The Global Fund

Version 24
20 Feb 2019

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 Authoritities of GHTF founding members and the WHO hosted Expert Review Panel.
The list is not exhaustive; PRs can procure product(s) not listed below as long as PRs demonstrate that the product is compliant with one of the above mentioned requirements.
The list is adapted from the lists posted in the following websites:
List of HIV diagnostics eligible for procurement by WHO: http://www.who.int/diagnostics_laboratory/procurement/purchase/en/
(which has also the products prequalified by WHO https://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
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
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
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.	WHO PQ
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	WHO PQ
THIV02	Toyo Anti-HIV 1/2		100%	100.00%	Turk Lab Turkey	HIV 1/2 antibodies combined detection	Whole Blood, Serum or Plasma	4 - 30°C		GHTF (CE mark)
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, blood, oral fluid)	99.9% (serum/plasma, whole blood, oral fluid)	Chembio Diagnostic Systems,Medford, USA	HIV 1/2 antibodies combined detection	Serum/Plasma/ Venous whole blood/ Fingerstick Whole Blood/Oral Fluid	24 months 2 to 30°C	Lancet, sterile gauze, antiseptic wipes Biohazard disposal container For venipuncture whole blood collection and serum/plasma specimens: Venipuncture apparatus and blood collection tubes Precision pipette capable of delivering 5µL of sample (with disposable tips) may be used in lieu of the disposable 5µL sample loop supplied with the kit (for other than fingerstick whole blood specimens)	WHO PQ
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.	WHO PQ
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.	WHO PQ
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)

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
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.	WHO PQ
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.	WHO PQ
72330 *	Genie Fast HIV 1/2	50	100%	99.00%	Bio-Rad Laboratories, Marnes La Coquette France and Steenvoorde, France	HIV 1/2 antibodies (group M and O)	Serum/Plasma/ Venous and Capillary Whole Blood	18 months 2 to 30°C	with support materials: diluent and disposable pipettes	WHO PQ
72327 *		25								
72347 *		25							with support materials: diluent, disposable pipette, microsafes, lancets, alcohol swabs	
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.	WHO PQ
HIV101 *	HIV 1/2 STAT-PAK™	20	99.30%	100%	Chembio Diagnostic Systems,Medford, USA	HIV 1/2 antibodies combined detection	Serum/Plasma/ Whole Blood	24 months 8 to 30°C	If whole blood: lancets, alcohol swabs. HIV Test Kit Controls (HIV104) available.	WHO PQ GHTF (FDA, PMA)

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
90-1010*	INSTI HIV-1/2 Antibody Test Kit	24	100%	99.70%	BioLytical Laboratories, Richmond, Canada	HIV 1/2 antibodies combined detection	Serum/Plasma/ Whole Blood	15 months 15 to 30 °C	24 T/kit; 24 T/kit with support materials; 48 T/kit; 48 T/kit with support materials If 90-1010, 90-1021: lancets, alcohol swabs, precision pipette plus tips.	WHO PQ
90-1013*		24								
90-1021*		48								
90-1022*		48								
25228	Multispot HIV-1/HIV-2 Rapid Test	50	100% HIV-1 (serum) 100% HIV-1 (plasma) 100% HIV-2 (serum/plasma)	99.93% serum 99.91% plasma	Bio-Rad Laboratories, Marnes La Coquette, France and Steenvoorde, France	Discrimination between HIV-1 and HIV-2 antibodies	Serum/Plasma	12 Months 2 to 8°C or room temperature (20-30°C) for up to 3 months	Disposable glass or polypropylene test tubes (not polystyrene) for diluttions, e.g. 12 x 75mm tubes Test tube racks Biohazard waste containers	GHTF (FDA, PMA)
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-	Serum/Plasma/ Whole Blood	24 months 2 to 28 °C	Additional devices which are necessary for performing the test are: - lancets (skin prick to gain the patients sample) - alcohol swaps (disinfection of the pricking position) ☐ timer	GHTF (CE mark)
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 HumanImmunodeficiency Virus (HIV) (Colloidal Gold Device)	10T/kit w/accessories	100%	98.48%	BeijingWantai Biological Pharmacy Enterprise Co.	HIV 1/2 antibodies combined detection	Serum/ Plasma/ Whole Blood	18 months 2 to 30 °C		WHO PQ
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	WHO PQ
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.	WHO PQ
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	WHO PQ GHTF (FDA, PMA)
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	WHO PQ
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.	WHO PQ

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)

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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 https://www.who.int/diagnostics_laboratory/evaluations/pq-list/181130_pqdx_0002_002_01_pqpr_insti_self_test.pdf?ua=1
5X4-1000*	OraQuick HIV Self-Test	50	99.02%	100.00%	OraSure Technologies Inc, Bethlehem, USA (manufactured in Thailand)	HIV 1/2 antibodies combined detection	Oral fluid	30 Months 2 to 30°C	Community Version Individual Test pouches are labeled 5X4-0004	WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/180622_amended_final_pqpr_0159_055_01_hiv_self_test_v8.pdf?ua=1
5X4-1001*		250								
5X4-2001*		110							Pharmacy Version (placed in individual cartons)	
On request	On request	1	on request	on request	On request	HIV 1/2 antibodies combined detection	Whole Blood	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	on request

N/A- NOT APPLICABLE

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

HIV Supplemental assays

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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 specimenPrecision 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 http://www.who.int/diagnostics_laboratory/evaluations/150508_final_report_innolia_hiv_score.pdf?ua=1 and GHTF (CE mark)
11030-018 *	MP Diagnostics HIV Blot 2.2	18	N/A	N/A	MP Biomedicals Asia Pacific, Singapore	Discrimination 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 http://www.who.int/diagnostics_laboratory/evaluations/160404_final_public_report_0198_071_00_v2.pdf?ua=1 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	Discrimination 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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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
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 http://www.who.int/diagnostics_laboratory/evaluations/160218_final_public_report_pqdx_0006_005_00_aid_anti_hiv_1_2_elisa.pdf?ua=1
WI-43480 *	AiD anti-HIV 1+2 ELISA	480	100.00%	99.92%	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	HIV-1/2 antibodies and HIV-1 p24 antigen	2 to 8°C	Serum or plasma	GHTF (CE mark)
790000	apDia HIV Ab & Ag Elisa	96	100.00%	99.60%	apDia bvba, Raadsherenstraat 3, B-2300 Turnhout, Belgium	HIV-1/2 antibodies and HIV-1 p24 antigen	15 months 2 to 8°C	Serum or plasma	GHTF (CE mark)
790001		196	100.00%	99.60%					
790005		480	100.00%	99.60%					
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 http://www.who.int/diagnostics_laboratory/evaluations/150302_final_report_biolisa_hiv_ag_ab_v3.pdf?ua=1
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 plama specimen	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/150729_final_report_0106_038_00_eia.pdf?ua=1 GHTF (CE mark)
I-1652 *		192/2 plates							
I-1656 *		480/5 plates							

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
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 http://www.who.int/diagnostics_laboratory/evaluations/160324_final_public_report_0214_064_00.pdf
72278	GenScreen™ HIV 1/2 Version 2	96	100%	99.80%	Bio-Rad Laboratories, Marnes La Coquette, France and Bio-Rad Laboratories, Steenvoorde, France	HIV 1/2 antibodies combined or discrimination	18 months 2 to 8°C	Serum and plasma specimen Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs	GHTF (CE mark, TGA)
72279		480							
* 72386	GenScreen™ ULTRA HIV Ag-Ab	96	100%	99.20%	Bio-Rad Laboratories, Steenvoorde, France	HIV 1/2 antibodies combined and HIV1- p24 antigen	18 months 2 to 8°C	Not suitable for whole blood Requires EIA incubator, washer, reader, precision pipette plus tips, deionised water.	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/130408_0096-031-00_public_report_final_v1.pdf
* 72388		480							
71120	Genscreen™ HIV-1 Ag Assay	192		99.95%	Bio-Rad 3, boulevard Raymond Poincaré 92430 Marnes-la-Coquette - France	HIV1- p24 antigen	months 2 to 8°C	Human Serum, Plasma and Cell Culture Supernatant	GHTF (CE mark)
26217	GS HIV Combo Ag/Ab EIA	192	100% (manual method) 100% (Evolis system)	99.87% (manual method) 99.97% (Evolis system)	Bio-Rad Laboratories, Steenvoorde, France	HIV-1 p24 antigen and HIV1/2 antibodies	18 months 2 to 8°C	Serum and plasma specimen For product code 26218 (960 tests): wash solution (25261) and stopping solution (25260) must be ordered separately. Biohazard disposal container For venipuncture serum/plasma specimens: Venipuncture apparatus and blood collection tubes Precision pipette (and tips), EIA plate washer, EIA plate incubator, EIA plate reader, vacuum disposal system, measuring cylinders, reagent troughs, deionized or distilled water. The GS HIV Combo Ag/Ab EIA is approved for use with the Bio-Rad EVOLIS™ Automated Microplate System.	GHTF (FDA, PMA)
26218		960							
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 Kingdon	HIV 1/2 Antibodies (IgG, IgM, IgA)	12 months 2 to 8°C	In EDTA/Citrate Plasma specimen 1. Stop Solution (0.5Mto 2MSulphuric Acid). 2. Freshly distilled or high quality deionized water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09 02). For use in laboratory incubators. 6. Instrumentation a) Automated microplate strip washer. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	GHTF (CE mark, TGA)
9E25-02		480							
7G79-09 *	Murex HIV Ag/Ab Combination	96	100%	99.78%	DiaSorin Dartford, United Kingdon	Combined detection of HIV-1 p24 and HIV 1/2 Antibodies (IgG, IgM, IgA)	12 months 2 to 8°C	Serum and plasma specimen 1. Stop Solution (0.5M to 2M Sulphuric Acid). 2. Freshly distilled or high quality deionised water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09-02). 6. Instrumentation a) Automated microplate stripwasher. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24-01). 8. Sodium hypochlorite for decontamination. (Refer to Health and Safety Information) 9. Sodium hydroxide solution (0.1M). (Refer to Analytical Precautions).	WHO PQ http://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])

