



# WHO BULK PROCUREMENT SCHEME 2005

## SPECIFICATIONS OF HIV TEST KITS

### SIMPLE/RAPID, ELISA and CONFIRMATORY ASSAYS

Assay Name (Manufacturer)	Order Code	No. of Tests per Kit	Sensitivity <sup>1</sup>	Specificity <sup>1</sup>	Guaranteed Shelf Life/ Storage Temp (°C)	HIV Type <sup>2</sup>	Assay Type/ Antigen Type	Sample Type	Equipment Requirements <sup>3</sup>	Cost/ Test <sup>4</sup>
<b>Simple/Rapid Assays</b>										
Advanced Quality™ HIV Rapid Test (InTec Products)	ITP02002- TC40	40	99.8%  99.8%	98.8%  <i>100%</i>	18 months/ 2°-30°	HIV 1+2	lateral flow/ recombinant proteins	serum/plasma  <i>whole blood</i>	C, G	US\$0.85
Capillus™ HIV-1/HIV-2 (Trinity Biotech)	6048G	100	100%  <i>100%</i>	100%  <i>98.8%</i>	15 months/ 2°-8°	HIV 1+2	agglutination/ recombinant proteins	serum/plasma  <i>whole blood</i>	G	€1.00
Determine™ HIV-1/2 Serum/Plasma Assay (Abbott Diagnostics)	7D23-13	100	-	-	6-9 months/ 2°-30°	HIV 1+2	lateral flow/ recombinant protein, synthetic peptide	serum/plasma	D, G	Access countries US\$0.80
<i>Determine™ HIV-1/2 Whole Blood Assay (Abbott Diagnostics)</i>	<i>7D23-33</i>	<i>100</i>	<i>100%</i>	<i>99.4%</i>				<i>whole blood</i>	<i>D, G</i>	Elsewhere US\$1.00
Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) (Shanghai Kehua)	KH-R-02	50	100%  -	100%  -	18 months/ 4°-30°	HIV 1+2	lateral flow/ recombinant protein, synthetic peptide	serum/plasma  whole blood	D, G	US\$0.60
DoubleCheck HIV 1&2 (Organics Ltd)	60332000	40	100%	99.4%	12 months/ 2°-8°	HIV 1+2	lateral flow/ recombinant proteins, synthetic peptides	serum/plasma	G	US\$1.41
First Response™ HIV 1-2-0 Card Test (Premier Medical Corp)	I05FRC30	30	-  <i>100%</i>	-  <i>98.8%</i>	18 months/ 2°-30°	HIV 1+2	lateral flow/ recombinant proteins	serum/plasma  <i>whole blood</i>	D, G	US\$0.67

28 June 2005 - This list supersedes all previous lists.

Notes:

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<sup>2</sup>Assays denoted as HIV 1 HIV 2 are capable of discrimination between HIV-1 and HIV-2, those denoted HIV 1+2 are not capable of discrimination

<sup>3</sup>Equipment Requirements A: ELISA reader, B: ELISA washer, C: Consumables, D: Pipette, E: Power supply, F: For large volume testing more than 40 samples daily, G: For small volume testing 1 to 40 samples daily

<sup>4</sup>Price does not include freight and administration charges

<sup>5</sup> Also marketed under the name OraQuick® ADVANCE Rapid HIV-1/2 (OraSure Technologies) in the US

<sup>6</sup> Also marketed under the name Hexagon HIV (Human GmbH)

N/A Not Applicable



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<b>Simple/Rapid Assays Cont'd</b>										
Genedia® HIV 1/2 Rapid 3.0 (Green Cross Corporation)	F3302	30	100%	99.7%	18 months/ 2°-30°	HIV 1+ 2	lateral flow/ recombinant proteins	serum/plasma  whole blood	D, G	US\$0.45
Genie II HIV-1/HIV-2 (Bio-Rad Laboratories)	72323	40	100%	99.7%	12 months/ 2°-8°	HIV 1 + 2	lateral flow/ recombinant proteins, synthetic peptides	serum/plasma	D, G	€2.00
HIV 1/2 Stat-Pak (Chembio Diagnostics)	HIV101	20	99.7%	99.3%	18 months/ 8°-30°	HIV 1+2	lateral flow/ synthetic peptides	serum/plasma  whole blood	G	US\$1.45
HIV 1/2 Stat-Pak <i>Dipstick</i> (Chembio Diagnostics)	HIV301	30	99%	100%	18 months/ 8°-30°	HIV 1+2	lateral flow/ synthetic peptides	serum/plasma  whole blood	C, G	US\$1.15
HIV Tridot (J Mitra & Co., India)	IR130050 IR130100 IR130200	50 100 200	99.6%	99.7%	10 months/ 4°-8°	HIV 1 HIV 2	flow through/ recombinant proteins	serum/plasma	G	€1.00 €0.90 €0.80
Immunocomb® II HIV 1 & 2 BiSpot (Orgenics Ltd)	60432002	36	100%	99.7%	12 months/ 2°-8°	HIV 1 HIV 2	immunodot/ synthetic peptides	serum/plasma	D, G	US\$1.60

