

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

According to Global Fund Quality Assurance Policy for Diagnostic Products (<http://www.theglobalfund.org/en/procurement/policy>), in force since 1st March 2011, Grant Funds may only be used to procure HIV RDTs if they have been:

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

**Criterion 2-** authorized for use by one of the Regulatory Authorities of the Founding Members of GHTF when stringently assessed (high risk classification),

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

**Categories falling under Criterion-1 and -3**

In-Vitro Diagnostic Products with respect to HIV, tuberculosis and malaria and to hepatitis B, hepatitis C and syphilis co-infections, as well as IVDs providing information that is critical for patient treatment of these diseases, such as testing for G6PD deficiency

**Categories falling under Criterion-2**

All under Criterion-1 excluding HIV Self Testing

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

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

The list is adapted from the lists posted in the following websites:

List of HIV diagnostics eligible for procurement by WHO: [http://www.who.int/diagnostics\\_laboratory/procurement/purchase/en/](http://www.who.int/diagnostics_laboratory/procurement/purchase/en/)  
(which has also the products prequalified by WHO [https://www.who.int/diagnostics\\_laboratory/evaluations/181204\\_prequalified\\_product\\_list.pdf?ua=1](https://www.who.int/diagnostics_laboratory/evaluations/181204_prequalified_product_list.pdf?ua=1))

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

### HIV Simple assays/Rapid Diagnostic Tests (RDTs)

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
IHI-T402WG*	ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	40	100.00%	99.70%	ABON Biopharm (Hangzhou) Co. Ltd. Hangzhou, PR China	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 2 to 30°C	Safety lancets, alcohol swabs, specimen droppers(for fingerstick whole blood), 2 chase buffers, specimen dropper for serum/plasma, whole blood	WHO PQ <a href="https://www.who.int/diagnostics_laboratory/evaluations/170317_pq_pr_0141_051_00_amended_final.pdf?ua=1">https://www.who.int/diagnostics_laboratory/evaluations/170317_pq_pr_0141_051_00_amended_final.pdf?ua=1</a>
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	If whole blood: lancets, alcohol swabs, and heparinized capillary tubes with 50 µL mark line and dispensing bulb.	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/170317_pq_pr_0141_051_00_amended_final.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/170317_pq_pr_0141_051_00_amended_final.pdf?ua=1</a>
7D2342*	Alere Determine™ HIV-1/2	20	100%	99.40%	Alere 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 <a href="http://www.who.int/diagnostics_laboratory/evaluations/11125_0033_013_00_public_report_final.pdf">http://www.who.int/diagnostics_laboratory/evaluations/11125_0033_013_00_public_report_final.pdf</a>
7D2343*		100								
7D2343SET*	Alere Determine™ HIV-1/2 SET	100	100%	98.94%	Alere Medical Co. Ltd, Matsudo, Japan	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	18 months 2 to 30°C	Kit of 10 cards of 10 tests, 1 bottle of chase buffer, 100 capillary tubes & 100 blood lancets	
7D2343SETS*									Kit of 10 cards of 10 tests, 1 bottle of chase buffer, 100 capillary tubes & 100 blood lancets (safety)	
7D2846	Alere HIV Combo	20	100%	99.72%	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*	Alere HIV Combo	20	100%	99.40%	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 (7D2222). If serum/plasma: requires precision pipette plus tips.	WHO PQ



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Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
7D2843 *	Alere HIV Combo	100	100%	99.40%	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 (7D2222). If serum/plasma: requires precision pipette plus tips.	<a href="#">WHO PQ</a>
7D2843SET *	Alere HIV Combo SET	100	100%	99.40%	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	Kit of 10 cards of 10 tests, 1 bottle of chase buffer, 100 capillary tubes & 100 blood lancets	<a href="#">WHO PQ</a>
THIV02	Anti-HIV 1/2		100%	100.00%	Turk Lab Turkey	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	4 - 30°C		GHTF (CE mark)
R-401-50-C-2, KH-R-02, A-GOLD-01 *	Diagnostic kit for HIV (1+2) antibody (colloidal gold) V2	50	100%	100.00%	Shanghai Kehua Bio-engineering Co., Ltd	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	18 months 4 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer, EDTA capillary tubes. If serum/plasma: requires, blood collection tubes precision pipette plus tips.	WHO PQ
Z09742CE	"DIAQUICK" HIV 1&2 Ab Cassette	30	100%	100%	Dialab GmbH, Austria	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	24 months 2 to 30°C		GHTF (CE mark)
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,	99.9% (serum/plasma, whole blood, oral fluid)	Chembio Diagnostic Systems, Medford, USA	HIV 1/2 antibodies combined detection	Serum/Plasma /Venous whole blood/ Fingerstick Whole Blood/Oral Fluid	24 months 2 to 30°C	Lancet, sterile gauze, antiseptic wipes Biohazard disposal container For venipuncture whole blood collection and serum/plasma specimens: Venipuncture apparatus and blood collection tubes Precision pipette capable of delivering 5µL of sample (with disposable tips) may be used in lieu of the disposable 5µL sample loop supplied with the kit (for other than fingerstick whole blood specimens)	<a href="#">WHO PQ</a>
I05FRC05 *	First Response™ HIV 1-2-0 Card Test	5	100%	99.39%	Premier Medical Corporation, Nani Daman, India	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	23 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	<a href="#">WHO PQ</a>
I05FRC25 CE	First Response™ HIV 1-2-0 Card Test	25	100%	99.39%	Premier Medical Corporation, Nani Daman, India	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	GHTF (CE mark)
I05FRC30 *	First Response™ HIV 1-2-0 Card Test	30	100%	99.39%	Premier Medical Corporation, Nani Daman, India	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	23 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	<a href="#">WHO PQ</a>
I05FRC30 CE	First Response™ HIV 1-2-0 Card Test	30	100%	99.39%	Premier Medical Corporation, Nani Daman, India	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	GHTF (CE mark)

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Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
I05FRC60 *	First Response™ HIV 1-2-0 Card Test	60	100%	99.39%	Premier Medical Corporation, Nani Daman, India	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	<a href="#">WHO PQ</a>
I05FRC100 *	First Response™ HIV 1-2-0 Card Test	100	100%	99.39%	Premier Medical Corporation, Nani Daman, India	Discrimination between HIV-1 and HIV-2 Antibodies	Serum/Plasma /Whole Blood	24 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	<a href="#">WHO PQ</a>
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	<a href="#">WHO PQ</a>
72327 *		25								
72347 *		25							with support materials: diluent, disposable pipette, microsafes, lancets, alcohol swabs	
57002P	Hexagon HIV	40	100%	99.90%	Human Gesellschaft für Biochemica und Diagnostica mbH Germany	HIV 1/2 antibodies combined detection	Whole blood, serum or plasma	2 to 8°C		GHTF (CE mark)
57004P	Hexagon HIV	100	100%	99.90%	Human Gesellschaft für Biochemica und Diagnostica mbH Germany	HIV 1/2 antibodies combined detection	Whole blood, serum or plasma	2 to 8°C		GHTF (CE mark)
HIV303 *	HIV 1/2 STAT-PAK Dipstick	30	100%	99.70%	Chembio Diagnostic Systems, Medford, USA	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 8 to 30°C	If whole blood: lancets, alcohol swabs. If alternate procedure: must order sample tubes and tube rack.	<a href="#">WHO PQ</a>
HIV101 *	HIV 1/2 STAT-PAK™	20	99.30%	100%	Chembio Diagnostic Systems, Medford, USA	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 8 to 30°C	If whole blood: lancets, alcohol swabs. HIV Test Kit Controls (HIV104) available.	WHO PQ <a href="https://www.who.int/diagnostics_laboratory/evaluations/120116_0007_006_00_public_report_final_v1.pdf?ua=1">https://www.who.int/diagnostics_laboratory/evaluations/120116_0007_006_00_public_report_final_v1.pdf?ua=1</a> GHTF (FDA, PMA)