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 80564	INNOTEST HIV Ag mAb	96 480	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)
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

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) http://www.who.int/diagnostics_laboratory/evaluations/151109_final_report_0156-053-00_aquios_cl_flow_cytometer.pdf
			1x10ml		B25697	18 - 26°C/18M			
			1x500ml		B25698	Safety lancets, alcohol swabs, specimen droppers(for fingerstick whole blood), 2 chase buffers, specimen dropper for serum/plasma, whole blood			
			4x50ml		B23536	18 - 26°C/12M			
			1 x 38ml,1 x 15ml (100 tests)		B23538	18 - 26°C/350 days			
			1 x 0.9ml (50 tests)		B23533	2 - 8°C/12M			
			1 x 0.9ml (50 tests)		B23534	2 - 8°C/12M			
			2x 3ml		B23535	2 - 8°C/270 days			
			2x 3ml		B25700	2 - 8°C/270 days			
			50 plates/box		B23502	N/A			
337858 * (Instrument) 340166 (control kit) 340167 (Test Kit)	BD FACSCount™ Instrument System with FACSCount™ Control Kit and BD FACSCount™ Reagent Kit	Absolute CD4+, CD8+, CD3+ Counts	337858: instrument system 340166: 25T /kit 340167: 50T/kit	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	23 months (reagents) 24 months (control) 2 to 8°C		Venous Whole Blood	N/A	WHO PQ (PQ Public Report) http://www.who.int/diagnostics_laboratory/evaluations/121115_0124_045_00_public_report_v2_final.pdf
337858 * (Instrument) 340166 (control kit) 339010 (Test Kit)	BD FACSCount™ Instrument System with FACSCountTM Control Kit and BD FACSCountTM CD4 Reagent Kit	Absolute and Percentage CD4+ Counts	337858: instrument system 340166: 25T/kit 339010: 50T/kit	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	15 months (reagents) 24 months (control) 2 to 8°C		Venous Whole Blood	N/A	WHO PQ (PQ Public Report) http://www.who.int/diagnostics_laboratory/evaluations/121115_0133_045_00_public_report_v1_final.pdf
On Request	BD FACSCount™ Instrument System with FACSCountTM Control Kit and BD FACSCountTM CD4/CD3 Reagent Kit	Absolute CD4+ Counts	On request	Becton, Dickinson and Company, BD Biosciences, San Jose, USA	on request		Venous Whole Blood	ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	ERPD until 29th January 2020
According model (Instrument) According 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/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 2019

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) 342 445 (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/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 2019
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 2019
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) http://www.who.int/diagnostics_laboratory/evaluations/131219_0099_032_00_public_report_final_v4.pdf?ua=1
260300001/ 260300003/ 260300004 *, 260100100 and 2603000011			100 cartridges/kit and instrument					
CY-S-3022 (equipment)* 05-8401 (absolute)* 05-8405 (percentage)*	CyFlow Instrument CD4 Easy-Count Reagent Kit CD4% Easy-Count Reagent Kit	Absolute and Percentage CD4+ Counts	100T/kit	Sysmex Partec, 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) http://www.who.int/diagnostics_laboratory/evaluations/pq-list/cd4/180524_amende_final_pqpr_0324_106_00.pdf?ua=1
MCA500101 (Test kit) 0500-3252 (equipment) *			500T/kit				N/A	
MCA1XK101 (Test kit) 0500-3252 (equipment) *			1000T/kit				N/A	
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: catridge (100/box) and 655495: pipette (100/box)	WHO PQ (PQ Public Report) http://www.who.int/diagnostics_laboratory/evaluations/140918_public_report_bdfacspresto_cd4.pdf?ua=1

Rapid Diagnostic Test for qualitative testing based on CD4 technologies

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
OD296 OD296Z (Brazil) OD296N (Nigeria)	VISITECT®CD4 Rapid Test		25T/kit	Omega Diagnostics Limited Omega House, Hillfoots Business Village, Alva, FK12 5DO, Scotland, United Kingdom		human venous whole blood or capillary blood	ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	ERPD until 13th December 2019

N/A- NOT APPLICABLE

The Global Fund

Version 24
20 Feb 2019

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 caliberators)	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 http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. For the Manual configuration see: http://www.who.int/diagnostics_laboratory/evaluations/130530_0151_027_00_public_report_final.pdf
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 http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. For the automated configuration see: http://www.who.int/diagnostics_laboratory/evaluations/130530_0084_027_00_public_report_final.pdf
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 http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	WHO PQ and GHTF (CE mark) http://www.who.int/diagnostics_laboratory/evaluations/120113_0146_027_00_final_public_report_v2.pdf
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

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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	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 http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	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	N/A	N/A	Abbott Molecular Inc, Des Plaines IL, USA	HIV1 Quantitative RNA	18 months	NA	Plasma	For consumables refer to WHO eligible list http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	WHO PQ and GHTF (CE mark) http://www.who.int/diagnostics_laboratory/evaluations/120113_0083_027_00_final_public_report_v2.pdf
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, 8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon, 34302, Republic of Korea	HIV-1/2 Quantitative RNA	12 months	-25°C to -15°C	EDTA Plasma	For consumables and details of componants refer to IFU	GHTF (CE mark)
A-2200-N	ExiStation™ Universal Molecular Diagnostic System	Instrument					Not applicable	Not applicable			

HIV Virological technologies

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Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	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		Not applicable	Not applicable	Whole Blood, Plasma	For consumables and alternative AlereTM q Complete (product code 270300002) AlereTM q Complete II (product code 270300002) refer to WHO Public Report	WHO PQ and GHTF (CE mark) http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/160902_amended_public_report_0226_032_00_alere_hiv_detect_v3.pdf?ua=1
270110010*	Alere™ q HIV-1/2 Detect	10 Cartridges				HIV-1/2 Qualitative RNA	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) http://www.who.int/diagnostics_laboratory/evaluations/pq-list/180207_final_pqpr_0236_078_00_v5_IFU_v4.pdf?ua=1
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 caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
V0-96/3FRT	HIV Real-TM Quant Dx	96	N/A	N/A	Sacace Biotechnologies Srl Como – Italy	HIV1 Quantitative RNA	12 months	2 to 8°C	Human Plasma		GHTF (CE mark)
*280140	NucliSENS EasyQ HIV-1 V2.0 (Automated)	instrument	N/A	N/A	bioMerieux SA, Marcy l'Etoile, France	HIV1 Quantitative RNA	NA		Plasma dried blood spot (venous whole blood)	For consumables refer to WHO eligible list http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	WHO PQ and GHTF (CE mark) http://www.who.int/diagnostics_laboratory/evaluations/120109_0127_016_00_public_report_v1.pdf
280130		4x1lit					24 months	2 to 30°C			
280131		4x1lit					18 months	2 to 30°C			
280132		4x1lit					15 months	2 to 8°C			
280133		4x1lit					18 months	2 to 8°C			
280134		4x1lit					24 months	2 to 30°C			
285056		instrument					NA				
200309											
285033		48T/kit					18 months	2 to 8°C			
*200305	NucliSENS EasyQ HIV-1 V2.0 (Semi Automated)		N/A	N/A	bioMerieux SA Marcy l'Etoile, France	HIV1 Quantitative RNA			Plasma dried blood spot (venous whole blood)	For consumables refer to WHO eligible list http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	WHO PQ and GHTF (CE mark) http://www.who.int/diagnostics_laboratory/evaluations/120109_0148_016_00_public_report_v1.pdf
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				
*03279332001	COBAS AmpliPrep/COBAS Taqman HIV-1 Test Version 2.0 (Taqman 48)	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 Quantitative RNA	NA		Plasma or PSC dried plasma spot (with PCS)	For consumables refer to WHO eligible list http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	WHO PQ and GHTF (CE mark) http://www.who.int/diagnostics_laboratory/evaluations/120502_0126_046_00_public_report_v1_final.pdf
05527503001		instrument					NA				
04862392001		software					NA				
05807875001		software					NA				
03051315001		instrument					NA				
05212294190		48T/kit					18 Months	2 to 8°C			
03587797190		5.1L					24 months	2 to 30°C			
*03121453001	COBAS AmpliPrep/COBAS Taqman HIV-1 Test Version 2.0 (Taqman 96)	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 Quantitative RNA	NA		Plasma or dried plasma spot (with PCS)	For consumables refer to WHO eligible list http://www.who.int/diagnostics_laboratory/procurement/140324_v11_pqed_products_eligible_for_procur_2014.pdf?ua=1	WHO PQ and GHTF (CE mark) http://www.who.int/diagnostics_laboratory/evaluations/120502_0147_046_00_public_report_v1_final.pdf
03051315001		instrument					NA				
04862392001		software					NA				
05807875001		software					NA				
05527503001		instrument					NA				
05212294190		48T/kit					18 Months	2 to 8°C			
03587797190		5.1L					24 months	2 to 30°C			
28127387001											

