

HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document

Fourth Edition

Edited by Abiola Johnson

Printed July 2007



Rational Pharmaceutical Management Plus Program
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmpplus@msh.org

This document was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning, and in promoting the appropriate use of health commodities in the public and private sectors.

Note: Although Management Sciences for Health (MSH)/RPM Plus Program has made every effort to ensure the accuracy of product, manufacturer, price, supplier, procurement agency, and other information presented in this document, the data and information contained herein are being provided as is; MSH/RPM Plus and USAID make no representation or warranties, either express or implied, as to its accuracy, completeness, or fitness for a particular purpose.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by USAID or RPM Plus in preference to others of a similar nature that are not mentioned. Errors or omissions excepted, the names of proprietary products are distinguished by initial capital letters.

This document may be reproduced if credit is given to RPM Plus. Please use the following citation.

Rational Pharmaceutical Management Plus. 2007. *HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document*. 4th ed. Edited by A. Johnson. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Acknowledgments

We thank the representatives of the manufacturing companies, procurement agencies, and suppliers for their cooperation and for providing us with information regarding their products and the services that they provide.

The editor would like to acknowledge the contributions of the RPM Plus staff members who provided technical assistance and direction for this edition.

Rational Pharmaceutical Management Plus Program
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmpplus@msh.org

CONTENTS

Acronyms	v
Glossary	vii
Incoterms.....	ix
Introduction.....	1
Background.....	1
Objective.....	2
HIV Test Kits Procurement Information Document: Fourth Edition.....	2
Methodology.....	2
Who Is This Procurement Information Document For?	3
How to Use This Document.....	3
Updates and Evaluation	3
Guidance Document for Obtaining USAID Approval to Procure USAID-Funded Pharmaceutical Products.....	4
Chapter 1: HIV Test Kits Listed in the USAID Source and Origin Waiver.....	5
What Is in This Section?.....	6
Aware™ HIV-1/2 BSP Rapid Test	9
Bioline HIV 1/2 3.0.....	11
Bionor™ HIV-1&2.....	13
Bundi™ HIV-1/2	15
Capillus™ HIV-1/HIV-2	17
CareStart™ HIV-1-2-O	20
Clearview® COMPLETE HIV 1/2.....	22
Determine™ HIV-1/2	23
DoubleCheck™ HIV 1&2	26
DoubleCheck Gold™ HIV 1&2	28
First Response® HIV 1-2.0	30
Genie II HIV-1/HIV-2	32
HIVSav 1/2/0 Rapid SeroTest™	35
HIV 1/2 STAT-PAK™ Assay	37
HIV 1/2 STAT-PAK™ Dipstick	39
ImmunoComb® II HIV 1 & 2 BiSpot	41
InstantCHEK™ HIV 1+2	43
INSTI™HIV-1/HIV-2 Rapid Antibody Test.....	45
OraQuick® ADVANCE™ Rapid HIV-1/2 Test	47
OraQuick® HIV-1/2 Rapid Antibody Test.....	50
Reveal™ G3 Rapid HIV-1 Antibody Test.....	53
Uni-Gold™ HIV	55
Uni-Gold™ Recombigen®	58

Chapter 2: Procurement Agencies and Suppliers.....	61
What Is in This Section?	62
Action Medeor	65
Crown Agents	66
Durbin PLC.....	68
IDA Foundation	69
Joint Medical Stores (JMS).....	71
Medical Export Group (MEG).....	72
Medical Stores Department (MSD)	73
Mission for Essential Drugs and Supplies (MEDS)	74
Missionpharma A/S	75
Orbi-Pharma.....	77
Tri-Med Group.....	78
UNFPA	79
UNICEF	80
World Health Organization.....	82
 REFERENCES	 85
 Annex 1. USAID Source and Origin Waiver for HIV/AIDS Diagnostic materials	 87
 Annex 2. USAID Geographic Codes	 109
 Annex 3. Summary Listings for HIV Test Kits	 111

ACRONYMS

AIDS	acquired immunodeficiency syndrome
CA	cooperating agency
CDC	U.S. Centers for Disease Control and Prevention
CIF	cost, insurance, and freight
DDU	delivered duty unpaid
DHIV	Division of HIV/AIDS [USAID] (now OHA)
EIA	enzyme immunoassay
EU	European Union
EUR	euro
EXW	ex works
FCA	free carrier
FDA	U.S. Food and Drug Administration
FOB	free on board
GMP	Good Manufacturing Practices
HIV	human immunodeficiency virus
ISO	International Standards Organization
MEDS	Mission for Essential Drugs and Supplies
MSH	Management Sciences for Health
NGO	nongovernmental organization
OHA	Office of HIV/AIDS [USAID]
PMTCT	prevention of mother-to-child-transmission
RPM	Rational Pharmaceutical Management (Project)
RPM Plus	Rational Pharmaceutical Management Plus (Program)
SCMS	Supply Chain Management System (Project)
SOP	standard operating procedure
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development

USD U.S. dollar
WHO World Health Organization

GLOSSARY

Efficacy	Efficacy is the ability of a drug or pharmaceutical product to produce a particular effect as determined by scientific methods.
FDA approval	FDA approval means that the product has met the standards of the U.S. Food and Drug Administration for safety, efficacy, and quality for the proposed application.
Incoterms¹	This is short for “International Commercial Terms.” They are standard trade definitions (devised and published by the International Chamber of Commerce) commonly used in international sales contracts. ² Examples are ex works (EXW); free on board (FOB); and cost, insurance, and freight (CIF).
Origin	The origin of a pharmaceutical product is the country in which it was produced.
Pharmaceutical products	For the purposes of USAID procurement regulations, pharmaceutical products are defined as drugs, vitamins, oral rehydration salts, biologicals, and some in vitro diagnostic reagents/test kits (including HIV test kits and antibiotic susceptibility test kits).
Quality	The quality of a pharmaceutical product is determined by its identity, purity, potency, uniformity of dosage form, bioavailability, and stability.
Safe medical product	The FDA defines a safe medical product as one that poses reasonable risks given the magnitude of the benefit expected and the alternatives available.
Sensitivity	The sensitivity of a test is the probability of testing positive if infection is truly present. As the sensitivity of a test increases, the number of false negatives decreases.
Source	The source of a commodity is the country it is shipped from and does not include free ports or bonded warehouses. The source can be the cooperating country, if that is where the commodity is located at the time of purchase.

¹ See the Incoterms Glossary for a list of incoterms used in this document and their corresponding explanations. A full glossary of incoterms used in the document starts on page ix.

² International Chamber of Commerce. 2007 “Understanding Incoterms.” <<http://www.iccwbo.org/incoterms/id3042/index.html>> (accessed Jan. 15, 2007).

Specificity

The specificity of a test is the probability of testing negative if infection/disease is truly absent. As the specificity of a test increases, the number of false positives decreases.

INCOTERMS

- Cost, insurance, and freight (CIF)** The selling costs include the cost of goods, the freight or transport costs, and also the cost of marine insurance. The seller's responsibility for the goods ends when the goods have been delivered on board a shipping vessel.³
- Delivered Duty Unpaid (DDU)** The seller pays for all transportation costs and bears all the risk until the goods have been delivered, but does not pay for the duty.⁴
- Ex works (EXW)** Seller X has the goods ready for collection at his premises (works, factory, warehouse, plant) on the date agreed upon. The buyer pays all transportation costs and also bears the risks for bringing the goods to their final destination. The term requires that the buyer must be able to carry out export formalities in the country of supply, these days almost impossible. Therefore in the vast majority of cases where terms are quoted EXW they actually intend the seller to carry out export formalities, which means the correct term is FCA (seller's premises).
- Free carrier (FCA)** The seller delivers the goods into the custody of the first carrier, and this is where the risk passes from the seller to the buyer. The buyer pays for transportation.⁵
- Free on board (FOB)** The seller pays for the transportation of the goods to the port of shipment, plus loading costs. The buyer pays freight, insurance, unloading costs and transportation from the port of destination to the factory. The passing of risk occurs when the goods pass the ship's rail at the port of shipment.⁶

³ Wikipedia. 2007. "Cost, Insurance and Freight." <http://en.wikipedia.org/wiki/Cost%2C_Insurance_and_Freight> (accessed Jan. 15, 2007).

⁴ Wikipedia. 2007. "Delivered Duty Unpaid." <http://en.wikipedia.org/wiki/Delivered_Duty_Unpaid> (accessed Jan. 15, 2007).

⁵ Wikipedia. 2007. "Free Carrier." <http://en.wikipedia.org/wiki/Free_Carrier> (accessed Jan. 15, 2007).

⁶ Wikipedia. 2007. "Free on Board." <http://en.wikipedia.org/wiki/Free_On_Board> (accessed Jan. 15, 2007).

INTRODUCTION

The Management Sciences for Health (MSH)/Rational Pharmaceutical Management (RPM) Plus Program is pleased to present the fourth edition of the *HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document*. This update replaces the third edition, published in 2005. The preparation of this document has been funded by the Office of HIV/AIDS (OHA) of the U.S. Agency for International Development (USAID).

Background

Prior to 1998, the U.S. Centers for Disease Control and Prevention (CDC) recommended withholding the results of an initially positive HIV test until a confirmatory Western blot test report had been received; because of this, market demand for U.S. Food and Drug Administration (FDA)-approved rapid HIV test kits in the United States was low. Although the CDC revised its recommendations in 1998 and encouraged wider use of rapid HIV testing, many of the rapid HIV test kits presently included in the HIV testing algorithms of developing and transitional countries are not available from U.S. sources and are not of U.S. origin; few are approved by the FDA.