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<b>Simple/Rapid Assays Cont'd</b>										
InstantCHEK™ HIV 1+2 Rapid Test (EY Laboratories)	8-1003-40 8-1003-100	40 100	100% -	97.6% -	9 months/ 22°-28°	HIV 1+2	lateral flow/ recombinant protein	serum/plasma  whole blood	G	US\$0.75 US\$0.60
OraQuick® HIV-1/2 - Rapid HIV-1/2 Antibody Test <sup>5</sup> (OraSure Technologies Inc)	5X4-0010 5X4-0012	100 500	100%  99.2%	99.2%  100%	8 months/ 2°-30°	HIV 1+2	lateral flow/ synthetic peptides	serum/plasma  <i>oral fluid</i> whole blood	G	US\$4.00 US\$4.00
Retrocheck HIV (Qualpro Diagnostics) also marketed Core™ HIV 1&2 (Core Diagnostics)	40501050 40501100	50 100	100% -	99.1% -	24 months/ 4°-30°	HIV 1+2	lateral flow/ recombinant protein, synthetic peptides	serum/plasma  whole blood	G	US\$0.75 US\$0.70
SD Bioline HIV 1/2 3.0 <sup>6</sup> (Standard Diagnostics)	03FK10	30	100% -	99.3% -	18 months/ 2°-30°	HIV 1 HIV 2	lateral flow/ recombinant proteins	serum/plasma  whole blood	D, G	US\$0.74
Serodia® HIV-1/2 (Fujirebio)	220658 226063	100 220	100%	100%	12 months/ 2°-10°	HIV 1 HIV 2	agglutination/ recombinant proteins	serum/plasma	C, D, G	¥130 ¥130
Uni-Gold™ HIV-1/HIV-2 (Trinity Biotech)	1206502	20	-  100%	-  100%	20 months/ 2°-27°	HIV 1+2	lateral flow/ recombinant proteins	serum/plasma  <i>whole blood</i>	G	€1.15

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<b>ELISA Assays</b>										
ANTI-HIV 1 + 2 Antibodies ELISA Diagnostics Kit (Shanghai Kehua)	KH-T-10	96	100%	98.3%	6 months/ 2°-8°	HIV 1+2	recombinant proteins, synthetic peptides	450/620nm	A, B, C, D, E, F	US\$0.27
Enzygnost® Anti-HIV 1/2 Plus (Dade Behring AG) Enzygnost Supplementary Reagents	OQFK135	2 x 96	100%	99.7%	12 months/ 2°-8°	HIV 1+2 O	recombinant proteins	450/650 nm	A, B, C, D, E, F	US\$0.99
	OQFK215	10 x 96								US\$0.75
	OUIV175	960								Gratis
Genedia® HIV Ag-Ab (Green Cross Corporation)	F1305	480	100%	99.7%	12 months/ 2°-8°	HIV 1+ 2 O HIV Ag	recombinant proteins, synthetic peptides, monoclonal antibody	450/620nm	A, B, C, D, E, F	US\$0.33
Genscreen Plus HIV Ag-Ab (Bio-Rad Laboratories)	72375	96	100%	98.3%	12 months/ 2°-8°	HIV 1+2 O HIV Ag	recombinant proteins, synthetic peptides, monoclonal antibody	450/620 nm	A, B, C, D, E, F	€0.55
	72376	480								€0.50
HIV EIA (AniLabsystems Ltd)	6111011	96	100%	99.4%	12 months/ 4°-8°	HIV 1+2	synthetic peptides	450 nm	A, B, C, D, E, F	€0.40
	6111012	480								€0.36
	6111013	960								€0.34
Murex HIV Ag-Ab Combination (Abbott Diagnostics)	7G79-01 7G79-02	96 480	100%	99.3%	12 months/ 2°-8°	HIV 1+ 2 O HIV Ag	recombinant proteins, synthetic peptides, monoclonal antibody	450/620-650nm	A, B, C, D, E, F	US\$1.20 US\$0.80
UBI® HIV-1/2 EIA (United Biomedical Inc)	680328	192	100%	100%	12 months/ 2°-8°	HIV 1+2	synthetic peptides	492/620 nm	A, B, C, D, E, F	US\$0.40
Vironostika® HIV Uni-Form II Ag/Ab (bioMérieux BV)	285046	192	100%	99%	6-9 months/ 2°-8°	HIV 1+2 HIV Ag	recombinant proteins, synthetic peptides, monoclonal antibody	450/620 nm	A, B, C, D, E, F	€0.81
	285047	576								€0.62

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<b>Confirmatory Assays</b>										
HIV BLOT 2.2 (Genelabs Diagnostics)	11031-036	36	N/A	N/A	15 months/ 2°-8°	HIV 1 HIV 2	Western blot/ viral lysate, synthetic peptide	serum/plasma	C, D, E	US\$10.97
INNO-LIA™ HIV I/II SCORE (Innogenetics)	80540	20	N/A	N/A	9 months/ 2°-8°	HIV 1 HIV 2	line immunoassay/ recombinant proteins, synthetic peptides	serum/plasma	C, D, E	€15.50
PEPTI-LAV 1-2 (Bio-Rad Laboratories)	72253	10	N/A	N/A	9 months/ 2°-8°	HIV 1 HIV 2	line immunoassay/ synthetic peptides	serum/plasma	C, D, E	€15.00
NEW LAV BLOT I (Bio-Rad Laboratories)	72251	18	N/A	N/A	9 months/ 2°-8°	HIV 1	Western blot/ viral lysate	serum/plasma	D, E	€13.00
NEW LAV BLOT II (Bio-Rad Laboratories)	72252	18	N/A	N/A	9 months/ 2°-8°	HIV 2	Western blot/ viral lysate	serum/plasma	D, E	€13.00

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