An assessment of Point of Care Tests for Hepatitis B, Hepatitis C, HIV and Syphilis for use in an Operational Environment to Provide Emergency Transfusion Support

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Evaluation methodology

Rapid test devices for the detection of four markers, antibodies to HIV, HCV and syphilis (*Treponema pallidum*) and Hepatitis B surface antigen were assessed. Devices capable of detecting more than one of these markers simultaneously were also considered.

Selection of rapid test devices

Due to financial and time constraints it was not possible to cover the whole market, but three kits (where available) of a single lot number were evaluated for each target marker. The following factors were taken into consideration for selection of these:

- CE marking (or if none, then other evidence of good performance)
- Ease of use and interpretation in a field environment / few procedural steps
- Use of the same manufacturer/ kit format across all markers (as far as possible)
- Good shelf life and suitable storage requirements

Details of the rapid test devices assessed are given in Table 1. All rapid tests for the detection of antibodies to HIV evaluated were CE marked. There was only one CE marked HCV rapid test available, and none for the detection of Hepatitis B surface antigen – the manufacturers supplied non-CE marked kits on the condition that these would not be used for diagnosis and that the results would not be made publicly available without permission. When asked, the companies indicated that the kits were not CE marked due to a lack of sensitivity insufficient for the requirements of the CE marking process. MedMira indicated that they were in the process of obtaining a CE mark for their HCV and multiple marker tests.

Table 1: Rapid test devices assessed

Marker	Supplier	CE	Kit name	Product code
HIV	BioLytical	Y	INSTI HIV-1/HIV-2	90-1016
	bioMérieux	Y	VIKIA HIV 1/2*	31 112
	Supplier A	Y	HIV Kit 3	X
	Supplier B	Y	HIV Kit 4	X

* VIKIA HIV 1/2 was evaluated previously (November 2008) – bioMérieux has given permission for the data to be incorporated into this report

Specimen panel

A moderate panel size of well-characterised serum or plasma specimens was used for assessment, including 100 positives, 100 negatives (unselected blood donor specimens obtained from the North London Blood Centre) and seroconversion panels - ten for single marker detection kits and five of each marker for multiple marker kits (syphilis seroconversion panels were not available). Details of the specimen panels are given in the individual result chapters. All of the specimens had been stored frozen prior to testing and were thawed at room temperature and centrifuged at 10,000g for ten minutes

before use to ensure that no particulate matter was introduced into the test devices. Some of the test device instructions for use indicated that freeze-thaw cycles were not permitted – in all cases, the manufacturer or supplier approved the use of our panel of specimens.

Method of assessment

The tests were used exactly as described in the kit insert for each assay unless indicated otherwise. For any test that requires visual interpretation of results, good lighting conditions are essential particularly when determining weak reactions. It was found by the evaluators that natural light allowed for the most trouble-free interpretation.

The test devices are intended for individual use, but for this project it was desirable to test them in batches due to the relatively large numbers of specimens. Batch sizes were chosen taking into consideration the time allowed from opening the test device pouches before use and the end point stabilities, in order to allow reading within the time stated in the kit inserts. The manufacturers were also consulted. The test batch sizes ranged between 5 and 25 and are indicated for each RTD.

Positive and negative specimens were randomised and each RTD was read independently by three individuals (two of whom were unaware of the expected result, and all without knowing the scores assigned by the other readers).
The following scoring system was used for recording the results:

0 = negative
1 = indeterminate result
2 = very weak, but definite reaction
3 = medium reaction
4 = strongly reactive

The consensus of the results from the three readers was used in the analysis (initial results). Where sufficient devices were available, any specimen which gave an invalid result, or one not consistent with the expected outcome, was repeated in duplicate to provide repeat reactivity results.

For each RTD, one individual performed the majority of testing and a second individual ran a smaller number to provide two sets of qualitative performance data.

All test devices were scanned immediately after reading and the images stored electronically for future reference, should this be required.

This report specifically relates to the kit version and lot numbers supplied for this evaluation (a single lot number was tested for each assay). We cannot guarantee that these will reflect the performance of other lot numbers or subsequent versions.

Interpretation of seroconversion data

Seroconversion panels comprise of a commercially available series of samples, collected at varying time periods, from persons at a high risk of exposure to the infectious agent in question. The specimens span the time when the person

seroconverted from a negative to a positive status and can give some indication of how early post-infection an assay can detect. For this assessment, seroconversion panels were available for HIV, HCV and HBsAg but only a small number (up to 10) were tested.