In 2000, USAID's Division of HIV/AIDS (DHIV) (now OHA) requested assistance from the Rational Pharmaceutical Management (RPM) Project to review the guidelines and procedures for USAID-funded procurement of HIV/AIDS-related pharmaceutical products. RPM's findings and recommendations are outlined in a report entitled *USAID-Funded Procurement of HIV/AIDS-Related Pharmaceutical Products: Constraints and Options for Improvement*.⁷ During the development of this report, the lack of information on non-U.S. suppliers and sources of pharmaceutical products was identified as a constraint by several USAID-funded cooperating agencies (CAs). In addition, the complexity of the process to prepare requests for approval to procure rapid HIV test kits in view of the "Buy America" objectives of USAID procurement procedures and the need for USAID to be confident of the quality, safety, and efficacy of all pharmaceutical commodities purchased with USAID funding was reported to result in delays in procuring USAID-funded HIV test kits.

In January 2001, the USAID Administrator approved the USAID Source and Origin Waiver for HIV/AIDS Diagnostic Materials to facilitate the process of preparing requests for approval to procure HIV test kits. DHIV (now OHA) also provided funding to the RPM Plus Program, RPM Project's successor, to develop this procurement information document to assist USAID Missions and CAs in identifying manufacturers and international agencies and suppliers of HIV test kits listed in Tab 1 (Approved List of Testing Kit Products and Manufacturers) of the USAID Source and Origin Waiver.

⁷ Keene, D., and H. Walkowiak. 2000. *USAID-Funded Procurement of HIV/AIDS-Related Pharmaceutical Products: Constraints and Options for Improvement*. Published for the U.S. Agency for International Development by the Rational Pharmaceutical Management Project. Arlington, VA: Management Sciences for Health.

Objective

The first edition of the HIV test kits listed in the USAID source and origin waiver was published in 2002 with subsequent editions published in 2004 and 2005. The primary aim of the document is to facilitate the process of procuring the HIV test kits listed in the USAID Source and Origin Waiver. The HIV test kits are eligible for procurement from Geographic Code 935 (see Annex 2) countries (any country or area excluding foreign policy restricted countries) by USAID Missions and USAID-funded CAs to use in HIV projects or programs. In addition to assisting USAID Missions and CAs to identify sources of procurement, the document also contains additional information that is useful for planning for procurement including information on prices, shelf life on delivery, and the source and origin of the product.

HIV Test Kits Procurement Information Document: Fourth Edition

The USAID Source and Origin Waiver for HIV/AIDS Diagnostic Materials is periodically reviewed and amended to remove discontinued products and include additional test kits. The HIV test kits included in the waiver have been reviewed by USAID and found to meet all the necessary suitability and price criteria for approval of a source and origin waiver. The CDC has also reviewed the listed HIV kits for safety and efficacy and recommends their use in resource-constrained settings.

The current edition of this document, which replaces the third edition published in 2005, is based on the approved list of HIV test kits that appear in the USAID Acquisition and Assistance Policy Directive (AAPD) 06-01 issued in December 2006. The AAPD is the policy document from USAID that provides the information on the approval of new HIV test kits to be included in the waiver. Annex 1 provides detailed information on the process of amending the waiver and the requirements of HIV test kits listed in the waiver.

There are 27 HIV test kits featured in this edition and 14 suppliers (national and international) and procurement agencies.⁸ As in previous editions, we have included the HIV test kit procurement information for the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF), and the World Health Organization (WHO).

Methodology

The same procedures used to prepare the previous editions were followed for the fourth edition of this document. Specifically, RPM Plus administered questionnaires to the manufacturers of the HIV test kits that appear in the USAID AAPD 06-01 issued in December 2006 to collect the information presented in this document. Questionnaires were also administered to procurement agencies and suppliers (international and national). It is important to point out that inclusion on this list does not imply that the product, manufacturer, or supplier or agency is endorsed by USAID or MSH/RPM Plus or preferred over any other.

⁸ The number of test kits and suppliers is subject to change depending on announcements from USAID.

Who Is This Procurement Information Document For?

This document has been developed to assist USAID Missions and CAs to identify procurement sources for the HIV test kits listed that appear in the USAID AAPD 06-01 issued in December 2006 and to plan for procurement. In addition, information is provided to assist in writing requests for approval to procure these HIV test kits using USAID funding.

How to Use This Document

The procurement information found in this document is intended for use by USAID Missions and CAs as an initial reference for identifying manufacturers and suppliers and for planning for procurement. Prices are given as an indication only and may vary according to quantities ordered and with fluctuations on the international market or in currency exchange rates. Additional shipping and handling charges may apply, as may import duties in some countries.

Due to the time-sensitive nature of the procurement information included in this guide, the supplier or agency should be contacted to verify the information, particularly with regard to price and availability, prior to placing an order or preparing a request for USAID approval to procure HIV test kits.

Updates and Evaluation

RPM Plus has been requested by USAID to produce this updated edition to reflect both changes in the procurement information and additions or deletions from Tab 1 of the Source and Origin Waiver. In addition to printed copies, this update will be posted on the RPM Plus website (<http://www.msh.org/projects/rpmplus/3.3.2b.cfm>) in both HTML and PDF format. The fourth edition of the document is also available in CD-ROM format

Feedback about the content, usefulness, ease of use, completeness, and timeliness of information can be mailed to—

Management Sciences for Health
Attn: Abiola Johnson
Rational Pharmaceutical Management Plus
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203-1627
United States

Or sent via e-mail to the editor at ajohnson@msh.org.

Guidance Document for Obtaining USAID Approval to Procure USAID-Funded Pharmaceutical Products

During the RPM review of guidelines and procedures for USAID-funded procurement of HIV/AIDS-related pharmaceutical products, the lack of guidance material to assist USAID Missions and CAs in preparing requests for approval to procure these commodities was identified as a major constraint. In response, RPM Plus developed a guidance document for USAID Missions and CAs entitled *Requesting USAID Approval to Procure HIV Test Kits and Other HIV/AIDS-Related Pharmaceutical Products: Guidance and Sources of Information*⁹ to provide information on how to apply for approval to procure USAID-funded pharmaceutical products. This document is available on the RPM Plus website (<http://www.msh.org/projects/rpmplus/3.3.2a.htm>).

⁹ Walkowiak, H. 2002. *Requesting USAID Approval to Procure HIV Test Kits and Other HIV/AIDS-Related Pharmaceutical Products: Guidance and Sources of Information*. Published for the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

CHAPTER 1: HIV TEST KITS LISTED IN THE USAID SOURCE AND ORIGIN WAIVER

This list of HIV test kits listed in the USAID source and origin waiver is revised as U.S.-manufactured HIV test kits or new HIV test kits from sources in Geographic Code 935 (Special Free World) (see Annex 2 for a description of geographic codes) that meet USAID program requirements become available.

Tab 1 (Approved List of Testing Kit Products and Manufacturers) of the USAID Source and Origin Waiver, as amended in July 2007, lists the following kits—

1. Aware™ HIV 1/2 BSP (Calypse Biomedical)
2. Bioline HIV 1/2 3.0 (Standard Diagnostics, Inc.)
3. Bionor™ HIV-1&2 (Bionor A/S)
4. Bundi Rapid HIV 1/2 (Bundi International Diagnostics Ltd)
5. Capillus™ HIV-1/HIV-2 (Trinity Biotech, Plc)
6. CareStart™ HIV 1-2-O (Access Bio, Inc)
7. Clearview® COMPLETE HIV 1/2 (Inverness Medical Innovations)¹⁰
8. Combaids RS Advantage (Span Diagnostics)¹¹
9. Determine™ HIV-1/2 (Inverness Medical Innovations and Abbott Laboratories)
10. DoubleCheck™ HIV 1&2 (Inverness Medical Innovations and Orgenics, Ltd.)
11. DoubleCheck Gold™ HIV 1&2 (Inverness Medical Innovations and Orgenics, Ltd)
12. First Response® HIV 1-2.0 (Premier Medical Corporation, Ltd.)
13. Genie II HIV-1/HIV-2 (Bio-Rad Laboratories)
14. HIVSav 1&2 Rapid SeroTest™ (Savyon Diagnostics)
15. HIV 1/2 Stat-Pak™ Assay (ChemBio Diagnostics, Inc.)
16. HIV 1/2 Stat-Pak™ Dipstick (ChemBio Diagnostics, Inc.)
17. HIV (1+2) Rapid Test Strip (KHB)¹²
18. ImmunoComb™ HIV 1&2 (Inverness Medical Innovations and Orgenics, Ltd.)
19. InstantCHEK™ HIV 1+2 (EY Laboratories)
20. INSTI™ HIV Antibody (Biolytical Laboratories)
21. Multispot™ HIV Antibody (Bio-Rad Laboratories)¹³
22. OraQuick® ADVANCE™ Rapid HIV-1/2 (OraSure Technologies)
23. OraQuick® HIV-1/2 Rapid Antibody Test (OraSure Technologies, Inc.)
24. Reveal™ Rapid HIV-1 (MedMira)
25. Signal HIV Rapid Test (Span Diagnostics)¹⁴
26. Uni-Gold™ HIV (Trinity Biotech, Plc)
27. Uni-Gold™ Recombigen® HIV (Trinity Biotech, Plc)

¹⁰ There are two versions of the Clearview® COMPLETE HIV 1/2 test kit—the U.S. product and the international product. It is the international product that appears in this document.

