



LABORATORY EVALUATION OF HIV RAPID ASSAY

KIT NAME:	NHM/WF HIV1/2 Test Device
SUPPLIER'S NAME:	Nel Henning Medicals (PTY) Ltd t/a NHM (PTY) Ltd
MANUFACTURER'S NAME:	Guangzhou Wondfo Biotech Co.Ltd
KIT LOT NUMBER	W00620806W
EXPIRY DATE OF SUBMITTED KIT	22/08/2014
SPECIMENS RECOMMENDED:	Serum, Plasma and Whole Blood
KIT CONTENT:	Test Device, Dropper, Buffer Solution, Package insert
TIME DURATION OF TEST:	15 minutes
STORAGE TEMPERATURE:	4 °C - 30 °C

ASSAY ASSESSMENT

Number of samples tested:	500
Number of known positive samples:	250
Number of known negative samples:	250
Number of known HIV-2 positive samples	10

NHM/WF HIV 1/2 RAPID TEST KIT RESULTS

Number of Positive (HIV1/2) Samples:	250
Number of Negative Samples:	250
Number of HIV-2 Positive samples:	10
Number of False Positive Samples:	0
Number of False Negative Samples:	0
Number of weak or very weak positives (HIV-1/2):	12
Number is weak or very weak positives HIV-2 only	0

STATISTICAL ANALYSIS - HIV-1 ONLY

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



SERIAL DILUTION

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

TECHNICAL SUITABILITY

	SCORE	KIT SCORE
1. Number of steps in the test kit		
1 - 2 steps	2	2
3 - 5 steps	1	
>5 steps	0	
2. Clarity of kit instructions:		
Good (must include instructions for whole blood, serum and plasma, incubation times and sample volume is precise)	2	2
Needs improvement (no test method for serum/plasma or whole blood)	1	
Poor (Sample volume and Incubation times are not specific instead ranges are provided)	0	
3. Kit and reagent packaging and labelling		
Good (kit name is clearly identified, all items required to perform test is packaged, kit insert available and in English, expiry date ≥ 12 months)	2	2
Needs improvement (kits labelled with more than one name, some items not provided)	1	
Poor (kits damaged, kit insert not in English, items not packaged together, kit expired)	0	
4. Lancets:		
Provided (single use retractable)	1	
Not Provided	0	
5. Alcohol swabs:		
Provided	1	
Not Provided	0	
6. Need to prepare:		
Controls supplied with Kit	1	
Controls Not supplied with kit - preparation required	0	0
7. Sensitivity:		
99 -100%	1	1





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<99%	0	
8. Specificity:		
98 -100%	1	1
<98%	0	
9. Serial Dilution		
≥1:160	2	2
≥1:80	1	
<1:80	0	
10. Number of HIV-2 Positive Samples		
≥8	2	2
≥5 -≤ 8	1	
< 5	0	
11. Number of Weak Positives		
<5%	1	1
>5%	0	
12. Incubation Temperature during testing:		
room temperature	1	1
other than room temperature	0	
13. Shelf-life:		
>1year	1	1
<1year	0	
14. Storage temperature of test device:		
Room Temperature	1	1
2°C - 8°C	0	
15. Rapidity of performance: 1 serum (Incubation Time)		
≤10 min	2	
>10 - ≤20 min	1	1
>20 min	0	
16. Reading:		
visual: inter-reader variability ≤5%	1	1
: inter-reader variability >5%	0	





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TOTAL (out of a possible 20) Minimum Score 14/20		20	18
Suitability for use:	Has Met the Requirements of the Evaluation		

Please note Criteria 4 and 5 not scored as this was not required for the evaluation.

Report compiled by Beverley Singh and Adrian Puren

Report approved by:

AJ Puren

19/11/2012

