

BỘ Y TẾ
BỆNH VIỆN PHỔI TRUNG ƯƠNG

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Số: 1089 /BVPTƯ – CTCLQG
V/v: Hướng dẫn đối với các đơn vị tự
mua test HIV năm 2026

Hà Nội, ngày 29 tháng 4 năm 2026

KHẨN

Kính gửi: - Chương trình chống lao các tỉnh/tp;
- Bệnh viện Phổi 74;
- Bệnh viện Phổi Trung ương – Khoa Dược, Khoa Vi sinh,
Phòng TCKT.

Bệnh viện Phổi Trung ương – Chương trình Chống lao Quốc Gia (BVPTƯ – CTCLQG) xin thông báo với các đơn vị như sau:

Đối với các đơn vị triển khai thực hiện theo phương án tự mua test HIV về làm xét nghiệm cho bệnh nhân: Đề nghị các đơn vị thực hiện mua test nhanh HIV theo **“Danh sách các bộ sinh phẩm xét nghiệm HIV theo Chính sách đảm bảo chất lượng của Quỹ Toàn Cầu - Bản cập nhật ngày 23/03/2026”** đính kèm sau công văn.

Đề nghị các đơn vị quản lý, báo cáo tình hình sử dụng test nhanh 6 tháng/lần; 1 năm/2 lần theo quy định và theo biểu mẫu đính kèm.

Trân trọng kính chào.

Nơi nhận:

- CTCL các tỉnh/tp.
- Đơn vị: KT;
- TCKT;
- BS Phạm, ThS. Hoàng Anh;
- Lưu: VT, CLKHHC_(Thảo)

GIÁM ĐỐC



Đinh Văn Lượng

Mẫu báo cáo sử dụng test nhanh HIV

(Ban hành theo công văn số...../ BVPTU – CTCLQG ngày.....tháng.....năm 2026)

BỘ Y TẾ

Chương trình Chống lao Quốc Gia

Tỉnh/Đơn vị:

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BÁO CÁO SỬ DỤNG TEST NHANH HIV CHƯƠNG TRÌNH CHỐNG LAO QUỐC GIA 6 tháng đầu/cuối năm 20.....

ST T	Đơn vị/Nội dung	Tồn đầu kỳ	Nhập trong kỳ	Xuất trong kỳ	Tồn cuối kỳ	Hạn sử dụng	Dự kiến mua trong 6 tháng đầu/cuối năm	Ghi chú
		(1)	(2)	(3)	$4=1+2-3$	(5)	(6)	(7)
I	Kho tuyến tỉnh							
	Cộng I	A1	A2	A3	A4		A5	
II	Kho tuyến huyện							
	Huyện 1							
	Huyện 2							
								
	Cộng II	B1	B2	B3	B4		B5	
	Toàn tỉnh	A1+B1	A2+B2	A3+B3	A4+B4		A5+B5	

.....ngày.....tháng..... năm

Thủ trưởng đơn vị

(Ký, ghi rõ họ tên, đóng dấu)

Người lập báo cáo

(Ký, ghi rõ họ tên)

Thông tin của người lập báo cáo:

Số điện thoại: 091xxxxx

Email: xyx@gmail.com

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

According to **Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and core Personal Protective Equipment** (<https://www.theglobalfund.org/en/sourcing-management/quality-assurance/in-vitro-diagnostics/>), in force since 1st March

2011, Grant Funds may only be used to procure HIV RDTs if they have been:

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

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

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

Categories falling under Criterion-1 and -3

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

Categories falling under Criterion-2

All under Criterion-1 excluding HIV Self Testing

The list is an overview of IVDs to assist Principal Recipients (PRs) of Global Fund grants to identify the status of IVDs according to the relevant Global Fund Quality Assurance Policy. It includes products recommended for use after technical evaluation by WHO Prequalification of Diagnostics Programme, Regulatory Authorities of GHTF founding members, WLAs and the WHO hosted Expert Review Panel.

The list is not exhaustive; PRs can procure product(s) not listed below as long as PRs demonstrate that the product is compliant with one of the above mentioned requirements.

Products prequalified by WHO: <https://extranet.who.int/prequal/vitro-diagnostics/prequalified/in-vitro-diagnostics>

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)

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

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

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

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

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								
03FK16	Bioline HIV-1/2 3.0	25	99.80%	99.90%	(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	If whole blood: lancets, alcohol swabs. If 03FK10: lancets, capillary pipettes, alcohol swabs.	WHO PQ								
03FK10		30																
29011-W20	Panbio HIV Verification Test	20	100%	99.70%	Abbott Rapid Diagnostics Jena GmbH, Germany	Discrimination between HIV 1/2 antibodies	Serum/Plasma/ Whole Blood	24 months 2 to 30°C	sterile single-use lancets, alcohol swabs,capillary tube	WHO PQ								
29011AW20		20																
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		50T/kit																
WJ-1850																		
WJ-1850E																		
WJ-1850EL																		
WJ-18S50																		
WJ-18S50E																		
WJ-18S50EL																		
90-1010	INSTI HIV-1/HIV-2 Antibody Test Kit	24			BioLytical Laboratories,	99.70%	HIV 1/2 antibodies	Serum/Plasma/	15 months	24 T/kit; 24 T/kit with support materials; If 90-1010: lancets, alcohol swabs, precision pipette plus tips.	WHO PQ							
90-1013		24																
90-1021		48								48 T/kit; 48 T/kit with support materials								

HIV Simple assays/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
90-1022		48			Richmond, Canada	combined detection	Whole Blood	15 to 30 °C	If 90-1021: lancets, alcohol swabs, precision pipette plus tips.	
90-1038		48							support material: only pipettes	
90-1064		48							Support material: none	
72330	Genie Fast HIV 1/2	50	100%	99.00%	Bio-Rad Laboratories, Marnes La Coquette France and Steenvoorde, France	HIV 1/2 antibodies (group M and O)	Serum/Plasma/ Venous and Capillary Whole Blood	18 months 2 to 30°C	with support materials: diluent and disposable pipettes	WHO PQ
72327		25							with support materials: diluent, disposable pipette, microsafes, lancets, alcohol swabs	
72347		25								
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 50L of sample (with disposable tips) may be used in lieu of the disposable 50L sample loop supplied with the kit (for other than fingerstick whole blood specimens)	WHO PQ
HIV101	HIV 1/2 STAT-PAK	20	99.30%	100%	Chembio Diagnostic Systems Medford, USA	HIV 1/2 antibodies combined detection	Serum/Plasma/ Whole Blood	33 months 8 to 30°C	If whole blood: lancets, alcohol swabs. HIV Test Kit Controls (HIV104) available.	WHO PQ
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)

HIV Simple assays/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
R0011C	OnSite HIV 1/2 Ab Plus Combo Rapid Test	30	100%	100%	CTK Biotech Inc, USA	HIV 1/2 antibodies combined detection	Serum/Plasma/ Venous and Capillary Whole Blood	24 months 2 to 30°C		<u>GHTF (CE mark)</u>
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	<u>WHO PQ</u>
W006-P0045		25					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: see IFU	
W006-P0046		25					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: see IFU	
W006-P0047		25					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: see IFU	
W006-P0048		25					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: see IFU	
W006-C4P2-F		40					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: not included	
W006-P0049		40					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: see IFU	
W006-P0050		40					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: see IFU	
W006-P0051		40					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: see IFU	
W006-P0052		40					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: see IFU	
GCHIV-402a	HIV 1/2 Human Immunodeficiency Virus Rapid Test (Whole blood/Serum/Plasma) (Cassette)	25	100%	99.90%	Healgen Scientific Limited Liability Company Houston, USA	HIV 1/2 antibodies combined detection	Whole blood, serum or plasma	24 months 2 to 30 °C		<u>GHTF (CE mark)</u>
GCHIV-302a	HIV 1/2 Human Immunodeficiency Virus Rapid Test (Serum/Plasma) (Cassette)	25	100%	99.90%	Healgen Scientific Limited Liability Company Houston, USA	HIV 1/2 antibodies combined detection	Serum or plasma	24 months 2 to 30 °C		<u>GHTF (CE mark)</u>
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		<u>GHTF (CE mark)</u>
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		<u>GHTF (CE mark)</u>
ITP02152-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		<u>GHTF (CE mark)</u>
ITP02152-TC25		25					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C		<u>GHTF (CE mark)</u>