¹¹ Information not currently available.

¹² Information not currently available.

¹³ Information not currently available.

¹⁴ Information not currently available.

Chapter 1 presents general information on each HIV test kit together with manufacturer information. Information on procurement agencies and suppliers (international and national) is presented in Chapter 2. The information presented in Chapter 1 is intended to be used as an initial reference for identifying manufacturers and planning for procurement.

Prices are given as an indication only and may vary according to currency exchange rates. Additional shipping and handling charges may apply. Due to the time-sensitive nature of the procurement information included in this guide, the supplier or agency should be contacted to verify the information, particularly with regard to price and availability, prior to placing an order or preparing a request for USAID approval to procure the HIV test kits. Inclusion in this document does not imply that the products or manufacturer are endorsed by USAID or MSH/RPM Plus or preferred over any other product or manufacturer.

What Is in This Section?

The following information is provided for each test kit—

- Technical information, including a basic description
- Product information
- Procurement information

Technical Information

This section contains a brief description of the product, including sensitivity, specificity, the test principle,¹⁵ ease of use, methodology, types of samples used (e.g., whole blood, urine), and the time needed to conduct the test procedure.

Product Information

Number of tests per kit	Number of test kits that are available in one kit; all order quantities must be in multiples of this number.
Items included in kit	Information specifying what is included and packed as part of the kit. Test kit components cannot be ordered separately.
Additional items required but not included	Usually standard laboratory equipment such as disposable gloves, biohazard bags, blood collection equipment, and disinfectant are sufficient, but some test kits have special requirements (e.g., reagents, centrifuges).
FDA approved	This section lists whether the test kit has been approved by the U.S. Food and Drug Administration. This information is needed when preparing a request for USAID approval to procure HIV test kits.

¹⁵ Current rapid tests are based on one of four test principles: particle agglutination, immunodot (dipstick), immunofiltration (flow-through testing), or immunochromatography (lateral-flow device).

Approved by other regulatory agency	This section lists whether the HIV test kit has been approved by regulatory body other than the FDA, such as the European Agency for the Evaluation of Medicinal Products (EMA).
Shelf life of the HIV test kit	This is the length of time before the HIV test kit reaches its expiry date. After expiry, a product can no longer be safely used and accurate results cannot be expected. Shelf life is measured from the date of manufacture and should reflect the expiration date of the first component in the kit to reach expiry (for rapid test kits, usually months). Shelf life assumes that the storage conditions specified by the manufacturer are met.
Language of package insert	Specifies the languages in which the standard package insert is written. Special language requirements must be negotiated and included in the procurement contract.
Recommended storage conditions	Manufacturer-recommended storage conditions that need to be adhered to during shipping, delivery, and storage to ensure that the quality and performance of the product are not compromised.
Weight/dimensions/volume of kits or tests	This information will help programs plan for proper storage and transportation requirements during distribution. Planning for adequate and appropriate storage is particularly important when refrigeration is required.

Procurement Information

The first item addressed in this section is whether USAID Missions and CAs can purchase the HIV test kits directly from the manufacturers.

Average price for one test/price for one kit	Prices are given as an indication only and may vary according to quantities ordered and with fluctuations on the international market or in currency exchange rates. Additional handling and shipping charges may apply. Also, because changes may have been made since the publication of this document, the manufacturer should be contacted to verify the information before an order is placed or a request for USAID approval to procure HIV test kits is prepared. The applicable incoterm used by the supplier is included in all price quotes
Additional pricing information	This section gives information on special prices offered to developing countries and nonprofit organizations working in resource-constrained settings.

Donation programs	Over the past few years, some manufacturers have set up donation programs to provide HIV test kits to selected programs in resource-constrained settings. Information on available donation programs and how to access them is included in this section.
Available from U.S. sources	This section lists sources in the United States from which the kit can be procured, if any. This information is needed when preparing a request for USAID approval to procure HIV test kits.
Minimum order from manufacturer	The minimum order is usually one kit, but some manufacturers require that more than one kit be ordered at a time.
Average minimum shelf life on delivery	The remaining time (usually months) for which a product can be safely used and accurate results can be expected after delivery by the manufacturer. Assuring that the shelf life can be maintained as stated on the product packaging is dependent on the product being stored and handled according to the conditions specified by the manufacturer. These instructions must be included in every package, carton, and/or shipping unit. The minimum accepted shelf life on delivery must be negotiated and included in the procurement contract.
Stock on hand	This section specifies whether kits are stocked or manufactured on demand. If stock is kept on hand, the order lead time is generally less. However, manufacturing kits upon receipt of an order has the advantage of providing a product with the longest shelf life.
Average time to fill order	This information helps programs ensure that orders are placed in sufficient time to prevent stock-outs.
Quality issues	Describes the company policy if the customer experiences problems with the quality of the test kits.
Payment method to manufacturer	Any general requirements for method of payment; these requirements are often country-, program-, or quantity-specific. The manufacturer may need to be contacted for additional information.
Available from	Indicates the international procurement agencies or suppliers who have stated that they either stock or can supply the product (see Chapter 2 for more information).



Photo appears courtesy of Calypte Biomedical Corporation

Aware™ HIV-1/2 BSP Rapid Test

Manufactured by Calypte Biomedical Corporation, Thailand

For further information, please contact:
Dr Ronald Mink, Chief Science Officer
Calypte Biomedical Corporation
5 Centerpointe Drive
Lake Oswego OR 97035
USA

Tel: +1-971-204-0282

Fax: +1-971-204-0284

E-mail: customerservice@calypte.com

Website: <http://www.calypte.com>

Information current as of September 2006

Technical Information

Calypte Biomedical Corporation's Aware™ HIV-1/2 BSP Rapid Test is a manually performed, visually read, 20-minute qualitative immunochromatographic assay for the detection of antibodies to HIV-1 and HIV-2 in venous or finger-stick whole blood, serum, or plasma. It utilizes a proprietary lateral flow immunoassay procedure incorporating synthetic peptide antigens representing the immunodominant regions of gp41 (HIV-1) and gp36 (HIV-2). The HIV test gives results in 20 minutes and must be read within 45 minutes.¹⁶ The test sensitivity is 100 percent (219/219) and specificity is 100 percent (446/446).¹⁷

Product Information

Number of tests per kit	25 or 50
Items included in kit	Test strips, BSP sample buffer, test tube, and sample loops
Additional items required but not included	Lancets or other blood collection materials, timer or watch, antiseptic wipes, gauze pads, disposable gloves, and biohazard disposable container
FDA approved	No
Approved by other regulatory agency	It is approved by regulatory agencies in Kenya, Malaysia, South Africa, Uganda, and Zimbabwe
Shelf life of the HIV test kit	18 months

¹⁶ Correspondence with manufacturer.

¹⁷ Calypte Biomedical. 2005. *Aware HIV-1/2 BSP Package Insert*. Rockville, MD USA: Calypte Biomedical Corporation. <http://www.calypte.com/PRODUCTS/INSERTS/pi_aware_bsp_english.pdf> (accessed Jan. 2007).

Language of package insert	English, French, Spanish, Portuguese, and Arabic
Recommended storage conditions	2–30°C (36–86°F)
Weight/dimensions/volume for one kit (25 tests)/(50 tests)	Weight: 0.37 kg (0.63 kg)/0.82 lb (1.4 lb) Dimensions: 14 × 14 × 8 cm (3.5 × 6.5 × 1.7 in)/ 14 × 18 × 13 cm (3.5 × 7.1 × 5.1 in) Volume: 1,568 cm ³ (0.06 cu ft)/3,276 cm ³ (0.12 cu ft)

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	1.30–1.70 U.S. dollars (USD) per test (FOB, depending on the location of purchase)
Additional pricing information	Price depends on volume purchased and if the test is purchased directly from the company or through a local distributor
Donation programs	The company has donation programs and additional information can be obtained by contacting the company directly
Available from U.S. sources	Yes, but not for domestic use in the United States
Minimum order from manufacturer	1 kit containing either 25 or 50 tests
Average minimum shelf life on delivery	Depends on the availability
Stock on hand	Stock is maintained in the inventory
Average time to fill order	30 days
Quality issues	Complaint Procedures and Preventive Corrective Actions Policy in compliance with International Standards Organization (ISO) 9001 and FDA Quality System Regulations. There is also a special recall procedure for the HIV test kit.
Payment method to manufacturer	Payment is required in advance
Available from	Crown Agents. The manufacturer also has distributors in several countries that can supply the HIV test kit (contact the manufacturer for additional information).



Photo appears courtesy of Standard Diagnostics, Inc.

Bioline HIV 1/2 3.0
Manufactured by Standard Diagnostics, Inc., Republic of Korea

For further information, please contact:

Taylor Hor, General Manager

Standard Diagnostics

156-68 Hagal-ri, Giheung-eup,

Yongin-si, Kyonggi-do

Republic of Korea

Tel: +82-31-889-9700

Fax: +82-31-899-9740

E-mail: taylor@standardia.com

Website: <http://www.standardia.com>

Information current as of September 2006

Technical Information

Standard Diagnostics Bioline HIV 1/2 3.0 is a rapid immunochromatographic test for the detection of antibodies of all isotypes (IgG, IgM, IgA) specific to HIV-1—including subtype O and HIV-2 simultaneously—in human serum, plasma, or whole blood. It takes 5–20 minutes to get the results.¹⁸ Sensitivity is 100 percent and specificity is 99.8 percent (WHO evaluation: sensitivity, 100 percent; specificity, 99.3 percent¹⁹).

