




**HIV Rapid Tests: Progress of the Prequalification of Diagnostics process by product**

Product name	Product code(s)	Manufacturer name	Application status	Dossier request and screening	Dossier full review	On-site inspection status	Laboratory evaluation status
Alere Determine HIV-1/2	7D2342 and 7D2343	Alere Medical Co. Ltd.	◆	◆	◆	◆	◆
Alere Determine HIV-1/2 Ag/Ab Combo	7D2643	Alere Medical Co. Ltd.	◆	◆	◆	◆	◆
HIV 1/ 2 STAT-PAK® Dipstick	HIV303	ChemBio Diagnostic Systems, Inc.	◆	◆	◆	◆	◆
HIV 1/2 STAT-PAK®	HIV101	ChemBio Diagnostic Systems, Inc.	◆	◆	◆	◆	◆
INSTI HIV-1/HIV-2 Antibody Test	90-1010, 90-1012, 90-1013, 90-1022 and 90-1023	bioLytical	◆	◆	◆	◆	◆
SD Biotline HIV Ag/Ab Combo	03FK30, 03FK35	Standard Diagnostics, Inc.	◆	◆	◆	◆	◆
SD BIOLINE HIV-1/2 3.0	03FK10, 03FK16 and 03FK13	Standard Diagnostics, Inc.	◆	◆	◆	◆	◆
Uni-Gold™ HIV	1206502	Trinity Biotech Manufacturing Ltd.	◆	◆	◆	◆	◆
DoubleCheckGold Ultra HIV 1&2	70635020 and 70635100	Orgenics Ltd.	◆	◆	◆	F	◆
VIKIA HIV 1/2	31112	bioMérieux SA	◆	◆	◆	◆	◆
Aware™ HIV-1/2 OMT	REF-98164, REF-98166 and REF-98169	Calypte Biomedical Corporation	◆	◆	F		
Diagnostic Kit for Antibody to Human Immunodeficiency Virus (1+2) (Colloidal Gold)	G1HIV3-223, G1HIV3-233, G1HIV3-123 and G1HIV3-133	NewScen Coast Bio-Pharmaceutical Co. Ltd.	◆	◆	◆		
Reveal Rapid HIV Antibody Test	815311000768, 815311000775, 815311000782 and 815311005619	MedMira Laboratories Inc.	◆	◆	F	◆	◆
ABON HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)	IHI-T402	ABON Biopharm (Hangzhou) Co. Ltd.	◆	◆	F	F	◆
Diagnostic kit for HIV(1+2) Antibody (Colloidal Gold)	KH-R02	Shanghai Kehua Bioengineering Co. Ltd.	◆	◆	F	F	◆
First Response® HIV 1-2-0 Card test	I05FRC30, I05FRC60, I05FRC05 and I05FRC01	Premier Medical Corporation Ltd	◆	◆	F	F	◆
One Step HIV 1/2 Whole Blood/Serum/Plasma Test	W6-C	Guangzhou Wondfo Biotech Co. Ltd.	◆	◆	F	F	◆
Signal HIV Flow Through HIV 1+2 Spot / Immunodot Test Kit	25971, 25971A, 25971B (OLD). 51FT100-10, 51FT100-50, 51FT100-60 (NEW)	M/S Span Diagnostics Ltd.	◆	◆	F	F	◆
One Step HIV 1/2 Oral Fluid	W76-C	Guangzhou Wondfo Biotech Co. Ltd.	◆	◆	F	F	
DPP® HIV 1/2 Assay	65-9500-1	ChemBio Diagnostic Systems, Inc.	◆	◆	F	fast-tracked	◆
Anti-human immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold)	WJ-1810 and WJ-1850	Beijing Wantai Biological Pharmacy Enterprise Co. Ltd.	◆	◆	📁	F	◆
Genie™ Fast HIV 1/2	72330 and 72327	Bio-Rad	◆	◆	📁	F	◆
Advanced Quality™ One Step Anti-HIV (1&2) Test	ITP02006TC40	InTec PRODUCTS INC.	◆	◆	📁	S	◆
Genedia HIV1/2 Rapid 3.0	20-0746-01-01, 20-0746-02-01	Green Cross Medical Science Corp.	◆	◆	F		📁
Biotracer HIV 1/2 Rapid Card	11112 and 11135	Bio Focus Co. Ltd.	◆	◆	R		
Pareekshak HIV-1/2 Triline Card Test	PTC-50	Bhat Bio-Tech India (P) Ltd.	◆	◆	📁		