The results are presented firstly as the total number of positive specimens detected in all of the panels to give a ranked scoring, and secondly as comparative timing of detection. For the latter, the most sensitive assay for each seroconversion panel is assigned a value of 'time zero' and any less sensitive assay a positive value based on the number of days after the most sensitive assay detected infection. An overall mean and median delay is then calculated and represented graphically. The mean delay can be influenced by outlying results from seroconversion panels for which the interval between the last negative and the first positive specimen is long; this can give rise to an artefact due to the timing of blood collection. The median delay is not affected in the same way.

Report

This report is divided up into five sections: one for each marker (three rapid test devices for each) and one for multiple marker detection (two RTDs). For each marker, the following information is given:

Description of the assays
Evaluation specimen panel composition
Specificity results
Sensitivity results
Seroconversion results (where available)
Quality Control results
Technical appraisal
Conclusions

Human Immunodeficiency Virus (HIV)

Introduction

Three rapid test devices for the detection of HIV-1 and/or HIV-2 antibodies were assessed as part of this evaluation: **HIV Kit 3** (product number X) from Supplier A; **INSTI HIV-1/HIV-2** (product number #90-1016) from bioLytical LABORATORIES Inc and **HIV Kit 4** (product number X) from Supplier B. Results from a previous evaluation of the **VIKIA HIV 1/2** from bioMérieux completed in November 2008[4] are also included for comparison.

Background and description of the assays

INSTI HIV-1/HIV-2

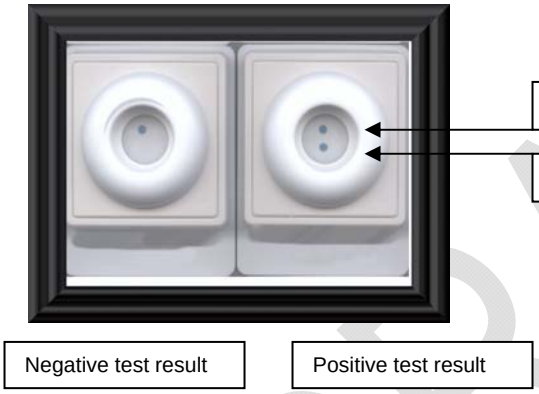

Figure H2: INSTI HIV-1/HIV-2

The INSTI HIV-1/HIV-2 antibody test from bioLytical LABORATORIES Inc is a rapid flow-through immunochromatographic assay for the qualitative detection of HIV-1 and HIV-2 in human blood (fingerstick or EDTA), serum or plasma. The kit is not suitable for diluted specimens.

The device consists of a synthetic filtration membrane positioned above absorbent material within a plastic cartridge. The membrane is coated with recombinant HIV-1 (gp41) and HIV-2 (gp36) proteins in a test spot, and a procedural control spot comprising of protein A to capture IgG antibodies. On addition of the patient's specimen to the device, any HIV specific antibodies bind to the antigens on the membrane and are detected following reaction with a proprietary chromic agent to generate a blue spot in the test zone. A blue spot is also obtained in the procedural control region. The INSTI HIV-1/HIV-2 kit insert states that the test has not been validated on Group O or N specimens.

Non-CE-marked positive (HIV-1 positive defibrinated human plasma) and negative (human serum substitute) INSTI quality control test samples are available for purchase separately from bioLytical who recommend that these be used in every batch of test runs, for new user verification and when switching to new kit lots. After consultation with bioLytical, these were not tested in this evaluation.

The kit provided for evaluation included 24 individually sealed pouches containing a ready to use test device and desiccant, and 24 vials each of Sample Diluent, Color Developer and Clarifying Solution. This kit version (product number 90-1016) also included alcohol swabs, single-use lancets and pipettes capable of dispensing 50µL. An alternative version of the kit (90-1014) is also available without these additional components for the collection of whole blood specimens.

An overview of the characteristics of the three assays under evaluation is given in Tables H1a and H1b.