Product Information

Number of tests per kit	30 (25 test/kit package available at customer's request)
Items included in kit	30 test devices (in individual aluminum pouches with silica gel), assay buffer (4 mL/vial)
Additional items required but not included	Lancets, pipettes, and capillary tubes
FDA approved	No
Approved by other regulatory agency	Korean Food and Drug Agency (KFDA)
Shelf life of the HIV test kit	24 months
Language of package insert	English, French, and Spanish (for larger orders, other languages can be provided)
Recommended storage	1–30°C (34–86°F)

¹⁸ Correspondence with manufacturer.

¹⁹ World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2004. *HIV Assays: Operational Characteristics (Phase I). Report 14: Simple/Rapid Tests*. Geneva: WHO.

conditions

Weight/dimensions/volume for one kit (30 tests) Weight: 0.3 kg (0.66 lb)
Dimensions: 22 × 12.4 × 7.0 cm (8.66 × 4.889 × 2.76 in)
Volume: 318,000 cm³ (0.318 m³) (11.230064 cu ft)

Procurement Information

USAID Missions and CAs can purchase kits directly from the manufacturer.

Average price for one test/ price for one kit	Approximately USD 0.80–0.85 per test; ~USD 24.00–25.50 per kit (FCA South Korea)
Additional pricing information	Price varies depending on the quantity being procured. Special prices are offered to developing countries, according to circumstances (contact company representative for additional information). Special prices can be negotiated for nonprofit groups or other organizations for certain programs based on long-term procurement contracts and annual value of requirements.
Donation programs	Donation programs will be considered if the company receives a formal request (e-mail, letter, or fax) from an organization/agency.
Available from U.S. sources	No
Minimum order from manufacturer	1 kit
Average minimum Shelf life on delivery	18 months (24 months from manufacturing date)
Stock on hand	Limited stock maintained (approximately 1,000 kits) for immediate shipment
Average time to fill order	For regular orders: on board in 1 week from order confirmation; for special orders: on board in 1–2 weeks; for emergencies: overnight delivery is provided from stock
Quality issues	In case of quality problems, the local supplier or manufacturer is informed by e-mail or fax. If there is a problem with a test kit, it is recalled and replaced after a quality assurance evaluation.
Payment method to manufacturer	International bank transfer (SWIFT) before order shipment is preferred. For large orders and tenders, the company will accept a letter of credit. For nongovernmental organizations (NGOs), 30 days from date of invoice by wire transfer is acceptable.
Available from	Crown Agents, Tri-Med Group, UNICEF, and the WHO Bulk Procurement Scheme (see Chapter 2). The company also uses Health Alliance International (HAI) (see http://depts.washington.edu/haiuw for additional information).



Photo appears courtesy of Bionor A/S

Bionor™ HIV-1&2

Manufactured by Bionor AS, Norway

For further information, please contact:

Gunnar Flåten, Marketing Manager

Bionor A/S

P.O. Box 1868 Gulset

NO-3703 Skien

Norway

Tel: +47-35-50-57-50

Fax: +47-35-50-57-01

E-mail: gunnar.flaten@bionor.no

Website: <http://www.bionor.no>

Information current as of October 2006

Technical Information

Bionor™ HIV-1&2 is a rapid enzyme immunoassay (EIA) that uses synthetic peptides and recombinant p24 proteins to detect antibodies to HIV-1 and HIV-2. The test can produce results in 30 minutes.²⁰ The sensitivity (tested on 1,542 samples) was found to be 100 percent (1,264 HIV-1 positive and 278 HIV-2 positive), and the specificity (of 5,274 samples) was found to be 98.8 percent.²¹

Product Information

Number of tests per kit	250
Items included in kit	Pipettes and ready-to-use reagents in dropper vials
Additional items required but not included	Testing station that can be operated on 115 or 230 volts of electrical current or on a 12-volt solar or car battery. The dimensions of the testing station are 35 × 20 × 12 cm (13.8 × 7.9 × 4.7 in).
FDA approved	No
Approved by other regulatory agency	No
Shelf life of the HIV test kit	12 months ²²
Language of package insert	English (for larger orders, other languages can be provided)
Recommended storage conditions	Store kit at 2–30°C (36–86°F). Do not leave kits in strong heat or light.

²⁰ Correspondence with manufacturer.

²¹ World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2004. *HIV Assays: Operational Characteristics (Phase I). Report 14: Simple/Rapid Tests*. Geneva: WHO.

²² Additional shelf life of 24 months can be obtained if the kit is stored at 2–8°C (36–46°F).

Weight/dimensions/volume for 4 kits (1,000 tests) Weight: 7.35 kg (16.17 lb)
Dimensions: 50.5 × 37 × 23.6 cm (19.9 × 14.6 × 9.3 in)
Volume: 44,097 cm³ (0.0441 m³) (2,691 cu in [1.557 cu ft])

Procurement Information

Average price for one test/ price for one kit	Price per test ~USD 1.20–1.90 (EXW, Norway)
Additional pricing information	Prices may vary according to quantities ordered and whether supplied directly or through a distributor
Donation programs	No information provided
Available from U.S. sources	No
Minimum order from manufacturer	1 kit (250 tests) but preferably not fewer than 1,000 tests (4 kits, which fill one export polystyrene box)
Average minimum shelf life on delivery	10 months
Stock on hand	Approximately 50 kits are kept on hand. However, to obtain the longest possible shelf life, kits are mostly manufactured on demand.
Average time to fill order	One day if supplied from stock held or approximately 3–4 weeks if a new batch is manufactured
Quality issues	Quality problems are resolved by replacing the kit. Bionor AS also runs a quality control test on the reference kit of the same batch. Subsequent actions taken usually depend on the outcome of the quality control test.
Payment method to manufacturer	Prepayment or letter of credit. MasterCard [®] and Visa [®] credit cards are also accepted.
Available from	Crown Agents, Medical Export Group, and Missionpharma AS. Kits can also be purchased directly from the manufacturer in Norway. Small quantities are dispatched by courier and larger quantities by air cargo. Orders are generally delivered to a single address in a country, although the company has worked with the Ministry of Health in some countries to develop an in-country distribution system. The manufacturer reports using additional distributors (contact the company representative for a list of distributors used).



Photo appears courtesy of Bundi International Diagnostics Limited

Bundi™ HIV-1/2

Manufactured by Bundi International Diagnostics Limited, Nigeria

For further information, please contact:

Bob Udeagha, Chairman/CEO

Bundi International Diagnostics Ltd.

157 Cameroun Road, Aba, Abia State, Nigeria

Tel: +234-82-230843, 234-82-232413,

234-82-232394, 234-803-3100130

Fax: +234-82-232406

E-mail: bundihivtest@yahoo.com

Website: <http://www.bundihivtest.com>

Information current as of December 2006

Technical Information

Bundi™ HIV-1/2 is a qualitative, membrane-based immunoassay for the detection of antibodies to HIV in serum or plasma. The test can produce results in 10 minutes and has a sensitivity of 100 percent and a specificity of 99.5 percent.²³

Product Information

Number of tests per kit	1 or 25
Items included in kit	Package insert, buffer, and disposable plastic calibrated pipette (available in all the kits). Alcohol prep pad and lancet (available in the single kits only).
Additional items required but not included	None
FDA approved	No
Approved by other regulatory agency	National Agency for Food and Drug Administration and Control (NAFDAC) (Nigeria)
Shelf life of the HIV test kit	18 months
Language of package insert	English, Yoruba, Hausa, and Ibo
Recommended storage conditions	4–30°C (39–86°F)
Weight/dimensions/volume for one test (25 tests)	Weight: 0.05 kg (0.11 lb) Dimensions: 14 × 8.5 × 2 cm (3.5 × 3.4 × 0.8 in) Volume: 238 cm ³ (0.01 cu ft)

²³ Correspondence with manufacturer.

Procurement Information

USAID Missions and CAs can purchase kits directly from the manufacturer.

