THE GLOBAL FUND

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List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

According to **Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and core Personal Protective Equipment** (https://www.theglobalfund.org/en/sourcing-management/quality-assurance/in-vitro-diagnostics/), in force since 1st March 2011, Grant Funds may only be used to procure HIV RDTs if they have been:

Criterion 1- prequalified by the WHO Prequalification of In Vitro Diagnostics Programme, or

Criterion 2- authorized for use by one of the Regulatory Authorities of the Founding Members of GHTF when stringently assessed (**as Class C or D**) **or by a WLA within their scope of listing**

Criterion 3- acceptable for procurement using Grant Funds, as determined by the Global Fund, based on the advice of the WHO Expert Review Panel

Categories falling under Criterion-1 and -3

In-Vitro Diagnostic Products with respect to HIV, tuberculosis and malaria and to hepatitis B, hepatitis C and syphilis co-infections, as well as IVDs providing information that is critical for patient treatment of these diseases

Categories falling under Criterion-2

All under Criterion-1 excluding HIV Self Testing

The list is an overview of IVDs to assist Principal Recipients (PRs) of Global Fund grants to identify the status of IVDs according to the relevant Global Fund Quality Assurance Policy. It includes products recommended for use after technical evaluation by WHO Prequalification of Diagnostics Programme, Regulatory Authoritities of GHTF founding members, WLAs and the WHO hosted Expert Review Panel.
The list is not exhaustive; PRs can procure product(s) not listed below as long as PRs demonstrate that the product is compliant with one of the above mentioned requirements.

Products prequalified by WHO https://extranet.who.int/prequal/sites/default/files/document_files/list-of-prequalified-in-vitro-diagnostic-products_0.pdf

The list is updated regularly based on evidence received by the Global Fund.

HIV Simple assays/Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
IHI-T402WA* (previously IHI-T402W)	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	40	100.00%	99.70%	ABON Biopharm (Hangzhou) Co. Ltd. Hangzhou, PR China	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 30°C	see WHO Public Report for consumables	WHO PQ
IHI-T402WG*	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	40	100.00%	99.70%	ABON Biopharm (Hangzhou) Co. Ltd. Hangzhou, PR China	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 30°C	see WHO Public Report for consumables	WHO PQ
IHI-T402WB*	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	40	100.00%	99.70%	ABON Biopharm (Hangzhou) Co. Ltd. Hangzhou, PR China	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 30°C	see WHO Public Report for consumables	WHO PQ
IHI-T402WD*	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	10	100.00%	99.70%	ABON Biopharm (Hangzhou) Co. Ltd. Hangzhou, PR China	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 30°C	see WHO Public Report for consumables	WHO PQ
IHI-T402WE*	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	40	100.00%	99.70%	ABON Biopharm (Hangzhou) Co. Ltd. Hangzhou, PR China	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 30°C	see WHO Public Report for consumables	WHO PQ
IHI-T402WF*	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	10	100.00%	99.70%	ABON Biopharm (Hangzhou) Co. Ltd. Hangzhou, PR China	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 30°C	see WHO Public Report for consumables	WHO PQ

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IHI-T402WI*	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	40	100.00%	99.70%	ABON Biopharm (Hangzhou) Co. Ltd. Hangzhou, PR China	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 30°C	see WHO Public Report for consumables	WHO PQ
7D2342*	Determine™ HIV-1/2	20	100%	99.40%	Abbott Diagnostic Medical Co. Ltd, Matsudo, Japan	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	18 months 2 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer (7D2243),EDTA capillary tubes (7D2227). serum/plasma: requires precision pipette plus tips.	WHO PQ
7D2343*		100								
7D2343SET*	Determine™ HIV-1/2 SET	100	100%	98.94%	Abbott Diagnostic Medical Co. Ltd, Matsudo, Japan	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	18 months 2 to 30°C	Kit of 10 cards of 10 tests, 1 bottle of chase buffer, 100 capillary tubes & 100 blood lancets	
7D2343SETS*									Kit of 10 cards of 10 tests, 1 bottle of chase buffer, 100 capillary tubes & 100 blood lancets (safety)	
7D2846	Alere HIV Combo	20	100%	99.72%	Abbott Alere Medical Co. Ltd, Matsudo, Japan	Discrimination between HIV 1/2 antibodies combined detection and HIV1- p24 antigen	Serum/Plasma /Whole Blood	18 months 2 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer (7D2243),EDTA capillary tubes (7D2227). If serum/plasma: requires precision pipette plus tips.	GHTF (CE mark)
7D2847		100								
7D2842*	Determine HIV Early Detect (former Alere HIV Combo)	20	100%	99.40%	Abbott Diagnostic Medical Co. Ltd, Matsudo, Japan	Discrimination between HIV 1/2 antibodies combined detection and HIV1- p24 antigen	Serum/Plasma /Whole Blood	18 months 2 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer (7D2243),EDTA capillary tubes (7D2222). If serum/plasma: requires precision pipette plus tips.	WHO PQ
7D2843*	Determine HIV Early Detect (former Alere HIV Combo)	100	100%	99.40%	Abbott Diagnostic Medical Co. Ltd, Matsudo, Japan	Discrimination between HIV 1/2 antibodies combined detection and HIV1- p24 antigen	Serum/Plasma /Whole Blood	18 months 2 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer (7D2243),EDTA capillary tubes (7D2222). If serum/plasma: requires precision pipette plus tips.	
7D2843SET*	Determine HIV Early Detect (former Alere HIV Combo)	100	100%	99.40%	Abbott Diagnostic Medical Co. Ltd, Matsudo, Japan	Discrimination between HIV 1/2 antibodies combined detection and HIV1- p24 antigen	Serum/Plasma /Whole Blood	18 months 2 to 30°C	Kit of 10 cards of 10 tests, 1 bottle of chase buffer, 100 capillary tubes & 100 blood lancets	
7D2843SETS*	Determine HIV Early Detect (former Alere HIV Combo)	100	100%	99.40%	Abbott Diagnostic Medical Co. Ltd, Matsudo, Japan	Discrimination between HIV 1/2 antibodies combined detection and HIV1- p24 antigen	Serum/Plasma /Whole Blood	18 months 2 to 30°C	Kit of 10 cards of 10 tests, 1 bottle of chase buffer, 100 capillary tubes & 100 blood lancets	
03FK17*	Bioline HIV-1/2 3.0	25	99.80%	99.90%	Abbott Diagnostics Korea Inc (former Standard Diagnostics) Giheung-gu,Yongin-si, Korea	Discrimination between HIV1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 1 to 30°C	Safety lancets, alcohol swabs,capillary tube, chase buffer	WHO PQ
03FK16*	Bioline HIV-1/2 3.0	25	99.80%	99.90%		Discrimination between HIV1 and	Serum/Plasma	24 months	If whole blood: lancets, alcohol swabs.	

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03FK10*	Biolline HIV-1/2 3.0	30	99.80%	99.90%		between HIV1 and HIV-2 antibodies	/Whole Blood	1 to 30°C	If 03FK10: lancets, capillary pipettes, alcohol swabs.	
29011-W20	Panbio HIV Verification Test	20	100%	99.70%	Abbott Rapid Diagnostics Jena GmbH, Germany	Discrimination between HIV 1/2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 30°C		WHO PQ
29011AW20		20							sterile single-use lancets, alcohol swabs,capillary tube	
WJ-1810*	Rapid Test for Antibody to HumanImmunodeficiency Virus (HIV) (Colloidal Gold Device)	10T/kit	100%	98.48%	BeijingWantai Biological Pharmacy Enterprise Co.	HIV 1/2 antibodies combined detection	Serum/ Plasma/ Whole Blood	18 months 2 to 30 °C	For accessories see IFU	WHO PQ
WJ-1810E*										
WJ-1810EL*										
WJ-18S10*										
WJ-18S10E*										
WJ-18S10EL*										
WJ-1850*		50T/kit								
WJ-1850E*										
WJ-1850EL*										
WJ-18S50*										
WJ-18S50E*										
WJ-18S50EL*										
90-1010*	INSTI HIV-1/HIV-2 Antibody Test Kit	24	100%	99.70%	BioLytical Laboratories, Richmond, Canada	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	15 months 15 to 30 °C	24 T/kit; 24 T/kit with support materials; If 90-1010: lancets, alcohol swabs, precision pipette plus tips.	WHO PQ
90-1013*		24								
90-1021*		48							48 T/kit; 48 T/kit with support materials If 90-1021: lancets, alcohol swabs, precision pipette plus tips.	
90-1022*		48								
90-1038*		48							support material: only pipettes	

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90-1064*		48							Support material: none	
72330*	Genie Fast HIV 1/2	50	100%	99.00%	Bio-Rad Laboratories, Marnes La Coquette France and Steenvoorde, France	HIV 1/2 antibodies (group M and O)	Serum/Plasma /Venous and Capillary Whole Blood	18 months 2 to 30°C	with support materials: diluent and disposable pipettes	WHO PQ
72327*		25								
72347*		25							with support materials: diluent, disposable pipette, microsafes, lancets, alcohol swabs	
857318	EXACTO© PRO TEST HIV	10	99.9%	99.9%	Biosynex SA, Strasbourg, France	HIV 1/2 antibodies combined detection	Serum/Plasma /Venous whole blood/ Fingerstick Whole Blood/Oral Fluid	24 months 2 to 30°C		GHTF (CE mark)
65-9506-0*	DPP HIV 1/2 Assay	20	99.8% HIV-1 (fingerstick whole blood) 99.9% HIV-1 (venous whole blood, serum, plasma) 98.9% HIV-1 (oral fluid) 100% HIV-2 (serum/plasma, blood, oral fluid)	99.9% (serum/plasma, whole blood, oral fluid)	Chembio Diagnostic Systems Medford, USA	HIV 1/2 antibodies combined detection	Serum/Plasma /Venous whole blood/ Fingerstick Whole Blood/Oral Fluid	24 months 2 to 30°C	Lancet, sterile gauze, antiseptic wipes Biohazard disposal container For venipuncture whole blood collection and serum/plasma specimens: Venipuncture apparatus and blood collection tubes Precision pipette capable of delivering 5µL of sample (with disposable tips) may be used in lieu of the disposable 5µL sample loop supplied with the kit (for other than fingerstick whole blood specimens)	WHO PQ
HIV101*	HIV 1/2 STAT-PAK™	20	99.30%	100%	Chembio Diagnostic Systems Medford, USA	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 8 to 30°C	If whole blood: lancets, alcohol swabs. HIV Test Kit Controls (HIV104) available.	WHO PQ https://extranet.who.int/prequal/WHOPR/public-report-hiv-12-stat-pakr-pqdx-0007-006-00 GHTF (FDA, PMA)
HIV201*	SURE CHECK® HIV 1/2 ASSAY	25	99.8% (serum/plasma) 100% HIV-2 (serum/plasma)	99.9% (serum/plasma)	Chembio Diagnostic Systems Medford, USA	HIV 1/2 antibodies combined detection	Serum/Plasma /Venous and Capillary Whole Blood	24 months 8 to 30°C	Lancet, sterile gauze, antiseptic wipes Biohazard disposal container For venipuncture whole blood collection and serum/plasma specimens: Venipuncture apparatus and blood collection tubes Precision pipette capable of delivering 2.5µL of specimen with disposable tips	WHO PQ GHTF (FDA, PMA)
R0011C	OnSite HIV 1/2 Ab Plus Combo Rapid Test	30	100%	100%	CTK Biotech Inc, USA	HIV 1/2 antibodies combined detection	Serum/Plasma /Venous and Capillary Whole Blood	24 months 2 to 30°C		GHTF (CE mark)
Z09742CE	"DIAQUICK" HIV 1&2 Ab Cassette	30	100%	100%	Dialab GmbH, Austria	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	24 months 2 to 30°C		GHTF (CE mark)