HIV Virological technologies

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	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 and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. http://www.who.int/diagnostics_laboratory/evaluations/141216_final_report_taqman48_0221_v2.pdf?ua=1
03051315001		instrument									
03279332001		instrument									
03587797190		5.1L					24 months	2 to 30°C			
06989861190		5 x 78ml									
05807875001		software									
03516440001		instrument									
28127387001											
*06693083190	COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 96)	48T/kit	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 DNA & RNA Qualitative	22 months	2 to 8°C	Plasma or dried blood spots		WHO PQ and GHTF (CE mark) For a full list of consumables required, see WHO Public Reports. http://www.who.int/diagnostics_laboratory/evaluations/141216_final_report_taqman96_0200_v2.pdf?ua=1
03587797190		5.1L					24 months	2 to 30°C			
06989861190		5 x 78ml					12 months	2 to 8°C			
03051315001		instrument									
03121453001		instrument									
28127387001											
05807875001		software									
03516440001		instrument									
5923468190	COBAS® TaqMan® HIV-1 Test, Version 2 for use with High pure system	48 tests	N/A	N/A	Roche Molecular System, Branchburg, USA	HIV1 Quantitative RNA	24 months*	2 to 8°C	Plasma		GHTF (CE mark)
3502295001	High Pure System Nucleic Acid Kit	48 tests					12 months*	15 to 25°C			
05 200 881 001	COBAS® z 480	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	N/A	N/A	N/A	N/A		GHTF (CE mark)
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
08 792992190	COBAS® HIV-1 Test for use with 4800	120 tests	N/A	N/A		HIV-1 Quantitative RNA	15 months	2 to 8°C	EDTA Plasma, dried plasma spot (with PCS card)		
05 200 881 001	COBAS® z 480	instrument	N/A	N/A	Roche Molecular System, Branchburg, USA	N/A	N/A	N/A	N/A		GHTF (CE mark)
05 200 890 001	COBAS® x 480	instrument	N/A	N/A		N/A	N/A	N/A	N/A		
08 792992190	COBAS® HIV-1 Test for use with 4800	120 tests	N/A	N/A		HIV-1 Qualitative RNA		2 to 8°C	EDTA Plasma, dried plasma spot, dried blood spot (DBS)	(with PCS card)	

HIV Virological technologies

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
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		
70 00995190	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	18 months	2 to 8°C	EDTA Plasma, dried plasma spot	(with PCS card)	
07 862113190	COBAS® HIV-1 Test for use with 6800/8800	96 tests/kit	N/A	N/A		HIV-1 Qualitative RNA	18 months	2 to 8°C	Serum, Plasma, dried blood spots (DBS)		
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

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	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 http://www.who.int/entity/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/170830_amended_final_pqpr_0192_0193_0194_0195_070_00_v3.pdf?ua=1
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 http://who.us4.list-manage.com/track/click?u=da88047022d4d926f4cfea1ed&id=b990797c46&e=92844040f7

N/A- NOT APPLICABLE

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

Hepatitis B and Hepatitis C / Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests)

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 http://www.who.int/entity/diagnostics_laboratory/evaluations/pq-list/hbsag/171222_pq_final_report_pqdx_0219_012_00.pdf?ua=1
31124 *	VIKIA® HBsAg	25	99.05%	99.80%	bioMérieux SA Marcy L'Etoile, France	HBsAg detection	Serum/Plasma/ Whole Blood	24 Months 4 to 30°C		WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/180724_FINAL_PQ_PR_0284-016-00_v2.pdf?ua=1
I10FRC25CE	First Response® HBsAg Card Test	25	100.00%	100.00%	Premier Medical Corporation, Nani Daman, India	HBsAg detection	Serum/Plasma/ Whole Blood	24 Months 4 to 30°C		GHTF (CE mark)
I10FRC30CE		30								
Hepatitis C (Rapid Diagnostic Tests)										
I03FRC25CE	First Response® HCV Card Test	25	100.00%	100.00%	Premier Medical Corporation, Nani Daman, India	HCV antibody detection	Serum/Plasma/ Whole Blood	25 Months 4 to 30°C		GHTF (CE mark)
I03FRC30CE		30								
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 http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/170309_amended_final_pr_0257-012-00_v5.pdf?ua=1
ITP01152-TC40	Rapid Anti-HCV Test	40	99.70%	99.80%	InTec Poducts Inc, (Haicang, Xiamen, P.R. China)	HCV antibody detection	Serum/Plasma/ Whole Blood	24 Months 2 to 30°C	Accessories included: Plastic pipettes, sample buffer	GHTF (CE mark)
ITP01152-TC25		25							Accessories included: Plastic pipettes, sample buffer	
ITP01153-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 http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/170301_final_pq_report_PQDx_0244_055_00.pdf?ua=1
1001-0274 *		100								

Hepatitis B and Hepatitis C / Rapid Diagnostic Tests (RDTs)
(not intended to be used as a donor screening tests)

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

N/A- NOT APPLICABLE

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

Hepatitis B and Hepatis C Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (not intended to be used as a donor screening tests)

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 http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/180313_amended_final_pqpr_0166_060_00_v3.pdf?ua=1
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 plama specimen	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/160415_final_public_report_0120_038_00_v2.pdf?ua=1 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 http://www.who.int/diagnostics_laboratory/evaluations/160324_final_public_report_0173_064_00.pdf?ua=1
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 Hepatis C Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (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	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 Kingdon	anti-HBsAg Antibodies	12 months 2 to 8°C	In EDTA/Citrate Plasma specimen 1. Stop Solution (0.5Mto 2MSulphuric Acid). 2. Freshly distilled or high quality deionized water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09 02). For use in laboratory incubators. 6. Instrumentation a) Automated microplate strip washer. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/161116_amended_final_public_report_0121_043_00.pdf?ua=1
9F80-05*		480							
2G27-01*	Murex HBsAg Confirmatory Version 3	50	100%	99.78%	DiaSorin Dartford, United Kingdon	anti-HBsAg Antibodies	17 months 2 to 8°C	Serum and plasma specimen 1. Stop Solution (0.5M to 2M Sulphuric Acid). 2. Freshly distilled or high quality deionised water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09-02). 6. Instrumentation a) Automated microplate stripwasher. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24-01). 8. Sodium hypochlorite for decontamination. (Refer to Health and Safety Information) 9. Sodium hydroxide solution (0.1M). (Refer to Analytical Precautions).	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/150330_final_report_murex_hiv_ag_ab.pdf?ua=1 GHTF (CE mark, TGA)
				Hepatis C Enzyme Immunoassays (EIAs)					
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 http://www.who.int/diagnostics_laboratory/evaluations/180313_amended_final_pqpr_0165_060_00_v6.pdf?ua=1 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 Hepatis C Enzyme Immunoassays (EIAs) (including chemiluminescence immunoassays [CLIA]) (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	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 (0.5Mto 2MSulphuric Acid). 2. Freshly distilled or high quality deionized water 3. Micropipettes and Multichannel micropipettes of appropriate volume. 4. Incubator capable of maintaining the temperature limits defined in the assay protocol. 5. Moulded Heating Block (Code 5F09 02). For use in laboratory incubators. 6. Instrumentation a) Automated microplate strip washer. b) Microplate reader. or c) Fully automated microplate processor. All instruments must be validated before use. 7. Disposable Reagent Troughs. (Code 5F24 01). 8. Sodium hypochlorite for decontamination (Refer to Health and Safety Information). 9. Sodium hydroxide solution (0.1M) (for instrument decontamination)	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/161222_final_amended_pqpr_0164_059_00_v5.pdf?ua=1
7F51-02 *		480							
80068 *	INNOTEST HCV Ab IV	192	100.00%	100.00%	Fujirebio Europe NV (Gent, Belgium)	HCV antigens	16 months 2 to 8°C	Human serum and plasma specimens	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/180215_final_pq_report_pqdx_0201_073_00.pdf?ua=1
80330 *		480							
80538 *	INNO-LIA HCV Score	20	100.00%	99.90%	Fujirebio Europe NV (Gent, Belgium)	HCV antigens	15 months 2 to 8°C	Human serum and plasma specimens	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/150729_final_report_0202_073_00_hcv.pdf?ua=1

N/A- NOT APPLICABLE

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

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

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

Manufacturer Product Catalogue number	Product Name (Equipment, Reagents, controls and caliberators)	Reference detail	Sensitivity	Specificity	Manufacturer	Detection type	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 caliberators)	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 (QIAsymphony® DSP / AS - Rotor-Gene Q)	24	N/A	N/A	QIAGEN GmbH, Qiagen Strasse 1, 40724 Hilden, Germany	HCV Quantitative RNA	17 months	-30°C to -15°C	Plasma		GHTF (CE mark)
4518366		72						-30°C to -15°C			
9001850 - 9002042		instrument									
937055	QIAsymphony® DSP Virus/Pathogen	extraction kit 96T/kit					14 months	15°C - 25°C			
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		
						N/A	N/A	N/A	N/A		
Infinity-80	GeneXpert® Infinity-80	Instrument				N/A	N/A	N/A	N/A		
GX4.0SWKIT or XPERTISE-G2-SWKIT	GeneXpert® Dx Software Version 4.6a or higher (GeneXpert Dx systems); or Xpertise 6.2a or higher (Infinity80/Infinity-48s)	Software				N/A	N/A	N/A	N/A		
GXHCV-VL-CE-10*	Xpert® HCV Viral Load	10 cartridges per pack				HCV Quantitative NA target	12 months	2-28°C	Serum / EDTA Plasma		GHTF (CE mark) and WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/171221_final_pq_report_pqdx_0268_070_0

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) (not intended to be used as a donor screening tests)

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	n/a	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/151028_final_report_0179-012-00_sd_bioline_hiv_syphilis2.pdf
on request	on request	on request	on request	on request	on request	HIV/Syphilis	Serum/Plasma/ Whole Blood	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	ERPD
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 2020
on request	on request	on request	on request	on request	on request	Syphilis	Serum/Plasma/ Whole Blood	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	ERPD