HIV Simple assays/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
ITP02153-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		GHTF (CE mark)
ITP02153-TC10		10					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C		GHTF (CE mark)
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	see WHO Public Report for consumables	WHO PQ
ITPW02152-TC25		25					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	see WHO Public Report for consumables	WHO PQ
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	see WHO Public Report for consumables	WHO PQ
ITPW02153-TC40SA	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	see WHO Public Report for consumables	WHO PQ
ITPW02154-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	see WHO Public Report for consumables	WHO PQ
ITPW02231-TC25	ONE STEP Anti-HIV(1&2) Test	25	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	see WHO Public Report for consumables	WHO PQ
ITPW02231-TC40		40					Serum/Plasma/ Whole Blood	24 months 2 to 30 °C	see WHO Public Report for consumables	WHO PQ
ITPW02232-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	see WHO Public Report for consumables	WHO PQ
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 swabs (disinfection of the pricking position) □ timer	GHTF (CE mark)
5X4-0010		100							If whole blood: lancets, alcohol swabs, additional	

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

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
5X4-0012	OraQuick® HIV-1/2 - Rapid Antibody Test	500	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	alcohol swabs, additional specimen loops (004-001).	WHO PQ
5X4-0014		100							If whole blood: lancets, alcohol swabs, additional specimen loops (004-001). Consult WHO PQ Public Report for country specific labelling.	
5X4-0015		500								
5X4-0062		100							Thailand-specific product code / No specimen collection loops	
1001-0079	OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test	25	99.3%*	99.8%*	OraSure Technologies Bethlehem, USA	HIV 1/2 antibodies combined detection	Serum/Plasma/ Whole Blood/Oral Fluid*	30 months 2 to 30°C	If whole blood: lancets, alcohol swabs, additional specimen loops (004-001).	GHTF (FDA, PMA)
1001-0078		100								
PI05FRC05	First Response® HIV 1-2.O Card Test (version 2.0)	5	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma/ Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
PI05FRC05CE	First Response® HIV 1-2.O Card Test (version 2.0)	5	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma/ Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	GHTF (CE mark)
PI05FRC10	First Response® HIV 1-2.O Card Test (version 2.0)	10	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma/ Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
PI05FRC10CE	First Response® HIV 1-2.O Card Test (version 2.0)	10	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma/ Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	GHTF (CE mark)
PI05FRC25	First Response® HIV 1-2.O Card Test (version 2.0)	25	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma/ Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
PI05FRC25CE	First Response® HIV 1-2.O Card Test (version 2.0)	25	100%	100.00%	Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam - 396 155, District Valsad, Gujarat, INDIA	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma/ Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	GHTF (CE mark)

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

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
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
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
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	
1502-100	Asante HIV-1/2 Oral Fluid Test	100			Sedia Biosciences Corporation, USA	HIV 1/2 antibodies combined detection	Oral fluid			WHO PQ
R-401-50-C-2, KH-R-02, A-GOLD-01, R-401-50-C-3	Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	50	100%	100.00%	Shanghai Kehua Bio-engineering Co., Ltd	HIV 1/2 antibodies combined detection	Serum/Plasma/ Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer, EDTA capillary tubes. If serum/plasma: requires, blood collection tubes precision pipette plus tips.	WHO PQ
THIV02	Toyo Anti-HIV 1/2	25	100%	100%	Turk Lab Turkey	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	4 - 30°C		GHTF (CE mark)

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

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
5551100	TrinScreen HIV	100	100%	100%	Trinity Biotech Manufacturing Ltd, Bray, Ireland	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	24 months 2 - 30°C		WHO PQ
1206502 1206502N	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	
1206502-C100		100								

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)

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 GHF countries
29012-W01	CHECKNOW® HIV SELF-TEST	1	99,50%	98,50%	Abbott Rapid Diagnostics Jena GmbH	HIV 1/2 antibodies combined detection	Whole Blood	24 Months 2 to 30°C		WHO PQ
ARST001-03-01 ARST001-03-02 ARST001-03-03	Mylan HIV Self-Test	1	99,80%	99,80%	Alom Diagnostics Pty Ltd, Leichhardt, Australia	HIV 1/2 antibodies combined detection	Whole Blood	18 Months 2 to 30°C		<u>WHO PQ</u>
WZ-4001	HIV SELF TEST BY URINE – Human Immunodeficiency Virus (HIV) type-1 urine antibody diagnostic kit (collidal gold)	1	see WHO Public Report	see WHO Public Report	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, China	HIV 1/2 antibodies combined detection	Urine	see WHO Public Report		WHO PQ
WZ-4010		10								
WY-1050		50								
90-1071	INSTI® HIV Self-Test		99,80%	99,50%	Biolytical Laboratories, Richmond, Canada	HIV 1/2 antibodies combined detection	Whole Blood	15 Months 2 to 30°C		WHO PQ
60-0508-0	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
W006P0058	Wondfo HIV Self-Test	1	95,80%	99,60%	Guangzhou Wondfo Biotech Co., Ltd	HIV 1/2 antibodies combined detection	Whole Blood	24 Months 2 to 30°C		WHO PQ
W006P0059		20								
W006P0060		100								
TTT W02155-TU1	ADVANCED QUALITY HIV Self-Test	1	100,00%	100,00%	InTec PRODUCTS, INC. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, 361022, P.R. China	HIV 1/2 antibodies combined detection	Whole Blood	24 Months 2 to 30°C		WHO PQ

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

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 GHTI countries	
5X4-0004.###	OraQuick HIV Self-Test	1	99.02%	100.00%	OraSure Technologies Inc, Bethlehem, USA (manufactured in Thailand)	HIV 1/2 antibodies combined detection	Oral fluid	30 Months 2 to 30°C	Community Version Individual Test pouches are labeled 5X4- 0004.###	WHO PQ	
5X4-1000.###		50									
5X4-1001.###		250									
5X4-2001.###		110							Pharmacy Version (placed in individual cartons)		
5X4-2001U.###		1							Community Version Individual Test boxes are labeled 5X4- 2001U.###		
5X4-7000.050		50									
5X4-7000.250		250							Pharmacy Version (placed in individual cartons)		
5X4-7000.200		200									
R-429-1-C1	KHB HIV 1/11 Ab Rapid Test (SELF-TEST)	1	100.00%	100.00%	Shanghai Kehua Bio- engineering Co., Ltd., Shanghai, China	HIV 1/2 antibodies combined detection	Whole Blood	24 Months 2 to 30°C	Products available from ERPQ as RISK CATE2-REV2 / Non-Objection- Letters are required for procurement	ERPQ until 13th July 2026	
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)**

