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 Diagnostic Products (https://www.theglobalfund.org/media/5885/psm_qadiagnostics_policy_en.pdf), 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 (high risk classification),
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, such as testing for G6PD deficiency

Categories falling under Criterion-2

All under Criterion-1 excluding HIV Self Testing

The list is an overview of HIV RDTs to assist Principal Recipients (PRs) of Global Fund grants to identify the status of HIV RDTs according to the 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 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.
The list is adapted from the lists posted in the following websites:
List of HIV diagnostics eligible for procurement by WHO: http://www.who.int/diagnostics_laboratory/procurement/purchase/en/
(which has also the products prequalified by WHO https://extranet.who.int/pqweb/sites/default/files/documents/210309_prequalified_product_list.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	12chase buffers, specimen dropper for serum/plasma, whole blood	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	Safety lancets, alcohol swabs, specimen droppers(for fingerstick whole blood), 2 chase buffers, specimen dropper for serum/plasma, whole blood	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	Safety lancets, specimen droppers(for fingerstick whole blood), 2 chase buffers, specimen dropper for serum/plasma, whole blood	WHO PQ
IHI-T402WC*	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	5	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	1 chase buffers, specimen dropper for serum/plasma, whole blood	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)	

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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	
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 HIV-2 antibodies	Serum/Plasma/ Whole Blood	24 months 1 to 30°C	If whole blood: lancets, alcohol swabs. If 03FK10: lancets, capillary pipettes, alcohol swabs.	
03FK10*		30								

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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*										
31112*	VIKIA HIV 1/2	25	99.40%	99.90%	bioMérieux SA Marcy L'Etoile, France	HIV 1/2 antibody combined detection	Serum/Plasma/ Whole Blood	21 months 4 to 30°C	If whole blood: lancets, alcohol swabs bioMérieux informs its customers that this product will be discontinued, with effect from January 1st, 2020	WHO PQ
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	
25228	Multispot HIV-1/HIV-2 Rapid Test	50	100% HIV-1 (serum) 100% HIV-1 (plasma) 100% HIV-2 (serum/plasma)	99.93% serum 99.91% plasma	Bio-Rad Laboratories, Marnes La Coquette, France and Steenvoorde, France	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma	12 Months 2 to 8°C or room temperature (20-30°C) for up to 3 months	Disposable glass or polypropylene test tubes (not polystyrene) for diluttions, e.g. 12 x 75mm tubes Test tube racks Biohazard waste containers	GHTF (FDA, PMA)

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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
HIV303*	HIV 1/2 STAT-PAK Dipstick	30	100%	99.70%	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. If alternate procedure: must order sample tubes and tube rack.	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 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)
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)
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)

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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	
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)
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)

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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	Capillary Tubes, Alcohol swabs and lancets	GHTF (CE mark)
HVWRPD-02		40								
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								
I05FRC25CE	First Response® HIV 1-2-0 Card Test	25	100%	99.39%	Premier Medical Corporation, Nani Daman, 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)
I05FRC30CE	First Response® HIV 1-2-0 Card Test	30	100%	99.39%	Premier Medical Corporation, Nani Daman, 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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PI05FRC05 ✲	First Response® HIV 1-2-0 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 1-2-0 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 1-2-0 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 1-2-0 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)
PI05FRC25 ✲	First Response® HIV 1-2-0 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 1-2-0 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 1-2-0 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 1-2-0 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 1-2-0 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 1-2-0 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

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PI05FRC100*	First Response® HIV 1-2-0 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
90-1010*	INSTI HIV-1/2 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; 48 T/kit; 48 T/kit with support materials If 90-1010, 90-1021: lancets, alcohol swabs, precision pipette plus tips.	WHO PQ
90-1013*		24								
90-1021*		48								
90-1022*		48								
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*	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	18 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
THIV02	Toyo Anti-HIV 1/2		100%	100.00%	Turk Lab Turkey	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	4 - 30°C		GHTF (CE mark)
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	

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
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	on request	on request	Abbott Rapid Diagnostics Jena GmbH	HIV 1/2 antibodies combined detection	Whole Blood	on request	Products available from ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	on request
ARST001-003* (former ARST-001)	Mylan HIV Self-Test (former Atomo 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	(former ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement / ERPD until 28th November 2019)	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/190708_pqdx_0320_090_00_pqpr_mylan_hiv_self_test.pdf?ua=1
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
855164	EXACTO© TEST HIV	1	on request	on request	Biosynex SA, Strasbourg, France	HIV 1/2 antibodies combined detection	Whole Blood	24 Months 2 to 30°C	Products available from ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	ERPD until 10th January 2022
855169	EXACTO© TEST HIV DUO	2	on request	on request	Biosynex SA, Strasbourg, France	HIV 1/2 antibodies combined detection	Whole Blood	24 Months 2 to 30°C	Products available from ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	ERPD until 10th January 2022
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