Table H1a: Assay information (1)

Kit name	HIV Kit 3	HIV Kit 4	INSTI HIV-1/HIV-2
Product code			90-1016
No. of tests per kit			24
Lot no. evaluated (expiry date)			B8K163 (25.07.2009)
Specimen types that can be used			Whole blood (fingerstick, EDTA), serum, plasma
Specimen handling prior to testing			Serum, plasma stored at 2-8°C for 5 days; -20°C for 3 months or -70°C for 1 year. Whole blood stored at 4°C and tested within 48 hrs (do not freeze)
Assay type			Immunochromatographic, flow-through
Conjugate			Recombinant HIV-1 (gp41) and HIV-2 (gp36) antigens – proprietary chromic agent
Solid phase coating			HIV-1 (gp41) and HIV-2 (gp36) antigens
Regulatory approval			CE marked
Claimed sensitivity % (from kit insert)			Fingerstick WB 97.84%; EDTA WB 98.90%; plasma 99.90%; serum 100%
Claimed specificity % (from kit insert)			Fingerstick WB 99.90%; EDTA WB, plasma 99.80%; serum 99.58%
No. of items needed but not provided:			N =3
(1)			Timer
(2)			Pipette
(3)			Pipette tips
Typical shelf life			**Data not available**
Specimen volume required			50µL
Final dilution of specimen			None
Recommended no. of specimens per run			5
No. of tests run contemporaneously for this evaluation			5

Table H1b: Assay information (2)

Kit name	HIV Kit 3	HIV Kit 4	INSTI HIV-1/HIV-2
Product code			90-1016
Total time to perform one test			8 mins
Dimensions of kit packaging: W x L x H (cm)			25.0 x 23.0 x 8.0
Storage conditions (unopened)			15 - 30°C
Stability after dilution/ reconstitution or opening and at what temp (°C)			
Reagent 1:			Sample diluent: expiry date at 15 - 30°C
Reagent 2:			Buffer 1: expiry date at 15 - 30°C
Reagent 3:			Buffer 2: expiry date at 15 - 30°C
Test units			Use immediately
Incubation temperature (°C)			**RT – please define in deg C**
Steps required for process:			N = 8
(1)			Open test device pouch
(2)			Label device
(3)			Add sample to diluent and mix
(4)			Add sample+diluent to device
(5)			Resuspend Buffer 1 by mixing
(6)			Add Buffer 1 to device
(7)			Add Buffer 2
(8)			Read
Reading endpoint stability (from earliest reading time)			5 mins
Internal control:			
Reagent control			Yes
Sample addition control			Yes
Definition of positive results			Coloured (blue) dots visible in both control and test zones

Where information differs from that given in the kit insert, variance was agreed with the manufacturer in advance

Evaluation panel and batch size

The evaluation panel for the three HIV rapid test devices assessed totalled 265 specimens (Table H2). Of these, 100 were anti-HIV negative specimens (serum samples from blood donors), 100 were anti-HIV-1 positive and 10 were anti-HIV-2 positive. Six quality control samples were tested. A more detailed breakdown is given in Table H2.

The evaluation panel used for assessment of the VIKIA HIV 1/2 assay was more comprehensive and is available in the associated report[4].

Table H2: Evaluation panel

	Specimen category	No. of specimens
1	**Anti-HIV negative serum/plasmas (blood donors)**	100
2	**Anti-HIV positive samples:**	
	HIV-1	99
	HIV-2	10
3	**Seroconversion panels[a] (10 Panels, 59 specimens):**	
	BBI - PRB916	6
	BBI - PRB917M	5
	BBI - PRB919	3
	BBI - PRB922	4
	BBI - PRB924	8
	BBI - PRB929	7
	BBI - PRB930	4
	BBI - PRB940	8
	BBI - PRB943	7
	BBI - PRB944	6
4	**QC specimens[b]:**	
	HPA-HIV1-QC1	1 (3x)
	HPA-HIV1-QC2	1 (3x)
	HPA-HIV1-QC3	1 (3x)
	HPA-HIV1-QC5	1 (3x)
	HPA-HIV2-QC2	1 (3x)
	HPA-HIV2-QC3	1 (3x)
	Total number of specimens	**274**

a: BBI: SeraCare, formerly Boston Biomedica Inc; b: from the Quality Control Reagents Unit, Health Protection Agency.

The panel of 100 HIV-positive specimens contained members from different risk categories, including injecting drug users (IVDU), transfusion recipients, multiple partners and contacts from high risk (Table H3).

For this evaluation, the following batch sizes were used: 20 for HIV Kit 3; 25 for HIV Kit 4 and five for INSTI HIV-1/HIV-2.

Table H3: HIV-1 antibody positive evaluation panel composition

Risk category	No. tested
Africa - Ghana	6
Africa - Mozambique	1
Africa - South Africa	3
Africa - Uganda	3
Argentina	2
India	1
North America	1
HIV-1Subtype CRF02_AG (+HIV-2)	1
HIV-1Subtype B	2
HIV-1Subtype C	2
HIV-1Subtype D	2
Prostitute	4
Bisexual	2
Homosexual	5
High risk sex	13
Multiple partners	39
HIV +ve partner	1
IVDU	7
Transfusion recipient	5

Results

Specificity

The panel used to assess specificity comprised 100 anti-HIV negative, unselected blood donors' specimens. On initial testing, all of the 100 specimens were unreactive in the three assays to give a specificity of 100% (95% CI 96.4-100%) (Table H4). This specificity was also obtained in the VIKIA HIV 1/2 evaluation[4].