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 GHF countries
08P0722	Alinity i HIV Ag/Ab Combo	2 x 100	100%	99.93%	Abbott GmbH, Wiesbaden, Germany	HIV-1 p24 antigen, antibodies to HIV-1 (group M and group O), and antibodies to HIV-2	10 months 2 to 8°C	Serum or plasma specimens; Note: The Alinity i HIV Ag/Ab Combo assay is to be used as an aid in the diagnosis of HIV-1/HIV-2 infection and as a screening test to prevent transmission of HIV-1/HIV-2 to recipients of blood, blood components, cells, tissue and organs. An Alinity i HIV Ag/Ab Combo result does not distinguish between the detection of HIV p24 antigen, HIV-1 antibody, or HIV-2 antibody reactivity.	GHF (IVDR CE mark, TGA, Health Canada)
08P0732		2x 600							
4J27-27	ARCHITECT HIV Ag/Ab Combo	100	100%	99.77%	Abbott GmbH, Wiesbaden, Germany	HIV-1 p24 antigen, antibodies to HIV-1 (group M and group O), and antibodies to HIV-2	10 months 2 to 8°C	Serum or plasma specimens; Note: The ARCHITECT HIV Ag/Ab Combo assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection and as a screening test to prevent transmission of HIV 1/HIV-2 to recipients of blood, blood components, cells, tissue and organs. An ARCHITECT HIV Ag/Ab Combo result does not distinguish between the detection of HIV p24 antigen, HIV 1 antibody, or HIV-2 antibody reactivity.	GHF (CE mark, TGA, Health Canada)
4J27-37		500							
4J27-22		4x100							
4J27-32		4x500							
7G46	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	GHF (TGA)
790000	apDia HIV Ab & Ag Elisa	96	100.00%	99.60%	apDia bvba, Raadsheerenstraat 3, B-2300 Turnhout, Belgium	HIV-1/2 antibodies and HIV-1 p24 antigen	15 months 2 to 8°C	Serum or plasma	GHF (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	GHF (CE mark)
880007s		480							

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

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
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 GHTF (CE mark)
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	
259851	Vironostika HIV Ag/Ab	192	100.00%	99.50%	bioMérieux SA 69280 - Marcy-l'Etoile / France RCS LYON 673 620 399	HIV-1/2 antibodies and HIV- 1 p24 antigen	2 to 8°C	Serum or plasma	GHTF (CE mark)
259852	Vironostika HIV Ag/Ab	576	100.00%	99.50%	bioMérieux SA 69280 - Marcy-l'Etoile / France RCS LYON 673 620 399	HIV-1/2 antibodies and HIV- 1 p24 antigen	2 to 8°C	Serum or plasma	GHTF (CE mark)
72278	GenScreen™ HIV 1/2 Version 2	96	100%	99.80%	Bio-Rad Laboratories, Marnes La Coquette, France and Bio-Rad Laboratories, Steenvoorde, France	HIV 1/2 antibodies combined or discrimination	18 months 2 to 8°C	Serum and plasma specimen Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs	GHTF (CE mark, TGA)
72279		480							
72386	GenScreen™ ULTRA HIV Ag-Ab	96	100%	99.20%	Bio-Rad Laboratories, Steenvoorde, France	HIV 1/2 antibodies combined and HIV1- p24 antigen	18 months 2 to 8°C	Not suitable for whole blood Requires EIA incubator, washer, reader, precision pipette plus tips, deionised water.	WHO PQ
72388		480							
71120	Genscreen™ HIV-1 Ag Assay	192		99.95%	Bio-Rad 3, boulevard Raymond Poincaré 92430 Marnes-la-Coquette - France	HIV-1 p24 antigen	months 2 to 8°C	Human Serum, Plasma and Cell Culture Supernatant	GHTF (CE mark)
26217	GS HIV Combo Ag/Ab EIA	192	100% (manual method) 100% (Evolis system)	99.87% (manual method) 99.97% (Evolis system)	Bio-Rad Laboratories, Steenvoorde, France	HIV-1 p24 antigen and HIV1/2 antibodies	18 months 2 to 8°C	Serum and plasma specimen For product code 26218 (960 tests): wash solution (25261) and stopping solution (25260) must be ordered separately. Biohazard disposal container For venipuncture serum/plasma specimens: Venipuncture apparatus and blood collection tubes Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs, deionized or distilled water. The GS HIV Combo Ag/Ab EIA is approved for use with the Bio-Rad EVOLIS™ Automated Microplate System.	GHTF (FDA, PMA)
26218		960							
IVCOMB.CE	HIV Ab & Ag Elisa	192	100.00%	99.50%	DIA.PRO Diagnostic Bioprobes S.r.l. Italy	HIV-1/2 antibodies and HIV- 1 p24 antigen	15 months 2 to 8°C	Serum or plasma	GHTF (CE mark)
IVCOMB.CE 96		96	100.00%	99.50%					
IVCOMB.CE 480		480	100.00%	99.50%					

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

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 960		960	100.00%	99.50%					
9E25-01	Murex HIV - 1.2.0	96	100%	99.91%	DiaSorin, Dartford, United Kingdom	HIV 1/2 Antibodies (IgG, IgM, IgA)	12 months 2 to 8°C	In EDTA/Citrate 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). For use in laboratory incubators. 6. Instrumentation a) Automated microplate strip washer. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	GHTF (CE mark, TGA)
9E25-02		480							
7G79-09	Murex HIV Ag/Ab Combination	96	100%	99.78%	DiaSorin Dartford, United Kingdom	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)

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

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
80563	INNOTEST HIV Ag mAb	96	100%	100.00%	Fujirebio Europe N.V., Ghent, Belgium	p24 core antigens of the human immunodeficiency virus type 1 (HIV-1), HIV-1 group O, and type 2 (HIV-2)		human serum, plasma, or cell culture supernatant	GHTF (CE mark)
80564		480							
HIV121	HIV Antigen and Antibodies to Human Immunodeficiency Virus (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	HIV p24 antigen, and antibodies to HIV-1 and/or HIV-2	18 months 2 to 8°C	human serum, plasma; Note: The CL-series HIV assay is intended to be used as an aid in the diagnosis of HIV-1/HIV-2 infection and as a screening test for donated blood and blood components.	GHTF (CE mark)
HIV122		2×100 tests							
684 2781	VITROS Immunodiagnostic Products HIV Combo Reagent Pack	100	100%	98.82%	Ortho-Clinical Diagnostics, Bridgend, United Kingdom	Combined detection of HIV-1 p24 and HIV 1/2 Antibodies	shelf life on request 2 to 8°C	serum or plasma specimens; Note: The VITROS HIV Combo test is not intended for use in screening blood or plasma donors. However, this assay can be used as a blood donor screening assay in urgent situations where traditional licensed blood donor screening tests are unavailable or their use is impractical.	GHTF (CE, PMA)
(05 390 095 190) being replaced by 08 924 163 190	Elecsys HIV Combi PT	100	100%	99.82% (blood donor specimens) 99.8% (diagnostic specimens)	Roche Diagnostics, Mannheim, Germany	HIV 1 p24 antigen and HIV1/2 antibodies	15 months 2 to 8°C (Do not freeze)	Serum and plasma specimen cobas e 411 analyzer, cobas e 601 / 602 modules Note: Specimen collected from living patients, blood donors, or individual organ, tissue or cell donors may be used, including donor samples obtained while the donor's heart is still beating.	GHTF (CE mark)
(07 914 504 190) being replaced by 08 924 180 190		200							
(07 229 542 190) being replaced by 08 836 973 190	Elecsys® HIV Duo	300	100%	99.87% (blood donor specimens) 99.92% (diagnostic specimens)	Roche Diagnostics, Mannheim, Germany	HIV 1 p24 antigen and HIV1/2 antibodies	18 months 2 to 8°C (Do not freeze)	Serum and plasma specimen: cobas e 402 / cobas e 801 analytical units Note: Specimen collected from living patients, blood donors, or individual organ, tissue or cell donors may be used, including donor samples obtained while the donor's heart is still beating.	GHTF (CE mark)

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

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-1654/1.2	DS-EIA-HIV-AGAB-SCREEN	96/1 plate	100%	99.60%	RPC «Diagnostic Systems», Ltd. Nizhny Novgorod Russian Federation	HIV1/2 antibodies combined and HIV1-p24 antigen	24 months 2-8 °C	Serum or plasma specimen	WHO PQ
I-1652/1.2		192/2 plates							
I-1656/1.2		480/5 plates							

