

Aim

# Evaluation Results of One Step Anti-HIV (1&2) Tri-line Test from InTec Product Inc

Evaluation period

The panel consisted of 150 anti-HIV reactive and WB positive, the 91 initially reactive for anti-HIV but had negative WB result, and 176 anti-HIV negative samples from 15 provinces throughout Indonesia were used in this evaluation. The specimens that initially reactive with negative WB result were referred as "difficult specimens" and the non-reactive specimens were referred as "negative specimens" in this evaluation.

### Evaluators:

Dr. July Kumalawati, D.M.M.  
Dr. Ninik Sukartini, D.M.M.

Table 1: Origin of specimens

Province	Number of plasma samples
Bali	15
Central Java	48
East Java	42
East Kalimantan	12
Jakarta	158
Lampung	5
North Sulawesi	11
North Sumatera	13
Papua	23
West Kalimantan	10
West Sumatera	10
Yogyakarta	10
Unknown	3
<b>Total</b>	<b>380</b>



**National Reference Laboratory for HIV  
Clinical Pathology Department  
Medical Faculty University of Indonesia  
Dr. Cipto Mangunkusumo Hospital  
Jakarta**



12 April 2006

## Aim

This evaluation was done to assess the performance of One Step Anti-HIV (1&2) Tri-line Test manufactured by InTec Product Inc under local conditions and using local specimens.

## Evaluation panel

The panel consisted of 150 anti-HIV reactive and WB positive, the 91 initially reactive for anti-HIV but had negative WB result, and 176 anti-HIV negative samples from 15 provinces throughout Indonesia were used in this evaluation. The specimens that initially reactive with negative WB result were referred as "difficult specimens" and the non-reactive specimens were referred as "negative specimens" in this evaluation.

Table 1: Origin of plasma samples by province.

Province	Number of plasma samples
Bali	15
Central Java	48
East Java	42
East Kalimantan	12
Jakarta	158
Lampung	5
North Sulawesi	11
North Sumatera	13
Papua	23
South Kalimantan	11
South Sumatera	11
Southeast Sulawesi	13
West Java	32
West Sumatera	13
Yogyakarta	7
Unknown	3
Total	417

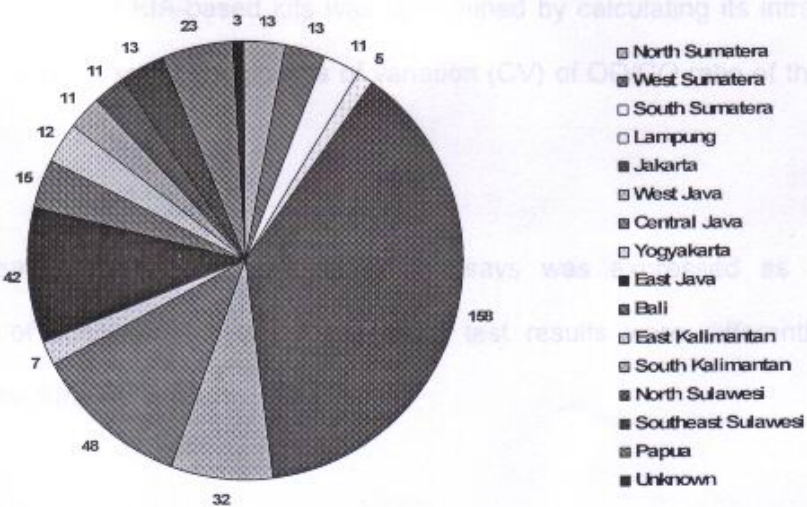


Figure 1: Provincial distribution of the evaluation panel.

**Site**

All testing was performed at Clinical Pathology Department, Medical Faculty, University of Indonesia, Dr. Cipto Mangunkusumo Hospital, Jakarta, which has been appointed as the National Reference Laboratory for HIV testing by Ministry of Health.

**Data analysis**

Sensitivity, specificity, positive predictive value and negative predictive value were calculated for each kit. Positive and negative delta values were calculated for each EIA.

The reproducibility of EIA-based kits was determined by calculating its intra-assay and between assay coefficients of variation (CV) of OD/CO ratio of the QC sample.

The inter-reader variability of simple/rapid assays was expressed as a percentage of specimens in which the initial test results were differently interpreted by different readers.

N = 150	99.33	95 % Confidence limits	98.03	100.00
Titrated specimens (N = 50)	98.47	95 % Confidence limits	96.31	98.51
Positive predictive value (%)				
at 5 % prevalence	90.20			
at 1 % prevalence	83.95			
	14.89			
	14.74			
	100.00			
	100.00			
with prevalence	100.00			
Coefficient of Variation (%)				
intra-batch				
Positive delta value	None			
Negative delta value	None			
Inter-reader variability (%)				
CV	0.25			

## Result

Sensitivity (%):	99.33	95 % Confidence limits:	98.03	-	100.00
N = 150					
Specificity (%)					
"Negative specimens":	99.43	95 % Confidence limits:	98.32	-	100.00
N = 176					
"Difficult specimens":	93.41	95 % Confidence limits:	88.31	-	98.51
N = 91					
Positive predictive values (%)					
at 5 % prevalence:	90.20				
at 1 % prevalence:	63.85				
at 0.1 % prevalence:	14.89				
Negative predictive values (%)					
at 5 % prevalence:	100.00				
at 1 % prevalence:	100.00				
at 0.1 % prevalence:	100.00				
Coefficient of Variation (%)					
intra-batch:	-				
Positive delta value:	None				
Negative delta value:	None				
Inter-reader variability (%):	0.95				

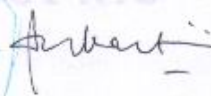
Note: None

Conclusion : This kit can be used for screening of blood products and first test in the diagnosis and surveillance of HIV infection.

Jakarta, 12 April 2006



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Evaluators

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