Table H4: Initial reactivity

Rapid test device	No. tested	Consensus results of 3 readers			
		Medium/ strong reactive	Weak reactive	Indeterminate	Negative
HIV Kit 3	100				
• HIV-1 result		0	0	0	100
• HIV-2 result		0	0	0	100
INSTI HIV-1/HIV-2	100	0	0	0	100
HIV Kit 4	100	0	0	0	100
VIKIA HIV 1/2	100	0	0	0	100

Sensitivity: HIV-1

One hundred anti-HIV-1 positive specimens were included in the specimen panel. The results are presented as the consensus result of the three independent readers, Table H5a,b.

On initial testing, the INSTI HIV-1/HIV-2 assay detected 100 specimens, to give a sensitivity of 100% (95% CI: 96.4-100%) (Table H5a). The HIV Kit 3 assay discriminates between HIV-1 and HIV-2: all 100 specimens were detected by the HIV-1 assay (sensitivity of 100%, 95% CI: 96.4-100%), and three were also reactive in the HIV-2

assay. One of these was a known dual HIV-1/HIV-2 positive specimen and the other two represent cross reactive results.

In the HIV Kit 4 assay, three specimens gave an invalid control result and the remaining 97 specimens were initially reactive (95 of medium or strong reactivities and two weakly reactive) to give an initial specificity of 100% (95% CI: 91.5-99.4%) (Table H5b). Upon retesting in duplicate, these three specimens were strongly reactive to give a final sensitivity of 100% (95% CI: 96.4-100%).

In the evaluation previously performed, 98 HIV-1 positive specimens were assessed using the VIKIA HIV 1/2. Two were found to be viscous and failed to migrate along the membrane – these were excluded from the results to give a sensitivity of 100% (95% CI: 96.4-100%).

Table H5a: Comparative HIV initial sensitivity for the anti-HIV assays

Rapid test device	No. tested	Consensus initial results of 3 readers			
		Medium/ strong reactive	Weak reactive	Indeterminate	Negative
HIV Kit 3	100				
• HIV-1 result		99	1	0	0
• HIV-2 result		1[a]	2	1	96
INSTI HIV-1/HIV-2	100	100	0	0	0
HIV Kit 4	100[b]	95	2	0	0
VIKIA HIV 1/2	98	96	0	0	0

a: specimen is a known HIV-1/HIV-2 dual positive; b: 3 HIV Kit 4 tests and 2 VIKIA HIV 1/2 were invalid

Table H5b: Comparative HIV repeat sensitivity for the anti-HIV assays

Rapid test device	No. tested	Consensus repeat results of 3 readers			
		Medium/ strong reactive	Weak reactive	Indeterminate	Negative
HIV Kit 3	100				
• HIV-1 result		99	1	0	0
• HIV-2 result		1[a]	2	1	96
INSTI HIV-1/HIV-2	100	100	0	0	0
HIV Kit 4	100	98	2	0	0
VIKIA HIV 1/2	98	96	0	0	0

a: specimen is a known HIV-1/HIV-2 dual positive.
There were no repeat tests performed for the VIKIA HIV 1/2 assay

Sensitivity: HIV-2

Ten anti-HIV-2 positive specimens were assessed. The consensus results of the three readers are given in Table H6. The three assays all detected the 10 HIV-2 specimens with a medium or strong reactive result (100%: 95% CI: 69.2-100%). The HIV Kit 3 assay showed some cross-reactivity in the HIV-1 test region, giving five positive results (three medium and two weak reactives), and three indeterminates. Only one of these specimens had an indeterminate HIV-1 result in reference tests performed by the Virus Reference Department of the HPA CfI; the others were confirmed to be HIV-1 negative.

From previous data, the VIKIA HIV 1/2 assay was assessed using 19 HIV-2 positive specimens, 12 were medium or strongly reactive while seven were weakly reactive, giving an HIV-2 sensitivity of 100% (95% CI: 82.4-100%).

