



# NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES

Practice No. 5200768



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## FAX TRANSMISSION COVER SHEET

DATE: 12 September 2007  
TO: Juel Health  
FAX NO.: 032 541 1064  
SUBJECT: Laboratory Evaluation Report  
SENDER: Lesley Short / Dr Adrian Puren's office

YOU SHOULD RECEIVE ...1+4.. PAGES, INCLUDING THIS COVER SHEET.



World Health Organization Collaborating Centre  
for Haemorrhagic Fevers & Arbovirus Diseases  
Member of the Regional EPI Laboratory Network  
in the capacity of a Regional Reference Laboratory

Complies with  
ISO 15189:2003  
No. M 0029



No. 2995 P. 1/5

MOLECULAR DIAGNOSTICS

12. Sep. 2007 15:05



# NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES

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Practice No. 5200768

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## LABORATORY EVALUATION OF HIV RAPID ASSAY

**KIT NAME:** Rapid Anti-HIV (1&2) Test

**SUPPLIER'S NAME:** Juel Health

**MANUFACTURER'S NAME:** Intec Products

**SPECIMENS RECOMMENDED:** Serum, Plasma, Whole Blood

**KIT CONTENT:** Test Cards, Plastic dropper, Sample diluent

**TIME DURATION OF TEST:** 15 minutes

**STORAGE TEMPERATURE:** 2 - 30°C

### TECHNICIANS APPRAISAL OF THE TEST KIT:

	SCORE	RAPID ANTI-HIV
<b>Number of steps in the test kit:</b>		
1 - 2 steps	6	6
3 - 5 steps	3	
>5 steps	1	
<b>Clarity of kit instructions:</b>		
good	2	2
needs improvement	1	
<b>Kit and reagent packaging and labelling:</b>		
good	2	2
needs improvement	1	
<b>Total (out of possible 10)</b>	<b>10</b>	<b>10</b>
<b>Comments on the test kit</b>		

### CALCULATION OF EASE OF PERFORMANCE:

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MOLECULAR DIAGNOSTICS

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	<b>RAPID ANTI-HIV</b>
<b>Need to prepare:</b>	
wash solution/buffer	1
controls	0
<b>Stability after dilution/opening:</b>	
(expiry date = 1; less = 0)	
controls	1
wash buffer	1
test strips	1
<b>Item needed but not provided in kit:</b>	
automatic pipette	1
disposable pipette tips	1
timer/stopwatch	1
tube rack	1
gloves	1
<b>Technician's appraisal of the test kit (rating out of 10)</b>	<b>9</b>
<b>Total (out of a possible 20 )</b>	<b>19</b>
<b>Ease of use:</b>	
less easy < 10	
easy 10 <= x <= 15	
very easy > 15	<b>very easy</b>

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

#### RAPID ANTI HIV TEST KIT RESULTS

Number of Positive Samples: 247 (1 weak positive)  
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 1:160

**TECHNICAL SUITABILITY**

	<b>SCORE</b>	<b>RAPID ANTI-HIV</b>
<b>Sensitivity:</b>		
100%	5	5
98 - 100%	3	
<98%	0	
<b>Specificity:</b>		
>98%	5	5
95 - 98%	3	
<95%	0	
<b>Incubation Temperature:</b>		
room temperature	3	3
other than room temperature	1	
<b>Shelf-life:</b>		
>1 year	3	3
>= 6 months <= 1 year	2	
< 6 months	1	
<b>Storage temperature:</b>		
room temperature (opened kit)	5	
room temperature (unopened kit)	2	2
2 - 8 °C required	1	
<b>Ease of performance:</b>		
very easy	5	5
easy	3	
less easy	1	
<b>Rapidity of performance: 1 serum</b>		
<10 min	3	
10 -30 min	2	2
>30 min	1	
<b>Reading:</b>		
visual: inter-reader variability <= 3%	5	5
inter-reader variability >30%	3	
<b>TOTAL (out of a possible 34)</b>	<b>34</b>	<b>30</b>
<b>Suitability for use:</b>		
less suitable: <19		
suitable: 19 <=x<=26		
very suitable: >26		<b>very suitable</b>



Report Review: Adrian Puren, Deputy Director, Virology

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



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