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
5X4-1000*	OraQuick HIV Self-Test	50	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://www.who.int/diagnostics_laboratory/evaluations/pq-list/200124_amended_pqpr_0159_055_01_oraquick_hiv_self_test.pdf?ua=1
5X4-1001*		250								
5X4-2001*		110							Pharmacy Version (placed in individual cartons)	

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
2P36	ARCHITECT HIV Ag/Ab Combo Reagent Kit (CLIA)	100 500	100%	99.77%	Abbott Laboratories, Abbott Diagnostics Division, 100 Abbott park Road Abbott Park, IL, USA	HIV-1 p24 antigen, antibodies to HIV-1 (group M and group O), and antibodies to HIV-2	2 to 8°C	Serum or plasma specimens; Note: The ARCHITECT HIV Ag/Ab Combo assay is not intended for use in screening blood or plasma donors. The effectiveness of ARCHITECT HIV Ag/Ab Combo for use in screening blood or plasma donors has not been established. 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)
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)
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)
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							
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)

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
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)

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
I-1654 *	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://www.who.int/diagnostics_laboratory/evaluations/150729_final_report_0106_038_00_eia.pdf?ua=1
I-1652 *		192/2 plates							
I-1656 *		480/5 plates							
OPKR03, * OPKR05, OPKR05(Q), OUVP17	Enzygnost HIV Integral 4 and Supplementary reagents kit for Enzygnost®/TMB	96T/kit 960T/kit 960T/kit (for higherthroughput)	100%	99.80%	Siemens Healthcare Diagnostics Products GmbH Marburg, Germany	Qualitative detection of HIV p24 antigen and specific antibodies to human immunodeficiency viruses of type 1 and 2 (HIV-1 including HIV-1 subtype O virus and HIV-2)	12 months 2-8 ˚C	Human serum and plasma specimens	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/160324_final_public_report_0214_064_00.pdf
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://www.who.int/diagnostics_laboratory/evaluations/130408_0096-031-00_public_report_final_v1.pdf
72388 *		480							
71120	Genscreen™ HIV-1 Ag Assay	192		99.95%	Bio-Rad 3, boulevard Raymond Poincaré 92430 Marnes-la-Coquette - France	HIV1- 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							

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
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%					
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							

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
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							
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							
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)

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
5390095190	Roche Elecsys HIV Combi	100	100%	99.82% (blood donor specimens) 99.8% (diagnostic specimens)	Roche Diagnostics, Mannheim, Germany	HIV 1 p24 antigen and HIV1/2 antibodies	5 months 2 to 8°C (Do not freeze)	Serum and plasma specimen cobas e411 Catalogue No/ Description 11662988122 /ProCell 11662970122 /CleanCell 11930346122 /Elecsys SysWash 11933159001 /Adapter for SysClean 11706802001 /Elecsys 2010 AssayCup 11706799001 /Elecsys 2010 AssayTip 11298500316 /Elecsys SysClean cobas e601, /cobas e602 04880340190/ ProCell M 04880293190 /CleanCell M 03023141001 /PC/CC-Cups 03005712190 /ProbeWash 03004899190 /PreClean M 12102137001 /AssayTip/AssayCup Combimagazine 0302315000 /WasteLiner 03027651001/ SysClean Adapter 11298500316 /Elecsys SysClean	GHTF (CE mark, TGA)

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
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)	WHO PQ (PQ Public Report) https://www.who.int/diagnostics_laboratory/evaluations/121115_0124_045_00_public_report_v2_final.pdf
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)	WHO PQ (PQ Public Report) https://www.who.int/diagnostics_laboratory/evaluations/121115_0133_045_00_public_report_v1_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
On Request	on request	on request	on request	on request	on request	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	on request
342 444 (Test Kit) According model (Instrument) According model (control kit)	BD Tritest CD3/CD4/CD45	Absolute and Percentage CD3/CD4/CD45 Counts	50T/kit with BD Trucount tubes	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	on request	Whole venous EDTA blood	ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement - End of Life (EOL) of FACSCalibur Instruments: 2022 (no support available beyond that date)	ERPD until 6th May 2021
342 445 (Test Kit) According model (Instrument) According model (control kit)	BD Tritest CD4/CD8/CD3	Absolute and Percentage CD4/CD8/CD3 Counts	50T/kit with BD Trucount tubes	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	on request	Whole venous EDTA blood	ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement - End of Life (EOL) of FACSCalibur Instruments: 2022 (no support available beyond that date)	ERPD until 6th May 2021
342 447 (Test Kit) According model (Instrument) According model (control kit)	BD Multitest CD3/CD8/CD45/CD4	Absolute and Percentage CD3/CD8/CD45/CD4 Counts	50T/kit with BD Trucount tubes	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	on request	Whole venous EDTA blood	ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement - End of Life (EOL) of FACSCalibur Instruments: 2022 (no support available beyond that date)	ERPD until 6th May 2021