Average price for one test/ price for one kit	USD 1.50–2.50 (CIF, Nigeria)
Additional pricing information	An organization can get the best price by signing a long-term contract with the company (minimum five years). Delivery is free to any location in Nigeria.
Donation programs	Planned for the future
Available from U.S. sources	No
Minimum order from manufacturer	None
Average minimum shelf life on delivery	Nine months
Stock on hand	Stock is maintained
Average time to fill order	This depends on the quantity ordered. Delivery can be done in batches within two weeks.
Quality issues	These are handled through the customer complaint handling system. There is a recall procedure for HIV test kits.
Payment method to manufacturer	Wire transfer or bank draft
Available from	Crown Agents



Photo appears courtesy of Trinity Biotech, Plc

Capillus™ HIV-1/HIV-2

**Manufactured by Trinity Biotech, Plc,
Ireland**

For further information, please contact:
*Fidelma Loftus, International Product
Manager
Trinity Biotech, Plc
IDA Business Park
Bray, Co. Wicklow
Ireland*

Tel: +353-1-276-9800

Fax: +353-1-276-9888

E-mail: fidelma.loftus@trinitybiotech.com

Website: <http://www.trinitybiotech.com>

Information current as of October 2006

Technical Information

Capillus™ HIV-1/HIV-2 is a rapid assay that uses the particle agglutination principle for the detection of antibodies to HIV-1 and/or HIV-2 in human whole blood, serum, or plasma. The sensitivity and specificity of Capillus™ HIV-1/HIV-2 has been reported by WHO to be 100 percent and 100 percent (whole blood samples). It is estimated that the test can produce results in three minutes.²⁴

Product Information

Number of tests per kit	100
Items included in kit	Reagents, controls, slides, pipettes, disposable pipette tips, and interpretation station
Additional items required but not included	Disposable gloves, biohazard bags, blood collection equipment, and disinfectant
FDA approved	No
Approved by other regulatory agency	Approved by regulatory agencies in a number of countries (contact the manufacturer for additional information)
Shelf life of the HIV test kit	15 months
Language of package insert	English (other languages can be provided on request)

²⁴ World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2002. *HIV Assays: Operational Characteristics (Phase 1). Report 12: Simple/Rapid Tests, Whole Blood Specimens.* WHO/BCT/02.07. Geneva: WHO.

Recommended storage conditions	Optimum storage is at 2–8°C (36–46°F). Stable for short periods (up to 4 weeks) at 25°C (77°F). ²⁵
Weight/dimensions/volume for one kit (100 tests)	Weight: 0.5 kg (1.1 lb) Dimensions: 22 × 14 × 8 cm (8.7 × 5.5 × 3.1 in) Volume: 2,464 cm ³ (0.00246 m ³) (150.4 cu in [0.09 cu ft])

Procurement Information

USAID Missions and CAs can purchase kits directly from the manufacturer.

Average price for one test/price for one kit	Price per test ~USD 1.50–1.75; price for kit varies from USD 150–175 (EXW, Ireland)
Additional pricing information	No handling charges are added, but shipping and insurance are extra. Prices may vary by quantity and region. Concessionary prices are offered to WHO, other United Nations (UN) agencies, and major international procurement agencies. Discounts from the listed price can be negotiated on a case-by-case basis either directly through the manufacturer or through local distributors.
Donation programs	There are currently no donation programs for this HIV test kit.
Available from U.S. sources	No
Minimum order from manufacturer	5 kits (500 tests)
Average minimum shelf life on delivery	10–11 months (kits are usually delivered with 75 percent of their shelf life remaining)
Stock on hand	Some stock is held, but levels vary according to demand.
Average time to fill order	6 weeks
Quality issues	Any quality problem with the product is investigated through the in-house quality control system. If a product problem is confirmed, replacement product or product notes are issued. The manufacturer does not have a specific recall procedure for the HIV test kit, but it has implemented standard operating procedures (SOPs) for the management of post-marketing activities including customer complaint handling, adverse event reporting, and product recalls. These SOPs have been developed in accordance with all relevant ISO, European Union (EU), and FDA requirements.

²⁵ The package insert contains instructions for testing negative and positive controls if users are concerned that product performance may have been adversely affected by temperature.

Payment method to manufacturer	The required payment method is up-front payments for three orders, after which credit terms can be accepted. Credit card orders are also accepted.
Available from	Action Medeor, Crown Agents, Durbin PLC, IDA Foundation, Joint Medical Stores (Uganda), Medical Export Group, Medical Stores Department (Tanzania), Mission for Essential Drugs and Supplies (MEDS) (Kenya), Missionpharma A/S, UNFPA, UNICEF, and the WHO Bulk Procurement Scheme (see Chapter 2 for more details). In addition, the manufacturer has exclusive/non-exclusive local suppliers in a large number of countries (contact the manufacturer for additional information).



Photo appears courtesy of Access Bio Inc

CareStart™ HIV-1-2-O

Manufactured by Access Bio Inc. in South Korea and in the United States

For further information, please contact:

Young Ho Choi, CEO

Access Bio, Inc

2033 Route 130

Monmouth Junction, NJ 08852

Tel: +1-732-297-2222

Fax: +1-732-297-3001

E-mail: info@accessbio.net

Website: <http://www.accessbio.net>

Information current as of October 2006

Technical Information

CareStart™ HIV 1-2-O is a rapid immunochromatographic test for the detection of HIV-1 and HIV-2 including subtype O in human whole blood, serum, and plasma. Recombinant antigens are used to produce the test kit. The sensitivity is 100 percent and the specificity is 99.5 percent.²⁶ The test produces results in 5–10 minutes.

Product Information

Number of tests per kit	60
Items included in kit	Assay buffer
Additional items required but not included	Pipette, lancet, and alcohol swab
FDA approved	No
Approved by other regulatory agency	Ministry of Health in Indonesia
Shelf life of the HIV test kit	21 months
Language of package insert	English
Recommended storage conditions	2–30°C (36–86°F)
Weight/dimensions/volume for one kit (30 tests)	Weight: 0.517 kg (1.14 lb) Dimensions: 23.5 × 12 × 6.2 cm (9.5 × 4.7 × 2.4 in) Volume: 1,748.4 cm ³ (107.8 cu ft)

²⁶ Correspondence with manufacturer.

Procurement Information

USAID Missions and CAs can purchase kits directly from the manufacturer.

Average price for one test/ price for one kit	Price per test USD 0.55–0.85; price for kit varies from USD 33–51 (EXW, New Jersey)
Additional pricing information	Special prices are available for developing countries with significant discounts available for large orders (greater than 500,000 tests). In order to qualify for the discounts, 30 percent of prepayment is recommended.
Donation programs	Donations are available (free-of-charge) for non-commercial use of the HIV test kits. An application process is required to qualify for the donation programs (contact the company for additional information).
Available from U.S. sources	Yes, but not for domestic use in the United States
Minimum order from manufacturer	50 kits (3,000 tests)
Average minimum shelf life on delivery	18 months
Stock on hand	Tests are manufactured on demand
Average time to fill order	1–6 weeks depending on the order volume
Quality issues	An internal investigation is carried out to address any quality issues that are reported. Action carried out will depend on the outcome of the investigation. There is a recall procedure for HIV test kits that have quality issues.
Payment method to manufacturer	International bank transfer (SWIFT) before shipment of order. For larger orders and tenders a letter of credit is acceptable. For qualified NGOs, 30 days term from date of wire transfer is acceptable.
Available from	Crown Agents



Photo appears courtesy of Inverness Medical.

Clearview® COMPLETE HIV 1/2

Manufactured by Inverness Medical Innovations

For further information, please contact:

Avi Pelossof, International Business Group

Inverness Medical

Priory Business Park

Bedford, MK 44 3UP

United Kingdom

Tel: +44 (0)1234 835000

Fax: +44 (0)1234 835009

E-mail: clearview@invmed.com

Website: <http://www.clearview.com>

Information current as of June 2007

Technical Information

Clearview® COMPLETE HIV 1/2 is a single-use, self-contained, closed system that uses the lateral flow system for the collection, processing, and analysis of whole blood, serum, or plasma sample for the detection of HIV-1 and HIV-2 antibodies. The test sensitivity is 99.7 percent and specificity is 99.0 percent. It can produce results in as little as 15 minutes.

Product Information

Number of tests per kit	25 tests
Items included in kit	Pouches (25) each containing sample with test strip, buffer vial, sterile lancet, bandage, and desiccant. Disposable rack for holding buffer vials.
Additional items required but not included	Clock, Pipettor capable of delivering 2.5µl of sample, disposable gloves, sterile gauze, antiseptic wipes, biohazard disposable container, collection device for samples other than finger stick whole blood samples
FDA approved	Yes
Approved by other regulatory agency	No
Shelf life of the HIV test kit	24 months
Language of package insert	English (additional languages will be available in the next year)
Recommended storage conditions	8–30°C (47–86°F)
Weight/dimensions/volume for one kit (25 tests)	Weight: 0.6 kg (1.3 lbs) Dimensions: 24 × 9.5 × 16 cm (9.4 × 3.7 × 6.2 in) Volume: 3,648 cm ³ (0.00364 m ³) (223 cu in [0.13 cu ft])



Photo appears courtesy of Inverness Medical

Determine™ HIV-1/2

**Manufactured by Abbott Laboratories in
Japan**

For further information, please contact:

Elaine Kerr, Group Product Manager

Inverness Medical

Priory Business Park

Bedford

MK44 3UP

UK

Tel: +44 (0)1234-835229

Fax: +44 (0)1234-835009

E-mail: elaine.kerr@unipath.com

Website: <http://www.determinetest.com>

Information current as of November 2006

Technical Information

Determine™ HIV-1/2 is an assay that uses the immunochromatographic principle for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma, and whole blood with finger-stick blood samples. A total of 1,594 serum and plasma specimens from Asia, West Africa, and North America were tested, and specificity was found to be 99.75 percent. A total of 869 HIV-1 and HIV-2 antibody-positive serum and plasma specimens from Asia, Africa, and North and South America were tested, and sensitivity was found to be 100 percent. In addition 368 negative and 102 positive paired serum, plasma and whole blood specimens from Thailand were tested and the specificity and sensitivity were both found to be 100 percent. It is estimated that the test can produce results in 17 minutes.²⁷

Product Information

Number of tests per kit	100
Items included in kit	Test cards and reagents
Additional items required but not included	Pipettes, pipette tips, lancets, and EDTA (ethylenediaminetetraacetic acid) capillary tubes
FDA approved	No
Approved by other regulatory agency	No information provided
Shelf life of the HIV test kit	14 months
Language of package insert	English, French, German, Portuguese, and Spanish

²⁷ Abbott Laboratories. 2006. *Determine™ HIV-1/2 Package Insert*. Abbott Park, IL: Abbott Laboratories.