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Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
90-1010*	INSTI HIV-1/2 Antibody Test Kit	24	100%	99.70%	BioLytical Laboratories, Richmond, Canada	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	15 months 15 to 30 °C	24 T/kit; 24 T/kit with support materials; 48 T/kit; 48 T/kit with support materials If 90-1010, 90-1021: lancets, alcohol swabs, precision pipette plus tips.	WHO PQ <a href="https://www.who.int/diagnostics_laboratory/evaluations/130829_0002-002-00_public_report_final_v1.pdf">https://www.who.int/diagnostics_laboratory/evaluations/130829_0002-002-00_public_report_final_v1.pdf</a>
90-1013*		24								
90-1021*		48								
90-1022*		48								
25228	Multispot HIV-1/HIV-2 Rapid Test	50	100% HIV-1 (serum) 100% HIV-1 (plasma) 100% HIV-2 (serum/plasma)	99.93% serum 99.91% plasma	Bio-Rad Laboratories, Marnes La Coquette, France and Steenvoorde, France	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma	12 Months 2 to 8°C or room temperature (20-30°C) for up to 3 months	Disposable glass or polypropylene test tubes (not polystyrene) for dilutions, e.g. 12 x 75mm tubes Test tube racks Biohazard waste containers	GHTF (FDA, PMA)
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)
ITP02121-TC40	ONE STEP Anti-HIV(1&2 ) Test	40	99.8%	99.23%	InTec PRODUCTS, INC. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, 361022, P.R. China	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Accessories: plastic dropper (pippette)	GHTF (CE mark)
ITP02122-TC40	ONE STEP Anti-HIV(1&2 ) Test	40	99.8%	99.23%	InTec PRODUCTS, INC. 332 Xinguang Road, Xinyang Ind. Area, Haicang, Xiamen, 361022, P.R. China	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Accessories: plastic dropper (pippette), safety lancets, alcohol swabs	GHTF (CE mark)
ITP02122-TC10		10					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Accessories: plastic dropper (pippette), safety lancets, alcohol swabs	GHTF (CE mark)
W006-C4P2	Wondfo® One Step HIV1/2 Whole Blood/Serum/Plasma Test	25			Guangzhou Wondfo Biotech Co. Ltd 8 Lizhishan Road, Science City, Luogang District, Guangzhou, 510663 P.R. China	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 1 bottle × 5mL/bottle Accessories: not included	WHO PQ
W006-C4P2-F		40					Serum/Plasma /Whole Blood	24 months 2 to 30 °C	Buffer solution included: 2 bottles × 5mL/bottle Accessories: not included	
5X4-0010*	OraQuick® HIV-1/2 - Rapid Antibody Test	100	100%	99.20%	OraSure Technologies Bethlehem, USA (manufactured in Thailand)	HIV 1/2 antibodies combined detection	Serum/Plasma /Whole Blood/Oral Fluid	30 months 2 to 30°C	If whole blood: lancets, alcohol swabs, additional specimen loops (004-001).	WHO PQ
5X4-0012*		500								
5X4-0014*		100							If whole blood: lancets, alcohol swabs, additional specimen loops (004-001). Consult WHO PQ Public Report for country specific labelling.	
5X4-0015*		500								
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								



## 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	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
WJ-1810*	Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device)	10T/kit w/accessories	100%	98.48%	Beijing Wantai Biological Pharmacy Enterprise Co.	HIV 1/2 antibodies combined detection	Serum/Plasma/ Whole Blood	18 months 2 to 30 °C		<a href="#">WHO PQ</a>
WJ-1810E*		10T/kit								
WJ-1850*		25T/kit								
WJ-1850E*		50T/kit								
03FK17*	SD Bioline HIV-1/2 3.0	25	99.80%	99.90%	Standard Diagnostics, (Giheung-gu, Yongin-si, Korea)	Discrimination between HIV1 and HIV-2 antibodies	Serum/Plasma /Whole Blood	24 months 1 to 30°C	Safety lancets, alcohol swabs, capillary tube, chase buffer	<a href="#">WHO PQ</a>
03FK16*	SD Bioline HIV-1/2 3.0	25	99.80%	99.90%	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.	<a href="#">WHO PQ</a>
03FK10*		30								
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	<a href="#">WHO PQ</a> <a href="#">GHTF (FDA, PMA)</a>
1206502 + 1206502N+ 1206502E*	UniGold 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	If whole blood: lancets, alcohol swabs. 20 Test Devices, 1 vial Wash Reagent (2 ml) and 20 Disposable Pipettes	<a href="#">WHO PQ</a>
1206502N-100*		100							If whole blood: lancets, alcohol swabs. 100 Test Devices, 5 vials Wash Reagent (2 ml) and 100 Disposable Pipettes	
31112*	VIKIA HIV 1/2	25	99.40%	99.90%	bioMérieux SA Marcy L'Etoile, France	HIV 1/2 antibody combined detection	Serum/Plasma /Whole Blood	21 months 4 to 30°C	If whole blood: lancets, alcohol swabs.	<a href="#">WHO PQ</a>

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

HIV Self Tests / 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	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
ARST-001	Atomo HIV Self-Test	1	on request	on request	Atomo Diagnostics Pty Ltd, Leichhardt, Australia	HIV 1/2 antibodies combined detection	Whole Blood	Shelf life on request 2 to 30°C	ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	ERPD until 28th November 2019
90-1071 *	INSTI HIV Self Test	1	99.80%	99.50%	BioLytical Laboratories, Richmond, Canada	HIV 1/2 antibodies combined detection	Whole Blood	15 Months 2 to 30°C		WHO PQ <a href="https://www.who.int/diagnostics_laboratory/evaluations/pq-list/181130_pqdx_0002_002_01_pqpr_insti_self_test.pdf?ua=1">https://www.who.int/diagnostics_laboratory/evaluations/pq-list/181130_pqdx_0002_002_01_pqpr_insti_self_test.pdf?ua=1</a>
5X4-1000 *	OraQuick HIV Self-Test	50	99.02%	100.00%	OraSure Technologies Inc, Bethlehem, USA (manufactured in Thailand)	HIV 1/2 antibodies combined detection	Oral fluid	30 Months 2 to 30°C	Community Version Individual Test pouches are labeled 5X4-0004	WHO PQ <a href="https://www.who.int/diagnostics_laboratory/evaluations/pq-list/180622_amended_final_pqpr_0159_055_01_hiv_self_test_v8.pdf?ua=1">https://www.who.int/diagnostics_laboratory/evaluations/pq-list/180622_amended_final_pqpr_0159_055_01_hiv_self_test_v8.pdf?ua=1</a>
5X4-1001 *		250								
5X4-2001 *		110								
60-9508-0	SURE CHECK® HIV Self-Test	1	on request	on request	Chembio Diagnostic Systems, Medford, USA	HIV 1/2 antibodies combined detection	Whole Blood	Shelf life on request 2 to 30°C	ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	ERPD until 28th November 2019