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
260300001/ 260300003/ 260300004 *, 260100025 and 2603000011	PIMA CD4 Test	Absolute CD4+ Counts	25 cartridges/kit and instrument;	Abbott Alere Technologies GmbH, Jena, Germany	12 months for reagents 2 to 30°C for reagents	Venous and Capillary whole blood	Accessories available	WHO PQ (PQ Public Report) http://www.who.int/diagnostics_laboratory/evaluations/131219_0099_032_00_public_report_final_v4.pdf?ua=1
260300001/ 260300003/ 260300004 *, 260100100 and 2603000011			100 cartridges/kit and instrument					
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
651000 , 657681 and 655495 *	BD FACSPresto™ Near-Patient CD4 Counter with BD CD4%CD4/Hb Cartridge and 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)	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/cd4/190328_amended_final_pqpr_0197_045_00_v3.pdf?ua=1
Rapid Diagnostic Test for qualitative testing based on CD4 technologies								
OD376	VISITECT®CD4 Advanced Disease	Semi-Quantitative Test (200 cells/µl cut-off)	25T/kit	Omega Diagnostics Limited Omega House, Hillfoots Business Village, Alva, FK12 5DO, Scotland, United Kingdom	2 to 30°C	human venous whole blood or capillary blood		WHO PQ

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	For consumables refer to IFU	GHTF (CE mark)
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	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*	Abbott Real Time HIV-1 Qualitative (m2000sp)	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	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
9K14-02		instrument									
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			

HIV Virological technologies
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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
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											
04J71-93		Optical Cal. Kit						15 to 30°C			
9K14-02		instrument						NA			

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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
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, Germany Loebstedter Str. 103-105 07749 Jena Germany	Not applicable	Not applicable	Not applicable	Whole Blood, Plasma	For consumables and alternative AlereTM q Complete (product code 270300002) AlereTM q Complete II (product code 270300002) refer to WHO Public Report	WHO PQ and GHTF (CE mark)
27011R010* (former 270110010)	m-PIMA HIV-1/2 Detect	10 Cartridges				HIV-1/2 Qualitative RNA	9 months	4-30°C			
27011R050* (former 270110050)		50 Cartridges					9 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	N/A	N/A	Bioneer Corporation, 8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon, 34302, Republic of Korea	HIV-1 Quantitative RNA	12 months	-25°C to -15°C	EDTA Plasma	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			

HIV Virological technologies
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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
TR001-250IC	Generic HIV Charge Virale	220	NA	NA	Biocentric Bandol France	HIV1 Quantitative RNA	12 months	-30°C to -8°C	EDTA or citrated Plasma		GHTF (CE mark)
TR001-440IC	Generic HIV Charge Virale	440									
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)
*280140	NucliSENS EasyQ HIV-1 V2.0 (Automated)	instrument	N/A	N/A	bioMerieux SA, Marcy l'Etoile, France	HIV1 Quantitative RNA	NA		Plasma dried blood spot (venous whole blood)	For consumables refer to WHO PQ public report	WHO PQ and GHTF (CE mark) https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/pqdx_0127_016_00_public_report_v3.pdf?ua=1
280130		4x1lit					24 months	2 to 30°C			
280131		4x1lit					18 months	2 to 30°C			
280132		4x1lit					15 months	2 to 8°C			
280133		4x1lit					18 months	2 to 8°C			
280134		4x1lit					24 months	2 to 30°C			
285056		instrument					NA				
200309											
285033		48T/kit					18 months	2 to 8°C			
*200305	NucliSENS EasyQ HIV-1 V2.0 (Semi Automated)		N/A	N/A	bioMerieux SA Marcy l'Etoile, France	HIV1 Quantitative RNA			Plasma dried blood spot (venous whole blood)	For consumables refer to WHO PQ public report	WHO PQ and GHTF (CE mark) https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/pqdx_0148_016_00_public_report_v2.pdf?ua=1
200293		48T/kit					18 months	2 to 8°C			
200292		48T/kit					24 months	2 to 30°C			
285056		instrument					NA				
200309											
285033		48T/kit					18 Months				