N/A- NOT APPLICABLE

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

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

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 GHIT countries
260100025	PIMA CD4	Absolute CD4+ Counts	25 cartridges/kit	Abbott Rapid Diagnostics Jena GmbH, Jena, Germany	12 months for reagents 2 to 30°C for reagents	Venous and Capillary whole blood	End of Life (EOL) of Pima Instruments: 2024 (no support available beyond that date)	WHO PQ
260100100			100 cartridges/kit					
260300003	PIMA Analyser		Flow cytometry instrument				DISCONTINUED	
B39101, B39102, B30166 B25697, B25698, B23536, B23538, B23533, B23534, B23535, B25700, B23502	Aquios CL flow cytometer	total CD3+, CD3+CD4+, CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts; CD45+ absolute count; and CD45+ Low SS (lymphocytes) percentage and absolute count.	Flow cytometry instrument	Beckman Coulter Life Sciences Miami, FL, USA (instrument site) and Hialeah, FL, USA (reagent site)	B30166	N/A	N/A	WHO PQ (PQ Public Report) http://www.who.int/diagnostics_laboratory/evaluat... www.171116..._report...-0120-0121-0122..._flow_cytometry.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		
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

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

Rapid Diagnostic Test for qualitative testing based on CD4 technologies

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
AB376	VISITECT®CD4 Advanced Disease	Semi-Quantitative Test (200 cells/ul cut-off)	25T/kit	AccuBio Ltd Omega House, Hillfoots Business Village, Alva, FK12 5DO, Scotland, United Kingdom	12 months 2 to 30°C	human venous whole blood or capillary blood		WHO PQ

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)

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
08N45-090	Alinity m HIV-1	192T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HIV Quantitative DNA	12 months	2 to 8°C	Plasma and Serum and Dried Blood Spots	For consumables refer to IFU	WHO PQ GHTF (CE mark/IVDD)
08N53-002		instrument									
08N45		instrument									
08N45-080		3 x 12 CTRL kit						-25 to -15°C			
08N45-070		2x4 CAL kit						-25 to -15°C			
09N12-001		sample prep kit 2									
09N66-001 (optional)		DBS Buffer kit									
4N66-90	Abbott Real Time HIV-1 Qualitative (Manual)	96T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HIV 1 Qualitative DNA	18 months	-10°C	Plasma and Dried Blood Spots	For consumables refer to WHO eligible list	WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. <u>For the Manual configuration</u> <u>see:</u> https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-v1/180221_amended_final_page_0101_142_01_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 Spots	For consumables refer to WHO eligible list	WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. <u>For the automated configuration</u> <u>see:</u> https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-v1/180221_amended_final_page_0104_027_01_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
(not intended to be used as a donor screening tests – unless otherwise specified)

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHIT 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 GHITF (CE mark) https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vr/191217_amended_final_pq-pr_0145_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 GHITF (CE mark) https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vr/191217_amended_final_pq-pr_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			
3N06-01		instrument						NA			
2G31-90		96T/kit						-10°C			
2G31-80		8 runs						-10°C			

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHIT countries
2G31-70	Abbott Real Time HIV-1 (m24sp)	4 calibrations	N/A	N/A	Abbott Molecular Inc, Des Plaines IL, USA	HIV1 Quantitative RNA	18 months	-10°C	Plasma	For consumables refer to WHO eligible list	WHO PQ and GHITF (CE mark) https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-1/11/217_amended_page_0081_027_04_abbott_real_time_hiv1_v1.pdf?ua=1
2G31-66								-10°C			
1L68-09											
9K15-01		instrument									
04J70-24											
04J71-93											
27030R001 (former 270300001)	m-PIMA Analyser (former Alere™ q System)	Instrument	N/A	N/A	Abbott Rapid Diagnostics Jena GmbH, 07749 Jena Germany	Not applicable	Not applicable	Not applicable	Whole Blood, Plasma	For consumables and alternative Alere q (product code 270300002) refer to WHO Public Report	WHO PQ
27011R010 (former 270110010)	m-PIMA HIV-1/2 Detect	10 Cartridges				HIV-1/2 Qualitative RNA	13 months	4-30°C			
27011R050* (former 270110050)		50 Cartridges					13 months	4-30°C			
27011W50		50 Cartridges					13 months	4-30°C			
27015-W50	m-PIMA HIV-1/2 VL	50 tests/kit	N/A	NA	Abbott Rapid Diagnostics Jena GmbH, 07749 Jena Germany	HIV-1/2 Quantitative RNA	9 months	4 to 30°C	Plasma	For consumables refer to WHO PQ public report	WHO PQ
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 Yuseong-gu, Daejeon, 34013, Republic of Korea	HIV-1 Quantitative RNA	12 months	-25°C to -15°C	EDTA Plasma	For consumables and details of components refer to IFU	GHITF (CE mark)
A-2400	ExiStation™ 48 Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			
A-2200-N	ExiStation™ Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			
HIV-1111	AccuPower® HIV-1 Quantitative RT-PCR Kit	96T/kit			BIONEER Corporation Yuseong-gu,	HIV-1	12 months	-25°C to -15°C		For consumables and details of	

HIV Virological technologies
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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
A-2200-N	ExiStation™ Universal Molecular Diagnostic System	Instrument	N/A	N/A	Daejeon, 34013, Republic of Korea	Quantitative RNA	Not applicable	Not applicable	EDTA Plasma	components refer to IFU	WHO PQ
TR001-250IC	Generic HIV Charge Virale	220	NA	NA	Biocentric Bandol France	HIV1 Quantitative RNA	18 months	-30°C to -8°C	EDTA or citrated Plasma	Product discontinuation in Sept 2025	GHTF (CE mark)
TR001-440IC	Generic HIV Charge Virale	440									
GX [Series]	GeneXpert® Systems I, II, IV & XVI	Instruments	N/A	N/A	Cepheid Inc., Rontgenavagen 5 SE-171, 54 Solna Sweden	N/A	N/A	N/A	N/A	For 10-channel optical system modules refer to WHO PQ public report	see relevant WHO PQ Public Report
Infinity-48	GeneXpert® Infinity-48s	Instrument				N/A	N/A	N/A	N/A		
Infinity-80	GeneXpert® Infinity-80	Instrument				N/A	N/A	N/A	N/A		
GXI-EDGE-L	GeneXpert Edge System	Instrument				N/A	N/A	N/A	N/A	Only for Xpert HIV-1 Qual Assay	
GXHIV-VL-CE-10	Xpert HIV-1 Viral Load	10 cartridges per pack				HIV-1 Quantitative NA target	18 months	2-28°C	Plasma	For further instruments refer to WHO Public Report	WHO PQ and GHTF (CE mark)
GXHIV-QA-CE-10	Xpert HIV-1 Qual Assay	10 cartridges per pack				HIV-1 Qualitative NA target	12 months	2-28 °C	Whole blood and DBS	For further instruments refer to WHO Public Report	WHO PQ and GHTF (CE mark)
GX [Series]	GeneXpert® Dx System with 10-color moduls	Instruments				N/A	N/A	N/A	N/A		GHTF (CE mark)
Infinity-48	GeneXpert® Infinity-48s	Instrument	N/A	N/A	Cepheid Inc., Rontgenavagen 5	N/A	N/A	N/A	N/A		
Infinity-80	GeneXpert® Infinity-80	Instrument				N/A	N/A	N/A	N/A		
GXI-EDGE-L	GeneXpert Edge System	Instrument				N/A	N/A	N/A	N/A	GeneXpert 6 or 10 color modules	