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**
**HIV Supplemental assays**

**\* (star) mark is WHO prequalified**

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Format	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
72460	Geenius HIV 1/2 Confirmatory assay	20	100%	100%	Bio-Rad Laboratories, Marnes La Coquette, France and Bio-Rad Laboratories, Steenvoorde, France	HIV 1/2 antibodies	Immuno Chromatographic Test/ Cassette	18 months 2 to 30°C	Serum, Plasma, Venous/capillary whole blood specimen Precision pipette (and disposable tips) Lancets and alcohol swab for fingerstick protocol	WHO PQ and GHTF (CE mark)
71121	Genscreen™ HIV-1 Ag Confirmatory Assay	25			Bio-Rad 3, boulevard Raymond Poincaré 92430 Marnes-la-Coquette - France	HIV-1 p24 antigen		18 months 2 to 30°C	To confirm the presence of HIV-1 p24 antigen	GHTF (CE mark)
80540 *	INNO-LIA™ HIV I/II Score	20	N/A	N/A	Fujirebio Europe N.V., Ghent, Belgium	Discrimination between HIV-1 and HIV-2 antibodies	Line Immuno Assay / recombinant proteins, synthetic peptides	16 months 2 to 8°C	Safety lancets, alcohol swabs, specimen droppers (for fingerstick whole blood), 2 chase buffers, specimen dropper for serum/plasma, whole blood	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/150508_final_report_innolia_hiv_score.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/150508_final_report_innolia_hiv_score.pdf?ua=1</a> and GHTF (CE mark)
11030-018 *	MP Diagnostics HIV Blot 2.2	18	N/A	N/A	MP Biomedicals Asia Pacific, Singapore	Discremination between HIV-1 and HIV-2 antibodies	Western Blot/ Viral Lysate, synthetic peptides	24 months 2 to 8°C	Not suitable for whole blood Requires precision pipette plus tips and other consumables.	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/160404_final_public_report_0198_071_00_v2.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/160404_final_public_report_0198_071_00_v2.pdf?ua=1</a> and GHTF (CE mark)
11030-036 *		36								
72251	NEW LAV BLOT I	18	N/A	N/A	Bio-Rad Laboratories Steenvoorde, France	HIV-1 antibodies	Western Blot/ Viral Lysate	18 months 2 to 8°C	Precision pipette (and disposable tips), measuring cylinders, distilled or deionised water	GHTF (CE mark)
72252	NEW LAV BLOT II	18	N/A	N/A	Bio-Rad Laboratories Steenvoorde, France	HIV-2 antibodies	Western Blot/ Viral Lysate	18 months 2 to 8°C	Not suitable for whole blood Precision pipette (and disposable tips), measuring cylinders, distilled or deionised water	GHTF (CE mark)
72253	Pepti-Lav 1-2	10	N/A	N/A	Bio-Rad Laboratories Steenvoorde, France	Discremination between HIV-1 and HIV-2	Line Immuno assay/ Synthetic peptides	4 months 2 to 8°C	Not suitable for whole blood Precision pipette (and disposable tips), measuring cylinders, distilled or deionised water	GHTF (CE mark)

**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

## HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA])

\* (star) mark is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
7G 46	Abbott PRISM HIV Ag/Ab Combo Assay	upto 5000	100% (but with 19% "void" results)	99.96% (blood donor specimens)	Abbott Diagnostics, Wiesbaden, Germany	HIV1/2 antibodies combined and HIV1-p24 antigen	3 months 2 to 8°C	Serum and plasma specimen Activator concentrate, Activator diluent	GHTF (TGA)
WI-4396 *	AiD anti-HIV 1+2 ELISA	96	100.00%	99.92%	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	HIV-1/2 antibodies and HIV-1 p24 antigen	2 to 8°C	Serum or plasma	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/160218_final_public_report_pqdx_006_005_00_aid_anti_hiv_1_2_elisa.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/160218_final_public_report_pqdx_006_005_00_aid_anti_hiv_1_2_elisa.pdf?ua=1</a>
WI-43480 *	AiD anti-HIV 1+2 ELISA	480	100.00%	99.92%	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	HIV-1/2 antibodies and HIV-1 p24 antigen	2 to 8°C	Serum or plasma	GHTF (CE mark)
790000	apDia HIV Ab & Ag Elisa	96	100.00%	99.60%	apDia bvba, Raadsherenstraat 3, B-2300 Turnhout, Belgium	HIV-1/2 antibodies and HIV-1 p24 antigen	15 months 2 to 8°C	Serum or plasma	GHTF (CE mark)
790001		196	100.00%	99.60%					
790005		480	100.00%	99.60%					
3000-1172 *	Bioelisa HIV 1+2 Ag/Ab	96	100%	99.40%	Biokit S.A. Barcelona, Spain	HIV-1/2 antibodies and HIV-1 p24 antigen	9 months 2 to 8°C	Human serum and plasma specimens	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/150302_final_report_biolisa_hiv_ag_ab_v3.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/150302_final_report_biolisa_hiv_ag_ab_v3.pdf?ua=1</a>
3000-1173 *		480							
259851	Vironostika HIV Ag/Ab	192	100.00%	99.50%	bioMérieux SA 69280 - Marcy-l'Etoile / France RCS LYON 673 620 399	HIV-1/2 antibodies and HIV-1 p24 antigen	2 to 8°C	Serum or plasma	GHTF (CE mark)
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)
I-1654 *	DS-EIA-HIV-AGAB-SCREEN	96/1 plate	100%	99.60%	RPC «Diagnostic Systems», Ltd. Nizhny Novgorod Russian Federation	HIV1/2 antibodies combined and HIV1-p24 antigen	24 months 2-8 °C	Serum or plasma specimen	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/150729_final_report_0106_038_00_cia.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/150729_final_report_0106_038_00_cia.pdf?ua=1</a> GHTF (CE mark)
I-1652 *		192/2 plates							
I-1656 *		480/5 plates							



## HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA])

\*  
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Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
OPKR03, OPKR05, OPKR05(Q), OUVP17	Enzygnost HIV Integral 4 and Supplementary reagents kit for Enzygnost®/TMB	96T/kit 960T/kit 960T/kit (for higherthroughput)	100%	99.80%	Siemens Healthcare Diagnostics Products GmbH Marburg, Germany	Qualitative detection of HIV p24 antigen and specific antibodies to human immunodeficiency viruses of type 1 and 2 (HIV-1 including HIV-1 subtype O virus and HIV-2)	12 months 2-8 °C	Human serum and plasma specimens	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/160324_final_public_report_0214_064_00.pdf">http://www.who.int/diagnostics_laboratory/evaluations/160324_final_public_report_0214_064_00.pdf</a>
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 <a href="http://www.who.int/diagnostics_laboratory/evaluations/160324_final_public_report_0214_064_00.pdf">http://www.who.int/diagnostics_laboratory/evaluations/160324_final_public_report_0214_064_00.pdf</a>
72388		480							
71120	Genscreen™ HIV-1 Ag Assay	192		99.95%	Bio-Rad 3, boulevard Raymond Poincaré 92430 Marnes-la-Coquette - France	HIV1- p24 antigen	months 2 to 8°C	Human Serum, Plasma and Cell Culture Supernatant	GHTF (CE mark)
26217	GS HIV Combo Ag/Ab EIA	192	100% (manual method) 100% (Evolis system)	99.87% (manual method) 99.97% (Evolis system)	Bio-Rad Laboratories, Steenvoorde, France	HIV-1 p24 antigen and HIV1/2 antibodies	18 months 2 to 8°C	Serum and plasma specimen For product code 26218 (960 tests): wash solution (25261) and stopping solution (25260) must be ordered separately. Biohazard disposal container For venipuncture serum/plasma specimens: Venipuncture apparatus and blood collection tubes Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs, deionized or distilled water. The GS HIV Combo Ag/Ab EIA is approved for use with the Bio-Rad EVOLIS™ Automated Microplate System.	GHTF (FDA, PMA)
26218		960							
IVCOMB.CE	HIV Ab & Ag Elisa	192	100.00%	99.50%	DIA.PRO Diagnostic Bioprobes S.r.l. Italy	HIV-1/2 antibodies and HIV-1 p24 antigen	15 months 2 to 8°C	Serum or plasma	GHTF (CE mark)
IVCOMB.CE 96		96	100.00%	99.50%					
IVCOMB.CE 480		480	100.00%	99.50%					
IVCOMB.CE 960		960	100.00%	99.50%					
Z01375	HIV 1&2 Ab, cut-off	1x96	100.00%	99.92%	Dialab GmbH, Austria	HIV-1/2 antibodies	15 months 2-8°C	Serum or plasma	GHTF (CE mark)
Z03502		5x96	100.00%	99.92%					
Z03503		6x96	100.00%	99.92%					
Z09375		2x96	100.00%	99.92%					



## HIV Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA])

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
880007	HIV 1+2 Ab Elisa	96	100.00%	99.90%	Axiom GmbH Am Jahnplatz 5 68642 Bürstadt Germany	HIV 1/2 antibodies combined	15 months 2 to 8°C	Human serum and plasma specimens	GHTF (CE mark)
880007s		480							
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 deionized water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09 02). For use in laboratory incubators. 6. Instrumentation a) Automated microplate strip washer. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	GHTF (CE mark, TGA)
9E25-02		480							
7G79-09 *	Murex HIV Ag/Ab Combination	96	100%	99.78%	DiaSorin Dartford, United 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 <a href="http://www.who.int/diagnostics_laboratory/evaluations/150330_final_report_murex_hiv_ag_ab.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/150330_final_report_murex_hiv_ag_ab.pdf?ua=1</a> 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])

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

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

N/A- NOT APPLICABLE

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

CD4 Enumeration technologies

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

Manufacturer Product Catalogue number	Product Name	Cell counting	Number of tests per kit	Manufacturer	Shelf life (months)/ Storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries	
B39101, B39102, B30166 B25697, * B25698, B23536, B23538, B23533, B23534, B23535, B25700, B23502	Aquios CL flow cytometer	total CD3+, CD3+CD4+, CD3+CD8+, CD3+CD4+/CD3+CD8+ (ratio only) lymphocyte percentages and absolute counts; CD45+ absolute count; and CD45+ Low SS (lymphocytes) percentage and absolute count.	Flow cytometry instrument	Beckman Coulter Life Sciences Miami, FL, USA (instrument site) and Hialeah, FL, USA (reagent site)	B30166	N/A	Venous Whole Blood	N/A	WHO PQ (PQ Public Report) <a href="http://www.who.int/diagnostics_laboratory/evaluations/151109_final_report_0156-053-oo_aquios_cl_flow_cytometer.pdf">http://www.who.int/diagnostics_laboratory/evaluations/151109_final_report_0156-053-oo_aquios_cl_flow_cytometer.pdf</a>
			1x10ml		B25697	18 - 26°C/18M			
			1x500ml		B25698	Safety lancets, alcohol swabs, specimen droppers (for fingerstick whole blood), 2 chase buffers, specimen dropper for serum/plasma, whole blood			
			4x50ml		B23536	18 - 26°C/12M			
			1 x 38ml, 1 x 15ml (100 tests)		B23538	18 - 26°C/350 days			
			1 x 0.9ml (50 tests)		B23533	2 - 8°C/12M			
			1 x 0.9ml (50 tests)		B23534	2 - 8°C/12M			
			2x 3ml		B23535	2 - 8°C/270 days			
			2x 3ml		B25700	2 - 8°C/270 days			
			50 plates/box		B23502	N/A			
337858 * (Instrument) 340166 (control kit) 340167 (Test Kit)	BD FACSCount™ Instrument System with FACSCount™ Control Kit and BD FACSCount™ Reagent Kit	Absolute CD4+, CD8+, CD3+ Counts	337858: instrument system 340166: 25T /kit 340167: 50T/kits	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	23 months (reagents) 24 months (control) 2 to 8°C	Venous Whole Blood	N/A	WHO PQ (PQ Public Report) <a href="http://www.who.int/diagnostics_laboratory/evaluations/121115_0124_045_oo_public_report_v2_final.pdf">http://www.who.int/diagnostics_laboratory/evaluations/121115_0124_045_oo_public_report_v2_final.pdf</a>	
337858 * (Instrument) 340166 (control kit) 339010 (Test Kit)	BD FACSCount™ Instrument System with FACSCount™ Control Kit and BD FACSCount™ CD4 Reagent Kit	Absolute and Percentage CD4+ Counts	337858: instrument system 340166: 25T/kits 339010: 50T/kits	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	15 months (reagents) 24 months (control) 2 to 8°C	Venous Whole Blood	N/A	WHO PQ (PQ Public Report) <a href="http://www.who.int/diagnostics_laboratory/evaluations/121115_0133_045_oo_public_report_v1_final.pdf">http://www.who.int/diagnostics_laboratory/evaluations/121115_0133_045_oo_public_report_v1_final.pdf</a>	
Accordinging model (Instrument) Accordinging model (control kit) 342 444 (Test Kit)	BD FACSCalibur™ / BD FACS Lyric / BD FACS Via Instrument System with Control Kit and BD Tritest CD3/CD4/CD45	Absolute and Percentage CD3/CD4/CD45 Counts	50T/kits with BD Trucount tubes	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	on request	Whole venous EDTA blood	ERP as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	ERP until 9th December 2019	
Accordinging model (Instrument) Accordinging model (control kit) 342 445 (Test Kit)	BD FACSCalibur™ / BD FACS Lyric / BD FACS Via Instrument System with Control Kit and BD Tritest CD4/CD8/CD3	Absolute and Percentage CD4/CD8/CD3 Counts	50T/kits with BD Trucount tubes	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	on request	Whole venous EDTA blood	ERP as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	ERP until 9th December 2020	