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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)
I19-0005	SAMBAprep	instrument	N/A	N/A	Diagnostics for the Real World, Sunnyvale, CA 94085 USA	N/A	N/A	N/A	N/A		GHTF (CE mark)
I19-0004	SAMBAamp	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
4100-12	SAMBA HIV-1 Semi-Q	12 tests	N/A	N/A		HIV-1 Semi-Q RNA target	9 months	2 to 37°C	Plasma		
4200-12	SAMBA I HIV-1 Qual Whole Blood Test	12 tests	N/A	N/A		HIV-1 Qualitative DNA/RNA target			Whole Blood		

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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		GHTF (CE mark)
I19-0006-TM	SAMBA II Tablet Module	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
4400-12	SAMBA II HIV-1 Semi-Q	12 Tests	N/A	N/A		HIV-1 Semi-Q RNA target	9 months	2 to 37°C	Plasma		
4500-12	SAMBA II HIV-1 Qual Whole Blood Test	12 tests	N/A	N/A		HIV-1 Qualitative DNA/RNA target			Whole Blood		
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	HIV1 Quantitative RNA	24 months	2°C-8°C	Plasma	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 GHTF (CE mark)
PRD-03001		5 runs						-15 to -35°C			
PRD-03002		5 calibrators						-15 to -35°C			
303095		instrument					NA	NA			
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	HIV1 Quantitative RNA	20 months	-30°C to -15°C	Plasma		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	HIV1 Quantitative RNA	17 months	-30°C to -15°C	Plasma		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			

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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
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, USA	HIV1 Quantitative RNA	NA		Plasma or 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_0147_046_00_public_report_v1_final.pdf
03051315001		instrument					NA				
04862392001		software					NA				
05807875001		software					NA				
05527503001		instrument					NA				
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											

HIV Virological technologies
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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
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 Molecular System, Branchburg, USA	HIV1 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			
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		
08 792992190	COBAS® HIV-1 Test for use with 4800	120 tests	N/A	N/A		HIV-1 Quantitative RNA	15 months	2 to 8°C	EDTA Plasma, dried plasma spot (with PCS card)		

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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
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		
08 792992190	COBAS® HIV-1 Test for use with 4800	120 tests	N/A	N/A		HIV-1 Qualitative RNA	15 months	2 to 8°C	EDTA Plasma, dried plasma spot, dried blood spot (DBS)	(with PCS card)	
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 PCS card)	
7862113190	COBAS® HIV-1 Test for use with 6800/8800	96 tests/kit	N/A	N/A		HIV-1 Qualitative RNA	18 months	2 to 8°C	Serum, Plasma, dried blood spots (DBS)		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 and Hepatitis C / 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
Hepatitis B (Rapid Diagnostic Tests)										
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 https://extranet.who.int/pqweb/sites/default/files/200123_pqdx_0451_013_00_determine_hbsag_2_final_pqpr_v2.pdf
7D2943 *		100								
7D2943 SET *		100								
01FK10W *	SD Bioline HBsAg WB	30	100.00%	99.00%	Standard Diagnostics Inc (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
31124 *	VIKIA® HBsAg	25	99.05%	99.80%	bioMérieux SA Marcy L'Etoile, France	HBsAg detection	Serum/Plasma/ Whole Blood	24 Months 4 to 30°C	bioMérieux informs its customers that this product will be discontinued, with effect from January 1st, 2020	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/180724_FINAL_PQ_PR_0284-016-00_v2.pdf?ua=1
I10FRC25CE	First Response® HBsAg Card Test	25	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)
I10FRC30CE		30								
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								

Hepatitis B and Hepatitis C / 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
Hepatitis C (Rapid Diagnostic Tests)										
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	Safety 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	
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 http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/170301_final_pq_report_PQDx_0244_055_00.pdf?ua=1
1001-0274*		100								

Hepatitis B and 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
I03FRC25CE	First Response® HCV Card Test	25	100.00%	100.00%	Premier Medical Corporation, Nani Daman, India	HCV antibody detection	Serum/Plasma/ Whole Blood	25 Months 4 to 30°C		GHTF (CE mark)
I03FRC30CE		30								
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								
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

N/A- NOT APPLICABLE

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

Hepatitis B and 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
B-1254 *	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://www.who.int/diagnostics_laboratory/evaluations/190301_amended_pqpr_0120_038_00_v3.pdf?ua=1
B-1252 *		192/2 plates							
B-1255 *		480/5 plates							
B-1256 *		1 plate 96 (for detection) or 48 (for confirmation)							
B-231 *		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							
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 http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/161116_amended_final_public_report_0121_043_00.pdf?ua=1
9F80-05 *		480							

