http://www.who.int/hiv/events/GLOBAL_FUND_HIV.pdf

Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

A streamlined approach to the WHO Prequalification of In Vitro Diagnostics Programme

Global Fund Meeting with HIV IVD Manufacturers
18 September 2014, Geneva

HIV Rapid Tests: Progress of the Prequalification of Diagnostics process by product

Product name	Product code(s)	Manufacturer name	Application status	Dossier request and screening	Dossier full review	On-site inspection status	Laboratory evaluation status
ABON HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)	IHI-T402	ABON Biopharm (Hangzhou) Co. Ltd.	◆	◆	R	S	
ACON HIV1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	IHI-T402	ACON Biotech (Hangzhou) Co. Ltd.	W	–	–	–	–
Advanced Quality™ One Step Anti-HIV (1&2) Test	ITP02006TC40	InTec PRODUCTS INC.	◆	◆	R		S
Advanced Quality™ Rapid Anti-HIV (1&2) POCT	ITP02009TC1	InTec PRODUCTS INC.	⧗	–	–	–	–
Aidscan HIV-1/2 Trispot Test Kit	ATS-50	Bhat Bio-Tech India (P) Ltd.	C	–	–	–	–
Alere Determine HIV-1/2	7D2342 and 7D2343	Alere Medical Co. Ltd.	◆	◆	◆	◆	◆
Alere Determine HIV-1/2 Ag/Ab Combo	7D2643	Alere Medical Co. Ltd.	◆	◆	◆	◆	◆
Anti-human immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold)	WJ-1810 and WJ-1850	Beijing Wantai Biological Pharmacy Enterprise Co. Ltd.	◆	◆	🗁		🗁
Anti-HIV 1/2 (S/P) Rapid Test	THIV01 / THV.01 and THV.02	Türklab Inc.	C	–	–	–	–
Anti-HIV 1/2 (WB/S/P) Rapid Test	THIV02	Türklab Inc.	C	–	–	–	–

R – требуется дополнительная информация от производителя
S – необходимы последующие правки
♦ **- этап завершен – прошёл Преквалификацию**
🗁 - в процессе
W – отказано
C – начато

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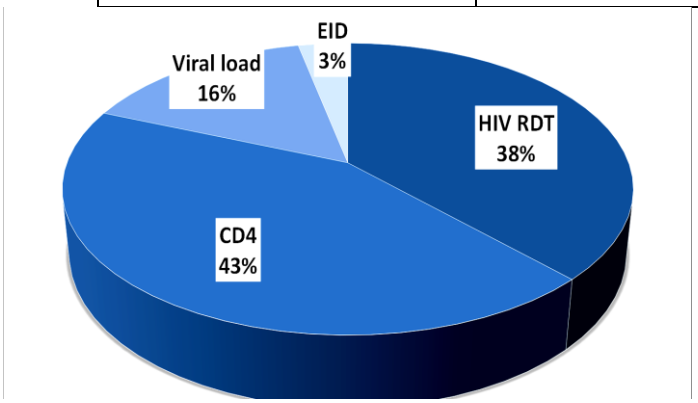
The HIV Diagnostic Forecast Spend for 2014 is $90 million

Утвержденные фонды на закупку в 2014 году	Сумма в $ США	Кол-во тестов, запланированных для закупки
Экспресс-тесты (Rapid tests)	34 миллионов	40 миллионов
CD4 тесты	39 миллионов	5 миллионов
Анализ на вирусную нагрузку	14 миллионов	500,000
EID tests	3 миллиона	200,000



The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Version-5
August 2014

List of Diagnostic test kits for HIV and HIV 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:
(1) recommended by WHO for use in HIV/AIDS programs, based on a technical review of quality and performance indicators,
OR
(2) approved by authorities founding member of Global Harmonization Task Force (US, EU, Canada, Japan, Australia) (GHTF)

criteria 1 applicable currently to HIV Rapid Diagnostics, Immunoassays and after 1st July 2014 also applicable to CD4 and Virological Technologies (VL and EID)
criteria 2 applicable currently to HIV Rapid Diagnostics, Immunoassays and after 1st July 2014 also applicable to Virological Technologies (VL and EID)

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 and GHTF founding members.

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 :http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

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

HIV Simple assays/Rapid Diagnostic Tests (RDTs)

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-T402.	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	Whole Blood/ Serum/Plasma	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 http://www.who.int/diagnostics_laboratory/evaluations/140825_public_report_abon_hiv_triline_rdt_v1.pdf?ua=1
ITP02002-TC40.	Advanced Quality™ HIV Rapid Test	40	99.40%	98.80%	InTec Products, Xiamen, PR China	HIV1/2 antibodies combined	Serum, Plasma and whole blood	18 months 2 to 30°C	If whole blood: lancets, alcohol swabs.	WHO PQ
7D2342.	Alere Determine™ HIV-1/2	20	100%	99.40%	Alere Medical Japan, Matsudo, Japan	HIV 1/2 antibodies combined	Serum, Plasma and whole blood	14 months 2 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer (7D2211), EDTA capillary tubes (7D2222). If serum/plasma: requires precision pipette plus tips.	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/111125_0033_023_00_public_report_final.pdf
7D2343.		100								
7D2643.	Alere Determine™ HIV- 1/2 Ag/Ab Combo	100	100%	98.80%	Alere Medical Japan, Matsudo, Japan	Discrimination between HIV 1/2 antibodies combined and HIV1- p24 antigen	Serum, Plasma and Whole blood	10 months 2 to 30°C	If whole blood: lancets, alcohol swabs, chase buffer (7D2211),EDTA capillary tubes (7D2222). If serum/plasma: requires precision pipette plus tips.	WHO PQ http://www.who.int/diagnostics_laboratory/evaluations/120320_0034_023_00_final_public_report_version2.pdf
7D2346	Alere Determine™ HIV-1/2	20	100%	99.75%	Alere Medical Japan, Matsudo, Japan	HIV 1/2 Antibodies combined	Serum, Plasma and Venous/capillary whole blood	14 months 2 to 30°C	Lancet, sterile gauze, antiseptic wipes Biohazard waste containers On order separately for whole blood procedure: Chase buffer 1x1.5ml (7D2243) EDTA capillary tubes (7D2222) *or* Microsafe capillary tubes (7D2223)	CE marked
7D2347		100								