N/A- NOT APPLICABLE

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

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

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

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
RPR / VDRL										
900025 900100	ASI RPR Card Test	25 100	99.00%	98.40%	Arlington Inc	RPR antigens	Serum/Plasma	see package insert 2 to 8°C	In absence of eligible products in compliance to the QA Policy, moderate risks criteria (assessment as GHTF Class C Device) will be acceptedon exceptional basis / Non-Objection-Letter required for procurement	(GHTF, US FDA)
TPHA / TPPA										
300615700	syphagen TPHA Test	200	99.30%	99.50%	Biokit S.A. Barcelona, Spain	treponema antigens	Serum/Plasma	see package insert 2 to 8°C	In absence of eligible products in compliance to the QA Policy, moderate risks criteria (assessment as GHTF Class C Device) will be accepted on exceptional basis / Non-Objection-Letter required for procurement	(GHTF, TGA)
DR0530M	TPHA Test Kit	200			ThermoFisherScientific / Oxoid Ltd, Wade Road Basingstoke, Hants, RG24 8PW United Kingdom	treponema antigens	Serum/Plasma	see package insert 2 to 8°C	In absence of eligible products in compliance to the QA Policy, moderate risks criteria (assessment as GHTF Class C Device) will be accepted on exceptional basis / Non-Objection-Letter required for procurement	(GHTF, TGA)
ELISA / EIA / LIA										
3000-1148 3000-1149	bioelisa SYPHILIS 3.0	96 480	99.40%	99.80%	Biokit S.A. Barcelona, Spain	treponema antigens	Serum/Plasma	see package insert 2 to 8°C	In absence of eligible products in compliance to the QA Policy, moderate risks criteria (assessment as GHTF Class C Device) will be accepted on exceptional basis / Non-Objection-Letter required for procurement	(GHTF, TGA)

N/A- NOT APPLICABLE

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

Other HIV Co-Infections and Co-Morbitities / 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 https://www.who.int/diagnostics_laboratory/evaluations/pq-list/180713_pqpr_pqdx_0085_028_00_carehpv_with_labelling.pdf?ua=1
9001772*	careHPV Test System	instrument						N/A		
GXHPV-CE-10*	Xpert HPV Assay	10	N/A	N/A	Cepheid AB (Solna, Sweden)	HPV DNA detection	cervical cells collected in PreservCytSolution	18 Months 2 to 28°C		WHO PQ https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/171221_final_pq_report_pqdx_0268_070_00.pdf?ua=1

N/A- NOT APPLICABLE

Data Efetiva: 2014-01-16

Número: 1156086502

ABON™

Dispositivo de teste rápido do antigénio de superfície da Hepatite B (Sangue Total/Soro/Plasma)

Instruções de Uso

Português

Um teste rápido para a detecção qualitativa do antigénio de superfície da hepatite B (HBsAg) em sangue total, soro ou plasma.
Exclusivamente para utilização profissional em diagnóstico in vitro.

USO INDICADO

O Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) é um imunoensaio cromatográfico rápido para a detecção qualitativa do antigénio de superfície da Hepatite B em sangue total, soro ou plasma.

RESUMO

A hepatite viral é uma doença sistémica que afecta principalmente o fígado. A maioria dos casos de hepatite viral aguda é causada pelo vírus da Hepatite A, pelo vírus da Hepatite B ou pelo vírus da Hepatite C. O complexo antigénio encontrado à superfície do VHB é conhecido como HBsAg. Entre as designações anteriores incluía-se o antigénio Austrália ou Au.[1] A presença do HBsAg em sangue total, soro ou plasma indica uma infecção activa pelo vírus da hepatite B, aguda ou crónica. Numa infecção por Hepatite B característica, o HBsAg é detectado 2 a 4 semanas antes de os níveis de ALT se tornarem anormais e 3 a 5 semanas antes do desenvolvimento de sintomas ou icterícia. O HBsAg possui quatro subtipos principais: adw, ayw, adr e ayr. Devido à heterogeneidade antigénica do determinante, existem 10 serotipos principais do vírus da Hepatite B.[2]
O Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) é um teste rápido destinado a detectar de forma qualitativa a presença de HBsAg em amostras de sangue total, soro ou plasma. O teste utiliza uma combinação de anticorpos monoclonais e policlonais para detectar selectivamente níveis elevados de HBsAg em sangue total, soro ou plasma.

PRINCÍPIO

O Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) é um imunoensaio qualitativo, de fase sólida, de dois locais "em sanduíche" para a detecção do HBsAg em sangue total, soro ou plasma. A membrana encontra-se pré-revestida com anticorpos anti-HBsAg na região da linha de teste do dispositivo. Durante o teste, a amostra de sangue total, soro ou plasma reage com as partículas conjugadas com anticorpos anti-HBsAg. A mistura migra no sentido ascendente da membrana, cromatograficamente por acção capilar, para reagir com os anticorpos anti-HBsAg na membrana e gerar uma linha colorida. A presença desta linha colorida na região de teste indica um resultado positivo, ao passo que a sua ausência indica um resultado negativo. Como controlo de procedimentos, aparecerá sempre uma linha colorida na região da linha de controlo. Se a linha de controlo não aparecer, o resultado do teste não pode ser considerado válido.

REAGENTES

O dispositivo de teste contém partículas anti-HBsAg e anti-HBsAg a revestir a membrana.

PRECAUÇÕES

- Exclusivamente para utilização profissional em diagnóstico *in vitro*. Não utilizar depois de expirado o prazo de validade.
- Não comer, beber nem fumar na área onde as amostras ou kits são manuseados.
- Não utilizar o teste se a bolsa estiver danificada.
- Manusear e eliminar todas as amostras e materiais utilizados na realização do teste como se estes contivessem agentes infecciosos. Respeitar as precauções estabelecidas contra os perigos microbiológicos ao longo de todos os procedimentos e seguir os procedimentos padrão para a eliminação adequada das amostras.
- Usar roupa de protecção, como batas de laboratório, luvas descartáveis e protecção ocular durante o teste das amostras.
- O teste empregue deve ser eliminado em conformidade com os regulamentos locais.
- A humidade e a temperatura podem afectar os resultados de forma adversa.
- Verificou-se, após uma investigação sobre anticoagulação, que o EDTA-K_2/o citrato de sódio/oxalato de potássio/a heparina de sódio podem ser utilizados com o produto e são, por este motivo, de utilização recomendada, quando necessário.

ARMAZENAMENTO E ESTABILIDADE

O kit pode ser armazenado à temperatura ambiente ou refrigerado (2 a 30 °C). O dispositivo de teste permanece estável até ao prazo de validade impresso na bolsa selada. O dispositivo de teste deve ser mantido na bolsa selada até à sua utilização. **NÃO CONGELAR.** Não utilizar depois de expirado o prazo de validade.

OBTENÇÃO E PREPARAÇÃO DA AMOSTRA

- O Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) pode ser utilizado com sangue total (proveniente de venopunção ou de picada no dedo), soro ou plasma.
- Para a colheita de amostras de sangue total obtido por picada no dedo:
  - Lave a mão do doente com água quente e sabão ou limpe com cotonete embebido em álcool. Deixe secar.
  - Massaje a mão sem tocar no local da punção, esfregando a mão no sentido descendente, até à ponta do dedo médio ou do anelar.
  - Pique a pele com uma lanceta estéril. Limpe a primeira gota de sangue.
  - Esfregue suavemente a mão, do pulso até à palma e da palma até ao dedo, para formar uma gota de sangue arredondada sobre o local da punção.
  - Adicione a amostra de sangue total obtida por picada no dedo ao dispositivo de teste utilizando um tubo capilar:
    - Toque com a extremidade do tubo capilar no sangue até obter cerca de 75 µL. Evite bolhas de ar.
    - Coloque a bolha na extremidade superior do tubo capilar e aperte a bolha para distribuir o sangue total no poço da amostra (S) do dispositivo de teste.
  - Adicione a amostra de sangue total obtida por picada no dedo ao dispositivo de teste utilizando
    - Posicione o dedo do paciente de tal forma que a gota de sangue se encontre imediatamente acima do poço da amostra (S) do dispositivo de teste.
    - Deixe cair 3 gotas suspensas de sangue total obtido por picada no dedo no centro do poço da amostra (S) do dispositivo de teste, ou mova o dedo do paciente de modo a que a gota suspensa toque no centro do poço da amostra (S). Evite que o dedo toque directamente no poço da amostra (S).
- Separe o soro ou o plasma do sangue logo que possível para evitar a hemólise. Utilize apenas amostras limpas, não hemolizadas.
- O teste deve ser realizado imediatamente após a colheita da amostra. Não deixe as amostras à temperatura ambiente por longos períodos de tempo. As amostras de soro ou plasma podem ser conservadas entre 2 e 8 °C até um máximo de 3 dias. Para um armazenamento mais prolongado, as amostras devem ser conservadas a uma temperatura inferior a -20 °C. O sangue total colhido por venopunção deve ser conservado entre 2 e 8 °C no caso da realização do teste nos 2 dias seguintes à colheita. Não congele as amostras de sangue total. O sangue total colhido por picada no dedo deve ser testado de imediato.
- Deixe as amostras atingirem a temperatura ambiente antes da realização do teste. As amostras congeladas devem ser totalmente descongeladas e bem misturadas antes da realização do teste. As amostras não devem ser congeladas e descongeladas repetidamente.
- No caso de envio das amostras, estas devem ser acondicionadas em conformidade com os regulamentos federais que cobrem o transporte de agentes etiológicos.

MATERIAIS

Materiais fornecidos

- Dispositivos de teste
- Instruções de Uso
- Conta-gotas descartável para amostras
- Solução tampão (apenas para sangue total)

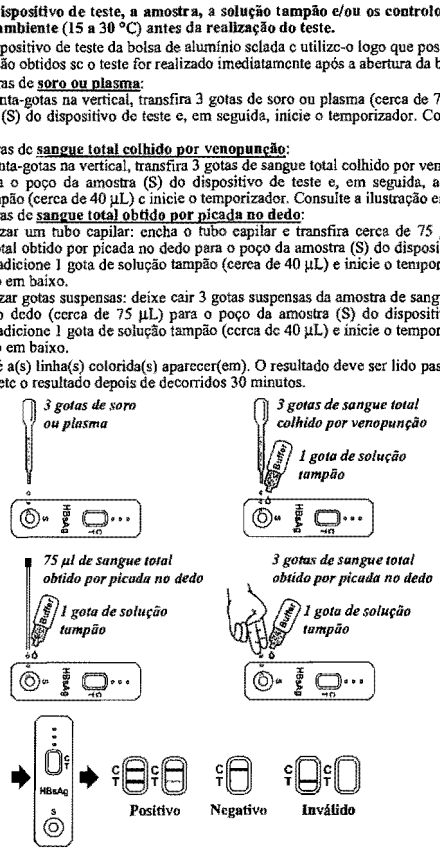
Materiais necessários mas não fornecidos

- Recipientes de colheita de amostras
- Centrífuga
- Tubos capilares heparinizados e bolha para distribuição descartáveis (apenas para sangue total obtido através do procedimento de picada no dedo)
- Lancetas (apenas para amostras de sangue total por picada do dedo)
- Temporizador

INSTRUÇÕES DE USO

Deixe que o dispositivo de teste, a amostra, a solução tampão e/ou os controlos se equilibrem à temperatura ambiente (15 a 30 °C) antes da realização do teste.