Recommended storage conditions	Store the kit at room temperature up to 30°C (86°F)
Weight/dimensions/volume for one kit (100 tests)	Weight: 0.15 kg (0.33 lb) Dimensions: 27 × 16 × 1 cm (10.6 × 6.3 × 0.4 in) Volume: 432 cm ³ (0.000432 m ³) (26.36 cu in [0.015 cu ft])

Procurement Information

USAID Missions and CAs can purchase kits directly from the manufacturer or from an Abbott country office.²⁸

Average price for one test/price for one kit	USD 1.20 per test; USD 120 per kit (FOB, Japan)
Additional pricing information	For nonprofit organizations ordering volumes in the thousands, price is dependent on quantities purchased and is determined by the country-specific Abbott Diagnostics Division office. Shipping costs are extra.
Donation programs	As part of the prevention of mother-to-child-transmission (PMTCT) donations program, Abbott Laboratories donates the HIV test kits in eligible countries for pregnant women, their spouses, and children (18 months and older) of those women who test HIV-positive. ²⁹
Available from U.S. sources	No
Minimum order from manufacturer	1 kit
Average minimum shelf life on delivery	Less than 14 months
Stock on hand	Country-dependent
Average time to fill order	Country-dependent
Quality issues	If a kit is defective for any reason, the client will be asked to send the kit back to the relevant Abbott Diagnostics Division country office, where it will be tested. If the defect is confirmed, Abbott will replace the kit free of charge.
Payment method to manufacturer	Payment options depend on the country where the kit is being purchased.

²⁸ Abbott has offices in 150 countries.

²⁹ PMTCTDonations.org. 2007. "Welcome to the PMTCT Donations Program." <<http://www.pmtctdonations.org/>> (accessed Nov. 27, 2006).

Available from

Action Medeor, Crown Agents, Durbin PLC, IDA Foundation, Joint Medical Stores (Uganda), Medical Export Group, Medical Stores Department (Tanzania), MEDS (Kenya), Missionpharma A/S, Orbi-Pharma, UNFPA, UNICEF, and the WHO Bulk Procurement Scheme (see Chapter 2 for more details)



Photo appears courtesy of Organics, Ltd.

DoubleCheck™ HIV 1&2

Manufactured by Organics, Ltd., Israel

For further information, please contact:

Rosanne Tzuk,

International Marketing Manager

Organics, Ltd.

North Industrial Zone

P.O. Box 360

70650 Yavne, Israel

Tel: +972-8-942-9206

Fax: +972-8-943-8758

E-mail: rosanne@organics.co.il

Website: <http://www.organics.com>

Information current as of October 2006

Technical Information

DoubleCheck™ HIV 1&2 is a dual-recognition EIA that uses a combined application of immunochromatography and immunoconcentration for the detection of antibodies to HIV-1 and HIV-2 in human serum or plasma. A clinical evaluation of HIV-positive and HIV-negative individuals revealed a sensitivity of 100 percent and a specificity evaluation of 315 specimens resulted in a specificity of 99.3 percent.³⁰ It is estimated that the test will produce results in 11 minutes.³¹

Product Information

Number of tests per kit	40
Items included in kit	Tests, reagents, and disposable pipettes
Additional items required but not included	Disposable gloves, biohazard bags, blood collection equipment, and disinfectant
FDA approved	No
Approved by other regulatory agency	No
Shelf life of the HIV test kit	15 months
Language of package insert	English, French, Portuguese, Russian, and Spanish
Recommended storage	Store the kit at 4–8°C (39–46°F). Do not freeze.

³⁰ Organics, Ltd. n.d. "DoubleCheck™ HIV 1&2 Package Insert." <<http://www.organics.com/files/pdf/60331000E-CE.pdf>> (accessed Nov. 2006).

³¹ World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2002. *HIV Assays: Operational Characteristics (Phase 1). Report 12: Simple/Rapid Tests, Whole Blood Specimens.* WHO/BCT/02.07. Geneva: WHO.

conditions

Weight/dimensions/volume for one kit (40 tests) Weight: 0.8 kg (1.8 lb)
Dimensions: 26 × 18 × 14 cm (10.2 × 7.1 × 5.5 in)
Volume: 6,916 cm³ (0.0069 m³) (421.9 cu in [0.244 cu ft])

Procurement Information

USAID Missions and CAs can purchase the kits directly from the manufacturer.

Average price for one test/ price for one kit	USD 1.41 per test; USD 56.45 per kit (EXW, Yavne, Israel)
Additional pricing information	Special pricing consideration is given for large orders. Special prices may also be considered for developing countries (contact the manufacturer for additional information).
Donation programs	No information provided
Available from U.S. sources	No
Minimum order from manufacturer	1 kit
Average minimum shelf life on delivery	12–14 months
Stock on hand	The manufacturer has a large stock available but may manufacture extra batches on demand, depending on quantities ordered.
Average time to fill order	If the order quantity is in stock, it is dispatched immediately. If it is a special manufacture, the order takes 2–3 weeks.
Quality issues	The company has a recall procedure for suspected defective products; in case of manufacturing problems, there is a Material Review Board. This forum convenes weekly or as needed. If necessary, the Troubleshooting Laboratory reworks the out-of-specification material. Any deviation from existing procedures is approved by the Material Review Board before implementation.
Payment method to manufacturer	Telegraphic bank transfer
Available from	Crown Agents, Missionpharma A/S, Tri-Med Group, UNICEF, and the WHO Bulk Procurement Scheme (see Chapter 2 for more details)



Photo appears courtesy of Organics, Ltd.

DoubleCheck Gold™ HIV 1&2

Manufactured by Organics, Ltd., Israel

For further information, please contact:

Rosanne Tzuk,

*International Marketing Manager
Organics, Ltd.*

North Industrial Zone

P.O. Box 360

70650 Yavne, Israel

Tel: +972-8-942-9206

Fax: +972-8-943-8758

E-mail: rosanne@organics.co.il

Website: <http://www.organics.com>

Information current as of October 2006

Technical Information

DoubleCheck Gold™ HIV 1&2 whole blood test is a single reagent immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in human serum or plasma and whole blood. The test results can be read in 15 minutes.³² WHO's evaluation of two lots of the HIV test kit reported a sensitivity of 99.4 and 100 percent and specificity of 95.6 percent and 94.6 percent.³³

Product Information

Number of tests per kit	100
Items included in kit	Wash reagent bottles and whole blood applications
Additional items required but not included	Precision pipette with disposable tips and timer or stopwatch
FDA approved	No
Approved by other regulatory agency	Information not available
Shelf life of the HIV test kit	15 months
Language of package insert	English, French, and Spanish
Recommended storage conditions	Store the kit at 2–30°C (36–86°F)

³² Correspondence with manufacturer.

³³ World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2004. *HIV Assays: Operational Characteristics (Phase I). Report 14: Simple/Rapid Tests*. Geneva: WHO.

Weight/dimensions/volume for one kit (100 tests) Weight: 0.8 kg (1.8 lb)
Dimensions: 26 × 18 × 14 cm (10.2 × 7.1 × 5.5 in)
Volume: 6,916 cm³ (0.0069 m³) (421.9 cu in [0.244 cu ft])

Procurement Information

USAID Missions and CAs can purchase the kits directly from the manufacturer.

Average price for one test/price for one kit	USD 0.79 per test; USD 79.00 per kit (EXW, Yavne, Israel)
Additional pricing information	Special pricing consideration is given to countries working with the Clinton Foundation HIV/AIDS Initiative (contact the manufacturer for additional information).
Donation programs	No information provided
Available from U.S. sources	No
Minimum order from manufacturer	1 kit
Average minimum shelf life on delivery	15 months
Stock on hand	The manufacturer has a large stock available but may manufacture extra batches on demand.
Average time to fill order	If the order quantity is in stock, it is dispatched immediately. If it is a special manufacture, the order takes 2–3 weeks.
Quality issues	The company has a recall procedure for suspected defective products; in case of manufacturing problems, there is a Material Review Board. This forum convenes weekly or as needed. If necessary, the Troubleshooting Laboratory reworks the out-of-specification material. Any deviation from existing procedures is approved by the Material Review Board before implementation.
Payment method to manufacturer	Telegraphic bank transfer
Available from	Crown Agents, IDA Foundation, Tri-Med Group, and the WHO Bulk Procurement Scheme (see Chapter 2 for more details).



Photo appears courtesy of Premier Medical Corporation, Ltd.

First Response[®] HIV 1-2.0
Manufactured by Premier Medical Corporation, Ltd., India

For further information, please contact:

Mr. Neil Mehta

Premier Medical Corporation Ltd.

