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LABORATORY EVALUATION OF HIV RAPID ASSAY

KIT NAME: INSTI HIV 1/2 Rapid Antibody Test

SUPPLIER'S NAME: Biocom Biotech

MANUFACTURER'S NAME: Biolytical Laboratories Inc

SPECIMENS RECOMMENDED: Whole Blood, Finger Stick Blood, Serum or Plasma

KIT CONTENT: Membrane Unit(Test Device), Sample Diluent, Colour Developer, Clarifying Solution, Controls(HIV-1 POS, HIV-2 POS and HIV1/2 NEG), Disposable Pipette

TIME DURATION OF TEST: 5 minutes to read the test. Takes approx 5 minutes to prepare sample for testing and to add reagents during testing

STORAGE TEMPERATURE: 15 -30 °C

TECHNICIANS APPRAISAL OF THE TEST KIT:

	SCORE	INSTI HIV 1/2
Number of steps in the test kit:		
1 - 2 steps	6	
3 - 5 steps	3	3
>5 steps	1	
Clarity of kit instructions:		
good	2	2
needs improvement	1	
Kit and reagent packaging and labelling:		
good	2	2
needs improvement	1	
Total (out of possible 10)	10	7
Comments on the test kit		
	Preparation of reagents required for the test is time consuming.	
	The background on the test device was very clear.	

	Results	
	were very easy to read and interpret.	

CALCULATION OF EASE OF PERFORMANCE:

Need to prepare:	
wash solution/buffer	1
controls	1
Stability after dilution/opening:	
(expiry date = 1; less = 0)	
controls	1
wash buffer	1
test strips	1
Item needed but not provided in kit:	
automatic pipette	1
disposable pipette tips	1
timer/stopwatch	1
tube rack	1
gloves	1
Technician's appraisal of the test kit (rating out of 10)	10
Total (out of a possible 20)	17
Ease of use:	
less easy < 10	
easy 10 <= x <= 15	
very easy > 15	Very Easy
1 -: positive rating: reagent needs no preparation; item provided in kit	
0 -: negative rating: reagent needs preparation; item not provided in kit	

ASSAY ASSESSMENT

Number of samples tested:	500
Number of positive samples:	247
Number of negative samples:	253

INSTI HIV 1/2 RAPID TEST KIT RESULTS

Number of Positive Samples:	247	(20 Weak Positives)
Number of Negative Samples:	253	
Number of False Positive Samples:	0	
Number of False Negative Samples:	0	

STATISTICAL ANALYSIS

Sensitivity:	100%
Specificity:	100%
PPV:	100%
NPV:	100%

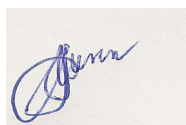
SERIAL DILUTION

The sample remained positive up to a dilution of 1:320

TECHNICAL SUITABILITY

	SCORE	INSTI HIV 1/2
Sensitivity:		
100%	5	5
98 - 100%	3	
<98%	0	
Specificity:		
>98%	5	5
95 - 98%	3	
<95%	0	
Incubation Temperature:		
room temperature	3	3
other than room temperature	1	
Shelf-life:		
>1 year	3	3
>= 6 months <= 1 year	2	
< 6 months	1	
Storage temperature:		
room temperature (opened kit)	5	5
room temperature (unopened kit)	2	
2 - 8 °C required	1	
Ease of performance:		

very easy	5	5
easy	3	
less easy	1	
Rapidity of performance: 1 serum		
<10 min	3	
10 -30 min	2	2
>30 min	1	
Reading:		
visual: inter-reader variability $\leq 3\%$	5	5
: inter-reader variability $>30\%$	3	
TOTAL (out of a possible 34)	34	33
Suitability for use:		
less suitable: <19		
suitable: $19 \leq x \leq 26$		
very suitable: >26		Very Suitable



Report Review: Adrian Puren, Deputy Director, Virology
15/02/2009

Please note that the evaluation is not an endorsement or otherwise by the NICD