## CD4 Enumeration technologies

* Product codes superscripted with a (star) mark is WHO prequalified								
Manufacturer Product Catalogue number	Product Name	Cell counting	Number of tests per kit	Manufacturer	Shelf life (months)/ Storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
According model (Instrument) According model (control kit) 342 447 (Test Kit)	BD FACSCalibur™ / BD FACS Lyric / BD FACS Via / BD FACS Canto / BD FACS Canto II Instrument System with Control Kit and BD Multitest CD3/CD8/CD45/CD4	Absolute and Percentage CD3/CD8/CD45/CD4 Counts	50T/kit with BD Trucount tubes	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	on request	Whole venous EDTA blood	ERPD as RISK CATEGORY-2 / Non-Objection- Letters are required for procurement	ERPD until 9th December 2021
260300001/ 260300003/ 260300004 * , 260100025 and 2603000011	PIMA CD4 Test	Absolute CD4+ Counts	25 cartridges/kit and instrument;	Alere Technologies GmbH, Jena, Germany	12 months for reagents 2 to 30°C for reagents	Venous and Capillary whole blood	Accessories available	WHO PQ (PQ Public Report) <a href="http://www.who.int/diagnostics_laboratory/evaluations/131219_0099_032_00_public_report_final_v4.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/131219_0099_032_00_public_report_final_v4.pdf?ua=1</a>
260300001/ 260300003/ 260300004 * , 260100100 and 2603000011			100 cartridges/kit and instrument					
CY-S-3022 (equipment)* 05-8401 (absolute)* 05-8405 (percentage)*	CyFlow Instrument CD4 Easy-Count Reagent Kit CD4% Easy-Count Reagent Kit	Absolute and Percentage CD4+ Counts	100T/kit	Sysmex Partec, Görlitz, Germany	14 months for reagents 2 to 8°C for reagents	Venous Whole Blood	N/A	WHO PQ (PQ Public Report)
MCA100101 (Test kit)  0500-3252 (equipment) *	Muse Auto CD4/CD5 kit (reagent and lysing solution) for Muse Cell Analyzer with Muse Auto CD4/CD4% software (equipment)	Absolute and Percentage CD4+ Counts	100T/kit	EMD Millipore Corporation, Temecula, USA	24 months 2 to 8°C for antibody cocktail 18 to 25°C for lysing solution	EDTA whole blood	N/A	WHO PQ (PQ Public Report) <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/cd4/180524_amende_final_pqr_0324_106_00.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/cd4/180524_amende_final_pqr_0324_106_00.pdf?ua=1</a>
MCA500101 (Test kit)  0500-3252 (equipment) *			500T/kit					
MCA1XK101 (Test kit)  0500-3252 (equipment) *			1000T/kit					
651000 , 657681 and 655495 *	BD FACSPresto™ Near-Patient CD4 Counter with BD CD4%CD4/Hb Cartridge and BD FACSPresto™ Cartridges Kit	Absolute and Percentage CD4+ counts and Hemoglobin measurement	each box contain 100 catridges and 100 pipets	Becton, Dickinson and Company, BD Biosciences San Jose, California, USA	12 months for cartridges 4 to 31°C for cartridges	human capillary and venous blood specimens	651000: instrument 657681: cartridge (100/box) and 655495: pipette (100/box)	WHO PQ (PQ Public Report) <a href="http://www.who.int/diagnostics_laboratory/evaluations/140918_public_report_bdfacspresto_cd4.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/140918_public_report_bdfacspresto_cd4.pdf?ua=1</a>

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**List of HIV Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy**
**HIV Virological technologies**
**\* Product codes superscripted with a (star) mark is WHO prequalified**

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
4N66-90*	Abbott Real Time HIV-1 Qualitative (Manual)	96T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HIV 1 Qualitative DNA	18 months	-10°C	Plasma and dried blood	For consumables refer to WHO eligible list <a href="http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1">http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1</a>	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> <a href="http://www.who.int/diagnostics_laboratory/evaluations/130530_0151_027_00_public_report_final.pdf">http://www.who.int/diagnostics_laboratory/evaluations/130530_0151_027_00_public_report_final.pdf</a>
4N66-80		8 runs						-10°C			
6K12-24		4x24						15 to 30°C			
9K15-01		instrument									
4N66-01											
4N66-66 (optional)								-30 to -10°C			
4N66-90*	Abbott Real Time HIV-1 Qualitative (m2000sp)	96T/kit	N/A	N/A	Abbott Molecular Inc Des Plaines IL, USA	HIV 1 Qualitative DNA	18 months	-10°C	Plasma and dried blood	For consumables refer to WHO eligible list <a href="http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1">http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1</a>	WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. <u>For the automated</u> <u>configuration</u> <u>see:</u> <a href="http://www.who.int/diagnostics_laboratory/evaluations/130530_0084_027_00_public_report_final.pdf">http://www.who.int/diagnostics_laboratory/evaluations/130530_0084_027_00_public_report_final.pdf</a>
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			
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 <a href="http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1">http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1</a>	WHO PQ and GHTF (CE mark) <a href="http://www.who.int/diagnostics_laboratory/evaluations/120113_0146_027_00_final_public_report_v2.pdf">http://www.who.int/diagnostics_laboratory/evaluations/120113_0146_027_00_final_public_report_v2.pdf</a>
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			

## HIV Virological technologies

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
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 <a href="http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1">http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1</a>	WHO PQ and GHTF (CE mark)
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*		Abbott Real Time HIV-1 (m24sp)						instrument			
2G31-90,	96T/kit		-10°C								
2G31-80	8 runs		-10°C								
2G31-70	4 calibrations		-10°C								
2G31-66			-10°C								
1L68-09											
9K15-01	instrument										
04J70-24											
04J71-93											
HIV-1211	AccuPower® HIV-1 Quantitative RT-PCR Kit	96T/kit	N/A	N/A	Bioneer Corporation, Cheongwon 151-27, Namseok-ro, Seowongu, Cheongju-si, Chngcheongbuk-do, 28182, Republic of Korea	HIV-1/2 Qualitative RNA	12 months	-25°C to -15°C	EDTA Plasma	For consumables and details of componants refer to IFU	GHTF (CE mark)
	ExiStation™ Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			