Hepatitis B and 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
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).	and GHTF (CE mark, TGA)
				Hepatis C Enzyme Immunoassays (EIAs)					
6L47-29	ARCHITECT HCV Ag assay	100	98%	99.50%	Abbott Denka Seiken Co., LTD, Kagamida Factory	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)
72561 *	Monolisa HCV Ag-Ab ULTRA V2 assay	96	100%	99.94%	Bio-Rad Laboratories, Marnes La Coquette, France	HCV antigens	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	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							

Hepatitis B and 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
7F51-01 *	Murex anti-HCV Version 4	96	100%	99.40%	DiaSorin, Dartford, South Africa (Pty) Ltd	HCV antigens	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 http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/161222_final_amended_pqpr_0164_059_00_v5.pdf?ua=1
7F51-02 *		480							
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

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									
HBV-1211	AccuPower® HBV Quantitative RT-PCR Kit	96T/kit	N/A	N/A	Bioneer Corporation, 8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon, 34302, Republic of Korea	HBV 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			
4506263	artus HBV RG RT-PCR Kit (AS - Rotor-Gene Q)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HBV Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4506265		96						-30°C to -15°C			
9002042		instrument									
60704	QIAamp DSP Virus Kit	extraction kit 96T/kit					12 months	2°C - 8°C			
4506363	artus HBV QS-RGQ Kit (QIAsymphony® DSP / AS - Rotor-Gene Q)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HBV Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4506366		72						-30°C to -15°C			
9001850 - 9002042		instrument									
60704	QIAsymphony® DSP Virus/Pathogen	extraction kit 96T/kit					14 months	15°C - 25°C			

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
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 / 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			

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
GX [Series}	GeneXpert® Dx	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) and WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/190730_amended_pqpr_0260_070_00.pdf?ua=1
Infinity-48	GeneXpert® Infinity-48	Instrument				N/A	N/A	N/A	N/A		
						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 Version 4.6a or higher (GeneXpert Dx systems); or Xpertise 6.2a or higher (Infinity80/Infinity-48s)	Software				N/A	N/A	N/A	N/A		
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		
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

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
4518263	artus HCV RG RT-PCR Kit (AS - Rotor-Gene Q MDx)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HCV Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4518265		96						-30°C to -15°C			
9002022		instrument									
60704	QIAamp DSP Virus Kit	extraction kit 96T/kit					12 months	2°C - 8°C			
4518363	artus HCV QS-RGQ Kit (QIAsymphony® DSP / AS - Rotor-Gene Q)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HCV Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4518366		72						-30°C to -15°C			
9001850 - 9002042		instrument									
937055	QIAsymphony® DSP Virus/Pathogen	extraction kit 96T/kit					14 months	15°C - 25°C			
06997732 190	COBAS® HCV Test for use with 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/Syphilis	Serum/Plasma/ Whole Blood	24 Months 1 to 30°C	For consumables refer to WHO Public Report	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/200820_amended_pqpr_0179_012_00_bioline_hiv_syp_v6.pdf?ua=1
06FK35*									For consumables refer to WHO Public Report	
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/Syphilis	Serum/Plasma/ Whole Blood	30 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
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/Syphilis	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/Syphilis	Serum/Plasma/ Whole Blood	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	ERPD
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	SD BIOLINE Syphilis 3.0	30	99.30%	99.50%	Standard Diagnostics, Inc. (Abbott Diagnostics Korea) (Giheung-gu,Yongin-si, Korea)	TP-antibodies	Serum/Plasma/ Whole Blood	24 Months 1 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 5th May 2021
09SYP10D	STANDARD™ Q Syphilis Ab test	25	100%	100%	SD Biosensor Inc (16, Deogyeong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690 Republic of Korea)	TP-antibodies	Serum/Plasma/ Whole Blood	24 Months 2 to 40°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 25th August 2021

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
on request	on request	on request	on request	on request	on request	TP-antibodies	on request	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	ERPD

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 / (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
removed	removed	removed	removed	removed	removed	removed	removed	removed	removed	removed
RPR / 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
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 COIM Diagnostic tests
(included to support Global Fund Policy for Co-Infections and Co-Morbidities)