HIV Virological technologies
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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
GXHIV-VL-XC-CE-10	Xpert HIV-1 Viral Load XC	10 cartridges per pack			SE-171, 54 Solna Sweden	HIV-1 Quantitative NA target	18 months	2-28°C	Plasma	For further instruments refer to IFU	WHO PQ and GHTF (CE mark)
GXHIV-QA-XC-CE-10	Xpert HIV-1 Qual Assay XC	10 cartridges per pack				HIV-1 Qualitative NA target	18 months	2-28 °C	Whole blood and DBS	For further instruments refer to IFU	WHO PQ and GHTF (CE mark)
I19-0006-AM	SAMBA II Assay Module	instrument	N/A	N/A	Diagnostics for the Real World, Sunnyvale, CA 94085 USA	N/A	N/A	N/A	N/A		WHO PQ
I19-0006-TM	SAMBA II Tablet Module	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
4500-12	SAMBA II HIV-1 Qual Whole Blood Test	12 Tests	N/A	N/A		HIV-1 Qualitative RNA	9 months	2 to 37°C	Whole Blood		
INT030	ELiTe InGenius	instrument	N/A	N/A	EliTechGroup S.p.A, Torino, Italy	N/A	N/A	N/A	N/A		GHTF (IVDR CE mark)
INT040	ELiTe BeGenius	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
RTK600ING	HIV1 ELiTe MGB® Kit	96 Tests	N/A	N/A		HIV-1 Quantitative RNA	18 months	below -20°C	EDTA or ACD Plasma		
TR001.2-192	GENERIC HIV-1 VIRAL LOAD VER 2.0	192	NA	NA	Hain Lifescience GmbH	HIV-1 Quantitative RNA	12 months	-30°C to -18°C	EDTA or citrated Plasma	New Product Introduction in Sept 2025	GHTF (IVDR CE mark)
PRD-03000	Aptima HIV-1 Quant Dx Assay Kit (Panther System)	100T/kit	N/A	N/A	Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121	HIV-1 Quantitative & Qualitative RNA	24 months	2°C-8°C	EDTA Plasma, see IFU for dried blood spots (DBS)	Multi-tube units (MTUs), Panther Waste Bag Kit, Panther Waste Bin Cover, Aptima Assay Fluids, and Tips are included and calculated based on number of kits ordered)	WHO PQ
PRD-03001		5 calibrators						-15 to -35°C			
PRD-03002		controls 5 runs						-15 to -35°C			
303095		instrument					NA	NA			
PRD-03000		100T/kit						2°C to 8°C	EDTA		

HIV Virological technologies
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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHF countries
PRD-03000B	Aptima HIV-1 Quant Dx Assay Kit (Panther System)	500T/kit	N/A	N/A	Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121	HIV-1 Quantitative & Qualitative RNA	24 months	2°C to 8°C	EDTA Plasma, see IFU warning for dried blood spots (DBS)	Multi-tube units (MTUs), Panther Waste Bag Kit, Panther Waste Bin Cover, Aptima Assay Fluids, and Tips are included and calculated based on number of kits ordered)	<u>WHO PQ</u>
PRD-03001		10 calibrators						-15 to -35°C			
PRD-03002		Controls 10 runs						-15 to -35°C			
303095		instrument					NA	NA			
PRD-03565	Aptima HIV-1 Quant Dx Assay Kit (Panther System)	100T/kit	N/A	N/A	Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121	HIV-1 Quantitative & Qualitative RNA	12 months	2°C-8°C	EDTA Plasma, see IFU for dried blood spots (DBS)	Multi-tube units (MTUs), Panther Waste Bag Kit, Panther Waste Bin Cover, Aptima Assay Fluids, and Tips are included and calculated based on number of kits ordered)	GHF (US FDA, TGA)
PRD-03567		Controls 10 runs						-15 to -35°C			
PRD-03566		10 calibrators						-15 to -35°C			
PRD-05490		instrument					NA	NA			
03279332001	COBAS AmpliPrep/COBAS Taqman HIV-1 Test Version 2.0 (Taqman 48)	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA (Roche Diagnostics GmbH)	HIV1 Quantitative RNA	NA		Plasma or PSC dried plasma spot (with PCS)	For consumables refer to WHO eligible list http://www.who.int/diagnostics/hiv/147124_v11_report_final.pdf	WHO PQ and GHF (CE mark)
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		instrument					NA				
03051315001		instrument					NA				

HIV Virological technologies
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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
04862392001	COBAS AmpliPrep/COBAS Taqman HIV-1 Test Version 2.0 (Taqman 96)	software	N/A	N/A	Roche Molecular System, Branchburg, USA (Roche Diagnostics GmbH)	HIV1 Quantitative RNA	NA		Plasma or dried plasma spot (with PCS)	For consumables refer to WHO eligible list http://www.who.int/diagnostics_laboratory/evaluations/121714_0147_046_00_public_report_v1_final.pdf	WHO PQ and GHTF (CE mark)
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 (Roche Diagnostics GmbH)	HIV1 DNA & RNA Qualitative	22 months	2 to 8°C	Plasma or dried blood spots		WHO PQ GHTF (CE mark)
03051315001		instrument									
03279332001		instrument									
03587797190		5.1L					24 months	2 to 30°C			
06989861190		5 x 78ml									
05807875001		software									
03516440001		instrument									
28127387001											
06693083190	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 96)	48T/kit	N/A	N/A	Roche Molecular System, Branchburg, USA (Roche Diagnostics GmbH)	HIV1 DNA & RNA Qualitative	22 months	2 to 8°C	Plasma or dried blood spots		WHO PQ GHTF (CE mark)
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					24 months*	2 to 8°C			

HIV Virological technologies
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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
3502295001	High Pure System Nucleic Acid Kit	48 tests	N/A	N/A	Roche Molecular System, Branchburg, USA (Roche Diagnostics GmbH)	HIV-1 Quantitative RNA	12 months*	15 to 25°C	Plasma		GHTF (CE mark)
05 200 881 001	COBAS® z 480	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA (Roche Diagnostics GmbH)	N/A	N/A	N/A	N/A		WHO PQ 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 & Qualitative RNA	15 months	2 to 8°C	EDTA Plasma, dried plasma spot (with PSC card), dried blood spots (DBS)		
05 200 881 001	COBAS® z 480	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA (Roche Diagnostics GmbH)	N/A	N/A	N/A	N/A		WHO PQ GHTF (CE mark)
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
06 979599190	COBAS® Quantitative HIV-1 Test for use with 4800	120 tests	N/A	N/A		HIV-1 Quantitative RNA	16 months	N/A	EDTA Plasma		
8707464001	cobas 5800 System	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA (Roche Diagnostics GmbH)	N/A	N/A	N/A	N/A		WHO PQ GHTF (CE mark)
05524245001 and 06379664001	cobas 6800 System (Option Moveable)	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
05524245001 and 06379664001	cobas 6800 System (Fix)	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
05412722001	cobas 8800 System	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
07000995190	COBAS® HIV-1 Quantitative nucleic acid test for use with 5800/6800/8800 Systems	96 tests/kit	N/A	N/A		HIV-1 Quantitative RNA	24 months	2 to 8°C	EDTA Plasma, dried plasma spot	(with PSC card)	

HIV Virological technologies
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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
09040803190	COBAS® HIV-1 Quantitative nucleic acid test for use on the cobas® 5800/6800/8800 Systems	192 tests/kit	N/A	N/A		HIV-1 Quantitative RNA	24 months	2 to 8°C	EDTA Plasma, dried plasma spot	(with PCS card)	
07862113190	COBAS® HIV-1/HIV-2 Test for use with 6800/8800	96 tests/kit	N/A	N/A	Roche Molecular System, Branchburg, USA / (Roche Diagnostics GmbH)	HIV-1/HIV-2 Qualitative RNA	24 months	2 to 8°C	Serum, Plasma, dried blood spots (DBS)		WHO PQ GHTF (CE mark)
09040528190	COBAS® HIV-1/HIV-2 Qualitative nucleic acid test for use on the cobas® 5800/6800/8800 Systems	192 tests/kit	N/A	N/A	Roche Molecular System, Branchburg, USA (Roche Diagnostics GmbH)	HIV-1/HIV-2 Qualitative RNA	24 months	2 to 8°C	EDTA Plasma, dried blood spots (DBS)		WHO PQ 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

Disclaimer: The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principals/Recipients of Global Fund grants to conduct their own independent confirmation that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with, the procurement, distribution and use of any product included on the list.