1. Retire o dispositivo de teste da bolsa de alumínio selada e utilize-o logo que possível. Os melhores resultados são obtidos se o teste for realizado imediatamente após a abertura da bolsa de alumínio.
2. Para amostras de **soro ou plasma**:
   segure o conta-gotas na vertical, transfira 3 gotas de soro ou plasma (cerca de 75 µL) para o poço da amostra (S) do dispositivo de teste e, em seguida, inicie o temporizador. Consulte a ilustração em baixo.
   Para amostras de **sangue total colhido por venopunção**:
   segure o conta-gotas na vertical, transfira 3 gotas de sangue total colhido por venopunção (cerca de 75 µL) para o poço da amostra (S) do dispositivo de teste e, em seguida, adicione 1 gota de solução tampão (cerca de 40 µL) e inicie o temporizador. Consulte a ilustração em baixo.
   Para amostras de **sangue total obtido por picada no dedo**:
   - para utilizar um tubo capilar: encha o tubo capilar e transfira cerca de 75 µL da amostra de sangue total obtido por picada no dedo para o poço da amostra (S) do dispositivo de teste e, em seguida, adicione 1 gota de solução tampão (cerca de 40 µL) e inicie o temporizador. Consulte a ilustração em baixo.
   - Para utilizar gotas suspensas: deixe cair 3 gotas suspensas da amostra de sangue total obtido por picada no dedo (cerca de 75 µL) para o poço da amostra (S) do dispositivo de teste e, em seguida, adicione 1 gota de solução tampão (cerca de 40 µL) e inicie o temporizador. Consulte a ilustração em baixo.
3. Aguarde até a(s) linha(s) colorida(s) aparecer(em). O resultado deve ser lido passados 15 minutos. Não interprete o resultado depois de decorridos 30 minutos.



INTERPRETAÇÃO DOS RESULTADOS

(Consulte a ilustração acima)

POSITIVO:* aparecem duas linhas coloridas diferentes. Uma linha deve estar na região linha de controlo (C) e a outra linha deve estar na região da linha de teste (T).

***NOTA:** a intensidade da cor na região da linha de teste (T) varia dependendo da concentração de HBsAg presente na amostra. Por essa razão, qualquer tonalidade de cor na região de teste (T) deve ser considerada positiva.

NEGATIVO: aparece uma linha colorida na região de controlo (C). Não aparece qualquer linha colorida aparente na região de teste (T).

INVÁLIDO: Não aparece nenhuma linha na região de controlo (C). Se tal ocorrer, leia as instruções novamente e repita o teste utilizando um novo kit de teste. Se o resultado continuar a ser inválido, não volte a utilizar o kit de teste contacte o seu distribuidor local.

CONTROLO DE QUALIDADE

O teste tem incluído um controlo de procedimento. Uma linha colorida que aparece na região de controlo (C) é o controlo de procedimento interno.
Os padrões de controlo não são fornecidos com este kit. Contudo, é aconselhável testar um controlo positivo (contendo 10 ng/mL de HBsAg) e um controlo negativo (contendo 0 ng/mL de HBsAg) enquanto boa prática laboratorial, para confirmar o procedimento de teste e verificar o desempenho adequado do teste.

LIMITAÇÕES

1. O Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) destina-se exclusivamente à utilização em diagnóstico *in vitro*. O teste deve ser utilizado apenas para a detecção de HBsAg em amostras de sangue total, soro ou plasma. Não é possível determinar nem o valor quantitativo nem a taxa de concentração de HBsAg através deste teste qualitativo.
2. O Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) indicará apenas a presença de HBsAg na amostra e não deve ser utilizado como o único critério para o diagnóstico de infecções pelo vírus da Hepatite B.
3. Tal como sucede com todos os testes de diagnóstico, todos os resultados devem ser interpretados em conjunto com outras informações clínicas à disposição do médico.
4. O Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) não consegue detectar menos de 1 ng/mL de HBsAg nas amostras. Se o resultado do teste for negativo e os sintomas clínicos persistirem, sugere-se a utilização de testes de seguimento adicionais que utilizem outros métodos clínicos. Um resultado negativo em qualquer altura não exclui a possibilidade de infecção pelo vírus da Hepatite B.

VALORES ESPERADOS

O Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) foi comparado a um teste EIA para o HBsAg líder de mercado. A correlação entre estes dois sistemas é de 99,4%.

CARACTERÍSTICAS DE DESEMPENHO

Sensibilidade

O Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) foi testado num controlo de sensibilidade que incluía os subtipos ad e ay, com concentrações entre os 0 e os 300 ng/mL. O teste pode detectar 1 ng/mL de HBsAg em sangue total, soro ou plasma após 15 minutos.

Especificidade

Os anticorpos utilizados no Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) foram desenvolvidos contra o antigénio total da Hepatite B, isolado a partir do vírus da Hepatite B. A especificidade do Dispositivo de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) foi também testada com cstirpes de laboratoriais da Hepatite A e da Hepatite C. Todas com resultados negativos.

Método		EIA		Resultados totais
HBsAg Rápido do NT-proBNP	Resultados	Positivo	Negativo	
	Positivo	409	5	414
	Negativo	1	617	618
Resultados totais		410	622	1032

Sensibilidade relativa: 99,8% (98,6%-100,0%)* Especificidade relativa: 99,2% (98,1%-99,7%)*
Exactidão: 99,4% (98,7%-99,8%)* * Intervalo de confiança de 95%

Precisão

Intra-ensaio

A precisão intra-série foi determinada utilizando 10 réplicas de oito amostras contendo 0 ng/mL, 2 ng/mL, 5 ng/mL e 10 ng/mL de Ad e Ay do HBsAg. Os valores negativos e positivos foram correctamente identificados >99% das vezes.

Inter-ensaio

A precisão entre séries foi determinada utilizando as mesmas oito amostras de 0 ng/mL, 2 ng/mL, 5 ng/mL e 10 ng/mL de Ad e Ay do HBsAg em 3 ensaios independentes. Foram testados três lotes diferentes de Dispositivos de teste rápido do antigénio de superfície da Hepatite B HBsAg (sangue total/soro/plasma) utilizando amostras negativas, positivas baixas e positivas altas. As amostras foram correctamente identificadas >99% das vezes.

BIBLIOGRAFIA

1. Blumberg, B.S. *The Discovery of Australian Antigen and its relation to viral hepatitis.* Vitro. 1971; 7: 223
2. Organização Mundial de Saúde. HEPATITIS B SURFACE ANTIGEN ASSAYS: OPERATIONAL CHARACTERISTICS (PHASE I) report 1. 2001; 2-4

Índice de Símbolos

	Consulte as instruções de utilização	Σ	Testes por kit	EC REP	Representante autorizado
IVD	Somente para uso de diagnóstico *in vitro*		Validade		Não reutilizar
	Armazenar entre 2-30°C	LOT	Número de lote	REF	N° de Catálogo

Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018, P.R.China

CE 1023

EC REP
MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert/Germany

Fecha efectiva: 2014-01-16

Número: 1156086502

Dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (para sangre completa/suero/plasma)

Ficha Técnica

Español

Prueba rápida para la detección cualitativa de los antígenos de superficie de la hepatitis B (HBsAg) en sangre completa, suero o plasma.
Sólo para uso diagnóstico profesional in vitro.

USO PREVISTO

El dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) es un inmunoensayo cromatográfico rápido para la detección cualitativa de los antígenos de superficie de la hepatitis B en sangre completa, suero o plasma.

RESUMEN

La hepatitis viral es una enfermedad sistémica que afecta al hígado. La mayoría de los casos de hepatitis viral aguda son consecuencia del virus de la hepatitis A, el virus de la hepatitis B (VHB) o el virus de la hepatitis C. El antígeno complejo hallado en la superficie del VHB se denomina HBsAg. Entre las designaciones anteriores se incluyen antígeno Australia o Au.[1] La presencia del HBsAg en sangre completa, suero o plasma indica una infección activa de hepatitis B, ya sea aguda o crónica. En una infección de hepatitis B común, el HBsAg se detectará entre 2 y 4 semanas antes de que los niveles de la ALT sean anormales y entre 3 y 5 semanas antes de que se presenten los síntomas o ictericia. El HBsAg cuenta con cuatro subtipos principales: adw, ayw, adr y ayr. Debido a que la heterogeneidad antigénica es determinante, existen 10 serotipos principales del virus de la hepatitis B.[2]
El dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) es una dispositivo que permite la deteeeión cualitativa rápida de la presencia del HBsAg en una muestra de sangre completa, suero o plasma. El dispositivo emplea una combinación de anticuerpos monoclonales y policlonales para realizar una deteeión selectiva de niveles elevados del HBsAg en sangre completa, suero o plasma.

