



USAID List of Approved HIV/AIDS Rapid Test Kits - April 1, 2008

| <u>Test Kit Name</u> | <u>Supplier</u> | <u>Approved by</u> |
|---|---|---------------------------|
| 1. Aware™ HIV-1/2 BSP | Calypte Biomedical* | USAID |
| 2. Bionline HIV 1/2 3.0 | Standard Diagnostics | USAID |
| 3. Bionor™ HIV-1&2 | Bionor A/S | USAID |
| 4. Bundi™ Rapid HIV 1/2 | Bundi International Diagnostics Ltd. | USAID |
| 5. Calypte® Aware™ HIV-1/2 OMT | Calypte Biomedical Corp.* | USAID |
| 6. Capillus™ HIV-1/HIV-2 | Trinity Biotech | USAID |
| 7. Care Start™ HIV 1-2-O | Access Bio, Inc.* | USAID |
| 8. Clearview® COMPLETE HIV1/2 (formerly SURE CHECK® HIV1/2) | Inverness Medical Innovations, Inc.* | USAID |
| 9. Clearview® COMPLETE HIV1/2 - US labeling** (formerly SURE CHECK® HIV1/2) | Inverness Medical Innovations, Inc.* | FDA |
| 10. Clearview ® HIV 1/2 STAT-PAK® Assay - US labeling (formerly HIV 1/2 STAT-PAK® Assay - US labeling)** | Inverness Medical Innovations, Inc.* | FDA |
| 11. Combaid RS Advantage | Span Diagnostics Ltd. | USAID |
| 12. Determine™ HIV-1/2 | Inverness Medical Innovations, Inc.*/ Abbott Laboratories* | USAID |
| 13. Double Check™ HIV 1&2 | InvernessMedical Innovations, Inc.*/ Orgenics, Ltd | USAID |
| 14. Double Check Gold™ HIV1&2 | InvernessMedical Innovations, Inc.*/ Orgenics, Ltd. | USAID |

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| 15. EZ-H2 | CS Innovation | USAID |
| 16. First Response® HIV 1-2.0 | Premier Medical Corporation | USAID |
| 17. Genie II HIV-1/HIV-2 | Bio-Rad Laboratories* | USAID |
| 18. HIV 1/2 Gold Rapid Screen Test | Medinostics Int'l * | USAID |
| 19. HIV 1/2 Rapid Test Kit | Medinostics Int'l * | USAID |
| 20. HIV 1/ 2 STAT-PAK® Assay | Chembio Diagnostic Systems, Inc* | USAID |
| 21. HIV 1/2 STAT-PAK® Dipstick Assay | Chembio Diagnostic Systems, Inc.* | USAID |
| 22. Diagnostic kit for HIV (1+2) Antibody (Colloidal Gold) | Shanghai Kehua Bioengineering | USAID |
| 23. HIVSav 1&2 Rapid SeroTest™ | Savyvon Diagnostics Ltd. | USAID |
| 24. ImmunoComb™ HIV 1&2 | Inverness Medical Innovations, Inc.*/ Orgenics, Ltd. | USAID |
| 25. InstantCHEK™ HIV1+2 | EY Laboratories | USAID |
| 26. INSTI™ HIV Antibody | Biolytical Laboratories | USAID |
| 27. Multispot™ HIV-1/HIV-2 | Bio-Rad laboratories* | FDA |
| 28. OraQuick® ADVANCE™ Rapid HIV-1/2** | OraSure Technologies* | FDA |
| 29. OraQuick® HIV-1/2 Rapid Antibody Test | OraSure Technologies* | USAID |
| 30. RAPID 1-2-3® HEMA EZ™ | Hema Diagnostics Systems* | USAID |
| 31. RAPID 1-2-3® HEMA EXPRESS™ | Hema Diagnostics Systems* | USAID |
| 32. Reveal®G3 Rapid HIV-1 Antibody Test | MedMira | FDA |
| 33. Signal HIV Rapid Test | Span Diagnostics Ltd. | USAID |
| 34. Uni-Gold™ HIV | Trinity Biotech | USAID |
| 35. Uni-Gold™ Recombigen® HIV** | Trinity Biotech | FDA |

* Parent Company is a United States-based firm.

** Generally distributed only in the United States.