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

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 GHIT countries
7D2942	Determine HBsAg 2	20	100.00%	99.70%	Abbott Diagnostics Medical Co. Ltd, Matsudo, Japan	HBsAg detection	Serum/Plasma/ Whole Blood	18 Months 2 to 30°C		WHO PQ
7D2943		100								
7D2943 SET		100								
01FK10W	Bioline HBsAg WB	30	100.00%	99.00%	Abbott Diagnostics Korea (Giheung-gu, Yongin-si, Korea)	HBsAg detection	Serum/Plasma/ Whole Blood	24 Months 1 to 40°C		WHO PQ
R0042C	OnSite HBsAg Combo Rapid Test	30	100%	100%	CTK Biotech Inc, USA	HBsAg detection	Serum/Plasma/ Venous and Capillary Whole Blood	24 months 2 to 30°C		GHITF (CE mark)
PH10FRC05CE	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		GHITF (CE mark)
PH10FRC10CE		10								
PH10FRC25CE		25								
PH10FRC30CE		30								
09HBS10D	STANDARD™ Q HBsAg Test	25	98.00%	100.00%	SD Biosensor, Inc (Gyeonggi-do 16690 Republic of Korea)	HBsAg detection	Serum/Plasma/ Whole Blood	24 Months 1 to 40°C	Products available from ERPD as RISK CATEGORY 2 / Non-objection-Letters are required for procurement	ERPD until 12th November 2026
N/A- NOT APPLICABLE										

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

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

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
08P10-22	Alinity i HBsAg Qualitative II Reagent Kit	2 x 100	100%	99.96% (blood donor specimens) 100% (diagnostic specimens)	Abbott Ireland Diagnostics Division, Sligo, Ireland	HBsAg antigens	12 months 2 to 8°C	Serum or plasma specimens; Note: The Alinity i HBsAg Qualitative II assay is to be used as an aid in the diagnosis of HBV infection and as a screening test to prevent transmission of HBV to recipients of blood, blood components, cells, tissue, and organs.	GHTF (TGA)
08P10-32		2 x 600							
02G22-25	ARCHITECT HBsAg Qualitative II	100			Abbott Ireland Diagnostics Division, Sligo, Ireland	HBsAg antigens	12 months 2 to 8°C	Serum or plasma specimens; Note: The ARCHITECT HBsAg Qualitative II assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum and plasma including specimens collected post-mortem (non-heart-beating). The ARCHITECT HBsAg Qualitative II assay is intended to be used as an aid in the diagnosis of HBV infection and as a screening test to prevent transmission of HBV to recipients of blood, blood components, cells, tissue and organs.	GHTF (CE mark, TGA, Canada)
02G22-35		500							
02G22-30		4x500							
B-1254/1.2 *	DS-EIA-HBsAg-O,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 plasma specimen	WHO PQ https://extranet.who.int/pqweb/sites/default/files/PQDx_0120-038-00_DS-EIA-HBsAg-001_ENZYME-IMMUNOASSAY_v4.0.pdf
B-1252/1.2 *		192/2 plates							
B-1255/1.2 *		480/5 plates							
B-1256/1.2 *		1 plate 96 (for detection) or 48 (for confirmation)							
B-231/1.2 *		200 tests							
72346	Monolisa HBsAg ULTRA assay	96	100%	99.94%	Bio-Rad Laboratories, Marnes La Coquette, France	anti-HBsAg Antibodies	see lot expiry 2 to 8°C	Serum and plasma specimen Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs	GHTF (CE mark)
72348		480							

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

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 GHF countries
9F80-01 *	Murex HBsAg Version 3	96	100%	99.00%	DiaSorin, Dartford, United Kingdom	anti-HBsAg Antibodies	12 months 2 to 8°C	In EDTA/Citrate Plasma specimen 1. Stop Solution (0.5M to 2M Sulphuric 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. c) Fully automated microplate processor. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	.WHO PQ https://extranet.who.int/pqweb/content/public-report-murex-hbsag-version-3 murex hbsag confirmatory version 3 p qdx 0121 043 00
9F80-05 *		480							
2G27-01 *	Murex HBsAg Confirmatory Version 3	50	100%	99.78%	DiaSorin Dartford, United Kingdom	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. c) Fully automated microplate processor. 7. Disposable Reagent Troughs. (Code 5F24-01). 8. Sodium hypochlorite for decontamination. (Refer to Health and Safety Information) 9. Sodium hydroxide solution (0.1M). (Refer to Analytical Precautions).	.WHO PQ https://extranet.who.int/pqweb/content/public-report-murex-hbsag-version-3 murex hbsag confirmatory version 3 p qdx 0121 043 00
HBsAg121	HBsAg Hepatitis B Surface Antigen (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	HBsAg	18 months 2 to 8°C	human serum, plasma; Note: The CL-series HBsAg assay is intended to be used as an aid in the diagnosis of HBV infection and as a screening test for donated blood and plasma.	GHF (CE mark)
HBsAg122		2×100 tests							
Anti-HBs121	Anti-HBs Antibody to Hepatitis B Surface Antigen (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	Anti-HBs	18 months 2 to 8°C	human serum, plasma;	GHF (CE mark)
Anti-HBs122		2×100 tests							

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
HBeAg121	HBeAg Hepatitis B e Antigen (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	HBeAg	18 months 2 to 8°C	human serum, plasma;	GHTF (CE mark)
HBeAg122		2×100 tests							
Anti-HBe121	Anti-HBe Antibody to Hepatitis B e Antigen (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	Anti-HBe	18 months 2 to 8°C	human serum, plasma;	GHTF (CE mark)
Anti-HBe121		2×100 tests							
Anti-HBc121	Anti-HBc Antibody to Hepatitis B Core Antigen (CLIA)	2×50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Shenzhen, 518057 P.R.China	Anti-HBc	18 months 2 to 8°C	human serum, plasma;	GHTF (CE mark)
Anti-HBc122		2×100 tests							
11 820 567 122	Elecsys® Anti-HBc IgM	100			Roche Diagnostics GmbH	HBc IgM antibodies	15 months 2 to 8°C	Human serum and plasma specimens cobas e immunoassay analyzer	GHTF (CE mark)
07 026 811 190		300							
07 374 160 190 / 09 014 918 190	Elecsys® Anti-HBc II	100			Roche Diagnostics GmbH	HBc IgG and IgM antibodies	15 months 2 to 8°C	Human serum and plasma specimens cobas e immunoassay analyzer NOTE: Consult the IFU for screening of blood donations and for use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating).	GHTF (CE mark)
07 394 764 190 / 09 109 463 190		200							
07 026 790 190 / 09 014 926 190		300							
11 820 583 122 / 09 015 540 190	Elecsys® HBeAg	100	100.00%	99.90%	Roche Diagnostics GmbH	anti-HBeAg Antibodies	24 months 2 to 8°C	Human serum and plasma specimens cobas e 801 immunoassay analyzer NOTE: Consult the IFU for diagnostic use and for testing of blood donations	GHTF (CE mark)
07 027 427 190 / 09 015 558 190		300							
05 894 816 190 / 08 498 598 190		100						Human serum and plasma specimens	

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

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
06 771 823 190 / 08 498 601 190	Elecsys® Anti-HBs II	200			Roche Diagnostics GmbH	HBs antibodies	15 months 2 to 8°C	cobas e immunoassay analyzer NOTE: Consult the IFU for diagnostic use and for testing of blood donations	GHTF (CE mark)
07 026 854 190 / 08 498 610 190		300							
04 687 787 190 / 08 814 856 190	Elecsys® HBsAg II	100			Roche Diagnostics GmbH	HBsAg antigens	12 months 2 to 8°C	Human serum and plasma specimens cobas e immunoassay analyzer NOTE: Consult the IFU for screening of blood donations and for use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating).	GHTF (CE mark)
07 914 482 190 / 08 814 864 190		200							
07 251 076 190 / 08 814 848 190		300							