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H18100	"DIAQUICK" HIV Plus	25	100%	100%	Dialab GmbH, Austria	HIV 1/2 antibodies combined detection	Serum or Plasma	24 months 2 to 30°C		GHTF (CE mark)
H18101	"DIAQUICK" HIV Plus WB	25	100%	100%	Dialab GmbH, Austria	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	25 months 2 to 30°C		GHTF (CE mark)
W006-C4P2	Wondfo® One Step HIV1/2 Whole Blood/Serum/Plasma Test	25	100.0%	100.00%	Guangzhou Wondfo Biotech Co. Ltd, 8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663, P.R. China	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: not included	WHO PQ
W006-P0045		25					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: see IFU	
W006-P0046		25					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: see IFU	
W006-P0047		25					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: see IFU	
W006-P0048		25					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: see IFU	
W006-C4P2-F		40					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: not included	
W006-P0049		40					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: see IFU	
W006-P0050		40					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: see IFU	
W006-P0051		40					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: see IFU	
W006-P0052		40					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: see IFU	
GCHIV-402a	HIV 1/2 Human Immunodeficiency Virus Rapid Test (Whole blood/Serum/Plasma) (Cassette)	25	100%	99.90%	Healgen Scientific Limited Liability Company Houston, USA	HIV 1/2 antibodies combined detection	Whole blood, serum or plasma	24 months 2 to 30 °C		GHTF (CE mark)
GCHIV-302a	HIV 1/2 Human Immunodeficiency Virus Rapid Test (Serum/Plasma) (Cassette)	25	100%	99.90%	Healgen Scientific Limited Liability Company Houston, USA	HIV 1/2 antibodies combined detection	Serum or plasma	24 months 2 to 30 °C		GHTF (CE mark)
57002P	Hexagon HIV	40	100%	99.90%	Human Gesellschaft für Biochemica und Diagnostica mbH Germany	HIV 1/2 antibodies combined detection	Whole blood, serum or plasma	2 to 8°C		GHTF (CE mark)
57004P	Hexagon HIV	100	100%	99.90%	Human Gesellschaft für Biochemica und Diagnostica mbH Germany	HIV 1/2 antibodies combined detection	Whole blood, serum or plasma	2 to 8°C		GHTF (CE mark)

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ITPW02153-TC40	ONE STEP Anti-HIV(1&2) Test	40	100.0%	100.00%	InTec PRODUCTS, INC. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, 361022, P.R. China	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Accessories: plastic dropper (pippette), sample diluent (2mLx4 bottles), sterile safety lancets, alcohol swabs	WHO PQ
ITPW02152-TC40	ONE STEP Anti-HIV(1&2) Test	40	100.0%	100.00%	InTec PRODUCTS, INC. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, 361022, P.R. China	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Accessories: plastic dropper (pippette), sample diluent (2mLx4 bottles)	
ITPW02152-TC25		25					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Accessories: plastic dropper (pippette), sample diluent (2mLx3 bottles)	
ITP02121-TC40	ONE STEP Anti-HIV(1&2) Test	40	99.8%	99.23%	InTec PRODUCTS, INC. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, 361022, P.R. China	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Accessories: plastic dropper (pippette)	GHTF (CE mark)
ITP02122-TC40	ONE STEP Anti-HIV(1&2) Test	40	99.8%	99.23%	InTec PRODUCTS, INC. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, 361022, P.R. China	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Accessories: plastic dropper (pippette), safety lancets, alcohol swabs	GHTF (CE mark)
ITP02122-TC10		10					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Accessories: plastic dropper (pippette), safety lancets, alcohol swabs	GHTF (CE mark)
HVWRPD-01	MERISCREEN HIV 1-2 WB	30	100%	100.00%	Meril Diagnostics Pvt. Ltd., Vapi+F56, India	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 2 to 30 °C	For accessories see IFU	WHO PQ
HVWRPD-02		40								
HVWRPD-06		50								
HVWRPD-07		10								
HVWRPD-08		100								
HVWRPD-09		25								
HVWRPD-10		30								
HVWRPD-11		60								
HVWRPD-12		40								

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43030-020	Multisure HIV Rapid Test	20	100%	99.12%	MP Biomedicals Asia Pacific Singapore	Detect antibodies specific to HIV-1 gp120, HIV-1 gp41, HIV-1 p24 (also react with HIV-2) and HIV-2 gp36 antigens in human serum, plasma, finger pricked whole blood or whole blood with anti-coagulants	Serum/Plasma /Whole Blood	24 months 2 to 28 °C	Additional devices which are necessary for performing the test are: - lancets (skin prick to gain the patients sample) - alcohol swaps (disinfection of the pricking position) ☐ timer	GHTF (CE mark)
5X4-0010*	OraQuick® HIV-1/2 - Rapid Antibody Test	100	100%	99.20%	OraSure Technologies Bethlehem, USA (manufactured in Thailand)	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood/Oral Fluid	30 months 2 to 30°C	If whole blood: lancets, alcohol swabs, additional specimen loops (004-001).	WHO PQ
5X4-0012*		500								
5X4-0014*		100							If whole blood: lancets, alcohol swabs, additional specimen loops (004-001). Consult WHO PQ Public Report for country specific labelling.	
5X4-0015*		500								
5X4-0062*		100							Thailand-specific product code / No specimen collection loops	
1001-0079	OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test	25	99.3%*	99.8%*	OraSure Technologies Bethlehem, USA	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood/Oral Fluid*	30 months 2 to 30°C	If whole blood: lancets, alcohol swabs, additional specimen loops (004-001).	GHTF (FDA, PMA)
1001-0078		100								
PI05FRC05*	First Response® HIV 1-2.O Card Test (version 2.0)	5	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
PI05FRC05CE	First Response® HIV 1-2.O Card Test (version 2.0)	5	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	GHTF (CE mark)
PI05FRC10*	First Response® HIV 1-2.O Card Test (version 2.0)	10	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
PI05FRC10CE	First Response® HIV 1-2.O Card Test (version 2.0)	10	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	GHTF (CE mark)

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PI05FRC25*	First Response® HIV 1-2.O Card Test (version 2.0)	25	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
PI05FRC25CE	First Response® HIV 1-2.O Card Test (version 2.0)	25	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	GHTF (CE mark)
PI05FRC30*	First Response® HIV 1-2.O Card Test (version 2.0)	30	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
PI05FRC30CE	First Response® HIV 1-2.O Card Test (version 2.0)	30	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	GHTF (CE mark)
PI05FRC50*	First Response® HIV 1-2.O Card Test (version 2.0)	30	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
PI05FRC60*	First Response® HIV 1-2.O Card Test (version 2.0)	60	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
PI05FRC100*	First Response® HIV 1-2.O Card Test (version 2.0)	100	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
09HIV30D*	STANDARD Q HIV 1/2 Ab 3-Line Test	25	100.00%	99.30%	SD Biosensor Inc (16, Deogyeong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690 Republic of Korea)	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 40°C	see WHO Public Report for consumables	WHO PQ
09HIV30DM*		25							see WHO Public Report for consumables	
R-401-50-C-2, KH-R-02, A-GOLD-01, R-401-50-C-3*	Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	50	100%	100.00%	Shanghai Kehua Bio-engineering Co., Ltd	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer, EDTA capillary tubes. If serum/plasma: requires, blood collection tubes precision pipette plus tips.	WHO PQ

HIV Simple assays/Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
THIV02	Toyo Anti-HIV 1/2		100%	100%	Turk Lab Turkey	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	4 - 30°C		GHTF (CE mark)
5551100	TrinScreen HIV	100	100%	100%	Trinity Biotech Manufacturing Ltd, Bray, Ireland	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	24 months 2 - 30°C		WHO PQ
1206502 + 1206502N+ * 1206502E	Uni-Gold HIV	20	99.80%	99.90%	Trinity Biotech Manufacturing Ltd, Bray, Ireland	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	20 months 2 to 27°C	Accessories: 1 vial Wash Reagent (2 ml) and 20 Disposable Pipettes	WHO PQ
1206502-100 1206502N- * 100		100							Accessories: 5 vials Wash Reagent (2 ml) and 100 Disposable Pipettes	
1206502-C * 1206502E-C	Uni-Gold HIV Complete	20	99.80%	99.90%	Trinity Biotech Manufacturing Ltd, Bray, Ireland	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	20 months 2 to 27°C	Accessories:lancets, alcohol swabs. 1 vial Wash Reagent (2 ml) and 20 Disposable Pipettes	

N/A- NOT APPLICABLE

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

HIV Self Tests / Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
29012-W01*	CHECKNOW© HIV SELFTEST	1	99.50%	98.50%	Abbott Rapid Diagnostics Jena GmbH	HIV 1/2 antibodies combined detection	Whole Blood	24 Months 2 to 30°C		WHO PQ https://extranet.who.int/pqweb/sites/default/files/PQDx_0481-032-00_CheckNOW_HIV-SelfTest_PR_v2.0.pdf
ARST001-03 ARST001-03-01 ARST001-03-02 ARST001-03-03 *	Mylan HIV Self-Test	1	99.80%	99.80%	Atomo Diagnostics Pty Ltd, Leichhardt, Australia	HIV 1/2 antibodies combined detection	Whole Blood	18 Months 2 to 30°C		WHO PQ
90-1071*	INSTI® HIV Self Test	1	99.80%	99.50%	BioLytical Laboratories, Richmond, Canada	HIV 1/2 antibodies combined detection	Whole Blood	15 Months 2 to 30°C		WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/181130_pqdx_0002_002_01_pqpr_insti_self_test.pdf?ua=1
60-9508-0*	SURE CHECK HIV SELF-TEST	1	97.00%	100.00%	Chembio Diagnostic Systems,Medford, USA	HIV 1/2 antibodies combined detection	Whole Blood	24 Months 8 to 30°C		WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/191129_pqdx_0054_006_01_sure_check_hiv_self_test.pdf?ua=1
W006P0058*	Wondfo HIV Self-Test	1	95.80%	99.60%	Guangzhou Wondfo Biotech Co., Ltd	HIV 1/2 antibodies combined detection	Whole Blood	24 Months 2 to 30°C		WHO PQ
W006P0059*		20								
W006P0060*		100								