NOTE: The particular requirements from section 8 of the Global Fund QA Policy of Diagnostic Products do not apply for these products. However, the requirements of section 7 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										
02N09-092*	Abbott RealTime High Risk HPV	96	N/A	N/A	Abbott GmbH & Co.KG (Delkenheim, Germany)	HPV DNA detection	cervical cells	18 Months 2 to 28°C		WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/191010_pqdx_0455_180_00_pqpr_abbott_realtime_highrisk_hpv.pdf?ua=1
614015*	careHPV™ Test	96	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HPV DNA detection	cervical cells	12 month / 4°C to -25°C	careHPV Collection Medium (CCM) and careBrushes Foam specimen tube rack	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/180713_pqpr_pqdx_0085_028_00_carehpv_with_labelling.pdf?ua=1
9001772*	careHPV Test System	instrument						N/A		
GXHPV-CE-10*	Xpert HPV Assay	10	N/A	N/A	Cepheid AB (Solna, Sweden)	HPV DNA detection	cervical cells collected in PreservCytSolution	18 Months 2 to 28°C		WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/171221_final_pq_report_pqdx_0268_070_00.pdf?ua=1
Cryptococcal Antigen										
11200001	BIOSYNEX Crypto PS	20	see IFU	see IFU	Biosynex SA	cryptococcus antigens	see IFU	see IFU	Diagnostic Products for CrAg testing were assessed by the ERPD on behalf of Unitaid. Section 8 of the GF QA Policy is not applicable to these products, however section 7 and all other parts of the QA Policy are applicable. The listing is motivated to support the Global Fund Policy for Co-Infections and Co-Morbidities. There is no need for Non-Objection-Letters with Global Fund resources in this case.	
CR2003	CrAg Lateral Flow Assay	see IFU	see IFU	see IFU	IMMY, Inc	cryptococcus antigens	see IFU	see IFU		
CR1003 CR1004	Latex Cryptococcus Antigen Detection System (CrAg® Latex Kit)	see IFU	see IFU	see IFU	IMMY, Inc	cryptococcus antigens	see IFU	see IFU		

NOTE: The particular requirements from section 8 of the Global Fund QA Policy of Diagnostic Products do not apply for these products. However, the requirements of section 7 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
CRY101	ALPHA Cryptococcal Antigen Enzyme Immunoassay (CrAg® EIA)	see IFU	see IFU	see IFU	IMMY, Inc	cryptococcus antigens	see IFU	see IFU		

List of HIV products deleted/delisted
Products not eligible for procurement

HIV Simple assays/Rapid Diagnostic Tests (RDTs)

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
	HIV Western Blot and Line Immunoassays		All	Mar-21	WHO consolidated guidelines on HIV testing services recommend that WB and line immunoassays should not be used in national HIV testing strategies and algorithms
I05FRC30 *	First Response™ HIV 1-2-0 Card Test	25	Premier Medical Corporation, Nani Daman, India	Dec-19	Manufacturer Voluntary withdrawal / Replaced by PI05FRC30, PI05FRC60 and PI05FRC100
I05FRC60 *					
I05FRC100 *		30			
03FK35 *	SD Bioline HIV Ag/Ab Combo	25	Standard Diagnostics, (Giheung-gu,Yongin-si, Korea)	Oct-17	Manufacturer Voluntary withdrawal / product discontinuation
03FK30 *		30			

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
60432002*	ImmunoComb® II HIV 1&2 BiSpot	36	Orgenics, Yavne, Israel	Dec-16	Manufacturer Voluntary withdrawal / product discontinuation

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
7D2643	Alere Determine™ HIV- 1/2 Ag/Ab Combo	100	Alere Medical Co. Ltd, Matsudo, Japan	Apr-16	Manufacturer Voluntary withdrawal
7D2243					
815311000577	Reveal™ Rapid HIV-1 Test POC	30	MedMira Laboratories, Halifax Canada	Mar-14	Voluntary withdrawal by manufacturer
815311000607	Reveal™ Rapid HIV-1 Test Lab A	30	MedMira Laboratories, Halifax Canada	Mar-14	Voluntary withdrawal by manufacturer
815311000690	Reveal™ Rapid HIV-1 Test Lab B	30	MedMira Laboratories, Halifax Canada	Mar-14	Voluntary withdrawal by manufacturer
220658	Serodia HIV-1/2	100	Fujirebio, Tokyo, Japan	Mar-14	Deleted from WHO eligibility list
226063	Serodia HIV-1/2	220	Fujirebio, Tokyo, Japan	Mar-14	Deleted from WHO eligibility list
8-1003-40	InstantCHEK™ HIV 1+2 Rapid Test	40	EY Laboratories, SAR Hong Kong, PR China	Jul-14	Does not meet the required standard
8-1003-100	InstantCHEK™ HIV 1+2 Rapid Test	100	EY Laboratories, SAR Hong Kong, PR China	Jul-14	Does not meet the required standard
ITP02002-TC40	Advanced Quality™ HIV Rapid Test	40	InTec Products, Xiamen, PR China	Nov-14	Voluntary withdrawal by the manufacturer