OraQuick HIV 1/2 Rapid Antibody Test	5x4-0010 and 5x4-0012	OraSure Technologies, Inc.	◆	◆	R		
Retrocheck HIV	40501001, 40501010, 40501025, 40501050 and 40501100	Qualpro Diagnostics	◆	◆	<b>ON HOLD</b>		◆
InstantChek™ HIV 1+2	8-1003-40 and 8-1003-100	EY Laboratories (H.K.) Ltd.	◆	◆	<b>ON HOLD</b>		
SURE CHECK® HIV 1/2 Assay	HIV201	Chembio Diagnostic Systems, Inc.	◆	R		fast-tracked	
Rapid 1-2-3 Hema Express HIV 1/2	HIV-0207-WB	Hema Diagnostic Systems	◆	R			
Vision Rapid HIV 1/2	VB09	Vision Biotech	◆	◆	R		
TOYO Anti-HIV 1/2/0 (WB/S/P) Rapid Test	n/a for the moment	Türklab Tibbi Mazleme San. Ve Tic. A.S.	◆	R			
Coretests® One Step HIV1+2 Test Device	B2021 and B2022	Core Technology Co. Ltd.	◆	R			
Efoora HIV Rapid Test	50000132, 5000140, 5000120, 5000134, 5000141	Applied Biomedical L.L.C.	R				
ACON HIV1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IHI-T402	ACON Biotech (Hangzhou) Co. Ltd.	W	-	-	-	-
NanoSign HIV1/2	RIHI10	Bioland Ltd.	W	-	-	-	-
VIKIA HIV 1/2	31112	bioMérieux SA	W	-	-	-	-
Advanced Quality™ Rapid Anti-HIV (1&2) POCT	ITP02009TC1	InTec PRODUCTS INC.	C	-	-	-	-
AidsScan HIV-1/2 Trispot Test Kit	ATS-50	Bhat Bio-Tech India (P) Ltd.	C	-	-	-	-
Anti-HIV 1/2 (S/P) Rapid Test	THIV01 / THV.01 and THV.02	Türklab Inc.	C	-	-	-	-
Anti-HIV 1/2 (WB/S/P) Rapid Test	THIV02	Türklab Inc.	C	-	-	-	-
Hexagon HIV	57002P, 57004P	Human GmbH	C	-	-	-	-
Retroquic HIV	40502010, 40502025, 40502050, 40502075 and 40502100	Qualpro Diagnostics	C	-	-	-	-
Retroscreen HIV	40504025, 40504050 and 40504100	Qualpro Diagnostics	C	-	-	-	-
SD BIOLINE HIV-1/2 Rapid	03FK50	Standard Diagnostics, Inc.	C	-	-	-	-
SureStep Easy™ HIV - 1/2 WB	71833025 and 71833100	Unipath Limited	C	-	-	-	-
BIONOTE HIV 1&2 Ab Rapid Test Kit	RB29-07	Bionote, Inc.	C	-	-	-	-
Ecotest® HIV 1+O/2 Rapid Test Device	n/a	Assure Tech. (Hangzhou) Co. Ltd.	C	-	-	-	-
HIV TRI-DOT	IR130010, IR130050 and IR130100	J Mitra & Co. Pvt. Ltd.	C	-	-	-	-

<b>R</b> information requested from manufacturer	 under assessment	 stage complete	<b>F</b> follow-up amendments after full assessment	<b>S</b> scheduled; date confirmed	 application not prioritized	<b>I</b> determined inadequate/ declined	<b>W</b> withdrawn by manufacturer	<b>C</b> closed
<p>Please note: these tables are updated regularly; while every attempt is made to provide current data, very recent information may not yet be reflected here.</p> <p>This table is intended only as an update on progress and does not reflect a final decision on prequalification. This table should not be used to inform procurement. Information may not yet be reflected here.</p> <p>Last update: 6 January 2014  <a href="http://www.who.int/diagnostics_laboratory/pq_status/en/index.html">http://www.who.int/diagnostics_laboratory/pq_status/en/index.html</a></p>								