HIV Self Tests / Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
5X4-0004.###*	OraQuick HIV Self-Test	1	99.02%	100.00%	OraSure Technologies Inc, Bethlehem, USA (manufactured in Thailand)	HIV 1/2 antibodies combined detection	Oral fluid	30 Months 2 to 30°C	Community Version Individual Test pouches are labeled 5X4-0004.###	WHO PQ https://extranet.who.int/pqweb/sites/default/files/PQDx_0159-055-01_OraQuickHIVSelfTest_v7.0.pdf
5X4-1000.###*		50								
5X4-1001.###*		250								
5X4-2001.###*		110							Pharmacy Version (placed in individual cartons)	
5X4-2001U.###*		1							Community Version Individual Test boxes are labeled 5X4-2001U.###	
5X4-7000.050*		50								
5X4-7000.250*		250								
5X4-7000.200*		200							Pharmacy Version (placed in individual cartons)	
1503-020	Asanté® HIV-1/2 Oral Self-Test	20	on request	on request	Sedia Biosciences Corporation, USA	HIV 1/2 antibodies combined detection	Oral fluid	24 Months 2 to 30°C	ERPD as CATEGORY-2, meaning that procurement with Global Fund resources of this product will be permitted / Non-Objection-Letter required for procurement	ERPD until 4th August 2024
1503-050		50								
1503-100		100								

HIV Self Tests / Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
N/A- NOT APPLICABLE										

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
4J27-27	ARCHITECT HIV Ag/Ab Combo	100	100%	99.77%	Abbott GmbH, Wiesbaden, Germany	HIV-1 p24 antigen, antibodies to HIV-1 (group M and group O), and antibodies to HIV-2	10 months 2 to 8°C	Serum or plasma specimens; Note: The ARCHITECT HIV Ag/Ab Combo assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection and as a screening test to prevent transmission of HIV-1/HIV-2 to recipients of blood, blood components, cells, tissue and organs. An ARCHITECT HIV Ag/Ab Combo result does not distinguish between the detection of HIV p24 antigen, HIV-1 antibody, or HIV-2 antibody reactivity.	GHTF (CE mark, TGA, Health Canada)
4J27-37		500							
4J27-22		4x100							
4J27-32		4x500							
7G 46	Abbott PRISM HIV Ag/Ab Combo Assay	up to 5000	100% (but with 19% "void" results)	99.96% (blood donor specimens)	Abbott Diagnostics, Wiesbaden, Germany	HIV1/2 antibodies combined and HIV1-p24 antigen	3 months 2 to 8°C	Serum and plasma specimen Activator concentrate, Activator diluent	GHTF (TGA)
790000	apDia HIV Ab & Ag Elisa	96	100.00%	99.60%	apDia bvba, Raadsherenstraat 3, B-2300 Turnhout, Belgium	HIV-1/2 antibodies and HIV-1 p24 antigen	15 months 2 to 8°C	Serum or plasma	GHTF (CE mark)
790001		196	100.00%	99.60%					
790005		480	100.00%	99.60%					
880007	HIV 1+2 Ab Elisa	96	100.00%	99.90%	Axiom GmbH Am Jahnplatz 5 68642 Bürstadt Germany	HIV 1/2 antibodies combined	15 months 2 to 8°C	Human serum and plasma specimens	GHTF (CE mark)
880007s		480							
WI-4396 *	AiD anti-HIV 1+2 ELISA	96	100.00%	99.92%	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	HIV-1/2 antibodies and HIV-1 p24 antigen	2 to 8°C	Serum or plasma	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/160218_final_public_report_pqdx_0006_005_00_aid_anti_hiv_1_2_elisa.pdf?ua=1
WI-43480 *	AiD anti-HIV 1+2 ELISA	480	100.00%	99.92%	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	HIV-1/2 antibodies and HIV-1 p24 antigen	2 to 8°C	Serum or plasma	GHTF (CE mark)

HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
259851	Vironostika HIV Ag/Ab	192	100.00%	99.50%	bioMérieux SA 69280 - Marcy-l'Etoile / France RCS LYON 673 620 399	HIV-1/2 antibodies and HIV-1 p24 antigen	2 to 8°C	Serum or plasma	GHTF (CE mark)
259852	Vironostika HIV Ag/Ab	576	100.00%	99.50%	bioMérieux SA 69280 - Marcy-l'Etoile / France RCS LYON 673 620 399	HIV-1/2 antibodies and HIV-1 p24 antigen	2 to 8°C	Serum or plasma	GHTF (CE mark)
72278	GenScreen™ HIV 1/2 Version 2	96	100%	99.80%	Bio-Rad Laboratories, Marnes La Coquette, France and Bio-Rad Laboratories, Steenvoorde, France	HIV 1/2 antibodies combined or discrimination	18 months 2 to 8°C	Serum and plasma specimen Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs	GHTF (CE mark, TGA)
72279		480							
72386*	GenScreen™ ULTRA HIV Ag-Ab	96	100%	99.20%	Bio-Rad Laboratories, Steenvoorde, France	HIV 1/2 antibodies combined and HIV1- p24 antigen	18 months 2 to 8°C	Not suitable for whole blood Requires EIA incubator, washer, reader, precision pipette plus tips, deionised water.	WHO PQ https://extranet.who.int/pqweb/sites/default/files/PQDx_0096-031-00_GenscreenULTRA-HIV_Ag-Ab_v2.0.pdf
72388*		480							
71120	Genscreen™ HIV-1 Ag Assay	192		99.95%	Bio-Rad 3, boulevard Raymond Poincaré 92430 Marnes-la-Coquette - France	HIV-1 p24 antigen	months 2 to 8°C	Human Serum, Plasma and Cell Culture Supernatant	GHTF (CE mark)
26217	GS HIV Combo Ag/Ab EIA	192	100% (manual method) 100% (Evolis system)	99.87% (manual method) 99.97% (Evolis system)	Bio-Rad Laboratories, Steenvoorde, France	HIV-1 p24 antigen and HIV1/2 antibodies	18 months 2 to 8°C	Serum and plasma specimen For product code 26218 (960 tests): wash solution (25261) and stopping solution (25260) must be ordered separately. Biohazard disposal container For venipuncture serum/plasma specimens: Venipuncture apparatus and blood collection tubes Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs, deionized or distilled water. The GS HIV Combo Ag/Ab EIA is approved for use with the Bio-Rad EVOLIS™ Automated Microplate System.	GHTF (FDA, PMA)
26218		960							
IVCOMB.CE	HIV Ab & Ag Elisa	192	100.00%	99.50%	DIA.PRO Diagnostic Bioprobes S.r.l. Italy	HIV-1/2 antibodies and HIV-1 p24 antigen	15 months 2 to 8°C	Serum or plasma	GHTF (CE mark)
IVCOMB.CE 96		96	100.00%	99.50%					
IVCOMB.CE 480		480	100.00%	99.50%					
IVCOMB.CE 960		960	100.00%	99.50%					
Z01375	HIV 1&2 Ab, cut-off	1x96	100.00%	99.92%	Dialab GmbH, Austria	HIV-1/2 antibodies	15 months 2-8°C	Serum or plasma	GHTF (CE mark)
Z03502		5x96	100.00%	99.92%					

HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
Z04380	HIV 1&2 Ag/Ab, Double Ag&Ab Sandwich Principle	1x96	100.00%	99.96%	Dialab GmbH, Austria	HIV-1/2 antibodies and HIV-1 p24 antigen	15 months 2-8°C	Serum or plasma	GHTF (CE mark)
Z13382		5x96	100.00%	99.96%					
9E25-01	Murex HIV - 1.2.0	96	100%	99.91%	DiaSorin, Dartford, United Kingdon	HIV 1/2 Antibodies (IgG, IgM, IgA)	12 months 2 to 8°C	In EDTA/Citrate Plasma specimen 1. Stop Solution (0.5Mto 2MSulphuric Acid). 2. Freshly distilled or high quality deionized water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09 02). For use in laboratory incubators. 6. Instrumentation a) Automated microplate strip washer. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	GHTF (CE mark, TGA)
9E25-02		480							
7G79-09 *	Murex HIV Ag/Ab Combination	96	100%	99.78%	DiaSorin Dartford, United Kingdon	Combined detection of HIV-1 p24 and HIV 1/2 Antibodies (IgG, IgM, IgA)	12 months 2 to 8°C	Serum and plasma specimen 1. Stop Solution (0.5M to 2M Sulphuric Acid). 2. Freshly distilled or high quality deionised water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09-02). 6. Instrumentation a) Automated microplate stripwasher. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24-01). 8. Sodium hypochlorite for decontamination. (Refer to Health and Safety Information) 9. Sodium hydroxide solution (0.1M). (Refer to Analytical Precautions).	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/150330_final_report_murex_hiv_ag_ab.pdf?ua=1 GHTF (CE mark, TGA)
7G79-11 *		480							

HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
310260	LIAISON XL	200	100%	99.50%	DiaSorin S.p.A., Saluggia (Vercelli), Italy	HIV-1 p24 antigen and HIV-1/2 antibodies	12 months 2 to 8°C	serum or plasma specimens	GHTF (CE mark, TGA)
80563	INNOTEST HIV Ag mAb	96	100%	100.00%	Fujirebio Europe N.V., Ghent, Belgium	p24 core antigens of the human immunodeficiency virus type 1 (HIV-1), HIV-1 group O, and type 2 (HIV-2)		human serum, plasma, or cell culture supernatant	GHTF (CE mark)
80564		480							
HIV121	HIV Antigen and Antibodies to Human Immunodeficiency Virus（CLIA）	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	HIV p24 antigen, and antibodies to HIV-1 and/or HIV-2	18 months 2 to 8°C	human serum, plasma; Note: The CL-series HIV assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection and as a screening test for donated blood and blood components.	GHTF (CE mark)
HIV122		2×100 tests							
684 2781	VITROS Immunodiagnostic Products HIV Combo Reagent Pack	100	100%	98.82%	Ortho-Clinical Diagnostics, Bridgend, United Kingdom	Combined detection of HIV-1 p24 and HIV 1/2 Antibodies	shelf life on request 2 to 8°C	serum or plasma specimens; Note: The VITROS HIV Combo test is not intended for use in screening blood or plasma donors. However, this assay can be used as a blood donor screening assay in urgent situations where traditional licensed blood donor screening tests are unavailable or their use is impractical.	GHTF (CE, PMA)
(05 390 095 190) being replaced by 08 924 163 190	Elecsys HIV Combi PT	100	100%	99.82% (blood donor specimens) 99.8% (diagnostic specimens)	Roche Diagnostics, Mannheim, Germany	HIV 1 p24 antigen and HIV1/2 antibodies	15 months 2 to 8°C (Do not freeze)	Serum and plasma specimen cobas e 411 analyzer, cobas e 601 / 602 modules Note: Specimen collected from living patients, blood donors, or individual organ, tissue or cell donors may be used, including donor samples obtained while the donor's heart is still beating.	GHTF (CE mark)
(07 914 504 190) being replaced by 08 924 180 190		200							

HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
(07 229 542 190) being replaced by 08 836 973 190	Elecsys® HIV Duo	300	100%	99.87% (blood donor specimens) 99.92% (diagnostic specimens)	Roche Diagnostics, Mannheim, Germany	HIV 1 p24 antigen and HIV1/2 antibodies	18 months 2 to 8°C (Do not freeze)	Serum and plasma specimen: cobas e 402 / cobas e 801 analytical units Note: Specimen collected from living patients, blood donors, or individual organ, tissue or cell donors may be used, including donor samples obtained while the donor's heart is still beating.	GHTF (CE mark)
I-1654/1.2 *	DS-EIA-HIV-AGAB-SCREEN	96/1 plate	100%	99.60%	RPC «Diagnostic Systems», Ltd. Nizhny Novgorod Russian Federation	HIV1/2 antibodies combined and HIV1-p24 antigen	24 months 2-8 °C	Serum or plama specimen	WHO PQ https://extranet.who.int/pqweb/sites/default/files/PQDx_0106-038-00_DS-EIA-HIV-AGAB-SCREEN_v4.0.pdf
I-1652/1.2 *		192/2 plates							
I-1656/1.2 *		480/5 plates							

N/A- NOT APPLICABLE

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

CD4 Enumeration technologies
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Cell counting	Number of tests per kit	Manufacturer	Anticipated Shelf life (months)/ Storage temperature		Specimen type	Comments	Eligibility WHO or GHTF countries
260100025	PIMA CD4	Absolute CD4+ Counts	25 cartridges/kit	Abbott Rapid Diagnostics Jena GmbH, Jena, Germany	12 months for reagents 2 to 30°C for reagents		Venous and Capillary whole blood	End of Life (EOL) of Pima Instruments: 2024 (no support available beyond that date)	WHO PQ https://extranet.who.int/pqweb/sites/default/files/PQDx_0099-032-00_PimaCD4-Test_v6.0.pdf
260100100			100 cartridges/kit						
260300003	PIMA Analyser		Flow cytometry instrument					DISCONTINUED	
B39101,B39102, B30166 B25697, * B25698, B23536, B23538, B23533, B23534, B23535, B25700, B23502	Aquios CL flow cytometer	total CD3+, CD3+CD4+,CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts; CD45+ absolute count; and CD45+ Low SS (lymphocytes) percentage and absolute count.	Flow cytometry instrument	Beckman Coulter Life Sciences Miami, FL, USA (instrument site) and Hialeah, FL, USA (reagent site)	B30166	N/A	Venous Whole Blood	N/A	WHO PQ (PQ Public Report) http://www.who.int/diagnostics_laboratory/evaluations/151109_final_report_0156-053-00_aquios_cl_flow_cytometer.pdf
			1x10ml		B25697	18 - 26°C/18M			
			1x500ml		B25698	Safety lancets, alcohol swabs, specimen droppers(for fingerstick whole blood), 2 chase buffers, specimen dropper for serum/plasma, whole blood			
			4x50ml		B23536	18 - 26°C/12M			
			1 x 38ml,1 x 15ml (100 tests)		B23538	18 - 26°C/350 days			
			1 x 0.9ml (50 tests)		B23533	2 - 8°C/12M			
			1 x 0.9ml (50 tests)		B23534	2 - 8°C/12M			
			2x 3ml		B23535	2 - 8°C/270 days			
			2x 3ml		B25700	2 - 8°C/270 days			
			50 plates/box		B23502	N/A			
337858 * (Instrument) 340166 (control kit) 340167 (Test Kit)	BD FACSCount™ Instrument System with FACSCount™ Control Kit and BD FACSCount™ Reagent Kit	Absolute CD4+, CD8+, CD3+ Counts	337858: instrument system 340166: 25T /kit 340167: 50T/kit	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	23 months (reagents) 24 months (control) 2 to 8°C		Venous Whole Blood	End of Life (EOL) of FACSCount Instruments: 2024 (no support available beyond that date) DISCONTINUED	WHO PQ (PQ Public Report) https://www.who.int/diagnostics_laboratory/evaluations/121115_0124_045_00_public_report_v2_final.pdf

CD4 Enumeration technologies
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Cell counting	Number of tests per kit	Manufacturer	Anticipated Shelf life (months)/ Storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
337858 * (Instrument) 340166 (control kit) 339010 (Test Kit)	BD FACSCount™ Instrument System with FACSCount™ Control Kit and BD FACSCount™ CD4 Reagent Kit	Absolute and Percentage CD4+ Counts	337858: instrument system 340166: 25T/kit 339010: 50T/kit	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	15 months (reagents) 24 months (control) 2 to 8°C	Venous Whole Blood	End of Life (EOL) of FACSCount Instruments: 2024 (no support available beyond that date) DISCONTINUED	WHO PQ (PQ Public Report) https://www.who.int/diagnostics_laboratory/evaluations/121115_0133_045_00_public_report_v1_final.pdf
651000 657681 655495 *	BD FACSPresto™ Near-Patient CD4 Counter BD CD4%CD4/Hb Cartridge Packaging with BD FACSPresto™ Cartridges Kit	Absolute and Percentage CD4+ counts and Hemoglobin measurement	each box contain 100 catridges and 100 pipets	Becton, Dickinson and Company, BD Biosciences San Jose, California, USA	23 months for cartridges 4 to 31°C for cartridges	human capillary and venous blood specimens	651000: instrument 657681: catridge (100/box) and 655495: pipette (100/box) - End of Life (EOL) of FACSPresto Instruments: 2024 (no support available beyond that date) DISCONTINUED	WHO PQ
CY-S-3022 (equipment)* 05-8401 (absolute)* 05-8405 (percentage)*	CyFlow Instrument CD4 Easy-Count Reagent Kit CD4% Easy-Count Reagent Kit	Absolute and Percentage CD4+ Counts	100T/kit	Sysmex Partec GmbH, Görlitz, Germany	14 months for reagents 2 to 8°C for reagents	Venous Whole Blood	N/A	WHO PQ
Rapid Diagnostic Test for qualitative testing based on CD4 technologies								
AB376	VISITECT®CD4 Advanced Disease	Semi-Quantitative Test (200 cells/µl cut-off)	25T/kit	AccuBio Ltd Omega House, Hillfoots Business Village, Alva, FK12 5DO, Scotland, United Kingdom	12 months 2 to 30°C	human venous whole blood or capillary blood		WHO PQ https://extranet.who.int/pqweb/sites/default/files/PQDx_0384-077-00_VISTECT-CD4_AdvancedDisease_v5.0.pdf

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

HIV Virological technologies
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
08N45-090	Alinity m HIV-1	192T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HIV Quantitative DNA	12 months	2 to 8°C	Plasma and Serum and Dried Blood Spots	For consumables refer to IFU	GHTF (CE mark/IVDD)
08N53-002		instrument									
08N45		instrument									
08N45-080		3 x 12 CTRL kit						-25 to -15°C			
08N45-070		2x4 CAL kit						-25 to -15°C			
09N12-001		sample prep kit 2									
09N66-001 (optional)											
08N45-090	Alinity m HIV-1	192T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HIV Quantitative DNA	12 months	2 to 8°C	Plasma and Serum	For consumables refer to IFU	WHO PQ
08N53-002		instrument									
08N45		instrument									
08N45-080		3 x 12 CTRL kit						-25 to -15°C			
08N45-070		2x4 CAL kit						-25 to -15°C			
09N12-001		sample prep kit 2									
4N66-90*	Abbott Real Time HIV-1 Qualitative (Manual)	96T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HIV 1 Qualitative DNA	18 months	-10°C	Plasma and Dried Blood Spots	For consumables refer to WHO eligible list	WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. For the Manual configuration see: https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/180531_amended_final_pqpr_0151_027_00_v2.pdf?ua=1
4N66-80		8 runs						-10°C			
6K12-24		4x24						15 to 30°C			
9K15-01		instrument									
4N66-01											
4N66-66 (optional)								-30 to -10°C			
4N66-90*		96T/kit						-10°C			WHO PQ and GHTF (CE

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9K14-02	Abbott Real Time HIV-1 Qualitative (m2000sp)	instrument	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HIV 1 Qualitative DNA	18 months		Plasma and Dried Blood Spots	For consumables refer to WHO eligible list	WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. For the automated configuration see: https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/191217_amended_final_pqpr_0084_027_00_v3.pdf?ua=1
9K15-01		instrument									
4N66-80		8 runs						-10°C			
4N66-01											
6K12-24		4x24						15 to 30°C			
4N66-66 (optional)								-30 to -10°C			
2G31-90*	Abbott Real Time HIV-1 (Manual)	96T/kit	N/A	N/A	Abbott Molecular Inc, Des Plaines IL, USA	HIV 1 Quantitative RNA	18 Months	-10°C	Plasma	For consumables refer to WHO eligible list	WHO PQ and GHTF (CE mark) https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/180531_amended_final_pqpr_0151_027_00_v2.pdf?ua=1
2G31-80		8 runs						- 10°C			
2G31-70		4 calibrations						- 10°C			
2G31-66											
1L68-09		software						NA			
9K15-01		instrument						NA			
04J70-24		4x24						15 to 30°C			
04J71-93								15 to 30°C			
2G31-90*	Abbott Real Time HIV-1 (m2000sp)	96T/kit	N/A	N/A	Abbott Molecular Inc, Des Plaines IL, USA	HIV1 Quantitative RNA	18 Months	-10°C	Plasma & DBS Processing	For consumables refer to WHO eligible list	WHO PQ and GHTF (CE mark) https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/191217_amended_final_pqpr_0145_027_00_v9.pdf?ua=1
2G31-010*								-15 to 25°C			
09N02-001											
09N03-001											
2G31-80		8 runs						- 10°C			
2G31-70		4 calibrations						- 10°C			
9K15-01		instrument						NA			
2G31-66											
1L68-14		software						NA			
04J70-24		4x24						15 to 30°C			
04J71-80											

