of tests used to detect HIV antibodies today – Enzyme Linked ImmunoSorbent Assays (ELISAs), Simple/Rapid assays and Confirmatory assays. There are 22 tests on the current Bulk Procurement Scheme List of Available Assays, including a greater number of Simple/Rapid Assays than ever before.

When selecting a test kit, the following issues should be considered:

- The number of samples to be tested
- The laboratory facilities available
- The level of laboratory staff training
- The objective of the testing
- The testing strategy being followed

No single test is suitable for all testing objectives in all settings. It is important to choose the test kit which will produce the best working performance in actual, routine use.

In addition to the Bulk Procurement Scheme, recommendations and guidelines have been developed by WHO to assist with the selection of appropriate kits.

Annex 4, continued

Low Cost

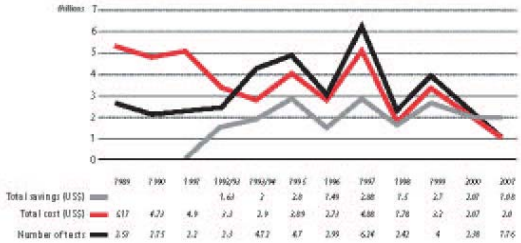
WHO negotiates prices for all assays in the Bulk Procurement Scheme directly with the manufacturers. This process enables WHO to offer a per test cost approximately half that of the open market price.

Main types of tests	Range – Open Market Price (US$)*	Average – Bulk Procurement Price (US$)*
ELISA	1.00 to 2.00	0.50
Simple/Rapid	2.00 to 8.00	1.00
Confirmatory	20.00 to 30.00	11.00

*Prices as of 2000

The resulting savings are substantial, enabling countries with limited resources to buy more HIV test kits with their funds, or to channel more resources into other areas of need, such as HIV care. The savings for 1999-2000 amounted to US$ 5 million.

HIV Bulk Purchase 1989–2001



Easy Purchase Procedure

The HIV Test Kit Bulk Procurement Scheme accepts purchase requests from programmes/institutions/organizations in 3 categories:

- Category A – WHO programmes & UN agencies
- Category B – WHO Member States & NGOs in official relations with WHO
- Category C – Other clients ie. Donor supported AIDS projects, regulatory bodies

The HIV Test Kit Bulk Procurement Scheme provides an easy-to-follow purchase procedure. Simply complete the steps indicated by this symbol ⓘ and let WHO do the rest!

ⓘ Step 1: Prepare a request which includes the following information:
- Name of requesting programme
- Contact person (ie. name, telephone)
- Test kit name & manufacturer*
- Order code*
- Number of test kits required (indicate number of tests per kit where necessary)

*as on the Bulk Procurement List

ⓘ Step 2: Submit this request to one of the appropriate offices for your category:
- WHO Headquarters, Geneva (Category A)
- WHO Regional Office (Category A, B)
- WHO Country Representative (Category B)
- UNAIDS Representative (Category B, C)
- Ministry of Health (Category C)

Step 3: Payment will be debited from your account (Category A) or a proforma invoice will be issued to you (Category B and C). Goods must be paid for in full before purchase is initiated.

Step 4: Procurement Services purchases the requested kits.

Step 5: WHO ships the goods to the airport of destination.

Step 6: The consignee is responsible for customs clearance and delivery of the goods.

Further Information

Further information on the WHO HIV Test Kit Bulk Procurement Scheme is available from the following sources:

WHO Headquarters —
for procurement assistance:
Procurement Services
Tel: +41 22 791 2801 Fax: +41 22 791 4196
Email: procurement@who.int

for technical assistance:
Blood Safety and Clinical Technology
World Health Organization
Avenue Appia 20, 1211 Geneva 27
Switzerland

Internet —
Visit the BCT section of the WHO website at www.who.int/bct and follow the links to Key Initiatives, HIV Diagnostics, HIV Test Kit Bulk Procurement Scheme. In addition to general information, PDF versions of the WHO HIV Test Kit Bulk Procurement Scheme Information Booklet, several fact sheets, and this brochure are (or will soon be) available for downloading. In addition, information on Test Kit Evaluation is available on this website.

Regional Offices/Country Representatives —
Contact your WHO Regional Office, WHO Country Representative, or nearest UNAIDS representative.

If you are a manufacturer and wish to submit your kit for evaluation by WHO to become eligible for inclusion in the Bulk Procurement Scheme, please visit our website or contact Blood Safety and Clinical Technology:
Fax: +41 22 791 4836
Email: bloodsafety@who.int

August 2002

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Dr P. Ghys, Projet Retro-ci, Abidjan, Côte Ivoire; Dr E Vinelli, Programa Nacional de Sangre, Comayaguela, Honduras; Dr O'Charoen, NBTS, Bangkok, Thailand; Dr E Sabino, Fundación Pró-sangue, Sao Paulo, Brazil; AIDS Reference Centre, Institute of Tropical Medicine, Antwerp, Belgium;

***