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
7D2346	Alere Determine™ HIV-1/2	20	Alere Medical Japan, Matsudo, Japan	Nov-14	No difference between the product with codes 7D2342, 7D 2243, 7D2343, 7D2643 which are WHO PQ
7D2347	Alere Determine™ HIV-1/2	100	Alere Medical Japan, Matsudo, Japan	Nov-14	No difference between the product with codes 7D2342, 7D 2243, 7D2343, 7D2643 which are WHO PQ
7D2646	Alere Determine™ HIV Ag/Ab	20	Alere Medical Japan, Matsudo, Japan	Nov-14	No difference between the product with codes 7D2342, 7D 2243, 7D2343, 7D2643 which are WHO PQ
7D2647	Alere Determine™ HIV Ag/Ab	100	Alere Medical Japan, Matsudo, Japan	Nov-14	No difference between the product with codes 7D2342, 7D 2243, 7D2343, 7D2643 which are WHO PQ
90-1009	INSTI HIV-1/2 Antibody Test Kit	24 without support materials	BioLytical Laboratories, Richmond, Canada	Nov-14	No difference between the product with codes 90-1007
90-1014	INSTI HIV-1/2 Antibody Test Kit	24 without support materials	BioLytical Laboratories, Richmond, Canada	Nov-14	No difference between the product with codes 90-1010, 90-1012 and 90-1013
90-1015	INSTI HIV-1/2 Antibody Test Kit	1 with support materials	BioLytical Laboratories, Richmond, Canada	Nov-14	No difference between the product with codes 90-1010, 90-1012 and 90-1013
90-1016	INSTI HIV-1/2 Antibody Test Kit	24 with support materials	BioLytical Laboratories, Richmond, Canada	Nov-14	No difference between the product with codes 90-1010, 90-1012 and 90-1013
90-1018	INSTI HIV-1 Antibody Test Kit	24 with support materials	BioLytical Laboratories, Richmond, Canada	Nov-14	No difference between the product with codes 90-1010, 90-1012 and 90-1013
90-1019	INSTI HIV-1 Antibody Test Kit	1 with support materials	BioLytical Laboratories, Richmond, Canada	Nov-14	No difference between the product with codes 90-1010, 90-1012 and 90-1013

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
90-1020	INSTI HIV-1 Antibody Test Kit	24 without support materials	BioLytical Laboratories, Richmond, Canada	Nov-14	No difference between the product with codes 90-1010, 90-1012 and 90-1013
90-1023	INSTI HIV-1/2 Antibody Test Kit	48 without support materials	BioLytical Laboratories, Richmond, Canada	Nov-14	No difference between the product with codes 90-1023 and 90-1026
90-1026	INSTI HIV-1/2 Antibody Test Kit	48 with support materials	BioLytical Laboratories, Richmond, Canada	Nov-14	No difference between the product with codes 90-1023 and 90-1026
1001-0284	OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test	25	OraSure Technologies Bethlehem, USA	Nov-14	Replaced by 5X4-0010 and 5X4-0012
1001-0285	OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test	100	OraSure Technologies Bethlehem, USA	Nov-14	Replaced by 5X4-0010 and 5X4-0012
815311000591	Reveal™ G 3 Rapid HIV-1 Antibody Test	30	MedMira Laboratories, Halifax Canada	Nov-14	Voluntary withdrawal by manufacturer
HIV Enzyme Immunoassays (EIAs)					
Manufacturer Product Catalogue number	**Product Name**	**Number of tests per kit**	**Manufacturer**	**Deleted period**	**Reason for deletion/delisting**
OPKR03, * OPKR05, OPKR05(Q), OUVP17	Enzygnost HIV Integral 4 and Supplementary reagents kit for Enzygnost®/TMB	96T/kit 960T/kit 960T/kit (for higherthroughput)	Siemens Healthcare Diagnostics Marburg, Germany	Sep-20	Deleted from WHO PQ list

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
3000-1172 *	Bioelisa HIV 1+2 Ag/Ab	96	Biokit S.A. Barcelona, Spain	Sep-20	Deleted from WHO PQ list
3000-1173 *		480			
Z03503	HIV 1&2 Ab, cutt-off	6x96	Dialab GmbH, Austria	Mar 19	Manufacturer Voluntary withdrawal / product discontinuation
Z09375		2x96			
OQFK135	Enzygnost Anti HIV 1/2 Plus	2 x 96	Siemens Healthcare Diagnostics Marburg, Germany	Mar-14	Deleted from WHO eligibility list
OUVP175	Enzygnost Supplementary Reagents	960	Siemens Healthcare Diagnostics Marburg, Germany	Mar-14	Deleted from WHO eligibility list
OQFK215	Enzygnost Anti HIV 1/2 Plus	10 x 96	Siemens Healthcare Diagnostics Marburg, Germany	Mar-14	Deleted from WHO eligibility list
680328	UBI HIV- 1/2 EIA	192	United Biomedical, Hauppauge, USA	Mar-14	Deleted from WHO eligibility list
KH-T-10	Anti-HIV 1+2 Antibodies ELISA Diagnostic Kit	96	Shanghai Kehua, Shanghai, PR China	Aug-14	Deleted from WHO eligibility list
61 11 011	HIV EIA	96	AniLabsystems Ltd, Vantaa, Finland	Aug-14	Deleted from WHO eligibility list