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04J71-93		Optical Cal. Kit						15 to 30°C			
9K14-02		instrument						NA			
3N06-01	Abbott Real Time HIV-1 (m24sp)	instrument	N/A	N/A	Abbott Molecular Inc, Des Plaines IL, USA	HIV1 Quantitative RNA	18 months	NA	Plasma	For consumables refer to WHO eligible list	WHO PQ and GHTF (CE mark) https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/191217_amended_pqpr_0083_027_00_abbott_real_time_hiv1_v3.pdf?ua=1
2G31-90*		96T/kit						-10°C			
2G31-80		8 runs						-10°C			
2G31-70		4 calibrations						-10°C			
2G31-66								-10°C			
1L68-09											
9K15-01		instrument									
04J70-24											
04J71-93											
27030R001* (former 270300001)	m-PIMA Analyser (former Alere™ q System)	Instrument	N/A	N/A	Abbott Rapid Diagnostics Jena GmbH, 07749 Jena Germany	Not applicable	Not applicable	Not applicable	Whole Blood, Plasma	For consumables and alternative Alere q (product code 270300002) refer to WHO Public Report	WHO PQ
27011R010* (former 270110010)	m-PIMA HIV-1/2 Detect	10 Cartridges				HIV-1/2 Qualitative RNA	13 months	4-30°C			
27011R050* (former 270110050)		50 Cartridges					13 months	4-30°C			
27011W50*		50 Cartridges					13 months	4-30°C			
27015-W50	m-PIMA HIV-1/2 VL	50 tests/kit	N/A	NA	Abbott Alere Technologies GmbH, Germany Loebstedter Str. 103-105 07749 Jena Germany	HIV-1 Quantitative RNA	9 months	4 to 30°C	Plasma	For consumables refer to WHO PQ public report	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/190923_pqdx_0359_032_00_amended_pqpr_v2.pdf?ua=1
27030R001	m-PIMA Analyser	instrument	NA	NA		NA	NA	NA	NA		
HIV-1211	AccuPower® HIV-1 Quantitative RT-PCR Kit	96T/kit			Bioneer Corporation, 8-11, Munpyeongseo-ro,	HIV-1	12 months	-25°C to -15°C	EDTA	For consumables and details of	

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A-2200-N	ExiStation™ Universal Molecular Diagnostic System	Instrument	N/A	N/A	Daedeok-gu, Daejeon, 34302, Republic of Korea	Quantitative RNA	Not applicable	Not applicable	Plasma	and details of componants refer to IFU	GHTF (CE mark)
TR001-250IC	Generic HIV Charge Virale	220	NA	NA	Biocentric Bandol France	HIV1 Quantitative RNA	18 months	-30°C to -8°C	EDTA or citrated Plasma		GHTF (CE mark)
TR001-440IC	Generic HIV Charge Virale	440									
GX [Series}	GeneXpert® Systems I, II, IV & XVI	Instruments	N/A	N/A	Cepheid Inc., Rontgenvagen 5 SE-171, 54 Solna Sweden	N/A	N/A	N/A	N/A	For 10-channel optical system modules refer to WHO PQ public report	see relevant WHO PQ Public Report
Infinity-48	GeneXpert® Infinity-48s	Instrument				N/A	N/A	N/A	N/A		
Infinity-80	GeneXpert® Infinity-80	Instrument				N/A	N/A	N/A	N/A		
GXI-EDGE-L	GeneXpert Edge System	Instrument				N/A	N/A	N/A	N/A	Only for Xpert HIV-1 Qual Assay	
GXHIV-VL-CE-10*	Xpert HIV-1 Viral Load	10 cartridges per pack				HIV-1 Quantitative NA target	18 months	2-28°C	Plasma	For further instruments refer to WHO Public Report	WHO PQ and GHTF (CE mark)
GXHIV-QA-CE-10*	Xpert HIV-1 Qual Assay	10 cartridges per pack				HIV-1 Qualitative NA target	12 months	2–28 °C	Whole blood and DBS	For further instruments refer to WHO Public Report	WHO PQ and GHTF (CE mark)
GX [Series}	GeneXpert® Dx System with 10-color moduls	Instruments	N/A	N/A	Cepheid Inc., Rontgenvagen 5 SE-171, 54 Solna Sweden	N/A	N/A	N/A	N/A		GHTF (CE mark)
Infinity-48	GeneXpert® Infinity-48s	Instrument				N/A	N/A	N/A	N/A		
Infinity-80	GeneXpert® Infinity-80	Instrument				N/A	N/A	N/A	N/A		
GXI-EDGE-L	GeneXpert Edge System	Instrument				N/A	N/A	N/A	N/A	GeneXpert 6 or 10 color modules	
GXHIV-VL-XC-CE-10	Xpert HIV-1 Viral Load XC	10 cartridges per pack				HIV-1 Quantitative NA target	18 months	2-28°C	Plasma	For further instruments refer to IFU	WHO PQ and GHTF (CE mark)

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GXHIV-QA-XC-CE-10	Xpert HIV-1 Qual Assay XC	10 cartridges per pack				HIV-1 Qualitative NA target	18 months	2–28 °C	Whole blood and DBS	For further instruments refer to IFU	WHO PQ and GHTF (CE mark)
I19-0006-AM	SAMBA II Assay Module	instrument	N/A	N/A	Diagnostics for the Real World, Sunnyvale, CA 94085 USA	N/A	N/A	N/A	N/A		WHO PQ
I19-0006-TM	SAMBA II Tablet Module	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
4500-12	SAMBA II HIV-1 Qual Whole Blood Test	12 Tests	N/A	N/A		HIV-1 Qualitative RNA	9 months	2 to 37°C	Whole Blood		
INT030	ELITe InGenius	instrument	N/A	N/A	EliTechGroup S.p.A, Torino, Italy	N/A	N/A	N/A	N/A		GHTF(IVDR CE mark)
INT040	ELITe BeGenius	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
RTK600ING	HIV1 ELITe MGB® Kit	96 Tests	N/A	N/A		HIV-1 Quantitative RNA	18 months	below -20°C	EDTA or ACD Plasma		
PRD-03000	Aptima HIV-1 Quant Dx Assay Kit (Panther System)	100T/kit	N/A	N/A	Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121	HIV-1 Quantitative & Qualitative RNA	24 months	$2^{o}C$-$8^{o}C$	EDTA Plasma, see IFU for dried blood spots (DBS)	Multi-tube units (MTUs), Panther Waste Bag Kit, Panther Waste Bin Cover, Aptima Assay Fluids, and Tips are included and calculated based on number of kits ordered)	WHO PQ
PRD-03001		5 runs						-15 to -35°C			
PRD-03002		5 calibrators						-15 to -35°C			
303095		instrument					NA	NA			
PRD-03000B		500T/kit			Hologic, Inc	HIV-1	24 months	$2^{o}C$-$8^{o}C$	EDTA Plasma, see IFU for dried blood spots (DBS)	Multi-tube units (MTUs), Panther Waste Bag Kit, Panther Waste	
PRD-03001		10 runs						-15 to -35°C			
PRD-03002		10 calibrators						-15 to -35°C			

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303095	Aptima HIV-1 Quant Dx Assay Kit (Panther System)	instrument	N/A	N/A	[illegible], Inc 10210 Genetic Center Drive San Diego, CA 92121	[illegible] Quantitative & Qualitative RNA	NA	NA		[illegible] Bin Cover, Aptima Assay Fluids, and Tips are included and calculated based on number of kits ordered)	WHO PQ
4513263	artus HI Virus-1 RG RT-PCR (Rotor-Gene Q 5plex)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HIV-1 Quantitative RNA	20 months	-30°C to -15°C	Plasma	discontinued in the future by manufacturer	GHTF (CE mark)
4513265		96						-30°C to -15°C			
9001640		instrument									
60704	QIAamp DSP Virus Kit	extraction kit 50T/kit					12 months	2°C to 8°C			
4513363	artus HI Virus-1 QS-RGQ (QIAsymphony SP/AS - Rotor-Gene Q)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HIV-1 Quantitative RNA	17 months	-30°C to -15°C	Plasma	discontinued in the future by manufacturer	GHTF (CE mark, TGA)
4513366		72						-30°C to -15°C			
9001297 and 9001640		instrument									
937055	QIAsymphony® DSP Virus/Pathogen	extraction kit 96T/kit					14 months	15°C - 25°C			
03279332001*	COBAS AmpliPrep/COBAS Taqman HIV-1 Test Version 2.0 (Taqman 48)	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 Quantitative RNA	NA		Plasma or PSC dried plasma spot (with PCS)	For consumables refer to WHO eligible list http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	WHO PQ and GHTF (CE mark) http://www.who.int/diagnostics_laboratory/evaluations/120502_0126_046_00_public_report_v1_final.pdf
05527503001		instrument					NA				
04862392001		software					NA				
05807875001		software					NA				
03051315001		instrument					NA				
05212294190		48T/kit					18 Months	2 to 8°C			
03587797190		5.1L					24 months	2 to 30°C			
03121453001*	COBAS AmpliPrep/COBAS Taqman HIV-1 Test Version 2.0 (Taqman 96)	instrument	N/A	N/A	Roche Molecular System, Branchburg	HIV1 Quantitative	NA		Plasma or dried	For consumables refer to WHO eligible list http://www.who.int/diagn	WHO PQ and GHTF (CE mark) http://www.who.int/diagnostics_la
03051315001		instrument					NA				
04862392001		software					NA				
05807875001		software					NA				

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05527503001	2.0 (Taqman 96)	instrument	N/A	N/A	System, Branchburg, USA	Qualitative RNA	NA		plasma spot (with PCS)	http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	http://www.who.int/diagnostics_laboratory/evaluations/120502_0147_046_00_public_report_v1_final.pdf
05212294190		48T/kit					18 Months	2 to 8°C			
03587797190		5.1L					24 months	2 to 30°C			
28127387001											
06693083190*	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 48)	48 T/KIT	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 DNA & RNA Qualitative	22 months	2 to 8°C	Plasma or dried blood spots		WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. http://www.who.int/diagnostics_laboratory/evaluations/141216_final_report_taqman48_0221_v2.pdf?ua=1
03051315001		instrument									
03279332001		instrument									
03587797190		5.1L					24 months	2 to 30°C			
06989861190		5 x 78ml									
05807875001		software									
03516440001		instrument									
28127387001											
06693083190*	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 96)	48T/kit	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 DNA & RNA Qualitative	22 months	2 to 8°C	Plasma or dried blood spots		WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. http://www.who.int/diagnostics_laboratory/evaluations/141216_final_report_taqman96_0200_v2.pdf?ua=1
03587797190		5.1L					24 months	2 to 30°C			
06989861190		5 x 78ml					12 months	2 to 8°C			
03051315001		instrument									
03121453001		instrument									
28127387001											
05807875001		software									
03516440001		instrument									
5923468190	COBAS® TaqMan® HIV-1 Test, Version 2 for use with High pure system	48 tests	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HIV-1 Quantitative RNA	24 months*	2 to 8°C	Plasma		GHTF (CE mark)
3502295001	High Pure System Nucleic Acid Kit	48 tests					12 months*	15 to 25°C			