## HIV Virological technologies

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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
270300001	Alere™ q System	Instrument	N/A	N/A	Abbott Alere Technologies GmbH, Germany Loebstedter Str. 103-105 07749 Jena Germany	HIV-1/2 Qualitative RNA	Not applicable	Not applicable	Whole Blood, Plasma	For consumables and alternative Alere™ q Complete (product code 270300002) Alere™ q Complete II (product code 270300002) refer to WHO Public Report	WHO PQ and GHTF (CE mark) <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/160902_amended_public_report_0226_03_2_00_alere_hiv_detect_v3.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/160902_amended_public_report_0226_03_2_00_alere_hiv_detect_v3.pdf?ua=1</a>
270110010*	Alere™ q HIV-1/2 Detect	10 Cartridges					9 months	4-30°C			
270110050*		50 Cartridges					9 months	4-30°C			
PRD-03000	Aptima HIV-1 Quant Dx Assay Kit (Panther System)	100T/kit	N/A	N/A	Hologic, Inc 10210 Genetic Center Drive San Diego, CA 92121	HIV1 Quantitative RNA	24 months	2°C-8°C	Plasma	Multi-tube units (MTUs), Panther Waste Bag Kit, Panther Waste Bin Cover, Aptima Assay Fluids, and Tips are included and calculated based on number of kits ordered)	WHO PQ and GHTF (CE mark) <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/180207_final_pqpr_0236_078_00_v5_IFU_v4.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/180207_final_pqpr_0236_078_00_v5_IFU_v4.pdf?ua=1</a>
PRD-03001		5 runs						-15 to -35°C			
PRD-03002		5 calibrators						-15 to -35°C			
303095		instrument					NA	NA			
4513263	artus HI Virus-1 RG RT-PCR (Rotor-Gene Q 5plex)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HIV1 Quantitative RNA	20 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4513265		96						-30°C to -15°C			
9001640		instrument									
60704	QIAamp DSP Virus Kit	extraction kit 50T/kit					12 months	2°C to 8°C			
4513363	artus HI Virus-1 QS-RGQ (QIASymphony SP/AS - Rotor-Gene Q)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HIV1 Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark, TGA)
4513366		72						-30°C to -15°C			
9001297 and 9001640		instrument									
937055	QIASymphony® DSP Virus/Pathogen	extraction kit 96T/kit					14 months	15°C - 25°C			
TR001-250IC	Generic HIV Charge Virale	220	NA	NA	Biocentric Bandol France	HIV1 Quantitative RNA	12 months	-30°C to -8°C	EDTA or citrated Plasma		GHTF (CE mark)
TR001-440IC	Generic HIV Charge Virale	440									

## 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	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
Vo-96/3FRT	HIV Real-TM Quant Dx	96	N/A	N/A	Sacace Biotechnologies Srl Como – Italy	HIV1 Quantitative RNA	12 months	2 to 8°C	Human Plasma		GHTF (CE mark)
<sup>*</sup> 280140	NucliSENS EasyQ HIV-1 V2.0 (Automated)	instrument	N/A	N/A	bioMerieux SA, Marcy l'Etoile, France	HIV1 Quantitative RNA	NA		Plasma dried blood spot (venous whole blood)	For consumables refer to WHO eligible list <a href="http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1">http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1</a>	WHO PQ and GHTF (CE mark) <a href="http://www.who.int/diagnostics_laboratory/evaluations/120109_0127_016_00_public_report_v1.pdf">http://www.who.int/diagnostics_laboratory/evaluations/120109_0127_016_00_public_report_v1.pdf</a>
280130		4x1lit					24 months	2 to 30°C			
280131		4x1lit					18 months	2 to 30°C			
280132		4x1lit					15 months	2 to 8°C			
280133		4x1lit					18 months	2 to 8°C			
280134		4x1lit					24 months	2 to 30°C			
285056		instrument					NA				
200309											
285033		48T/kit					18 months	2 to 8°C			
<sup>*</sup> 200305	NucliSENS EasyQ HIV-1 V2.0 (Semi Automated)		N/A	N/A	bioMerieux SA Marcy l'Etoile, France	HIV1 Quantitative RNA			Plasma dried blood spot (venous whole blood)	For consumables refer to WHO eligible list <a href="http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1">http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1</a>	WHO PQ and GHTF (CE mark) <a href="http://www.who.int/diagnostics_laboratory/evaluations/120109_0127_016_00_public_report_v1.pdf">http://www.who.int/diagnostics_laboratory/evaluations/120109_0127_016_00_public_report_v1.pdf</a>
200293		48T/kit					18 months	2 to 8°C			
200292		48T/kit					24 months	2 to 30°C			
285056		instrument					NA				
200309											
285033		48T/kit					18 Months				
<sup>*</sup> 03279332001	COBAS AmpliPrep/COBAS Taqman HIV-1 Test Version 2.0 (Taqman 48)	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 Quantitative RNA	NA		Plasma or PSC dried plasma spot (with PCS)	For consumables refer to WHO eligible list <a href="http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1">http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1</a>	WHO PQ and GHTF (CE mark) <a href="http://www.who.int/diagnostics_laboratory/evaluations/120502_0126_046_00_public_report_v1_final.pdf">http://www.who.int/diagnostics_laboratory/evaluations/120502_0126_046_00_public_report_v1_final.pdf</a>
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			
<sup>*</sup> 03121453001	COBAS AmpliPrep/COBAS Taqman HIV-1 Test Version 2.0 (Taqman 96)	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 Quantitative RNA	NA		Plasma or dried plasma spot (with PCS)	For consumables refer to WHO eligible list <a href="http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1">http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procurement_2014.pdf?ua=1</a>	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/120502_0127_046_00_public_report_v1_final.pdf">http://www.who.int/diagnostics_laboratory/evaluations/120502_0127_046_00_public_report_v1_final.pdf</a>
03051315001		instrument					NA				
04862392001		software					NA				
05807875001		software					NA				
05527503001		instrument					NA				
05212294190		48T/kit					18 Months	2 to 8°C			
03587797190		5.1L					24 months	2 to 30°C			
28127387001											



## 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	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
06693083190*	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 48)	48 T/KIT	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 DNA & RNA Qualitative	22 months	2 to 8°C	Plasma or dried blood spots		WHO PQ For a full list of consumables required, see WHO Public Reports. <a href="http://www.who.int/diagnostics_laboratory/evaluations/141216_final_report_taqman48_0221_v2.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/141216_final_report_taqman48_0221_v2.pdf?ua=1</a>
03051315001		instrument									
03279332001		instrument									
03587797190		5.1L					24 months	2 to 30°C			
06989861190		5 x 78ml									
05807875001		software									
03516440001		instrument									
28127387001											
06693083190*	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 96)	48T/kit	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 DNA & RNA Qualitative	22 months	2 to 8°C	Plasma or dried blood spots		WHO PQ For a full list of consumables required, see WHO Public Reports. <a href="http://www.who.int/diagnostics_laboratory/evaluations/141216_final_report_taqman96_0200_v2.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/141216_final_report_taqman96_0200_v2.pdf?ua=1</a>
03587797190		5.1L					24 months	2 to 30°C			
06989861190		5 x 78ml					12 months	2 to 8°C			
03051315001		instrument									
03121453001		instrument									
28127387001											
05807875001		software									
03516440001		instrument									
5923468190	COBAS® TaqMan® HIV-1 Test, Version 2 for use with High pure system	48 tests	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 Quantitative RNA	24 months*	2 to 8°C	Plasma		GHTF (CE mark)
3502295001	High Pure System Nucleic Acid Kit	48 tests					12 months*	15 to 25°C			
05 200 881 001	COBAS® z 480	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	N/A	N/A	N/A	N/A		GHTF (CE mark)
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
06 979 599 190	COBAS® HIV-1 Test for use with 4800	120 tests	N/A	N/A		HIV-1 Quantitative RNA		2 to 8°C	Plasma		
05524245001 and 06379664001	COBAS® p 680	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	N/A	N/A	N/A	N/A		GHTF (CE mark)
5412722001	COBAS® p 880	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
06 998 836 190 with 07 963 084 190	COBAS® HIV-1 Test for use with 6800/8800 and PCS	96 tests/kit	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV-1 Quantitative RNA		2 to 8°C	Plasma or dried plasma spot (with PCS)		GHTF (CE mark)
06 998 836 190	COBAS® HIV-1 Test for use with 6800/8800	96 tests/kit	N/A	N/A		HIV-1 Qualitative RNA		2 to 8°C	Plasma and dried blood spots		