Table H6: Comparative HIV-2 sensitivity for the anti-HIV assays

Rapid test device	No. tested	Consensus results of 3 readers			
		Medium/ strong reactive	Weak reactive	Indeterminate	Negative
HIV Kit 3: • HIV-1 result • HIV-2 result	10	 3[a] 10	 2 0	 3 0	 2 0
INSTI HIV-1/HIV-2	10	10	0	0	0
HIV Kit 4*	10	10	0	0	0
VIKIA HIV 1/2	19	12	7	0	0

a: one of these specimens was equivocal for HIV-1, the remainder were HIV-1 negative

Overall sensitivity (HIV-1 plus HIV-2)

Combining the HIV-1 and HIV-2 results, the sensitivities of the three assays were all 100% (95% CI: 96.7-100); this sensitivity was also obtained using the VIKIA HIV 1/2 (95% CI: 96.8-100).

Seroconversion sensitivity

The ability to detect early infection in ten seroconversion panels from SeraCare (formerly Boston Biomedica Inc, BBI) was compared for HIV Kit 3, INSTI HIV-1/HIV-2, HIV Kit 4 and with previous data from the assessment of VIKIA HIV 1/2[4] and three EIAs.

The highest score obtained of the rapid tests was 25 out of 58 obtained from the INSTI HIV-1/HIV-2, followed by VIKIA HIV 1/2 with a score of 24, HIV Kit 4 with a score of 23 and HIV Kit 3 with a score of 22.

Table H7 and Appendix Table A1 show the sum of positives found in each panel for the assays evaluated.

Table H7: Comparative seroconversion sensitivity based on 10 HIV panels

HIV assay	No. of positive specimens (no. of days from initial bleed to first positive result)										Score (max=58)
	PRB916 N=6	PRB917M N=5	PRB919 N=3	PRB922 N=4	PRB924 N=8	PRB929 N=7	PRB930 N=4	PRB940 N=8	PRB943 N=7	PRB944 N=6	
INSTI HIV-1/HIV-2	2 (30)	2 (65)	2 (9)	3 (4)	3 (33)	2 (25)	1 (10)	6 (11)	2 (19)	2 (14)	25
VIKIA HIV 1/2	2 (30)	2 (65)	3 (0)	3 (4)	3 (33)	1 (28)	2 (7)	5 (15)	1 (21)	2 (14)	24
HIV Kit 4	2 (30)	2 (65)	2 (9)	2 (7)	2 (35)	2 (25)	2 (7)	5 (15)	2 (19)	2 (14)	23
HIV Kit 3	2 (30)	2 (65)	2 (9)	2 (7)	3 (33)	2 (25)	2 (7)	4 (18)	1 (21)	2 (14)	22
Architect HIV Ag/Ab	3 (15)	5 (0)	3 (0)	4 (0)	4 (26)	5 (14)	4 (0)	8 (0)	5 (7)	5 (2)	46
Genscreen HIV Ultra Ag/Ab	3 (15)	5 (0)	3 (0)	4 (0)	4 (26)	5 (14)	3 (3)	7 (7)	5 (7)	5 (2)	44
Genscreen HIV 1/2 V2	2 (30)	2 (65)	3 (0)	4 (0)	3 (33)	5 (14)	2 (7)	6 (11)	2 (19)	4 (7)	33

Timing of detection was analysed by assigning the most sensitive assay for each seroconversion panel a value of 'time zero', and any less sensitive assay a positive value based on the number of days after the most sensitive assay detected infection. An overall mean and median delay was then calculated for the seroconversion panels tested (Table H8, Figure H4).

Table H8: Comparative timing of detection based on 10 HIV panels

HIV assay	Overall delay in detecting seroconversion compared with the most sensitive assay (days)		
	Range	Mean	Median
INSTI HIV-1/HIV-2	4 - 65	15.6	11
HIV Kit 4	7 - 65	16.2	11.5
HIV Kit 3	7 - 65	16.5	11.5
VIKIA HIV 1/2	0 - 65	15.3	13
Architect HIV Ag/Ab	0 - 0	0	0
Genscreen HIV Ultra Ag/Ab	0 - 7	1.0	0
Genscreen HIV 1/2 V2	0 - 65	13.3	9

Using mean values, the VIKIA HIV 1/2 rapid test detected seroconversion 15.3 days later than the most sensitive test overall, 2 days later than the most sensitive antibody detection only EIA and had the earliest detection value for the rapid tests. The other rapid tests had similar mean delays; the INSTI HIV-1/HIV-2 detected seroconversion a mean of 0.3 days later, the HIV Kit 4 detected 0.9 days later and the HIV Kit 3 detected 1.2 days later than the VIKIA HIV 1/2.