	N/A- NOT APPLICABLE
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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)

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	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 PCR Kit	96T/kit	N/A	N/A	Bioneer Corporation, Yuseong-gu, Daejeon, 34013, Republic of Korea	HBV Quantitative DNA	12 months	-25°C to -15°C	EDTA Plasma and Serum	For consumables and details of components refer to IFU	GHTF (CE mark)
A-2400	ExiStation™ 48 Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			
A-2200-N	ExiStation™ Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			
GX [Series]	GeneXpert® Dx	Instrument	N/A	N/A	Cepheid Inc., Rontgenavagen 5 SE-171, 54 Solna Sweden	N/A	N/A	N/A	N/A		GHTF (CE mark)
Infinity-48	GeneXpert® Infinity-48	Instrument				N/A	N/A	N/A	N/A		
Infinity-80	GeneXpert® Infinity-80	Instrument				N/A	N/A	N/A	N/A		
GX4.0SWKIT or XPRTISE-G2-SWKIT	GeneXpert® Dx Software	Software				N/A	N/A	N/A	N/A		
GXHBV-VL-CE-10	Xpert® HBV Viral Load	10 cartridges per pack				HBV Quantitative DNA	18 months	2-35°C	Serum / EDTA Plasma		
INT030	ELiTe InGenius	instrument	N/A	N/A	EliTechGroup S.p.A, Torino, Italy	N/A	N/A	N/A	N/A		GHTF (IVDR CE mark)
INT040	ELiTe BeGenius	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
RTK602ING	HBV ELiTe MGB® Kit	96 Tests	N/A	N/A		HBV Quantitative DNA	18 months	below -20°C	EDTA or ACD Plasma		

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
TR004.2-250IC	Generic HBV Viral Load Version 2.0	220T/kit	N/A	N/A	Hain Lifescience GmbH, Nehren, Germany	HBV Quantitative DNA	18 months	-30°C to -18°C	EDTA Plasma	not intended for use as a screening test in blood or blood products for HBV or to confirm the presence of HBV infection.	GHTF (IVDR CE mark)
	see IFU for compatible instruments	Instrument					Not applicable	Not applicable			
PRD-03424	Aptima HBV Quant Dx Assay Kit (Panther System)	100T/kit	N/A	N/A	Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121	HBV Quantitative	12 months	2 to 8°C	Plasma and Serum		GHTF (CE mark IVDD; Health Canada)
PRD-03426		10 runs						-15 to -35°C			
PRD-03425		10 calibrators						-15 to -35°C			
PRD-05490		instrument					NA	NA			
PRD-03868	Aptima HBV Quant Assay Box	100T/kit	N/A	N/A	Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121	HBV Quantitative RNA	12 months	2 to 8°C	Plasma and Serum		GHTF (US FDA)
PRD-03869		controls						-15 to -35°C			
PRD-03872		10 calibrators						-15 to -35°C			
PRD-05490		instrument					NA	NA			
05 200 881 001	COBAS® z 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
06 979564190	COBAS® Quantitative HBV Test for use with 4800	120 tests	N/A	N/A	Roche Molecular System, Branchburg, USA	HBV Quantitative DNA	24 months	2°C to 8°C	EDTA Plasma / Serum	not intended for use as a screening test for the presence of HBV in blood or blood products or as a diagnostic test to confirm the presence of HBV infection.	GHTF (CE mark)
09040820190	COBAS® HBV Quantitative nucleic acid test for use on the cobas® 5800/6800/8800 Systems	192 tests/kit	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HBV Quantitative DNA	24 months	2 to 8°C	Plasma / serum / whole blood	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)
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 to 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

Global Fund does not warrant the fitness of any product on the list for a particular purpose. In addition, the Global Fund assumes no responsibility for any misinterpretation or confusion from the list and directs Principal Recipients of Global Fund grants to conduct their own independent confirmation of the information on a given product or the list is a complete listing on it to make a purchase order for their purpose, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's procurement policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use in any particular country or the world, or that their use is otherwise in compliance with the various laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damages or loss of any kind or otherwise that may arise as a result of reliance on, or conflict with, the procurement, distribution and use of any product included in the list.

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

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

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

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

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
GCHCV-302a	HCV Hepatitis C Virus Rapid Test (Serum/Plasma) (Cassette)	25	100%	99.90%	Healgen Scientific Limited Liability Company, Houston, USA	HCV antibody detection	Serum or plasma	24 months 2 to 30 °C		GHTF (CE mark)
ITP01152-TC40	Rapid Anti-HCV Test	40	99.70%	99.80%	InTec Products 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 Products Inc, (Haicang, Xiamen, P.R. China)	HCV antibody detection	Serum/Plasma/ Whole Blood	24 Months 2 to 30°C	for accessories see IFU	WHO PQ
ITPW01152-TC25		25								
ITPW01153-TC40		40								
ITPW01253-TC40		40								
ITPW01153-TC25		25								
ITPW01132-TC25		25								
ITPW01233-TC25		25								
ITPW01232-TC40		40								
ITPW01233-TC40		40								
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
1001-0274		100								

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

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
PI03FRC25	First Response® HCV Card Test	25	100.00%	100.00%	Premier Medical Corporation, Nani Daman, India	HCV antibody detection	Serum/Plasma/ Whole Blood	24 Months 4 to 30°C		WHO PQ
PI03FRC50		50								
PI03FRC100		100								
PI03FRC05CE	First Response® HCV Card Test	5	100.00%	100.00%	Premier Medical Corporation, Nani Daman, India	HCV antibody detection	Serum/Plasma/ Whole Blood	24 Months 4 to 30°C		GHTF (CE mark)
PI03FRC10CE		10								
PI03FRC25CE		25								
PI03FRC30CE		30								
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
HCV Self Test										
3001-3217.###	OraQuick HCV Self-Test	1	see IFU	see IFU	OraSure Technologies Inc, Bethlehem, USA (manufactured in Thailand)	HCV antibodies	Oral fluid	18 Months 2 to 30°C	Community Version Individual Test pouches are labeled 3001- 3217.###	WHO PQ
7X4-1000.###		50								
7X4-1001.###		250								
7X4-2001.###		200							Pharmacy Version (placed in individual cartons)	
7X4-2001U.###		1							Community Version Individual Test boxes are labeled 3001- 3217.###	

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

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
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	N/A- NOT APPLICABLE
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List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

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

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
08P06-23	Alinity i Anti-HCV Reagent Kit	1 x 200	100%	99.96% (blood donor specimens) 100% (diagnostic specimens)	Abbott Ireland Diagnostics Division, Sligo, Ireland	HCV antibodies	12 months 2 to 8°C	Serum or plasma specimens; Note: The Alinity i Anti-HCV assay is to be used as an aid in the diagnosis of HCV infection and as a screening test to prevent transmission of HCV to recipients of blood, blood components, cells, tissue, and organs.	GHTF (CE mark, TGA)
08P06-33		2 x 600							
6L47-29	ARCHITECT HCV Ag assay	100	98%	99.50%	Abbott GmbH, Germany	HCV antigens	12 months 2 to 8°C	Human serum and plasma specimens	WHO PQ GHTF (CE mark)
06C37-28	ARCHITECT Anti-HCV	100			Abbott GmbH, Germany	HCV antibodies	12 months 2 to 8°C	Serum or plasma specimens; Note: The ARCHITECT Anti-HCV assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in human serum and plasma including specimens collected post-mortem (non-heart-beating). The ARCHITECT Anti-HCV assay is intended to be used as an aid in the diagnosis of Hepatitis C infection and as a screening test to prevent transmission of Hepatitis C Virus to recipients of blood, blood components, cells, tissue and organs.	GHTF (CE mark, TGA, Canada)
06C37-38		500							
06C37-33		4x500							
72561	Monolisa HCV Ag-Ab ULTRA V2 assay	96	100%	99.94%	Bio-Rad Laboratories, Marnes La Coquette, France	HCV antigens / antibodies	12 months 2 to 8°C	Serum and plasma specimen Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs	WHO PQ GHTF (CE mark)
72562		480							