PRINCIPIO

El dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) es un inmunoensayo cualitativo de fase sólida en dos laboratorios tipo "sándwich" que permite deteetar la presencia del HBsAg en sangre completa, suero o plasma. La membrana está previamente recubierta con anticuerpos anti-HBsAg en la zona de la línea de prueba del dispositivo. Durante la detección, la muestra de sangre completa, suero o plasma reacciona con las partículas conjugadas con anticuerpos anti-HBsAg. La mezcla se desplaza hacia arriba en la membrana cromatográficamente por capilaridad para reaccionar con los anticuerpos anti-HBsAg de la membrana y generar una línea coloreada. La presencia de esta línea coloreada en la zona de prueba indica un resultado positivo, mientras que su auseneia indiea un resultado negativo. Como control del procedimiento, siempre aparecerá una línea coloreada en la zona de la línea de control. Si la linea de control no aparece, el resultado de la prueba no es válido.

REACTIVOS

El dispositivo de detección contiene partículas anti-HBsAg y la membrana está recubierta con anti-HBsAg.

PRECAUCIONES

- Sólo para uso diagnóstico profesional *in vitro*. No utilizar después de la fecha de caducidad.
- No coma, beba o fume en la zona en que se manipulan los kits o las muestras.
- No utilice este dispositivo si el envase está dañado.
- Manipule y deseche todas las muestras y materiales utilizados en esta prueba como si contuvieran agentes infecciosos. Siga las medidas de precaución establecidas frente a peligros microbiológicos durante todos los procedimientos y siga los procedimientos estándar para un desecho adecuado de las muestras.
- Utilice ropa proteetora como batas de laboratorio, guantes deseehables y gafas de protección cuando se estén analizando las muestras.
- El análisis utilizado deberá desecharse según la legislación local.
- La humedad y la temperatura pueden afeetar de forma perjudicial a los resultados.
- El EDTA-K_2/la solución de citrato de sodio/el oxalato potásico/la heparina sódica pueden funcionar con el producto tras el estudio de anticoagulantes y, por tanto, se recomienda su uso cuando sea necesario.

ALMACENAMIENTO Y ESTABILIDAD

El kit puede conservarse a temperatura ambiente o refrigerado (2 – 30 °C). El dispositivo de detección es estable hasta la fecha de caducidad impresa en el envase sellado. El dispositivo de detección debe permanecer dentro del envase sellado hasta su uso. **NO CONGELAR.** No lo utilice después de la fecha de caducidad.

OBTENCIÓN Y PREPARACIÓN DE LA MUESTRA

- El dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) puede utilizarse con muestras de sangre completa (procedente de venopunción o de punción digital), suero o plasma.
- Para extraer muestras de sangre completa por punción digital:
  - Lávese las manos con jabón y agua templada o límpielas con una gasa con alcohol. Deje que se sequen.
  - Masajee la mano sin tocar la zona de puneión frotándose la mano hacia la punta del dedo del dedo corazón o anular.
  - Realice una punción en la piel con una lanceta estéril. No extraiga la primera gota de sangre.
  - Frote la mano con suavidad desde la muñeca hacia la palma y hasta el dedo para formar una gota de sangre redonda en la zona de punción.
  - Añada la muestra de sangre completa obtenida por punción digital al dispositivo de detección usando un tubo capilar:
    - Toque la sangre con el extremo del tubo capilar y espere hasta que llegue aproximadamente a 75 µl. Evite la formación de burbujas de aire.
    - Coloque la perilla en el extremo superior del tubo capilar, a continuación apriete la perilla para aplicar la sangre completa al pocillo de la muestra (S) del dispositivo de detección.
  - Añada la muestra de sangre completa obtenida por puneión digital al dispositivo de detección usando la gota suspendida:
    - Deje que 3 gotas suspendidas de sangre completa obtenida por punción digital caigan en el pocillo de la muestra (S) del dispositivo de detección, o mueva el dedo del paciente de manera que la gota suspendida toque el centro del pocillo de la muestra (S). Evite que el dedo toque directamente el pocillo de la muestra (S).
- Separe el suero o el plasma de la sangre lo antes posible para evitar hemólisis. Utilice solo muestras transparentes, no hemolizadas.
- El análisis deberá realizarse inmediatamente después de la extracción de muestras. No deje las muestras a temperatura ambiente durante un periodo de tiempo prolongado. Las muestras de suero y plasma pueden conservarse a 2 – 8 °C durante un máximo de 3 días. Si deben conservarse durante un periodo de tiempo prolongado, las muestras deberán mantenerse a una temperatura inferior a -20 °C. Las muestras de sangre completa obtenidas por venopunción deberán conservarse a una temperatura de 2 a 8 °C si el análisis se va a realizar en el plazo de 2 días desde la extracción. No congelar las muestras de sangre completa. Las muestras de sangre completa obtenidas mediante punción digital deberán analizarse de inmediato.
- Deje que las muestras alcancen la temperatura ambiente antes de analizarlas. Las muestras congeladas deben descongelarse por completo y mezclarse bien antes de analizarlas. Las muestras no se deben congelar y descongelar repetidamente.
- Si las muestras deben transportarse, deberán embalarse dc acuerdo con la normativa estatal en materia de transporte de agentes etiológicos.

MATERIALES

Materiales suministrado

- Dispositivos de detección
- Ficha técnica
- Cuentagotas desechables para muestras
- Tampón (solo para sangre completa)

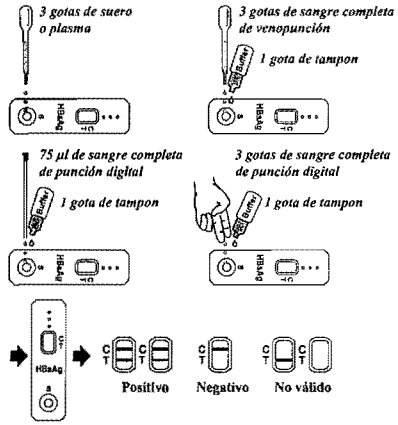
Materiales Requerido no suministrado

- Recipiente para la obtención de la muestra
- Centrífuga
- Tubos capilares desechables heparinizados y perilla dispensadora (solo para muestras dc sangre completa obtenidas por punción digital)
- Lanecas (solo para la obtención de sangre completa por punción digital)
- Cronómetro

INSTRUCCIONES DE USO

Deje que el dispositivo de detección, la muestra, el tampón y/o los controles alcancen la temperatura ambiente (15 - 30 °C) antes del análisis.

1. Saque el dispositivo de detección de la bolsa de aluminio sellada y utilícela a la mayor brevedad posible. Los mejores resultados se obtendrán si el análisis se realiza inmediatamente después de abrir la bolsa de aluminio.
2. Para muestras de **suero o plasma**:
   Sostenga el cuentagotas verticalmente y transfiera 3 gotas dc suero o plasma (aproximadamente 75 µl) al pocillo para muestras (S) del dispositivo de detección y ponga en marcha el cronómetro. Consulte la ilustraeión que aparece más abajo.
   Para muestras de **sangre completa obtenidas por venopunción**:
   Sostenga el cuentagotas verticalmente, transfiera 3 gotas de sangre completa obtenida por venopunción (aproximadamente 75 µl) al poeillo para muestras (S) del dispositivo de detección, añada 1 gota de tampón (aproximadamente 40 µl) y ponga en marcha el cronómetro. Consulte la ilustraeión que aparece más abajo.
   Para muestras de **sangre completa obtenidas por punción digital**:
   - Si se usa un tubo capilar: llene el tubo capilar y transfiera aproximadamente 75 µl de la muestra de sangre completa de punción digital al poeillo para muestras (S) del dispositivo de detección; a continuación añada 1 gota de tampón (aproximadamente 40 µl) y ponga en marcha el cronómetro. Consulte la ilustración que aparece más abajo.
   - Si se usa gota suspendida: deje que 3 gotas suspendidas de la muestra de sangre completa dc punción digital (aproximadamente 75 µl) caigan sobre el pocillo para muestras (S), añada a continuación 1 gota de tampón (aproximadamente 40 µl) y ponga en marcha el cronómetro. Consulte la ilustración que aparece más abajo.
3. Espere hasta que aparezcan las líneas coloreadas. El resultado deberá leerse transcurridos 15 minutos. No interprete el resultado después de 30 minutos.



INTERPRETACIÓN DE LOS RESULTADOS

(Consulte la ilustraeión anterior)

POSITIVO:* aparecen dos líneas diferentes coloreadas. Una línea debe estar en la zona de control (C) y otra línea en la zona de prueba (T).

***NOTA:** la intensidad del eolor de la zona de línea de detección (T) variará dependiendo de la concentración de HBsAg presente en la muestra. Por tanto, cualquier tono de color en la zona de prueba (T) se debe considerar positiva.

coloreada en la zona de la línea de prueba (T).

NO VÁLIDO: No aparece ninguna línea en la zona de la línea de control (C). Si esto ocurre, lea las indicaciones de nuevo y repita la prueba con una prueba nueva. Si el resultado sigue sin ser válido, deje de utilizar el kit de prueba inmediatamente y póngase en contacto con su distribuidor local.

CONTROL DE CALIDAD

En el análisis se incluye un control del procedimiento. La aparición de una línea coloreada en la zona dc control (C) es un control interno del procedimiento.
Los estándares de control no se suministran con este kit; sin embargo, se recomienda que se realice un análisis de control positivo (que contenga 10 ng/ml de HBsAg) y un análisis de control negativo (que contenga 0 ng/ml de HBsAg) como buena práctica de laboratorio para confirmar el procedimiento del análisis y garantizar un rendimiento adeeuado.

LIMITACIÓNES

1. El dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) es de uso exclusivo para diagnóstico *in vitro*. Esta prueba debe usarse para la detección de HBsAg en muestras de sangre completa, suero o plasma. Con este análisis cualitativo no se puede determinar ni el valor cuantitativo ni la tasa en la concentración de HBsAg.
2. El dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) solo indicará la presencia del HBsAg en la muestra, por lo que no debe utilizarse como único criterio para el diagnóstico de la infección de hepatitis B viral.
3. Al igual que todos los análisis diagnósticos, deberán considerarse todos los resultados junto con el resto de información clínica de que disponga el médico.
4. El dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) no puede detectar menos de 1 ng/ml de HBsAg en las muestras. Si el resultado del análisis es negativo pero los síntomas clínicos persisten, se recomienda realizar un análisis adicional con otros métodos clínicos. Un resultado negativo no excluye en ningún momento la posibilidad de una infección de hepatitis B.

