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In reply please refer to:
Prière de rappeler la référence: B14/445/9

Ms Jean Zhao
Asia Sales & Product Manager
InTec Products Inc
332 Xinyang Road
Xiamen 361022
République populaire de Chine

Your reference:
Votre référence:

3 May 2005

Dear Ms Zhao,

Please find enclosed the final report of the WHO evaluation of the **ADVANCED QUALITY™ Rapid HIV (1&2) Test**. A summary of the results of the evaluation is given below:

The **ADVANCED QUALITY™ Rapid HIV (1&2) Test** was evaluated by WHO in the first quarter of 2005. From this evaluation we drew the following conclusions:

The **ADVANCED QUALITY™ Rapid HIV (1&2) Test** is an immunochromatographic assay for the detection of antibodies to HIV in human serum/plasma or whole blood. A volume of 5µL of serum/plasma is needed to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities. Reading of the results can be done visually.

In this limited evaluation on a panel of 699 samples we found an initial sensitivity (95% CL) of 99.36% (98.8% - 100%) and an initial specificity (95% CL) of 99.78% (98.8% - 100%) compared to the reference assays. The final sensitivity (95% CL) was 99.68% (98.2% - 99.8%) and the final specificity (95% CL) was 99.78% (98.2% - 99.8%) compared to the reference assays. In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 0.78%.

Thank you for submitting the **ADVANCED QUALITY™ Rapid HIV (1&2) Test** for a WHO evaluation. The detailed data from this evaluation will be published in a composite report entitled "HIV Simple/Rapid Assays: Operational Characteristics."

Yours sincerely

Dr Gaby Vercauteren
Essential Health Technologies

ENCLS: as stated



Date: 29 April 2005

Final Report
WHO Re-Assessment
***ADVANCED QUALITY™* Rapid HIV (1&2) Test**
Serum/Plasma Specimens
(InTec Products)

WHO Collaborating Centre for HIV/AIDS Diagnostic and Laboratory Support
Department of Microbiology
Institute of Tropical Medicine
Antwerp, Belgium

Department of Essential Health Technologies
World Health Organization
Geneva, Switzerland

False Negative Results

Specimen WHO2-733 was initially false negative with batch 200501250 and twice negative on repeat testing with the same batch. When tested with batch 2005012503 in triplicate, both samples were still false negative.

Sample WHO2-735 was initially false negative when tested with batch 2005012502 and twice negative on repeat testing with the same batch. When tested with batch 2005012503 in triplicate, the sample was three times positive.

False Positive Results

Sample WHO3-0247 was initially false positive when tested with batch 2005012503 and twice positive on repeat testing with the same batch. When tested in triplicate with batch 2005012502, the sample was three times positive.

8.3 Positive and Negative Predictive Values

PPV (1% prevalence) : 81.97%

PPV (10% prevalence) : 98.04%

NPV (1% prevalence) : 99.99%

NPV (10% prevalence) : 99.89%

8.4 Inter-Reader Variability

Initial inter-reader variability: 0.78%

8.5 Results of the *ADVANCED QUALITY*TM Rapid HIV (1&2) Test with HIV Mixed Titer Panel

The *ADVANCED QUALITY*TM Rapid HIV (1&2) Test detected 21/25 samples in the HIV mixed titer panel.

8.2.2.1 Comparison of *ADVANCED QUALITY*TM Rapid HIV (1&2) Test
 Final Results with Reference Results for African Panel Specimens

		Reference Results**		
		+	-	
<i>ADVANCED QUALITY</i> TM Rapid HIV (1&2) Test Final Results	+	43	0	43
	-	1	55	56
		44	55	

Sensitivity (95 % CL) : 43/44 = 97.73% (88.0%-99.9%)
 Specificity (95 % CL) : 55/55 = 100% (93.5%-100%)
 Indeterminate : 0/99 = 0%
 False negatives : (see annex 3)

**+ : sera positive for anti-HIV
 - : sera negative for anti-HIV

8. Results

8.1 Validation of the *ADVANCED QUALITY™* Rapid HIV (1&2) Test Results

All test runs were valid based on the presence of internal kit control (reagent addition line).

8.2 Comparison of Initial Results with Reference Results

8.2.1 Comparison of *ADVANCED QUALITY™* Rapid HIV (1&2) Test Initial Results with Reference Results

		Reference Results**		
		+	-	
<i>ADVANCED QUALITY™</i> Rapid HIV (1&2) Test Initial Results	+	312	1	313
	-	2	454	456
		314	455	

Sensitivity (95 % CL)	: 312/314 = 99.36% (98.8%-100%)
Specificity (95 % CL)	: 454/455 = 99.78% (98.8%-100%)
Indeterminate	: 0/699 = 0%
False positives	:(see annex 3)
False negatives	:(see annex 3)

**+ : sera positive for anti-HIV
- : sera negative for anti-HIV

1. Name of the Assay

ADVANCED QUALITY™ Rapid HIV (1&2) Test

A colloidal gold enhanced rapid immunochromatographic assay for the qualitative detection of antibodies to human immunodeficiency virus (HIV) in human whole blood, serum or plasma.

Code: ITP02002-TC40
Kit Insert Version: 41217

2. Manufacturer

InTec Products, Inc
332 Xinguang Road
Xinyang Industry Area
Haicang, Xiamen 361022
P R China
Tel. +86-592-6807188
Web site: www.intecasi.com

3. Distributor

InTec Products, Inc
332 Xinguang Road
Xinyang Industry Area
Haicang, Xiamen 361022
P R China
Tel. +86-592-6807188
Web site: www.intecasi.com

4. Price per Test and Product Code

Product Code	No. of Tests per Kit	Price Local Currency	Price US\$	Conver Rat
ITP02002-TC40	40		0.80-0.90	

10. Summary

The **ADVANCED QUALITY™ Rapid HIV (1&2) Test (InTec Products)** was evaluated by WHO in the first quarter of 2005 using serum/plasma specimens. From this evaluation, we drew the following conclusions:

The **ADVANCED QUALITY™ Rapid HIV (1&2) Test (InTec Products)** is an immunochromatographic assay for the detection of antibodies to HIV in human serum/plasma or whole blood. A volume of 5 µL of specimen is needed to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities. Reading of the results can be done visually.

In this limited evaluation on a panel of 699 samples, we found an initial sensitivity (95% CL) of 99.36% (98.8%-100%) and an initial specificity (95% CL) of 99.78% (98.8%-100.0%) compared to the reference assays. The final sensitivity (95% CL) was 99.68% (98.2%-99.8%) and the final specificity (95% CL) was 99.78% (98.8%-100.0%) compared to the reference assays. In this study, 0% of the results were recorded as indeterminate.

Results were interpreted independently by three technicians; the inter-reader variability was 0.78%.

The detailed data of this evaluation will be published in an official WHO report of the operational characteristics of commercially available assays to detect antibodies to HIV in human serum/plasma. The report will be made available on the Department of Essential Health Technologies section of the WHO web site at:

http://www.who.int/diagnostics_laboratory/publications/en/