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
61 11 012	HIV EIA	480	AniLabsystems Ltd, Vantaa, Finland	Aug-14	Deleted from WHO eligibility list
61 11 013	HIV EIA	960	AniLabsystems Ltd, Vantaa, Finland	Aug-14	Deleted from WHO eligibility list
CD4 Technologies					
Manufacturer Product Catalogue number	**Product Name**	**Number of tests per kit**	**Manufacturer**	**Deleted period**	**Reason for deletion/delisting**
OD296	VISITECT®CD4 Rapid Test	25	Omega Diagnostics Limited Omega House, Hillfoots Business Village, Alva, FK12 5DO, Scotland, United Kingdom	Dec-19	Manufacturer Voluntary withdrawal / product discontinuation
OD296Z (Brazil) OD296N (Nigeria)	VISITECT®CD4 Rapid Test	25T/kit	Omega Diagnostics Limited	Dec-19	Manufacturer Voluntary withdrawal
MCA100101 (Test kit)	Muse Auto CD4/CD5 kit (reagent and lysing solution) for Muse Cell Analyzer with Muse Auto CD4/CD4% software (equipment)	100T/kit	EMD Millipore Corporation, Temecula, USA	Jul-19	Deleted from WHO eligibility list
MCA500101 (Test kit)		500T/kit		Jul-19	Deleted from WHO eligibility list
MCA1XK101 (Test kit)		1000T/kit		Jul-19	Deleted from WHO eligibility list

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
HIV Viral Technologies					
Manufacturer Product Catalogue number	**Product Name**	**Number of tests per kit**	**Manufacturer**	**Deleted period**	**Reason for deletion/delisting**
4100-12	SAMBA HIV-1 Semi-Q Test for use with SAMBA I instrument	12	Diagnostics for the Real World (DRW)	Jun-18 to Sep-18	Global Fund Information Notice 2018-03 - Re-listed on 1-Oct-2018
4400-12	SAMBA II HIV-1 Semi-Q Test for use with SAMBA II instrument	12	Diagnostics for the Real World (DRW)	Jun-18 to Sep-18	Global Fund Information Notice 2018-03 - Re-listed on 1-Oct-2018
HBV & HCV RDTs					
Manufacturer Product Catalogue number	**Product Name**	**Number of tests per kit**	**Manufacturer**	**Deleted period**	**Reason for deletion/delisting**
n/a	n/a	n/a	n/a	n/a	n/a
HBV & HCV Enzyme Immunoassays (EIAs)					
Manufacturer Product Catalogue number	**Product Name**	**Number of tests per kit**	**Manufacturer**	**Deleted period**	**Reason for deletion/delisting**
OPFM03, * OPFM05, OPFM07(Q), OUVP17	Enzygnost HBsAg 6.0 and Supplementary reagents kit for Enzygnost®/TMB	96T/kit 960T/kit 960T/kit (for higherthroughput)	Siemens Healthcare Diagnostics Marburg, Germany	Sep-20	Deleted from WHO PQ list

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
3000-1115*	Bioelisa HCV 4.0	96	Biokit S.A. Barcelona, Spain	Sep-20	Deleted from WHO PQ list
3000-1116*		480			
3000-1158 *	Bioelisa HBsAg 3.0 & 4.0	96	Biokit S.A. Barcelona, Spain	Sep-20	Deleted from WHO PQ list
3000-1159 *		480			

Treponema Pallidum Infections for diagnosis of Syphilis to initiate patient treatment / (other than RDTs)

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
65-9520-0	DPP® Syphilis Screen & Confirm Assay	20	Chembio Diagnostic Systems,Medford, USA	Dec-20	Expiry of ERPD Status
900025/900100	ASI RR Card Test	25/100	Arlington Scientific Inc.	Jul-19	Global Fund decision
300615700	syphagen TPHA Test	200	Biokit S.A. Barcelona, Spain	Jul-19	Global Fund decision
DR0530M	TPHA Test Kit	200	ThermoFisherScientific / Oxoid Ltd, United Kingdom	Jul-19	Global Fund decision

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Manufacturer	Deleted period	Reason for deletion/delisting
3000-1148/3000-1149	bioelisa SYPHILIS 3.0	96/480	Biokit S.A. Barcelona, Spain	Jul-19	Global Fund decision