VALORES PREVISTOS

El dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) se ha comparado con el principal inmunoensayo (EIA) comercial para HBsAg. La correlación entre estos dos sistemas es del 99,4%.

CARACTERÍSTICAS DE RENDIMIENTO

Sensibilidad

El dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) se ha comparado con un panel de sensibilidad en el que se incluyen los subtipos ad y ay con concentraciones que oscilan entre 0 y 300 ng/ml. El dispositivo puede detectar 1 ng/ml dc HBsAg en sangre completa, suero o plasma en 15 minutos.

Especificidad

Los anticuerpos empleados en el dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) se han desarrollado para todos los antígenos de hepatitis B aislados del virus de la hepatitis B. También se ha comprobado la especificidad del dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) con cepas de laboratorio de hepatitis A y C. Todas cllas arrojaron resultados negativos.

Método		EIA		Resultados totales
Dispositivo de detección de HBsAg	Resultados	Positivo	Negativo	
	Positivo	409	5	414
	Negativo	1	617	618
Resultados totales		410	622	1,032

Sensibilidad relativa: 99,8% (98,6%-100,0%)* Especificidad relativa: 99,2% (98,1%-99,7%)*
Precisión: 99,4% (98,7%-99,8%)* * Intervalo de confianza 95%

Precisión

Intraensayo

Se ha determinado la precisión intraanálisis usando 10 replieados de ocho muestras que contenían 0 ng/ml, 2 ng/ml, 5 ng/ml y 10 ng/ml de Ad y Ay de HBsAg. Los valores negativo y positivo se identificaron correctamente más del 99% de las veces.

Interensayo

Se ha determinado la precisión entre análisis usando ocho muestras de 0 ng/ml, 2 ng/ml, 5 ng/ml y 10 ng/ml de Ad e Ay de HBsAg en 3 análisis independientes. Se han examinado tres lotes diferentes del dispositivo de detección rápida de los antígenos de superficie de la hepatitis B (HBsAg) (para sangre completa/suero/plasma) usando las muestras negativa, positiva baja y positiva alta. Las muestras se identificaron correctamente más del 99% de las veces.

BIBLIOGRAFÍA

1. Blumberg, B.S. *The Discovery of Australian Antigen and its relation to viral hepatitis.* Vitro. 1971; 7: 223
2. World Health Organization. HEPATITIS B SURFACE ANTIGEN ASSAYS: OPERATIONAL CHARACTERISTICS (PHASE I) report 1. 2001; 2-4

Índice de Símbolos

	Consulte las instrucciones de uso	Σ	Pruebas por kit	EC REP	Representante autorizado
IVD	Solo para uso dc diagnóstico *in vitro*		Caducidad		No reutilizar
2°C 30°C	Almacenar entre 2-30°C	LOT	Número de lote	REF	Nº de referencia

Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018, P.R.China

CE 1023

EC REP
MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert/Germany

Effective date: 2015-01-13

Number: 1156096302

ABON™ HCV

Hepatitis C Virus Rapid Test Device (Serum/Plasma)
Package Insert
English

REF IHC-302

A rapid test for the qualitative detection of antibodies to Hepatitis C Virus in serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in serum or plasma.

SUMMARY

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis.
Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens.[1,2] Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.[3,4]
The HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes a combination of recombinant HCV antigen coated particles and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma. The recombinant HCV antigens used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

PRINCIPLE

The HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the serum or plasma specimen reacts with the recombinant HCV antigen coated particles. The mixture migrates upward on the membrane by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region. If the control line does not appear, the test result is not valid.

REAGENTS

The test device contains recombinant HCV antigen coated particles and another recombinant HCV antigen coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- EDTA-K_2/Sodium citrate/Potassium oxalate/Sodium heparin can work with the product after anticoagulant study and are hence recommended to use when necessary.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Buffer
- Package insert

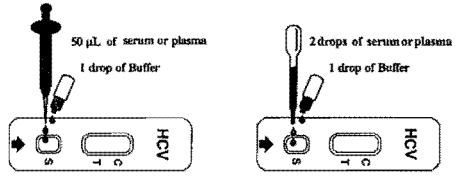
Materials Required But Not Provided

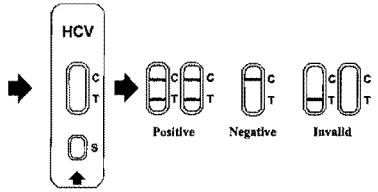
- Specimen collection container
- Centrifuge (for plasma only)
- Pipette and disposable tips (optional)
- Timer

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Transfer the specimen by a pipette or a dropper:
   - To use a **Pipette**: Transfer 50 µL of serum or plasma to the specimen well (S) of the test device, then add 1 full drop of buffer (approximately 30 µL) and start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
   - To use a **Disposable Specimen Dropper**: Hold the dropper vertically, draw serum or plasma as shown in illustration below. Transfer 2 full drops of the specimen (approximately 50 µL) to the specimen well (S) of the test device, then add 1 full drop of buffer (approximately 30 µL) and start the timer. Avoid trapping air bubbles in the specimen well (S).
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: * Two distinct colored lines appear. One line should be in the control region (C) and another line should be in the test region (T).
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of HCV antibodies present in the specimen. Therefore, any shade of color in the test region should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION

1. The HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HCV in serum or plasma specimen.
2. The HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.

EXPECTED VALUES

The HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) has been compared with a leading commercial rapid test product. The correlation between these two systems is 99.85%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) has compared with a leading commercial rapid test product.

Specificity

The recombinant antigen used for the HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) is highly specific for antibodies to Hepatitis C Virus compared with a leading commercial rapid test product.

Method		Commercial Rapid Test		Total Results
HCV Test Device	Results	Positive	Negative	
	Positive	630	3	633
	Negative	0	1367	1367
Total Results		630	1370	2000

Sensitivity: >99.53% (99.53%-100.0%)*
Specificity: 99.78% (99.36%-99.95%)*
Accuracy: 99.85% (99.56%-99.97%)*
*95% Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using 20 replicates of four specimens: a buffer, a low positive, a middle positive and a high positive. The buffer, low positive, middle positive and high positive values were correctly identified 98% of the time.

Inter-Assay

Between-run precision has been determined by 20 independent assays on the same four specimens: a buffer, a low positive, a middle positive and a high positive. Three different lots of the HCV Hepatitis C Virus Rapid Test Device (Serum/Plasma) have been tested using buffer, low positive, middle positive and high positive specimens. The specimens were correctly identified 98% of the time.

BIBLIOGRAPHY

1. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. *Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome.* Science 1989; 244:359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. *An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis.* Science 1989; 244:362
3. van der Poel, C. L., H.T.M. Cuypers, H.W. Reesink, and P.N.Lelie. *Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay.* Lancet 1991; 337:317
4. Wilber, J.C. *Development and use of laboratory tests for hepatitis C infection: a review.* J. Clin. Immunoassay 1993; 16:204

Index of Symbols

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East,
Hangzhou Economic & Technological Development Area,

CE 1023

EC REP
MT Promedt Consulting GmbH
Altenhofstrasse 80

Date efficace: 2015-01-13

Nombre: 1156096302

ABON™ VHC

Dispositif de diagnostic rapide du virus de l'hépatite C (sérum/plasma)
Mode d'Emploi

Français

REF IHC-302

Test rapide de détection qualitative des anticorps dirigés contre le virus de l'hépatite C dans le sérum ou le plasma.
Réservé exclusivement à un usage diagnostique in vitro professionnel.

INDICATION

Le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) est un immunodosage chromatographique rapide qui permet la détection qualitative des anticorps dirigés contre le virus de l'hépatite C dans le sérum ou le plasma.

RÉSUMÉ

Le virus de l'hépatite C (VHC) est un virus à ARN simple brin, de polarité positive, enveloppé, de petite taille. Le VHC est connu comme étant l'une des principales causes d'hépatite non A et non B à transmission parentale. On trouve des anticorps contre le VHC chez plus de 80 % des patients porteurs d'une hépatite non A et non B bien documentés.
Les méthodes classiques ne parviennent pas à isoler le virus en culture cellulaire ou à le visualiser au microscope électronique. Le clonage du génome viral a rendu possible le développement de tests sérologiques utilisant des antigènes recombinants.[1,2] Comparé aux tests immunoenzymatiques de première génération, plusieurs antigènes utilisant des protéines recombinantes et/ou des peptides de synthèse ont été ajoutés dans les nouveaux tests sérologiques afin d'éviter les réactions croisées non spécifiques et d'améliorer la sensibilité des tests sur les anticorps contre le VHC.[3,4]
Le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) est un test rapide qui permet la détection qualitative des anticorps dirigés contre le VHC dans un échantillon de sérum ou de plasma. Le test utilise une combinaison de particules recouvertes d'antigènes recombinants du VHC et de protéines recombinantes du VHC afin de détecter de façon sélective les anticorps dirigés contre le VHC dans le sérum ou le plasma. Les antigènes recombinants du VHC utilisés dans le kit de test sont encodés par les gènes des protéines à la fois structurelles (nucléocapside) et non structurelles.

PRINCIPE

Le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) est un immunodosage qualitatif sur membrane qui permet la détection des anticorps dirigés contre le VHC dans le sérum ou le plasma. La membrane est recouverte d'antigènes recombinants du VHC au niveau de la zone de test du dispositif. Au cours du test, l'échantillon de sérum ou de plasma réagit avec les particules recouvertes d'antigènes recombinants du VHC. Le mélange migre par capillarité le long de la membrane et réagit avec l'antigène recombinant du VHC présent sur cette dernière, entraînant l'apparition d'une ligne colorée. La présence de cette ligne colorée indique un résultat positif et son absence un résultat négatif. En guise de procédure de contrôle, une ligne colorée apparaîtra toujours dans la zone de contrôle. Si la ligne de contrôle n'apparaît pas, le résultat du test n'est pas valide.