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05 200 881 001	COBAS® z 480	instrument	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	N/A	N/A	N/A	N/A		WHO PQ and GHTF (CE mark) https://extranet.who.int/pqweb/sites/default/files/PQDx_0710-118-00_cobasHIV-1NucleicAcidTest-4800System_v2.0.pdf
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
08 792992190	COBAS® HIV-1 Test for use with 4800	120 tests	N/A	N/A		HIV-1 Quantitative & Qualitative RNA	15 months	2 to 8°C	EDTA Plasma, dried plasma spot (with PSC card), dried blood spots (DBS)		
05 200 881 001	COBAS® z 480	instrument	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	N/A	N/A	N/A	N/A		WHO PQ and GHTF (CE mark) PQDx 0373-118-00
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
06 979599190	COBAS® Quantitative HIV-1 Test for use with 4800	120 tests	N/A	N/A		HIV-1 Quantitative RNA	16 months	N/A	EDTA Plasma		
05524245001 and 06379664001	COBAS® p 680	instrument	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	N/A	N/A	N/A	N/A		WHO PQ and GHTF (CE mark)
05412722001	COBAS® p 880	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
07000995190	COBAS® HIV-1 Test for use with 6800/8800 and PCS	96 tests/kit	N/A	N/A		HIV-1 Quantitative RNA	18 months	2 to 8°C	EDTA Plasma, dried plasma spot	(with PSC card)	
07862113190	COBAS® HIV-1/HIV-2 Test for use with 6800/8800	96 tests/kit	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HIV-1/HIV-2 Qualitative RNA	18 months	2 to 8°C	Serum, Plasma, dried blood spots (DBS)		GHTF (CE mark)
09040803190	COBAS® HIV-1 Quantitative nucleic acid test for use on the cobas® 5800/6800/8800 Systems	192 tests/kit	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HIV-1 Quantitative RNA	24 months	2 to 8°C	EDTA Plasma, dried plasma spot	(with PCS card)	GHTF (CE mark)

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09040528190	COBAS® HIV-1/HIV-2 Qualitative nucleic acid test for use on the cobas® 5800/6800/8800 Systems	192 tests/kit	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HIV-1/HIV-2 Qualitative RNA	24 months	2 to 8°C	EDTA Plasma, dried plasma spot, dried blood spots (DBS)	(with PCS card)	GHTF (CE mark)
V0-96/3FRT	HIV Real-TM Quant Dx	96	N/A	N/A	Sacace Biotechnologies Srl Como – Italy	HIV1 Quantitative RNA	12 months	2 to 8°C	Human Plasma		GHTF (CE mark)
10729727	VERSANT® HIV-1 RNA 1.5 Assay (kPCR)	96T/kit	N/A	N/A	Siemens Healthcare Diagnostics, Tarrytown NY, USA	Quantitative RNA	12 months	-20°C	Plasma	For consumables refer to IFU	GHTF (CE mark)
10729728		96T/kit					12 months	-80°C			
10286026		96T/kit					24 months	15 to 30°C			
10286027		96T/kit					24 months	4°C			
		instruments					N/A	N/A			

N/A- NOT APPLICABLE

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

Hepatitis B / Rapid Diagnostic Tests (RDTs)
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Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
7D2942 *	Determine HBsAg 2	20	100.00%	99.70%	Abbott Diagnostics Medical Co. Ltd, Matsudo, Japan	HBsAg detection	Serum/Plasma /Whole Blood	18 Months 2 to 30°C		WHO PQ
7D2943 *		100								
7D2943 SET *		100								
01FK10W *	Bioline HBsAg WB	30	100.00%	99.00%	Abbott Diagnostics Korea (Giheung-gu,Yongin-si, Korea)	HBsAg detection	Serum/Plasma /Whole Blood	24 Months 1 to 40°C		WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/200820_amended_pqpr_0219_012_00_bioline_hbsag_wb_v4.pdf?ua=1
R0042C	OnSite HBsAg Combo Rapid Test	30	100%	100%	CTK Biotech Inc, USA	HBsAg detection	Serum/Plasma /Venous and Capillary Whole Blood	24 months 2 to 30°C		GHTF (CE mark)
PI10FRC05CE	First Response® HBsAg Card Test	5	100.00%	100.00%	Premier Medical Corporation, Nani Daman, India	HBsAg detection	Serum/Plasma /Whole Blood	24 Months 4 to 30°C		GHTF (CE mark)
PI10FRC10CE		10								
PI10FRC25CE		25								
PI10FRC30CE		30								
09HBS10D	STANDARD™ Q HBsAg Test	25	98.00%	100.00%	SD Biosensor, Inc (Gyeonggi-do 16690 Republic of Korea)	HBsAg detection	Serum/Plasma /Whole Blood	24 Months 1 to 40°C	Products available from ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	ERPD until 12th November 2025

N/A- NOT APPLICABLE

Hepatitis B / Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests – unless otherwise specified)

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Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

Hepatitis B Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
02G22-25	ARCHITECT HBsAg Qualitative II	100			Abbott Ireland Diagnostics Division, Ireland	HBsAg antigens	12 months 2 to 8°C	Serum or plasma specimens; Note: The ARCHITECT HBsAg Qualitative II assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum and plasma including specimens collected post-mortem (non-heart-beating). The ARCHITECT HBsAg Qualitative II assay is intended to be used as an aid in the diagnosis of HBV infection and as a screening test to prevent transmission of HBV to recipients of blood, blood components, cells, tissue and organs.	GHTF (CE mark, TGA, Canada)
02G22-35		500							
02G22-30		4x500							
B-1254/1.2 *	DS-EIA-HBsAg-0,01	96/1 plate	100%	99.00%	RPC «Diagnostic Systems», Ltd. Nizhny Novgorod Russian Federation	anti-HBsAg antibodies	24 months 2-8 °C	Human serum or plama specimen	WHO PQ https://extranet.who.int/pqweb/sites/default/files/PQDx_0120-038-00_DS-EIA-HBsAg-001_ENZYME-IMMUNOASSAY_v4.0.pdf
B-1252/1.2 *		192/2 plates							
B-1255/1.2 *		480/5 plates							
B-1256/1.2 *		1 plate 96 (for detection) or 48 (for confirmation)							
B-231/1.2 *		200 tests							
72346	Monolisa HBsAg ULTRA assay	96	100%	99.94%	Bio-Rad Laboratories, Marnes La Coquette, France	anti-HBsAg Antibodies	see lot expiry 2 to 8°C	Serum and plasma specimen Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs	GHTF (CE mark)
72348		480							

Hepatitis B Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
9F80-01*	Murex HBsAg Version 3	96	100%	99.00%	DiaSorin, Dartford, United Kingdon	anti-HBsAg Antibodies	12 months 2 to 8°C	In EDTA/Citrate Plasma specimen 1. Stop Solution (0.5Mto 2MSulphuric Acid). 2. Freshly distilled or high quality deionized water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09 02). For use in laboratory incubators. 6. Instrumentation a) Automated microplate strip washer. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	WHO PQ https://extranet.who.int/pqweb/content/public-report-murex-hbsag-version-3-murex-hbsag-confirmatory-version-3-pqdx-0121-043-00
9F80-05*		480							
2G27-01*	Murex HBsAg Confirmatory Version 3	50	100%	99.78%	DiaSorin Dartford, United Kingdon	anti-HBsAg Antibodies	17 months 2 to 8°C	Serum and plasma specimen 1. Stop Solution (0.5M to 2M Sulphuric Acid). 2. Freshly distilled or high quality deionised water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09-02). 6. Instrumentation a) Automated microplate stripwasher. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24-01). 8. Sodium hypochlorite for decontamination. (Refer to Health and Safety Information) 9. Sodium hydroxide solution (0.1M). (Refer to Analytical Precautions).	WHO PQ https://extranet.who.int/pqweb/content/public-report-murex-hbsag-version-3-murex-hbsag-confirmatory-version-3-pqdx-0121-043-00
HBsAg121	HBsAg Hepatitis B Surface Antigen (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	HBsAg	18 months 2 to 8°C	human serum, plasma; Note: The CL-series HBsAg assay is intended to be used as an aid in the diagnosis of HBV infection and as a screening test for donated blood and plasma.	GHTF (CE mark)
HBsAg122		2×100 tests							
Anti-HBs121	Anti-HBs Antibody to Hepatitis B Surface Antigen (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	Anti-HBs	18 months 2 to 8°C	human serum, plasma;	GHTF (CE mark)
Anti-HBs122		2×100 tests							

Hepatitis B Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
HBeAg121	HBeAg Hepatitis B e Antigen CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	HBeAg	18 months 2 to 8°C	human serum, plasma;	GHTF (CE mark)
HBeAg122		2×100 tests							
Anti-HBe121	Anti-HBe Antibody to Hepatitis B e Antigen (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	Anti-HBc	18 months 2 to 8°C	human serum, plasma;	GHTF (CE mark)
Anti-HBe121		2×100 tests							
Anti-HBc121	Anti-HBc Antibody to Hepatitis B Core Antigen（CLIA）	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	Anti-HBc	18 months 2 to 8°C	human serum, plasma;	GHTF (CE mark)
Anti-HBc122		2×100 tests							
11 820 567 122	Elecsys® Anti-HBc IgM	100			Roche Diagnostics GmbH	HBc IgM antibodies	15 months 2 to 8°C	Human serum and plasma specimens cobas e immunoassay analyzer	GHTF (CE mark)
07 026 811 190		300							
07 374 160 190 / 09 014 918 190	Elecsys® Anti-HBc II	100			Roche Diagnostics GmbH	HBc IgG and IgM antibodies	15 months 2 to 8°C	Human serum and plasma specimens cobas e immunoassay analyzer NOTE: Consult the IFU for screening of blood donations and for use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating).	GHTF (CE mark)
07 394 764 190 / 09 109 463 190		200							
07 026 790 190 / 09 014 926 190		300							
11 820 583 122 / 09 015 540 190	Elecsys® HBeAg	100	100.00%	99.90%	Roche Diagnostics GmbH	anti-HBeAg Antibodies	24 months 2 to 8°C	Human serum and plasma specimens cobas e 801 immunoassay analyzer NOTE: Consult the IFU for diagnostic use and for testing of blood donations	GHTF (CE mark)
07 027 427 190 / 09 015 558 190		300							

Hepatitis B Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
05 894 816 190 / 08 498 598 190	Elecsys® Anti-HBs II	100			Roche Diagnostics GmbH	HBs antibodies	15 months 2 to 8°C	Human serum and plasma specimens cobas e immunoassay analyzer NOTE: Consult the IFU for diagnostic use and for testing of blood donations	GHTF (CE mark)
06 771 823 190 / 08 498 601 190		200							
07 026 854 190 / 08 498 610 190		300							
04 687 787 190 / 08 814 856 190	Elecsys® HBsAg II	100			Roche Diagnostics GmbH	HBsAg antigens	12 months 2 to 8°C	Human serum and plasma specimens cobas e immunoassay analyzer NOTE: Consult the IFU for screening of blood donations and for use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating).	GHTF (CE mark)
07 914 482 190 / 08 814 864 190		200							
07 251 076 190 / 08 814 848 190		300							

