



### USAID List of Approved HIV Rapid Test Kits - February 1, 2017

The U.S. Agency for International Development (USAID) List of Approved HIV Rapid Test Kits includes (1) the HIV rapid test kits below and (2) HIV rapid test kits approved by the World Health Organization (WHO) Prequalification of Medicines Programme.

The HIV rapid test kits are for approved for clinical use. HIV rapid test kits used in research settings are approved separately by the Supply Chain for Health Division, Office of HIV/AIDS, Bureau for Global Health (OHA/SCH).

For questions on USAID approval of HIV rapid test kits please contact OHA/SCH at ADS312approvals@usaid.gov.

	Test Kit Name	Supplier	Approved by
1	ABON™ HIV 1/2/O Tri-line HIV Rapid Test Device (Whole Blood/Serum/Plasma)	Alere*	USAID
2	Alere Determine™ HIV-1/2	Alere*/ Abbott Laboratories*	USAID
3	Alere Determine™ HIV-1/2 Ag/Ab Combo Rapid Test Kit	Alere*	USAID
4	Aware™ HIV-1/2 BSP	Calypte Biomedical*	USAID
5	Bioline HIV 1/2 3.0	Standard Diagnostics	USAID
6	Bionor™ HIV-1&2	Bionor A/S	USAID
7	BioTracer™ HIV 1/2 Rapid Card (Whole Blood/Serum/Plasma)	Bio Focus Co., Ltd.	USAID
8	Bundi™ Rapid HIV 1/2	Bundi International Diagnostics Ltd.	USAID
9	Calypte® Aware™ HIV-1/2 OMT	Calypte Biomedical Corp.*	USAID
10	Capillus™ HIV-1/HIV-2	Trinity Biotech	USAID
11	Care Start™ HIV 1-2-O	Access Bio, Inc.*	USAID
12	Chembio SURE CHECK® HIV1/2(formerly Clearview® COMPLETE HIV1/2)	Chembio Diagnostic Systems, Inc*	USAID
13	Chembio HIV 1/2 STAT-PAK® Assay - US labeling** (formerly Clearview® HIV 1/2 STAT-PAK® Assay )	Chembio Diagnostic Systems, Inc*	FDA
14	Clearview® COMPLETE HIV1/2 - US labeling** (formerly SURE CHECK® HIV1/2)	Alere*	FDA
15	Combaid RS Advantage	Span Diagnostics Ltd.	USAID
16	DPP® HIV 1 / 2 Assay– Oral Fluid, Whole Blood, Serum & Plasma - US labeling**	Chembio Diagnostic Systems, Inc*	FDA
17	DPP® HIV 1/2 Screen	Chembio Diagnostic Systems, Inc*	USAID
18	DPP® HIV 1 / 2 Screen Assay – Oral Fluid, Whole Blood, Serum & Plasma	Chembio Diagnostic Systems, Inc*	USAID
19	DPP® HIV-Syphilis Assay	Chembio Diagnostic Systems, Inc*	USAID
20	Double Check™ HIV 1&2	Alere*/ Organics, Ltd	USAID

21	Double Check Gold™ HIV1&2	Alere*/ Orgenics, Ltd	USAID
22	EZ-TRUST™ Rapid Anti-HIV (1&2) Test	CS Innovation	USAID
23	First Response® HIV 1-2.0	Premier Medical Corporation	USAID
24	Genie™ Fast HIV 1/2	Bio-Rad Laboratories*	USAID
25	HIV 1/2 Gold Rapid Screen Test	Medinostics Int'l *	USAID
26	HIV 1/2 Rapid Test Kit	Medinostics Int'l *	USAID
27	HIV 1/ 2 STAT-PAK® Assay	Chembio Diagnostic Systems, Inc*	USAID
28	HIV 1/2 STAT-PAK® Dipstick Assay	Chembio Diagnostic Systems, Inc.*	USAID
29	HIV(1+2) Rapid Test Strip	Shanghai Kehua Bio-engineering Co., Ltd (KHB)	USAID
30	HIVSav 1&2 Rapid SeroTest™	Savyon Diagnostics Ltd. [not Savyvon]	USAID
31	iCARE Rapid Anti-HIV (1&2)	JAL Innovation	USAID
32	ImmunoComb™ HIV 1&2	Alere*/ Orgenics, Ltd	USAID
33	InstantCHEK™ HIV1+2	EY Laboratories	USAID
34	INSTI™ HIV-1/HIV-2 Antibody	bioLytical™ Laboratories, Inc.	FDA
35	KSII – HIV 1/2 Rapid Diagnostic Test Kit	K. Shorehill Int'l, Inc.*	USAID
36	MPI Diagnostics Anti-HIV (1&2) Test	MPI Diagnostics*	USAID
37	Multispot™ HIV-1/HIV-2	Bio-Rad laboratories*	FDA
38	OraQuick® ADVANCE™ Rapid HIV-1/2**	OraSure Technologies*	FDA
39	OraQuick® HIV-1/2 Rapid Antibody Test	OraSure Technologies*	USAID
40	RAPID 1-2-3® HEMA™ Dipstick	Hema Diagnostics Systems*	USAID
41	RAPID 1-2-3® HEMA EZ™	Hema Diagnostics Systems*	USAID
42	RAPID 1-2-3® HEMA EXPRESS™	Hema Diagnostics Systems*	USAID
43	Reveal® Rapid HIV Test	MedMira	USAID
44	Reveal® G3 Rapid HIV-1 Antibody Test	MedMira	FDA
45	RightSign HIV 1.2.0 Rapid Test Cassette	Hangzhou Biotest Biotech Co. Ltd.	USAID
46	Signal HIV Rapid Test	Span Diagnostics Ltd.	USAID
47	Uni-Gold™ HIV	Trinity Biotech	USAID
48	Uni-Gold™ Recombigen® HIV**	Trinity Biotech	FDA
49	SD Bioline HIV/Syphilis Duo	Standard Diagnostics	USAID
	*Parent Company is a United States-based firm.		
	**Generally distributed only in the United States.		