259 Amherst Ave

Colonia, NJ 07067

USA

Tel: +1-732-815-0462

Fax: +1-530-869-7966

E-mail: info@premiermedcorp.com

Website: <http://www.premiermedcorp.com>

Information current as of October 2006

Technical Information

First Response[®] HIV 1-2.0 test is a rapid lateral-flow immunochromatographic test that can be performed on whole blood, serum, or plasma. The test requires only 10 microliter of serum or 20 microliter of whole blood as sample and one drop of developer solution. The results are obtained in 5 minutes.³⁴ The sensitivity of the test is 100 percent, and the specificity is 99.18 percent.³⁵

Product Information

Number of tests per kit	1, 5, 10, 30, and 60
Items included in kit	One bottle of developer solution and sample collection droppers
Additional items required but not included	Lancet to prick finger is provided in single test pack, but not included in larger pack sizes.
FDA approved	No
Approved by other regulatory agency	Approved by regulatory agencies in a number of countries (contact the manufacturer for additional information).
Shelf life of the HIV test kit	18 months
Language of package insert	English, French, Portuguese, and Spanish
Recommended storage conditions	4–30°C (39–86°F)

³⁴ Correspondence with manufacturer.

³⁵ PMC Medical (India) Pvt. Ltd. 2007. *First Response HIV Card Test 1-2.0 Rapid HIV Care Test (product insert)*. Daman, India: PMC Medical. <<http://www.premiermedcorp.com/data/hiv-%20product%20insert.pdf>>.

Weight/dimensions/volume for one kit (30 tests)	Weight: 0.03 kg (0.066 lb) Dimensions: 13 × 13 × 22 cm (5 × 5 × 9 in) Volume: 3,681 cm ³ (0.003681 m ³) (225 cu in [0.130208 cu ft]) Single test pack: 10 gms Dimensions 12 × 9 × 1 cm (5 × 2 × 0.3 in)
---	--

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	USD 0.70–0.95 per test (FOB, Mumbai, India)
Additional pricing information	All shipping charges are extra. Special prices are offered to developing countries on a case-by-case basis. The lowest price given for an annual volume off-take commitment of 2 million tests or more.
Donation programs	The manufacturer states that it will consider donation of tests to PMTCT programs combined with tests for general testing purposes.
Available from U.S. sources	Yes, but not for domestic use in the United States
Minimum order from manufacturer	Manufacturer will ship any quantity required by courier; however, a minimum order of 50,000 tests is required to take advantage of the lowest shipping costs.
Average minimum shelf life on delivery	Less than 18 months
Stock on hand	Stock is always available. Large shipments exceeding 500,000 tests will require 2 weeks advance notice.
Average time to fill order	1 week
Quality issues	Premier Medical Corporation is ISO 9001-2000 and ISO 13485 certified. Product is Conformité Européenne (CE) marked. Certificate of analysis is provided with each shipment along with one extra kit for evaluation. The same batch of kits will be retained by the company in India and will be used for evaluation. A technician will be sent to the site to resolve problems in the event of any quality issues. The company has a recall procedure for test kits.
Payment method to manufacturer	Check from a U.S. bank or a letter of credit
Available from	Crown Agents, IDA Foundation, UNICEF, and the WHO Bulk Procurement Scheme (see Chapter 2 for more details).



Photo appears courtesy of Bio-Rad Laboratories

Genie II HIV-1/HIV-2

**Manufactured by Bio-Rad Laboratories,
France**

For further information, please contact:
*Stephane Garcia, Export Area Manager
(Africa)*

*Bio-Rad Laboratories
3 Boulevard Raymond Poincaré
92430 Marnes-la-Coquette
France*

Tel: +33-1-47-95-6285

Fax: +33-1-47-95-6181

E-mail: stephane.garcia@bio-rad.com

Website: <http://www.bio-rad.com>

Information current as of October 2006

Technical Information

Genie II HIV-1/HIV-2 is a rapid EIA test that uses the immunochromatography principle with recombinant and peptide antigens for the specific detection and differentiation of HIV-1 and HIV-2 antibodies in human serum or plasma. It utilizes ready-to-use reagents and dropper reagent bottles and can provide results in 10 minutes.³⁶ The sensitivity and specificity of the test are 99.5 percent and 99.1 percent, respectively.³⁷

Product Information

Number of tests per kit	40
Items included in kit	Reaction devices and microtubes for diluting specimens
Additional items required but not included	Pipettes, pipette tips, disposable gloves, biohazard bags, blood collection equipment, and disinfectant
FDA approved	Yes
Approved by other regulatory agency	Secretaria de Salud, Mexico; Ministerio de Saude, Brazil; Directia Generala Farmaceutica, Inspectie de Farmacie si Aparatura Medicala (attached to the Ministry of Health), Romania; Food & Drugs Board (N° FDB/D.06-1012), Ghana; and National Agency for Food and Drug Administration and Control (N° 03-0646), Nigeria
Shelf life of the HIV test kit	12 months

³⁶ Bio-Rad Laboratories. 2000. *Genie II HIV-1/HIV-2 Package Insert*. Hercules, CA: Bio-Rad Laboratories.

³⁷ World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2004. *HIV Assays: Operational Characteristics (Phase I). Report 14: Simple/Rapid Tests*. Geneva: WHO.

Language of package insert	English and French
Recommended storage conditions	2–8°C (36–46°F). Do not freeze.
Weight/dimensions/volume for one kit (40 tests)	Weight: 1.01 kg (2.2 lb) Dimensions: 26 × 18.5 × 14 cm (10.2 × 7.3 × 5.5 in) Volume: 6,700 cm ³ (0.0067 m ³) (408.9 cu in [0.237 cu ft])

Procurement Information

USAID Missions and CAs can purchase kits directly from the manufacturer.

Average price for one test/price for one kit	Fewer than 75 kits: ~USD 3.45 per test; USD 138 per kit 75–200 kits: ~USD 3.12 per test; USD 125 per kit More than 200 kits: ~USD 2.77; USD 111 per kit (EXW, Paris, France)
Additional pricing information	Special pricing is available for developing countries through bulk procurement at USD 2.60 per test (USD 104 per kit)
Donation programs	No information provided
Available from U.S. sources	No
Minimum order from manufacturer	Minimum order value of ~USD 280
Average minimum shelf life on delivery	6–9 months
Stock on hand	The manufacturer has stock available to cover an average of 1.5 months' worth of sales; large quantities may be staggered or need to be ordered at least 2 months in advance.
Average time to fill order	9 days; can be longer for unexpected orders
Quality issues	Complaints should be addressed to Bio-Rad's technical support staff in France at diags-support@bio-rad.com . Complaints are usually investigated, and if the quality problem is confirmed, the product is either replaced or a credit note is issued. The company has a recall procedure.
Payment method to manufacturer	The required payment method for orders worth more than USD 14,000 is a letter of credit. Orders between USD 7,000 and USD 14,000 require a 50 percent payment in advance and the remainder on delivery. For orders less than USD 7,000, 30 days credit is given.

Available from

Crown Agents, IDA Foundation, Medical Export Group, Missionpharma A/S, UNFPA, UNICEF, and the WHO Bulk Procurement Scheme (see Chapter 2 for more details).

HIVSav 1/2/0 Rapid SeroTest™

**Manufactured by Savyon Diagnostics,
Israel**

For further information, please contact:

Elana Bitton, Marketing Assistant

Savyon Diagnostics

3 Habosem Street

Ashdod 77610

Israel

Tel: +972-8-856-2920 Ext. 202

Fax: +972-8-852-3176

E-mail: elana@savyondiagnosics.com

Website: <http://www.savyondiagnosics.com>

Information current as of October 2006

Technical Information

The HIVSav 1/2/0 Rapid SeroTest™ is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1, HIV-2, and Subtype O in whole blood, serum, or plasma to aid in the diagnosis of HIV infection. Results from clinical studies demonstrate a sensitivity of greater than 99.9 percent and a specificity of 99.8 percent.³⁸

Product Information

Number of tests per kit	25 or 50
Items included in kit	Cassettes, reagents, controls, and pipettes
Additional items required but not included	Disposable gloves, biohazard bags, blood collection equipment, and disinfectant
FDA approved	No
Approved by other regulatory agency	No information provided
Shelf life of the HIV test kit	15 months
Language of package insert	English (other languages can be provided on request)
Recommended storage conditions	2–30°C. Do not freeze.

³⁸ Savyon Diagnostics. 2006. *HIVSav 1/2/0 Rapid SeroTest™ Instruction Manual*. Ashdod: Israel. <http://www.savyondiagnosics.com/Uploads/177HIVSAV_120_English_V2.pdf>.

Weight/dimensions/volume for one kit (25 tests)/(50 tests)	Weight: 0.385 kg (0.9 lb)/0.528 kg (1.2 lb) Dimensions: 9 × 16 × 11 cm (3.5 × 6.3 × 1.7 in)/same Volume: 3,344 cm ³ (0.0033 m ³) (204.1 cu in [0.12 cu ft])/same
--	---

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	USD 1.50 per test (FOB, Israel)
Additional pricing information	Shipping and insurance is extra. Special prices can be given to developing countries upon request if information such as the quantity of kits to be ordered is provided.
Donation programs	No information provided
Available from U.S. sources	No
Minimum order from manufacturer	1 kit
Average minimum shelf life on delivery	10 months
Stock on hand	The manufacturer stated that some stock is held but did not specify the quantity.
Average time to fill order	The order is dispatched immediately if sufficient stock is held. If the order is specially manufactured, it takes 4 weeks.
Quality issues	If there is a problem with the quality of the kit, the company will replace it.
Payment method to manufacturer	Letter of credit, prepayment, or open account, depending on the customer
Available from	Crown Agents (see Chapter 2 for more details). The manufacturer also has a number of distributors in several countries that can supply the test kit (contact the manufacturer for additional information).