N/A- NOT APPLICABLE

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

Hepatitis B / Virological technologies
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
08N47-090	Alinity m HBV	192T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HBV Quantitative DNA	12 months	2 to 8°C	Plasma and Serum		GHTF (CE mark)
08N53-002		instrument									
08N47		instrument									
08N47-080		3 x 12 CTRL kit						-25 to -15°C			
08N47-070		2x4 CAL kit						-25 to -15°C			
09N12-001		sample prep kit 2									
TR004.2-250IC	Generic HBV Charge Viral Version 2.0	220T/kit	N/A	N/A	Biocentric, France	HBV Quantitative DNA	18 months	-30°C to -18°C	EDTA Plasma	not intended for use as a screening test in blood or blood products for HBV or to confirm the presence of HBV infection.	GHTF (CE mark)
	see IFU for compatible instruments	Instrument					Not applicable	Not applicable			
HBV-1211	AccuPower® HBV Quantitative PCR Kit	96T/kit	N/A	N/A	Bioneer Corporation, 8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon, 34302, Republic of Korea	HBV Quantitative DNA	12 months	-25°C to -15°C	EDTA Plasma and Serum	For consumables and details of componants refer to IFU	GHTF (CE mark)
A-2200-N	ExiStation™ Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			
GX [Series}	GeneXpert® Dx	Instrument	N/A	N/A	Cepheid Inc., Rontgenvagen 5 SE-171, 54 Solna Sweden	N/A	N/A	N/A	N/A		GHTF (CE mark)
Infinity-48	GeneXpert® Infinity-48	Instrument				N/A	N/A	N/A	N/A		
Infinity-80	GeneXpert® Infinity-80	Instrument				N/A	N/A	N/A	N/A		
GX4.0SWKIT or XPERTISE-G2-SWKIT	GeneXpert® Dx Software	Software				N/A	N/A	N/A	N/A		
GXHBV-VL-CE-10	Xpert® HBV Viral Load	10 cartridges per pack				HBV Quantitative DNA	18 months	2-35°C	Serum / EDTA Plasma		
INT030	ELITe InGenius	instrument	N/A	N/A		N/A	N/A	N/A	N/A		

Hepatitis B / Virological technologies
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
INT040	ELITe BeGenius	instrument	N/A	N/A	EliTechGroup S.p.A, Torino, Italy	N/A	N/A	N/A	N/A		GHTF(IVDR CE mark)
RTK602ING	HBV ELITe MGB® Kit	96 Tests	N/A	N/A		HBV Quantitative DNA	18 months	below -20°C	EDTA or ACD Plasma		
05 200 881 001	COBAS® z 480	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	N/A	N/A	N/A	N/A		GHTF (CE mark)
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
06 979564190	COBAS® Quantitative HBV Test for use with 4800	120 tests	N/A	N/A		HBV Quantitative DNA	24 months	2°C - 8°C	EDTA Plasma / Serum	not intended for use as a screening test for the presence of HBV in blood or blood products or as a diagnostic test to confirm the presence of HBV infection.	
09040820190	COBAS® HBV Quantitative nucleic acid test for use on the cobas® 5800/6800/8800 Systems	192 tests/kit	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HBV Quantitative DNA	24 months	2 to 8°C	Plasma / serum / whole blood		GHTF (CE mark)
04894570 190	COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, version 2.0	72	N/A	N/A	Roche Molecular	HBV Quantitative DNA	24 months	2°C - 8°C	Plasma and Serum	not intended for use as a screening test for the presence of HBV in blood or blood products or as a diagnostic test to confirm the presence of HBV infection	GHTF (CE mark)
	COBAS® AmpliPrep Instrument	instrument					n/a	n/a			
	COBAS® TaqMan® Analyzer	instrument					n/a	n/a			
03587797 190	COBAS® AmpliPrep/COBAS® TaqMan® Wash Reagent	extraction kit 96T/kit					24 months	2°C - 30°C			

N/A- NOT APPLICABLE

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

Hepatitis C / Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
02FK10*	Bioline HCV	30	100.00%	99.40%	Abbott Diagnostics Korea Inc. (Giheung-gu,Yongin-si, Korea)	HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 1 to 30°C	1 chase buffers,	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/200820_amended_pqpr_0257_012_00_bioline_hcv_v8.pdf?ua=1
02FK16*		25	100.00%	99.40%		HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 1 to 30°C	Sterile lancets, alcohol swabs, specimen droppers(for fingerstick whole blood), 1 chase buffers, specimen dropper for serum/plasma, whole blood	
02FK17*		25	100.00%	99.40%		HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 1 to 30°C	Safety lancets, alcohol swabs, specimen droppers(for fingerstick whole blood), 1 chase buffers, specimen dropper for serum/plasma, whole blood	
IHC-402WA	HCV Hepatitis C Virus Rapid Test Device	40	100.00%	100.00%	ABON Biopharm (Hangzhou) CO., LTD	HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 2 to 30°C		WHO PQ
IHC-402WB		25								
IHC-402WC		40							Accessories for Fingerstick Whole Blood	
IHC-402WD		25							Accessories for Fingestick Whole Blood	
90-1062	INSTI HCV Antibody Test	50	100.00%	97.67%	bioLytical® Laboratories Inc	HCV antibody detection	Serum/Plasma /Whole Blood	6 Months 2 to 30°C	with support materials (lancet, pipette and alcohol swab)	GHTF (CE mark)
R0024C	OnSite HCV Ab Plus Combo Rapid Test	30	100%	100%	CTK Biotech Inc, USA	HCV antibody detection	Serum/Plasma /Venous and Capillary Whole Blood	24 months 2 to 30°C		GHTF (CE mark)
GCHCV-402a	HCV Hepatitis C Virus Rapid Test (Whole blood/Serum/Plasma) (Cassette)	25	100%	99.90%	Healgen Scientific Limited Liability Company; Houston, USA	HIV 1/2 antibodies combined detection	Whole blood, serum or plasma	24 months 2 to 30 °C		GHTF (CE mark)
GCHCV-302a	HCV Hepatitis C Virus Rapid Test (Serum/Plasma) (Cassette)	25	100%	99.90%	Healgen Scientific Limited Liability Company, Houston, USA	HIV 1/2 antibodies combined detection	Serum or plasma	24 months 2 to 30 °C		GHTF (CE mark)

Hepatitis C / Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
ITP01152-TC40	Rapid Anti-HCV Test	40	99.70%	99.80%	InTec Poducts Inc, (Haicang, Xiamen, P.R. China)	HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 2 to 30°C	Accessories included: Plastic pipettes, sample buffer	GHTF (CE mark)
ITP01152-TC25		25							Accessories included: Plastic pipettes, sample buffer	
ITP01153-TC40		40							Accessories included: Plastic pipettes, sample buffer, safety lancets, and alcohol swabs	
ITP01153-TC10		10							Accessories included: Plastic pipettes, sample buffer, safety lancets, and alcohol swabs	
ITPW01152-TC40*	Rapid Anti-HCV Test	40	99.70%	99.80%	InTec Poducts Inc, (Haicang, Xiamen, P.R. China)	HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 2 to 30°C	Accessories included: Plastic pipettes, sample buffer	WHO PQ
ITPW01152-TC25*		25							Accessories included: Plastic pipettes, sample buffer	
ITPW01153-TC40*		40							Accessories included: Plastic pipettes, sample buffer, safety lancets, and alcohol swabs	
1001-0270*	OraQuick HCV Rapid Antibody Test Kit	25	99.30%	99.50%	OraSure Technologies Inc. (Bethlehem, USA)	HCV antibody detection	Serum/Plasma /Whole Blood/Oral Fluid	18 Months 2 to 30°C	for accessories see IFU	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/170301_final_pq_report_PQDx_0244_055_00.pdf?ua=1
1001-0274*		100								
PI03FRC25	First Response® HCV Card Test	25	100.00%	100.00%	Premier Medical Corporation, Nani Daman, India	HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 4 to 30°C		WHO PQ
PI03FRC50		50								
PI03FRC100		100								
PI03FRC05CE	First Response® HCV Card Test	5	100.00%	100.00%	Premier Medical Corporation, Nani Daman, India	HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 4 to 30°C		GHTF (CE mark)
PI03FRC10CE		10								
PI03FRC25CE		25								
PI03FRC30CE		30								

Hepatitis C / Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
09HCV10D	STANDARD Q HCV Ab Test	25	100.00%	97.67%	SD Biosensor, Inc (Gyeonggi-do 16690 Republic of Korea)	HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 2 to 40°C		WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/200305_final_pqpr_0360_117_00_standard_q_hcv_ab_test.pdf?ua=1
HCV Self Test										
7X4-0004.### *	OraQuick HIV Self-Test	1	see IFU	see IFU	OraSure Technologies Inc, Bethlehem, USA (manufactured in Thailand)	HCV antibodies	Oral fluid	18 Months 2 to 30°C	Community Version Individual Test pouches are labeled 3001-3217.###	WHO PQ https://extranet.who.int/prequal/sites/default/files/whopr_files/oraquick-hepatitis-c-self-test-pqdx-0244-055-01-public-report-v-1.0.pdf
7X4-1000.### *		50								
7X4-1001.### *		250								
7X4-2001.### *		200							Pharmacy Version (placed in individual cartons)	
7X4-2001U.### *		1							Community Version Individual Test boxes are labeled 3001-3217.###	

N/A- NOT APPLICABLE

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

Hepatis C Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
6L47-29	ARCHITECT HCV Ag assay	100	98%	99.50%	Abbott GmbH, Germany	HCV antigens	12 months 2 to 8°C	Human serum and plasma specimens	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/190731_pqdx_0374_130_00_architecth_hcv.pdf?ua=1 GHTF (CE mark)
06C37-28	ARCHITECT Anti-HCV	100			Abbott GmbH, Germany	HCV antibodies	12 months 2 to 8°C	Serum or plasma specimens; Note: The ARCHITECTAnti-HCV assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in human serum and plasma including specimens collected post-mortem (non-heart-beating). The ARCHITECT Anti-HCV assay is intended to be used as an aid in the diagnosis of Hepatitis C infection and as a screening test to prevent transmission of Hepatitis C Virus to recipients of blood, blood components, cells, tissue and organs.	GHTF (CE mark, TGA, Canada)
06C37-38		500							
06C37-33		4x500							
72561*	Monolisa HCV Ag-Ab ULTRA V2 assay	96	100%	99.94%	Bio-Rad Laboratories, Marnes La Coquette, France	HCV antigens / antibodies	12 months 2 to 8°C	Serum and plasma specimen Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/200124_fina_pqpr_pqdx_0229_031_00_monolisa_hcv_ag_ab_ultra.pdf?ua=1 GHTF (CE mark)
72562*		480							
7F51-01*		96						In EDTA/Citrate Plasma specimen 1. Stop Solution (0.5Mto 2MSulphuric Acid). 2. Freshly distilled or high quality deionized water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol.	