## 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	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
I19-0005	SAMBAprep	instrument	N/A	N/A	Diagnostics for the Real World, Sunnyvale, CA 94085 USA	N/A	N/A	N/A	N/A		GHTF (CE mark)
I19-0004	SAMBAamp	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
4100-12	SAMBA HIV-1 Semi-Q	12 tests	N/A	N/A		HIV-1 Semi-Q RNA target	9 months	2 to 37°C	Plasma		
4200-12	SAMBA I HIV-1 Qual Whole Blood Test	12 tests	N/A	N/A		HIV-1 Qualitative DNA/RNA target			Whole Blood		
I19-0006-AM	SAMBA II Assay Module	instrument	N/A	N/A	Diagnostics for the Real World, Sunnyvale, CA 94085 USA	N/A	N/A	N/A	N/A		GHTF (CE mark)
I19-0006-TM	SAMBA II Tablet Module	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
4400-12	SAMBA II HIV-1 Semi-Q	12 Tests	N/A	N/A		HIV-1 Semi-Q RNA target	9 months	2 to 37°C	Plasma		
4500-12	SAMBA II HIV-1 Qual Whole Blood Test	12 tests	N/A	N/A		HIV-1 Qualitative DNA/RNA target			Whole Blood		
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 toIFU	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			



## 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	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries	
GX [Series]	GeneXpert® Systems I, II, IV & XVI	Instruments	N/A	N/A	Cepheid Inc., Rontgenvagen 5 SE-171, 54 Solna Sweden	N/A	N/A	N/A	N/A			
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			
GXHIV-VL-CE-10 *	Xpert HIV-1 Viral Load	10 cartridges per pack				HIV-1 Quantitative NA target	12 months	2-28°C	Plasma	For further instruments refer to WHO Public Report	GHTF (CE mark) and WHO PQ <a href="http://www.who.int/entity/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/170830_amended_final_pgpr_0192_0193_0194_0195_070_00_v3.pdf?ua=1">http://www.who.int/entity/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/170830_amended_final_pgpr_0192_0193_0194_0195_070_00_v3.pdf?ua=1</a>	
GXHIV-QA-CE-10 *	Xpert HIV-1 Qual Assay	10 cartridges per pack				HIV-1 Qualitative NA target	8 months	2-28 °C	Whole blood and DBS	For further instruments refer to WHO Public Report	GHTF (CE mark) and WHO PQ <a href="http://who.us4.list-manage.com/track/click?u=da88047022d4d926f4cfea1ed&amp;id=b990797c46&amp;e=92844040f7">http://who.us4.list-manage.com/track/click?u=da88047022d4d926f4cfea1ed&amp;id=b990797c46&amp;e=92844040f7</a>	

**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 and Hepatitis C / Rapid Diagnostic Tests (RDTs)

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
01FK10W *	SD BIOLINE HBsAg WB	30	100.00%	99.00%	Standard Diagnostics, Inc. (Giheung-gu, Yongin-si, Korea)	HBsAg detection	Serum/Plasma /Whole Blood	24 Months 1 to 40°C		WHO PQ <a href="http://www.who.int/entity/diagnostics_laboratory/evaluations/pq-list/hbsag/171222_pq_final_report_pqdx_0219_012_00.pdf?ua=1">http://www.who.int/entity/diagnostics_laboratory/evaluations/pq-list/hbsag/171222_pq_final_report_pqdx_0219_012_00.pdf?ua=1</a>
31124 *	VIKIA® HBs Ag	25	99.50%	99.04%	bioMérieux SA Marcy L'Etoile, France	HBsAg detection	Serum/Plasma /Whole Blood	25 Months 4 to 30°C		WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/180724_FINAL_PQ_PR_0284-016-00_v2.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/180724_FINAL_PQ_PR_0284-016-00_v2.pdf?ua=1</a>
02FK10 *	SD BIOLINE HCV	30	100.00%	99.40%	Standard Diagnostics, Inc. (Giheung-gu, Yongin-si, Korea)	HCV antibody detection	Serum/Plasma /Whole Blood	24 Months 1 to 30°C	Safety lancets, alcohol swabs, specimen droppers (for fingerstick whole blood), 2 chase buffers, specimen dropper for serum/plasma, whole blood	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/170309_amended_final_pr_0257-012-00_v5.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/170309_amended_final_pr_0257-012-00_v5.pdf?ua=1</a>
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-TC-40		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	
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	24 Months 1 to 30°C		WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/170301_final_pq_report_PQDx_0244_055_00.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/170301_final_pq_report_PQDx_0244_055_00.pdf?ua=1</a>
1001-0274 *		100								

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 and Hepatitis C Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA])

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
3000-1158 *	Bioelisa HBsAg 3.0 & 4.0	96	100%	99.70%	Biokit S.A. Barcelona, Spain	anti-HBsAg antibodies	14 months 2 to 8°C	Human serum and plasma specimens	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/180313_amended_final_pqpr_0166_060_00_v3.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/180313_amended_final_pqpr_0166_060_00_v3.pdf?ua=1</a>
3000-1159 *		480							
B-1254 *	DS-EIA-HBsAg-0,01	96/1 plate	100%	99.00%	RPC «Diagnostic Systems», Ltd. Nizhny Novgorod Russian Federation	anti-HBsAg antibodies	24 months 2-8 °C	Human serum or plasma specimen	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/160415_final_public_report_0120_038_00_v2.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/160415_final_public_report_0120_038_00_v2.pdf?ua=1</a> GHTF (CE mark)
B-1252 *		192/2 plates							
B-1255 *		480/5 plates							
B-1256 *		1 plate 96 (for detection) or 48 (for confirmation)							
B-231 *		200 tests							
OPFM03, * OPFM05, OPFM07(Q), OUVP17	Enzygnost HBsAg 6.0 and Supplementary reagents kit for Enzygnost®/TMB	96T/kit 960T/kit 960T/kit (for higherthroughput)	100%	100.00%	Siemens Healthcare Diagnostics Products GmbH Marburg, Germany	anti-HBsAg Antibodies	12 months 2-8 °C	Human serum and plasma specimens	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/160324_final_public_report_0173_064_00.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/160324_final_public_report_0173_064_00.pdf?ua=1</a>
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 and Hepatitis C Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA])