Using median values, the INSTI HIV-1/HIV-2, HIV Kit 4, HIV Kit 3 and VIKIA HIV 1/2 detected seroconversion 11, 11.5, 11.5 and 13 days later, respectively, than the most sensitive assay overall.

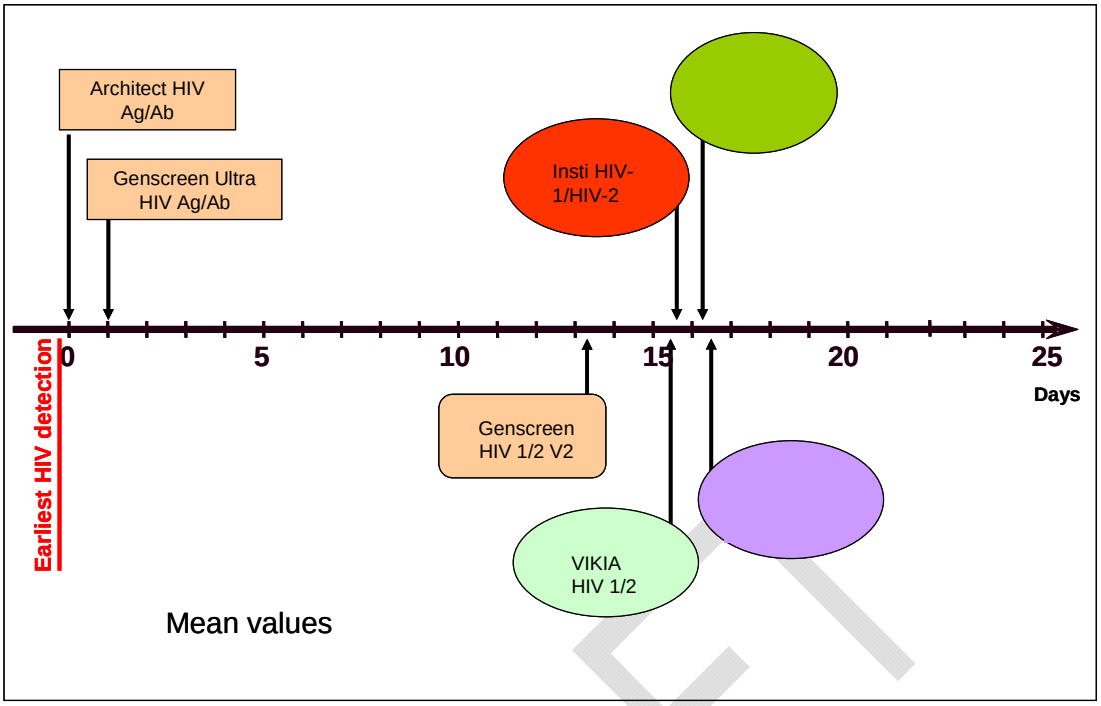

Figure H4: <u>Mean</u> comparative timing of detection of primary HIV seroconversion