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

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 GHF 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 (0.5M to 2M Sulphuric 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. c) Fully automated microplate processor. 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
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
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
06 368 921 190 / 08 836 981 190	Elecsys® Anti-HCV II	100	100.00%	99.90%	Roche Diagnostics GmbH	HCV antibodies	12 months 2 to 8°C	Human serum and plasma specimens cobas e 801 immunoassay analyzer NOTE: Consult the IFU for screening of blood donations and for use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating).	GHF (CE mark)
06 427 405 190 / 08 837 031 190		200							
07 026 889 190 / 08 837 058 190		300							
105 024999 00	Anti HCV Antibody	2x50 tests	100%	100.00%	Shenzhen Mindray Bio-Medical Electronics Co., Ltd	HCV antibodies	18 months	human serum, plasma; Note: It is intended to be used as an aid in the diagnosis of	GHF (EU IVDD CE mark)

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

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 GHF countries
105 025000 00	HCV antibody to Hepatitis C Virus (CLIA)	2×100 tests	100.0%	100.00%	ELIACHEMICS CO., LTD, Shenzhen, 518057 P.R.China	HCV ANTIBODIES	2 to 8°C	HCV infection and as a screening test for donated blood and blood components.	GHF (CC BY-NC-SA)

	N/A- NOT APPLICABLE
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List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	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) WHO PQ
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) 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, Yuseong-gu, Daejeon, 34013, Republic of Korea	HCV Quantitative RNA	12 months	-25°C to -15°C	EDTA Plasma and Serum	For consumables and details of components refer to IFU	GHTF (CE mark)
A-2400	ExiStation™ 48 Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			
A-2200-N	ExiStation™ Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			
GX [Series]	GeneXpert® Dx	Instruments				N/A	N/A	N/A	N/A	For 10-channel optical system modules refer to WHO PQ public report	
Infinity-48	GeneXpert® Infinity-48	Instrument				N/A	N/A	N/A	N/A		
						N/A	N/A	N/A	N/A		

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Infinity-80	GeneXpert® Infinity-80	Instrument	N/A	N/A	Cepheid Inc., Rontgenvägen 5 SE-171, 54 Solna Sweden	N/A	N/A	N/A	N/A		GHTF (CE mark) WHO PQ
GX4.0SWKIT or XPRTISE-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 / blood		
ID-HCV-03	Genedrive HCV ID Kit	10	99.8	100	Genedrive Diagnostics Ltd., United Kingdom	HCV Qualitative RNA	12 months	2 to 30°C	Plasma		GHTF (CE mark) WHO PQ
PRD-03506	Aptima HCV Quant Dx Assay Kit (Panther System)	100T/kit	N/A	N/A	Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121	HCV Quantitative & Qualitative RNA	12 months	2 to 8°C	Plasma and Serum		GHTF (CE mark IVDD, Health Canada)
PRD-03508		10 runs						-15 to -35°C			
PRD-03507		10 calibrators						-15 to -35°C			
303095		instrument					NA	NA			
PRD-03705		100T/kit			Hologic, Inc	HCV	12 months	2 to 8°C	Plasma and Serum		
PRD-03706		10 runs						-15 to -35°C			
PRD-03707		10 calibrators						-15 to -35°C			

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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
PRD-05490	Aptima HCV Quant Dx Assay Box	instrument	N/A	N/A	10210 Genetic Center Drive San Diego, CA 92121	Quantitative & Qualitative RNA	NA	NA			GHTF (US FDA)
05 200 881 001	COBAS® z 480	instrument	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	N/A	N/A	N/A	N/A		GHTF (CE mark)
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
06 979602190	COBAS® Quantitative HCV Test for use with 4800	120 tests	N/A	N/A		HCV Quantitative RNA	24 months	2°C - 8°C	EDTA Plasma / Serum	not intended for use as a screening test for the presence of HCV in blood or blood products or as a diagnostic test to confirm the presence of HBV infection.	
06997732190	COBAS® HCV Test for use with 5800/6800/8800 Systems	96 tests/kit	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HCV Quantitative RNA	24 months	2 to 8°C	EDTA Plasma	not intended for use as a screening test for the presence of HCV in blood or blood products or as a diagnostic test to confirm the presence of HBV infection.	WHO PQ
09040765190	COBAS® HCV Test for use with 5800/6800/8800 Systems	192 tests/kit	N/A	N/A	Roche Diagnostics GmbH / Roche Molecular System, Branchburg, USA	HCV Quantitative RNA	24 months	2 to 8°C	EDTA Plasma	not intended for use as a screening test for the presence of HCV in blood or blood products or as a diagnostic test to confirm the presence of HBV infection.	

N/A- NOT APPLICABLE

Hepatitis C / Virological technologies
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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
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Disclaimer: The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose. In addition, the Global Fund disclaims any responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent verification that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use in any particular country, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, international property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with, the procurement, distribution and use of any product included in the list.

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)

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%	HIV 99.5% Syphilis 99.5%	Abbott Diagnostics Korea Inc. (Giheung-gu,Yongin-si, Korea)	HIV/TP-antibodies	Serum/Plasma/ Whole Blood	24 Months 1 to 30°C	For consumables refer to WHO Public Report	WHO PQ
06FK35										
06FK37										
I20FRC25 I20FRC30 I20FRC50 I20FRC60 I20FRC100	First Response® HIV1+2/Syphilis Combo Card Test	25 T/kit 30 T/kit 50 T/kit 60 T/kit 100T/kit	HIV-100% Syphilis-99%	HIV 99.5% Syphilis 100%	Premier Medical Corporation Private Limited (Sarigam, Gujarat, India)	HIV/TP-antibodies	Serum/Plasma/ Whole Blood	30 Months 4 to 30°C	For consumables refer to WHO Public Report	WHO PQ
09HIV20D	STANDARD™ Q HIV/Syphilis Combo Test	25 T/kit	HIV-100% Syphilis-98.8%	HIV-99.9% Syphilis-100%	SD Biosensor Inc (16, Deogyong-daero, 1556 beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690 Republic of Korea)	HIV/TP-antibodies	Serum/Plasma/ Whole Blood	24 Months 2 to 40°C	For consumables refer to WHO Public Report	WHO PQ
CPK-038	Determine Antenatal Care Panel	10T/kit	See IFU	See IFU	Abbott Diagnostics Medical Co., Ltd. Japan	HIV- Ab/Ag/HBsAg/TP- antibodies	Serum/Plasma/ Whole Blood	14 Months 2 to 30°C	For consumables refer to WHO Public Report	WHO PQ
on request	on request	on request	on request	on request	on request	HIV/TP-antibodies	Serum/Plasma/ Whole Blood	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection- Letters are required for procurement	ERPD
06FK10	Bioline Syphilis 3.0	30 T/kit			Abbott Diagnostics Korea	TP-antibodies	Serum/Plasma/ Whole Blood	24 Months 2 to 40°C	Products available from ERPD as RISK CATEGORY-2 / Non-Objection- Letters are required for procurement	ERPD until 5 May 2026

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)

[illegible]

	N/A- NOT APPLICABLE
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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)

LIST OF DIAGNOSTIC TEST KITS FOR HIV
classified according to the QF-QA Policy
HIV Simple Assay

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

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

[illegible]

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

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 GHF countries
Human Papilloma Virus										
The particular requirements from section 10 of the Global Fund QA Policy of Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and core Personal Protective Equipment do not apply for these products. However, the requirements of section 8 should be met.										
Cryptococcal Antigen										
The particular requirements from section 10 of the Global Fund QA Policy of Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and core Personal Protective Equipment do not apply for these products. However, the requirements of section 8 should be met.										