Hepatis C Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
7F51-02 *	Murex anti-HCV Version 4	480	100%	99.40%	DiaSorin, Dartford, South Africa (Pty) Ltd	HCV antigens	12 months 2 to 8°C	defined in the assay protocol. 5. Moulded Heating Block (Code 5F09 02). For use in laboratory incubators. 6. Instrumentation a) Automated microplate strip washer. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	WHO PQ https://extranet.who.int/pqweb/sites/default/files/180517_amended_final_pqpr_0164_059_00_v7.pdf
80068 *	INNOTEST HCV Ab IV	192	100.00%	100.00%	Fujirebio Europe NV (Gent, Belgium)	HCV antigens	16 months 2 to 8°C	Human serum and plasma specimens	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/180215_final_pq_report_pqdx_0201_073_00.pdf?ua=1
80330 *		480							
80538 *	INNO-LIA HCV Score	20	100.00%	99.90%	Fujirebio Europe NV (Gent, Belgium)	HCV antigens	15 months 2 to 8°C	Human serum and plasma specimens	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/150729_final_report_0202_073_00_hcv.pdf?ua=1
06 368 921 190 / 08 836 981 190	Elecsys® Anti-HCV II	100	100.00%	99.90%	Roche Diagnostics GmbH	HCV antibodies	12 months 2 to 8°C	Human serum and plasma specimens cobas e 801 immunoassay analyzer NOTE: Consult the IFU for screening of blood donations and for use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating).	GHTF (CE mark)
06 427 405 190 / 08 837 031 190		200							
07 026 889 190 / 08 837 058 190		300							
105 024999 00	Anti HCV Antibody to Hepatitis C Virus (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	HCV antibodies	18 months 2 to 8°C	human serum, plasma; Note: It is intended to be used as an aid in the diagnosis of HCV infection and as a screening testfor donated blood and blood components.	GHTF (EU IVDR CE mark)
105 025000 00		2×100 tests							

N/A- NOT APPLICABLE

Hepatis C Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

Hepatitis C / Virological technologies
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
4J86-90*	Abbott Realtime HCV	96T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HCV Quantitative RNA	18 months	<-10°C	Plasma and Serum and DBS		GHTF (CE mark) and WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/200915_amended_final_pqpr_0450_027_00_abbot_realtime_hcv.pdf
various		instrument									
4J86-80		CTRL kit						<-10°C			
4J86-70		CAL kit						<-10°C			
08N50-090*	Alinity m HCV	4 x 48T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HCV Qualitative and Quantitative RNA	12 months	2 to 8°C	Plasma and Serum		GHTF (CE mark) and WHO PQ
08N53-002		instrument									
08N50		instrument									
08N50-080		3 x 12 CTRL kit						-25 to -15°C			
08N50-070		2x4 CAL kit						-25 to -15°C			
09N12-001		sample prep kit 2									
HCV-1211	AccuPower® HCV Quantitative RT-PCR Kit	96T/kit	N/A	N/A	Bioneer Corporation, 8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon, 34302, Republic of Korea	HCV Quantitative RNA	12 months	-25°C to -15°C	EDTA Plasma and Serum	For consumables and details of componants refer to IFU	GHTF (CE mark)
A-2200-N	ExiStation™ Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			
GX [Series}	GeneXpert® Dx	Instruments				N/A	N/A	N/A	N/A	For 10-channel optical system modules refer to WHO PQ public report	GHTF (CE mark) and
Infinity-48	GeneXpert® Infinity-48	Instrument				N/A	N/A	N/A	N/A		
Infinity-80	GeneXpert® Infinity-80	Instrument				N/A	N/A	N/A	N/A		

Hepatitis C / Virological technologies
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
GX4.0SWKIT or XPERTISE-G2-SWKIT	GeneXpert® Dx Software Version 4.6a or higher (GeneXpert Dx systems); or Xpertise 6.2a or higher (Infinity80/Infinity-48s)	Software	N/A	N/A	Cepheid Inc., Rontgenvagen 5 SE-171, 54 Solna Sweden	N/A	N/A	N/A	N/A		GHTF (CE mark) and WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/190730_amended_pqpr_0260_070_00.pdf?ua=1
GXHCV-VL-CE-10*	Xpert® HCV Viral Load	10 cartridges per pack				HCV Qualitative and Quantitative RNA	12 months	2-28°C	Serum / EDTA Plasma / blood		
ID-HCV-03*	Genedrive HCV ID Kit	10	99.8	100	Genedrive Diagnostics Ltd., United Kingdom	HCV Qualitative RNA	12 months	2 to 30°C	Plasma		GHTF (CE mark) and WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/200501_final_pqpr_pqdx_0380_133_00_genedrive_hcv_id_v1.pdf?ua=1
PRD-03506	Aptima HCV Quant Dx Assay Kit (Panther System)	100T/kit	N/A	N/A	Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121	HIV-1 Quantitative & Qualitative RNA	24 months	2 to 8°C	Plasma and Serum		GHTF (Health Canada approval)
PRD-03508		10 runs						-15 to -35°C			
PRD-03507		10 calibrators						-15 to -35°C			
303095		instrument					NA	NA			
05 200 881 001	COBAS® z 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		

Hepatitis C / Virological technologies
(not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
06 979602190	COBAS® Quantitative HCV Test for use with 4800	120 tests	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HCV Quantitative RNA	24 months	2°C - 8°C	EDTA Plasma / Serum	not intended for use as a screening test for the presence of HCV in blood or blood products or as a diagnostic test to confirm the presence of HBV infection.	GHTF (CE mark)
06997732 190*	COBAS® HCV Test for use with 5800/6800/8800 and PCS	96 tests/kit	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HCV Quantitative RNA	18 months	2 to 8°C	EDTA Plasma, dried plasma spot	(with PCS card)	WHO PQ

N/A- NOT APPLICABLE

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

Treponema Pallidum Infections for diagnosis of Syphilis to initiate patient treatment /Rapid Diagnostic Tests (RDTs) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
06FK30*	Bioline HIV/Syphilis Duo (formerly SD Bioline HIV/Syphilis Duo)	25	HIV-100% Syphilis-87%	99.5% 99.5%	Abbott Diagnostics Korea Inc. (Giheung-gu,Yongin-si, Korea)	HIV/TP-antibodies	Serum/Plasma /Whole Blood	24 Months 1 to 30°C	For consumables refer to WHO Public Report	WHO PQ https://extranet.who.int/pqweb/sites/default/files/PQDx_0179-012-00_BiolineHIVSyphilisDuo_PublicReport_v7.0.pdf
06FK35*										
06FK37*										
I20FRC25* I20FRC30 I20FRC50 I20FRC60 I20FRC100	First Response® HIV1+2/Syphilis Combo Card Test	25 T/kit 30 T/kit 50 T/kit 60 T/kit 100T/kit	HIV-100% Syphilis-99%	99.5% 100%	Premier Medical Corporation Private Limited (Sarigam, Gujarat, India)	HIV/TP-antibodies	Serum/Plasma /Whole Blood	30 Months 4 to 30°C	For consumables refer to WHO Public Report	WHO PQ
09HIV20D	STANDARD™ Q HIV/Syphilis Combo Test	25 T/kit	HIV-100% Syphilis-98.8%	HIV-99.9% Syphilis-100%	SD Biosensor Inc (16, Deogyeong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690 Republic of Korea)	HIV/TP-antibodies	Serum/Plasma /Whole Blood	24 Months 2 to 40°C	For consumables refer to WHO Public Report	WHO PQ
on request	on request	on request	on request	on request	on request	HIV/TP-antibodies	Serum/Plasma /Whole Blood	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	ERPD
7D2452*	Determine Syphilis TP	30	Syphilis-100%	98.70%	Abbott Diagnostics Medical Co., Ltd.	TP-antibodies	Serum/Plasma /Whole Blood	14 Months 2 to 30°C	For consumables refer to WHO Public Report	WHO PQ
7D2453*		100								
7D2453SET*		100								

Treponema Pallidum Infections for diagnosis of Syphilis to initiate patient treatment /Rapid Diagnostic Tests (RDTs) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
PI08FRC25* PI08FRC50 PI08FRC100	First Response® Syphilis Anti-TP Card Test	25 T/kit 50 T/kit 100T/kit	99.60%	100.00%	Premier Medical Corporation Private Limited (Sarigam, Gujarat, India)	TP-antibodies	Serum/Plasma /Whole Blood	24 Months 4 to 30°C	For consumables refer to WHO Public Report	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/190625_pqdx_0364_010_00_final_pqpr.pdf
06FK10	BIOLINE Syphilis 3.0 (former SD Bioline Syphilis 3.0)	30 T/kit	see IFU	see IFU	Abbott Diagnostics Korea	TP-antibodies	Serum/Plasma /Whole Blood	on request		GHTF (IVDR CE-mark)
on request	on request	on request	on request	on request	on request	TP-antibodies	Serum/Plasma /Whole Blood	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	ERPD
on request		on request								

N/A- NOT APPLICABLE

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List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

Treponema Pallidum Infections for diagnosis of Syphilis to initiate patient treatment / (other than RDTs) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
RPR										
275005	BD Macro-Vue™ RPR (Rapid Plasma Reagin) 18 mm Circle Card Test	500t/kit	see IFU	see IFU	Becton, Dickinson and Company, USA	reagin	see IFU			GHTF (Health Canada, TGA)
275239	BD Macro-Vue™ RPR (Rapid Plasma Reagin) 18 mm Circle Card Test	150t/kit	see IFU	see IFU	Becton, Dickinson and Company, USA	reagin	see IFU			GHTF (Health Canada, TGA)
VDRL										
removed	removed	removed	removed	removed	removed	removed	removed	removed	removed	removed
TPHA / TPPA										
removed	removed	removed	removed	removed	removed	removed	removed	removed	removed	removed
ELISA / EIA / LIA										
removed	removed	removed	removed	removed	removed	removed	removed	removed	removed	removed

N/A- NOT APPLICABLE

List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

Syphilis Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests – unless otherwise specified)

Product codes superscripted with a * (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
08D06-32	ARCHITECT Syphilis TP	100	99%	99.88% (blood donor specimens) 99.76% (diagnostic specimens)	Abbott GmbH, Wiesbaden, Germany	antibodies to TP	13 months 2 to 8°C	Serum or plasma specimens; Note: The ARCHITECT Syphilis TP assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of antibodies to Treponema pallidum (TP) in human serum and plasma, including specimens collected post-mortem (non-heart-beating). The ARCHITECT Syphilis TP assay is intended to be used as an aid in the diagnosis of Syphilis infection and as a screening test to prevent transmission of Treponema pallidum to recipients of blood, blood components, cells, tissue and organs.	GHTF (TGA, Canada)
08D06-42		500							

N/A- NOT APPLICABLE

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List of COIM Diagnostic tests
(included to support Global Fund Policy for Co-Infections and Co-Morbidities)

NOTE: The particular requirements from section 10 of the Global Fund QA Policy of Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and core Personal Protective Equipment do not apply for these products. However, the requirements of section 8 should be met. An additional assessment by WHO PQ or the ERP-D provides increased assurance on meeting the needs of low-ressource settings.

Product codes superscripted with a * (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
Human Papilloma Virus										
The particular requirements from section 10 of the Global Fund QA Policy of Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and core Personal Protective Equipment do not apply for these products. However, the requirements of section 8 should be met.										
Cryptococcal Antigen										
The particular requirements from section 10 of the Global Fund QA Policy of Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and core Personal Protective Equipment do not apply for these products. However, the requirements of section 8 should be met.										