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF 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. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/161116_amended_final_public_report_0121_043_00.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/161116_amended_final_public_report_0121_043_00.pdf?ua=1</a>
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. 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 <a href="http://www.who.int/diagnostics_laboratory/evaluations/150330_final_report_murex_hiv_ag_ab.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/150330_final_report_murex_hiv_ag_ab.pdf?ua=1</a>  GHTF (CE mark, TGA)
<b>Hepatitis C Enzyme Immunoassays (EIAs)</b>									
3000-1115 *	Bioelisa HCV 4.0	96	100%	100.00%	Biokit S.A. Barcelona, Spain	HCV antigens	12 months 2 to 8°C	Human serum and plasma specimens	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/180313_amended_final_pqpr_0165_060_00_v6.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/180313_amended_final_pqpr_0165_060_00_v6.pdf?ua=1</a> GHTF (CE mark)
3000-1116 *		480							
72561	Monolisa HCV Ag-Ab ULTRA V2 assay	96	100%	99.94%	Bio-Rad Laboratories, Marnes La Coquette, France	HCV antigens	see lot expiry 2 to 8°C	Serum and plasma specimen Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs	GHTF (CE mark)
72562		480							



## Hepatitis B and Hepatitis C Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA])

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
7F51-01 *	Murex anti-HCV Version 4	96	100%	99.40%	DiaSorin, Dartford, South Africa (Pty) Ltd	HCV antigens	12 months 2 to 8°C	In EDTA/Citrate Plasma specimen 1. Stop Solution (0.5M 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. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/161222_final_amended_pqr_0164_059_00_v5.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/161222_final_amended_pqr_0164_059_00_v5.pdf?ua=1</a>
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 <a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/180215_final_pq_report_pqdx_0201_073_00.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/180215_final_pq_report_pqdx_0201_073_00.pdf?ua=1</a>
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 <a href="http://www.who.int/diagnostics_laboratory/evaluations/150729_final_report_0202_073_00_hcv.pdf?ua=1">http://www.who.int/diagnostics_laboratory/evaluations/150729_final_report_0202_073_00_hcv.pdf?ua=1</a>

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)**

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
4506263	artus HBV RG RT-PCR Kit (AS - Rotor-Gene Q)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HBV Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4506265		96						-30°C to -15°C			
9002042		instrument									
60704	QIAamp DSP Virus Kit	extraction kit 96T/kit					12 months	2°C - 8°C			
4506363	artus HBV QS-RGQ Kit (QIASymphony® DSP / AS - Rotor-Gene Q)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HBV Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4506366		72						-30°C to -15°C			
9001850 - 9002042		instrument									
60704	QIASymphony® DSP Virus/Pathogen	extraction kit 96T/kit					14 months	15°C - 25°C			

**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)

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and calibrators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
4518263	artus HCV RG RT-PCR Kit (AS - Rotor-Gene Q MDx)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HCV Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4518265		96						-30°C to -15°C			
9002022		instrument									
60704	QIAamp DSP Virus Kit	extraction kit 96T/kit					12 months	2°C - 8°C			
4518363	artus HCV QS-RGQ Kit (QIAasymphony® DSP / AS - Rotor-Gene Q)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HCV Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4518366		72						-30°C to -15°C			
9001850 - 9002042		instrument									
937055	QIAasymphony® DSP Virus/Pathogen	extraction kit 96T/kit					14 months	15°C - 25°C			
GX [Series]	GeneXpert® Dx	Instruments	N/A	N/A	Cepheid Inc., Rontgenvagen 5 SE-171, 54 Solna Sweden	N/A	N/A	N/A	N/A		
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.oSWKIT or XPERTISE-G2-SWKIT	GeneXpert® Dx Software Version 4.6a or higher (GeneXpert Dx systems); or Xpertise 6.2a or higher (Infinity80/Infinity-48s)	Software				N/A	N/A	N/A	N/A		
GXHCV-VL-CE-10*	Xpert® HCV Viral Load	10 cartridges per pack				HCV Quantitative NA target	12 months	2-28°C	Serum / EDTA Plasma		

N/A- NOT APPLICABLE

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

Treponema Pallidum Infections for diagnosis of Syphilis to initiate patient treatment /Rapid Diagnostic Tests (RDTs)

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
06FK30 and 06FK35 *	SD BIOLINE HIV/Syphilis Duo	25	HIV-100% Syphilis-87%	99.5% 99.5%	Standard Diagnostics, Inc. (Giheung-gu, Yongin-si, Korea)	HIV/Syphilis	Serum/Plasma /Whole Blood	24 Months 1 to 30°C		WHO PQ <a href="http://www.who.int/diagnostics_laboratory/evaluations/151028_final_report_0179-012-00_sd_bioline_hiv_syphilis2.pdf">http://www.who.int/diagnostics_laboratory/evaluations/151028_final_report_0179-012-00_sd_bioline_hiv_syphilis2.pdf</a>
06FK10	SD BIOLINE Syphilis 3.0	30	99.30%	99.50%	Standard Diagnostics, Inc. (Giheung-gu, Yongin-si, Korea)	Syphilis	Serum/Plasma /Whole Blood	24 Months 1 to 30°C	ERPD as CATEGORY-2, meaning that procurement with Global Fund resources of this product will be permitted / Non-Objection-Letter required for procurement	ERPD until 21st February 2019
7D2442	Alere Determine™ Syphilis TP	30	100.00%	100% (92.31% in whole blood)	Alere Medical Co. Ltd, Matsudo, Japan	Treponema Pallidum antibody detection	Serum/Plasma /Whole Blood	shelf life accord. Lot description 2 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer (7D2243), EDTA capillary tubes (7D2227). serum/plasma: requires precision pipette plus tips.	GHTF (TGA)
7D2443		100								

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

Other HIV Co-Infections and Co-Morbidities / Virological Technologies

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
614015*	careHPV™ Test	96	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HPV DNA detection	cervical cells	12 month / 4°C to -25°C	careHPV Collection Medium (CCM) and careBrushes Foam specimen tube rack	WHO PQ <a href="https://www.who.int/diagnostics_laboratory/evaluations/pq-list/180713_pqpr_pqdx_0085_028_00_carehpv_with_labelling.pdf?ua=1">https://www.who.int/diagnostics_laboratory/evaluations/pq-list/180713_pqpr_pqdx_0085_028_00_carehpv_with_labelling.pdf?ua=1</a>
9001772*	careHPV Test System	instrument						N/A		
GXHPV-CE-10*	Xpert HPV Assay	10	N/A	N/A	Cepheid AB (Solna, Sweden)	HPV DNA detection	cervical cells collected in PreservCytSolution	18 Months 2 to 28°C		WHO PQ <a href="https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/171221_final_pq_report_pqdx_0268_070_00.pdf?ua=1">https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/171221_final_pq_report_pqdx_0268_070_00.pdf?ua=1</a>

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