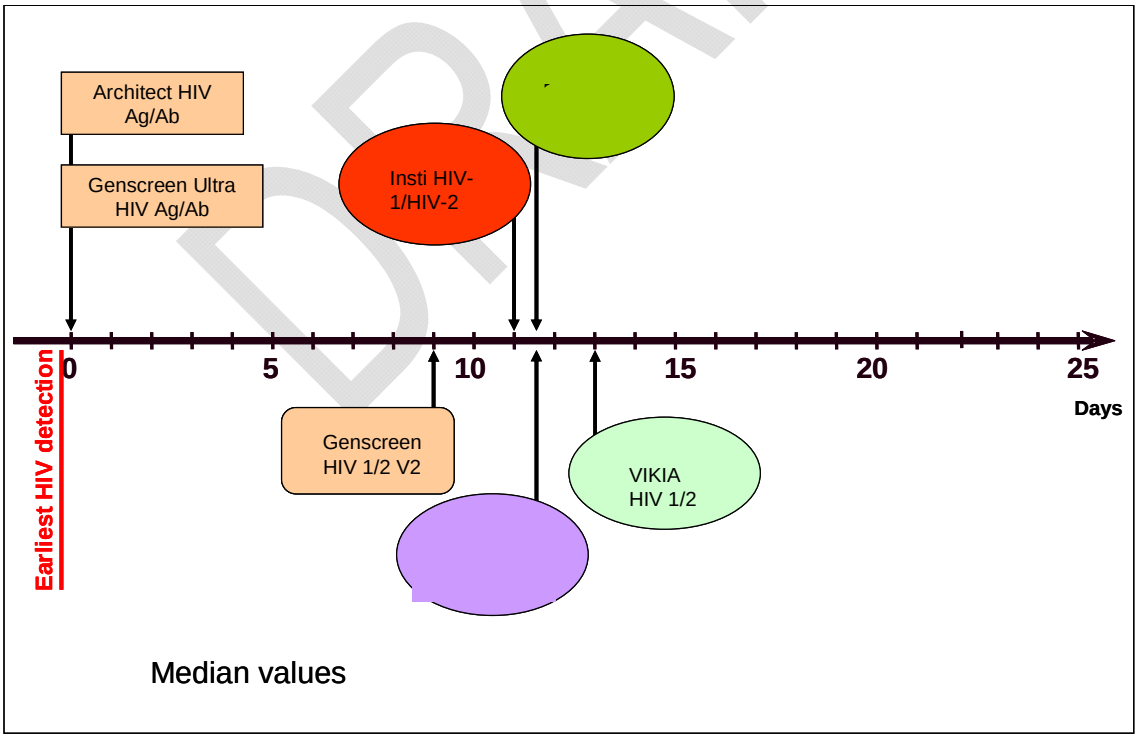

Figure H5: <u>Median</u> comparative timing of detection of primary HIV seroconversion

Results for Quality Control samples

Six quality control specimens (four HIV-1 and two HIV-2) were tested in triplicate in the assays under evaluation and compared with results obtained from the VIKIA HIV 1/2 assay (Table H10).

Table H10: Internal quality controls for HIV kit monitoring

Control name	Product reference[a]	Consensus result			
		Determine HIV-1/2	HIV Kit 3	INSTI HIV-1/HIV-2	VIKIA HIV 1/2
HIV-1 QC1	QCRHIV1QC1	Med/strong pos	Weak pos	Negative	Med/strong pos
HIV-1 QC2	QCRHIV1QC2	Weak pos	Negative	Negative	Indeterminate
HIV-1 QC3	QCRHIV1QC3	Negative	Negative	Negative	Invalid
HIV-1 QC5	QCRHIV1QC5	Med/strong pos	Weak pos[b]	Negative	Med/strong pos
HIV-2 QC2	QCRHIV2QC2	Weak pos	Weak pos	Negative	Med/strong pos
HIV-2 QC3	QCRHIV2QC3	Negative	Negative	Negative	Weak pos[c]

a: Controls obtained from the Quality Control Reagents Unit, Health Protection Agency
b: Two tests were weakly reactive and one was indeterminate
c: Two tests were weakly reactive and one was medium/strongly reactive

The HIV-1 QC3 control was not reactive in any of the assays and hence is not suitable for use with these devices. Similarly, HIV-2 QC3 was negative in all except the VIKIA HIV 1/2 assay.

None of the QCs were reactive in the INSTI HIV-1/HIV-2 test – this is likely to be because the QCs tested are diluted specimens which are not suitable for this assay; QC samples for use with the INSTI HIV-1/HIV-2 assay are available from bioLytical. The HIV-1 QC1, HIV-1 QC5 and HIV-2 QC3 specimens were all reactive in the remaining three assays and hence would be suitable as QCs for these tests.

Technical appraisal

INSTI HIV-1/HIV-2

One test was invalid on initial testing, however the specimen gave a valid result on retesting. The majority of control lines were scored as 4 (strongly reactive) with only a few as 3 (medium reactivity) by all three readers for the specimens tested.

One sample in the evaluation was replaced as it was too cloudy/viscous to pass through the membrane of the test device.

A subjective analysis was completed by two staff members who had both conducted testing on the three assays. Their findings are as follows.

The clarity and presentation of the instructions in the kit insert were considered moderately good by both operators: on a scale of 1 (good) to 5 (poor), one operator gave a score of 2 and one a score of 3 for these factors. The kit and reagent packaging were deemed to be moderately clearly labelled and easy to identify (scores of 3 from both operators).

All three readers assessed the assay for ease of interpretation, ie how easy/difficult to determine whether the specimen result was positive or negative. On a scale of 1-10, where 1=very easy to 10=very difficult, all of the readers gave a score of 1.

An overall opinion was sought from the two operators of the assay and on a score of 1 to 5 (1=good, 5=poor), one operator gave a score of 3 and one of 4.

The main reasons why this test scored lower than others in the subjective analysis were: difficulties using the pipettes provided in the kit, which did not always reliably pick up the sample; the relatively large number of steps involved in the test process which could lead to mistakes in operation; the number of reagents required which were felt to make the kit heavy and bulky compared to other RTDS; and the very short time reading time.