RÉACTIFS

Le dispositif de test contient des particules recouvertes d'antigènes recombinants du VHC ainsi qu'un autre antigène recombinant du VHC présent sur la membrane.

PRÉCAUTIONS

- Réservé exclusivement à un usage diagnostique *in vitro* professionnel. Ne pas utiliser après la date d'expiration.
- Ne pas manger, boire ou fumer dans la pièce où les échantillons et les kits sont manipulés.
- Ne pas utiliser le test si la pochette est endommagée.
- Manipuler tous les échantillons comme s'ils étaient potentiellement infectieux. Observer toutes les mises en garde relatives aux risques microbiologiques pendant le test et suivre les procédures standard relatives à la mise au rebut des échantillons.
- Porter des vêtements de protection tels que des blouses de laboratoire, des gants jetables et des lunettes de protection pour manipuler les échantillons.
- Les tests utilisés doivent être mis au rebut conformément aux réglementations locales en vigueur.
- L'humidité et la température peuvent affecter les résultats.
- Les anti-coagulants de type EDTA dipotassique, citrate de sodium, oxalate de potassium et héparine sodique peuvent agir avec le produit après l'étude des anti-coagulants. Il est dès lors recommandé de les utiliser lorsque cela est nécessaire.

CONSERVATION ET STABILITÉ

Le kit peut être conservé à température ambiante ou réfrigéré (entre 2 et 30 °C). Le dispositif de diagnostic est stable jusqu'à la date d'expiration imprimée sur la pochette scellée. Le test doit rester dans la pochette scellée jusqu'à son utilisation. **NE PAS CONGELER.** Ne pas utiliser après la date d'expiration.

PRÉLÈVEMENT ET PRÉPARATION DES ÉCHANTILLONS

- Le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) peut être utilisé sur du sérum ou du plasma.
- Séparer le sérum ou le plasma du sang dès que possible pour éviter toute hémolyse. Utiliser uniquement des échantillons clairs non hémolysés.
- Le test doit être effectué immédiatement après le prélèvement des échantillons. Ne pas laisser les échantillons à température ambiante pendant une période prolongée. Les échantillons peuvent être conservés à 2-8 °C pendant une période maximale de 3 jours. Pour une conservation prolongée, les échantillons doivent être stockés à une température inférieure à -20 °C.
- Laisser les échantillons revenir à température ambiante avant de commencer le test. Les échantillons congelés doivent être entièrement décongelés et mélangés avant de commencer le test. Ne pas congeler et décongeler les échantillons plus d'une fois.
- Si les échantillons doivent être transportés, les protéger conformément aux réglementations nationales en vigueur relatives au transport d'agents étiologiques.

MATÉRIEL

Matériel fourni

- Dispositifs de test
- Compte-gouttes jetables
- Tampon
- Mode d'Emploi

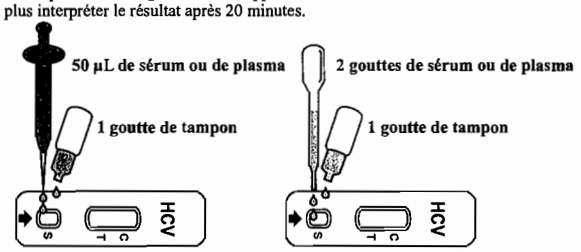
Matériel nécessaire mais non fourni

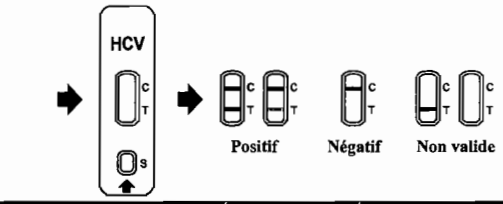
- Conteneur de collecte des échantillons
- Centrifugeuse (plasma uniquement)
- Pipette et embouts jetables (disponibles en option)
- Minuteur

MODE D'EMPLOI

Laisser le dispositif de diagnostic, l'échantillon, le tampon et/ou les contrôles atteindre la température ambiante (entre 15 et 30 °C) avant la réalisation du test.

1. Retirer le dispositif de diagnostic de la pochette en feuille d'aluminium et l'utiliser dès que possible. Pour des résultats optimaux, réaliser le dosage dans l'heure.
2. Poser le dispositif de diagnostic sur une surface plane et propre. Transférer l'échantillon à l'aide d'une pipette ou d'un compte-gouttes:
   - Avec une **pipette** : transférer 50 µL de sérum ou de plasma dans le puits d'échantillonnage (S) du dispositif de test, puis ajouter une grosse goutte de tampon (environ 30 µL) et démarrer le minuteur. Éviter de piéger des bulles d'air dans le puits d'échantillonnage (S). Voir l'illustration ci-dessous.
   - Avec un **compte-gouttes à échantillon jetable** : tenir le compte-gouttes à la verticale et prélever le sérum ou le plasma (voir l'illustration ci-dessous). Transférer 2 grosses gouttes d'échantillon (environ 50 µL) dans le puits d'échantillonnage (S) du dispositif de test, puis ajouter 1 grosse goutte de tampon (environ 30 µL) et démarrer le minuteur. Éviter de piéger des bulles d'air dans le puits d'échantillonnage (S).
3. Attendre que la ou les lignes colorées apparaissent. Lire le résultat au bout de 10 minutes. Ne plus interpréter le résultat après 20 minutes.





INTERPRÉTATION DES RÉSULTATS

(Voir l'illustration ci-dessous)

POSITIF: deux lignes colorées distinctes apparaissent*. Une ligne se situe dans la zone de contrôle (C) et l'autre dans la zone de test (T).

***REMARQUE:** l'intensité de la couleur dans la zone de test (T) peut varier selon la concentration en anticorps du VHC présente dans l'échantillon. Ainsi, toute nuance de couleur dans la zone de test révèle un résultat positif.

NÉGATIF: une seule ligne colorée apparaît dans la zone de contrôle (C). Aucune ligne colorée n'apparaît dans la zone de test (T).

NON VALIDE: Aucune ligne n'apparaît dans la zone de contrôle (C). Dans ce cas, lisez à nouveau les instructions et répétez le test en utilisant un autre test. Si le résultat est toujours non valide, cesser immédiatement d'utiliser le kit de test et contacter le distributeur local.

CONTRÔLE QUALITÉ

Des contrôles de procédure internes sont inclus dans le test. L'apparition d'une ligne colorée dans la zone de contrôle (C) indique un contrôle de procédure interne positif.
Les normes de contrôle ne sont pas fournies avec ce kit ; cependant, il est recommandé de tester les contrôles positifs et négatifs, dans le cadre d'une bonne pratique de laboratoire, pour confirmer la procédure de test et vérifier les performances du test.

LIMITES

1. Le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) est réservé à un usage diagnostique *in vitro* et sert à la détection des anticorps dirigés contre le VHC dans
2. Le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) indique uniquement la présence d'anticorps dirigés contre le VHC dans l'échantillon et ne doit pas être utilisé comme seul critère de diagnostic d'une infection virale de l'hépatite C.
3. Comme pour tous les tests diagnostiques, l'interprétation des résultats doit tenir compte de toutes les autres informations cliniques à la disposition du médecin.
4. Si le résultat du test est négatif mais que les symptômes cliniques persistent, il est recommandé de procéder à des tests complémentaires utilisant d'autres méthodes cliniques. Un résultat négatif n'exclut en aucun cas une infection par le virus de l'hépatite C.

VALEURS ATTENDUES

Le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) a été comparé au principal test rapide disponible sur le marché. La corrélation entre ces deux systèmes est de 99,85 %.

PERFORMANCE

Sensibilité

Le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) a été comparé au principal test rapide disponible sur le marché.

Spécificité

L'antigène recombinant utilisé pour le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) est encodé par les gènes des protéines à la fois structurelles (nucléocapside) et non structurelles. Le dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) utilise des anticorps très spécifiques au virus de l'hépatite C, par rapport au principal test rapide disponible sur le marché.

Méthode		Test rapide disponible sur le marché		Résultats totaux
Dispositif de diagnostic du VHC	Résultats	Positif	Négatif	
	Positif	630	3	633
	Négatif	0	1367	1367
Résultats totaux		630	1370	2000

Sensibilité : >99,53 % (99,53 %-100,0 %)* Spécificité : 99,78 % (99,36 %-99,95 %)*
Précision : 99,85 % (99,56 %-99,97 %)* *Intervalle de confiance de 95 %

Précision

Intra-série

La précision intra-série a été déterminée à l'aide de 20 réplicats de quatre échantillons : un tampon, un faiblement positif, un moyennement positif et un fortement positif. Les valeurs tampon, faiblement positives, moyennement positives et fortement positives ont été correctement identifiées dans 98 % des cas.

Inter-séries

La précision inter-séries a été déterminée par 20 tests indépendants sur les quatre mêmes échantillons : un tampon, un faiblement positif, un moyennement positif et un fortement positif. Trois lots différents du dispositif de test rapide du virus de l'hépatite C VHC (sérum/plasma) ont été testés à l'aide d'échantillons tampon, faiblement positifs, moyennement positifs et fortement positifs. Les échantillons ont été correctement identifiés dans 98 % des cas.

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Liste des Symboles

	Consulter la notice d'utilisation		Tests par coffret	EC REP	Représentant autorisé
IVD	Pour diagnostic *in vitro* uniquement		Péremption		Usage unique
2°C 30°C	Conserver entre 2-30°C	LOT	No. de lot	REF	Code produit

Abon Biopharm (Hangzhou) Co., Ltd.
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CE 1023

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