Conclusions – HIV tests

When tested against a panel of100 anti-HIV negative serum/plasma specimens the INSTI HIV-1/HIV-2, HIV Kit 3 and HIV Kit 4 assays gave specificity of 100%. In a previous evaluation, the VIKIA HIV 1/2 also gave a specificity of 100%.

When tested against a panel of 100 anti-HIV positive specimens, all three assays gave an initial sensitivity of 100% as did the VIKIA HIV 1/2 assay.

The seroconversion sensitivity of the three assays was similar to each other but less sensitive than currently available antibody-only detection EIAs and, as would be expected, poor in comparison with currently available antigen/antibody detection enzyme immunoassays.

When assessed subjectively, the HIV Kit 3 and INSTI HIV-1/HIV-2 score equally highest for ‘ease of interpretation’. The HIV Kit 3 scored highest for ‘overall opinion’, followed by the HIV Kit 4 and then the INSTI HIV-1/HIV-2.

References

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3 **Cole MJ, Perry KR, Parry JV** (2007): Comparative evaluation of 15 serological assays for the detection of syphilis infection; *European Journal of Clinical Microbiology & Infectious Diseases26 (10) 705-13* http://dx.doi.org/10.1007/s10096-007-0346-9

4 **Gonen G, Perry K** (2008): Evaluation of the VIKIA HIV 1/2 rapid test (bioMérieux); *PER07008, p1-14*. Available from www.hpa-midas.org.uk/reports

5 **Burgess C, Perry K, Newham J, Kitchen A** (2008): Evaluation of Abbott Architect HBsAg Assay Product code 6C36 *NBSR7002, p1-18*. Available from www.hpa-midas.org.uk/reports

Appendix A: raw data for seroconversion panels

Table A1: Raw data for HIV seroconversion panel analysis of three RTDs

Panel member*	Consensus result of three readers			
	HIV Kit 3		HIV Kit 4	INSTI HIV-1/HIV-2
	HIV-1 result	(HIV-2 result)		
PRB 916-01	0	0	0	0
PRB 916-02	0	0	0	0
PRB 916-03	0	0	0	0
PRB 916-04	0	0	0	0
PRB 916-05	3	0	4	3
PRB 916-06	3	1	4	3
PRB 917M-01	0	0	0	0
PRB 917M-02	0	0	0	0
PRB 917M-03	0	0	0	0
PRB 917M-05	2	0	4	4
PRB 917M-06	2	0	4	4
PRB 919-01	0	0	0	0
PRB 919-02	2	0	4	3
PRB 919-03	2	0	4	3
PRB 922-01	0	0	0	1
PRB 922-02	1	0	0	3
PRB 922-03	2	0	2	4
PRB 922-04	2	0	2	4
PRB 924-01	0	0	0	0
PRB 924-02	0	0	0	0
PRB 924-03	0	0	0	0
PRB 924-04	0	0	0	0
PRB 924-05	0	0	0	0
PRB 924-06	2	0	0	3
PRB 924-07	2	0	2	3
PRB 924-08	2	0	3	3
PRB 929-01	0	0	0	0
PRB 929-02	0	0	0	0
PRB 929-03	0	0	0	0
PRB 929-04	0	0	0	0
PRB 929-05	0	0	0	0
PRB 929-06	2	0	2	2
PRB 929-07	2	0	3	4
PRB 930-01	0	0	0	0
PRB 930-02	0	0	0	0
PRB 930-03	2	0	3	0
PRB 930-04	3	0	4	3
PRB 940-01	0	0	0	0
PRB 940-02	0	0	0	0
PRB 940-03	1	0	1	2
PRB 940-04	1	0	4	3
PRB 940-05	2	1	4	3
PRB 940-06	2	1	4	4
PRB 940-07	2	1	4	4
PRB 940-08	2	1	4	4
PRB 943-01	0	0	0	0
PRB 943-02	0	0	0	0
PRB 943-03	0	0	0	0
PRB 943-04	0	0	0	0
PRB 943-05	0	0	0	0
PRB 943-06	1	0	2	2
PRB 943-07	3	0	2	4
PRB 944-01	0	0	0	0
PRB 944-02	0	0	0	0
PRB 944-03	0	0	0	0
PRB 944-04	0	0	0	0
PRB 944-05	2	0	3	3
PRB 944-06	2	0	4	4

* PRB 917M excludes specimens 4 and 7. Negative or borderline results are shaded in grey

Appendix B: Manufacturer/supplier details

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