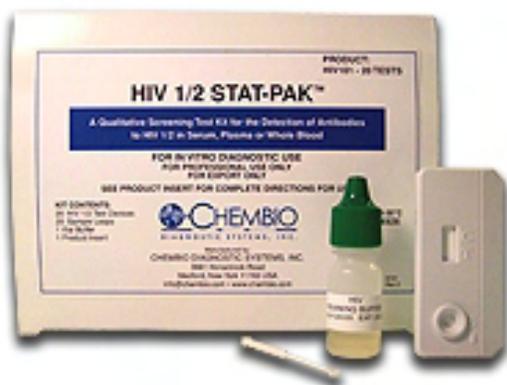


Photo appears courtesy of ChemBio Diagnostic Systems, Inc.

HIV 1/2 STAT-PAK™ Assay Manufactured by ChemBio Diagnostic Systems, Inc., USA

For further information, please contact:
Cathy Dudnanski, Director of Marketing
ChemBio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, NY 11763
USA

Tel: +1-631-924-1135

Fax: +1-631-924-6033

E-mail: cdudnanski@chembio.com

Website: <http://www.chembio.com>

Information current as of February 2007

Technical Information

HIV 1/2 STAT-PAK™ Assay is a single-use, immunochromatographic rapid test that uses a cocktail of antigens to detect antibodies to HIV-1 and HIV-2 in finger-stick whole blood, venous whole blood, serum, or plasma.³⁹ Results from a controlled clinical trial on 2,700 patients demonstrated a sensitivity of 99.7 percent and a specificity of 99.9 percent on whole blood, serum, and plasma samples. Another evaluation conducted by WHO on a worldwide panel of 770 samples demonstrated a sensitivity of 99.7 percent and a specificity of 99.3 percent.⁴⁰ The test can produce results in 10 minutes or less.⁴¹

Product Information

Number of tests per kit	20
Items included in kit	Running buffer, sample loops, package insert
Additional items required but not included	Timer, safety lancets, alcohol swabs, disposable gloves
FDA approved	Yes
Approved by other regulatory agency	It is registered for use in 35 countries (contact the manufacturer for additional information).
Shelf life of the HIV test kit	24 months
Language of package insert	English

³⁹ Correspondence with manufacturer.

⁴⁰ WHO evaluation conducted the third quarter of 2004 to be published in Report 16, *HIV Assays: Operational Characteristics*.

⁴¹ Correspondence with manufacturer.

Recommended storage conditions	8–30°C (46–86°F).
Weight/dimensions/volume for one kit (20 tests)	Weight: 0.28 kg (0.60 lb) Dimensions: 16.5 × 12.7 × 7 cm (6.5 × 5 × 2.75 in) Volume: 1,467 cm ³ (0.001864 m ³) (89 cu in)

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	USD 1.45–1.60 per test; USD 29–32 per kit (EXW Medford, NY, USA)
Additional pricing information	Special pricing consideration is given for large procurements. Above pricing is not available in United States.
Donation programs	There are currently no donation programs for this HIV test kit.
Available from U.S. sources	Yes
Minimum order from manufacturer	1 kit
Average minimum shelf life on delivery	15–20 months
Stock on hand	Some stock is usually maintained; stock is also manufactured on demand depending on the order size.
Average time to fill order	3–4 weeks; less if it is in stock
Quality issues	Quality issues are addressed through the manufacturer’s Quality Assurance/Quality Control Department. The company has a recall procedure.
Payment method to manufacturer	Prepayment, credit card, letter of credit. Credit terms are available in specific cases.
Available from	Crown Agents, IDA Foundation, Missionpharma A/S, and UNICEF (see Chapter 2 for more details). The product is also available directly from the manufacturer and from local distributors (contact the manufacturer for a list of distributors).



Photo appears courtesy of Chembio Diagnostic Systems, Inc.

HIV 1/2 STAT-PAK™ Dipstick

Manufactured by Chembio Diagnostic Systems, Inc., USA

For further information, please contact:
Cathy Dudnanski, Director of Marketing
Chembio Diagnostic Systems, Inc.

3661 Horseblock Road
Medford, NY 11763

USA

Tel: +1-631-924-1135

Fax: +1-631-924-6033

E-mail: cdudnanski@chembio.com

Website: <http://www.chembio.com>

Information current as of February 2007

Technical Information

HIV 1/2 STAT-PAK™ Dipstick is a single-use, immunochromatographic screening test that uses a cocktail of antigens to detect antibodies to HIV-1 and HIV-2 in whole blood, serum, or plasma. In an evaluation of 770 samples conducted by WHO the final sensitivity demonstrated was 99.0 percent and the final specificity was 100 percent compared to the reference assays. Evaluations in Zambia with 236 specimens, in Uganda with 503 specimens and most recently, in the Republic of South Africa with 500 specimens each resulted in 100 percent sensitivity and 100 percent specificity. There are two versions of the test kit—HIV302 and HIV303—the HIV302 performs the test using a test tube while the HIV303 performs the test using a card. The test can produce results in 15 minutes or less.⁴²

Product Information

Number of tests per kit	30
Items included in kit	HIV302 contains running buffer, sample loops, sample tubes, disposable rack, and product insert. HIV303 contains running buffer, sample loops, backing cards to run the test flat, and product insert.
Additional items required but not included	Timer, safety lancets, alcohol swabs, disposable gloves
FDA approved	No
Approved by other regulatory agency	This kit is registered for use in 35 countries (contact the manufacturer for additional information).

⁴² Correspondence with manufacturer. See also Chembio Diagnostic Systems, Inc. 2006. *HIV 1/2 STAT-PAK™ DIPSTICK Assay Product Insert*. Medford, NY: Chembio Diagnostic Systems, Inc.
<<http://www.chembio.com/pdfs/10-6261-0%20Rev%202%20HIV303%20Dipstick%20Product%20Insert.pdf>>.

Shelf life of the HIV test kit	18–24 months
Language of package insert	English (other languages available on request)
Recommended storage conditions	8–30°C (46–86°F).
Weight/dimensions/volume for one kit (20 tests)	Weight: 0.11 kg (0.25 lb) Dimensions: 13.65 × 6 × 5.4 cm (5.375 × 2.375 × 2.125 in) Volume: 442 cm ³ (0.001864 m ³) (89 cu in)

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	USD 0.90–1.05 per test (USD 27.00–31.50 per kit) to nonmember countries (EXW Medford, NY, USA)
Additional pricing information	Special pricing is available for Clinton Foundation HIV/AIDS Initiative-member countries, which includes a local distributor fee—USD 0.72 per test (USD 21.60 per kit). Special pricing consideration is also dependent on the volume of kits ordered and will need to be negotiated with the manufacturer.
Donation programs	There are currently no donation programs for this HIV test kit.
Available from U.S. sources	Yes, but not for domestic use in the United States
Minimum order from manufacturer	1 kit
Average minimum shelf life on delivery	15–20 months
Stock on hand	Some stock is usually maintained; stock is also manufactured on demand depending on the order size.
Average time to fill order	3–4 weeks; less if it is in stock
Quality issues	Quality issues are addressed through the manufacturer’s Quality Assurance/Quality Control Department. The company has a recall procedure.
Payment method to manufacturer	Prepayment, credit card, letter of credit. Credit terms are available in specific cases.
Available from	Crown Agents, IDA Foundation, Joint Medical Stores (Uganda), Missionpharma A/S, and UNICEF (see Chapter 2 for more details). The product is also available directly from the manufacturer and from local distributors (contact the manufacturer for a list of distributors).



Photo appears courtesy of Organics, Ltd.

ImmunoComb® II HIV 1 & 2 BiSpot

**Manufactured by Organics, Ltd.,
Israel**

For further information, please contact:

Rosanne Tzuk,

International Marketing Manager

Organics, Ltd.

North Industrial Zone

P.O. Box 360

70650 Yavne

Israel

Tel: +972-8-942-9206

Fax: +972-8-943-8758

E-mail: rosanne@organics.co.il

Website: <http://www.organics.com>

Information current as of October 2006

Technical Information

ImmunoComb® II HIV 1 & 2 BiSpot is a rapid test intended for the qualitative and differential detection of IgG antibodies to HIV-1 and HIV-2 in human serum or plasma. The test duration is 36 minutes at room temperature. Results are visible within minutes.⁴³ A multicenter study of the test carried out in Europe showed the sensitivity as 100 percent and the specificity at 99.4 percent.⁴⁴

Product Information

Number of tests per kit	36
Items included in kit	3 plastic combs, 3 developing plates, positive and negative controls, and a perforator
Additional items required but not included	Precision pipette with disposable tips, scissors, laboratory timer or watch
FDA approved	No
Approved by other regulatory agency	No information provided
Shelf life of the HIV test kit	15 months

⁴³ Correspondence with manufacturer.

⁴⁴ Organics Limited. 2005. *ImmunoComb® II HIV 1 & 2 BiSpot Package Insert*. Yavne, Israel: Organics Limited.

Language of package insert	English, French, Russian, and Spanish
Recommended storage conditions	2–8°C (36–46°F). Do not freeze.
Weight/dimensions/volume for one kit (36 tests)	Weight: 0.42 kg (0.92 lb) Dimensions: 17.5 × 13 × 5.5 cm (6.9 × 5.1 × 2.2 in) Volume: not stated

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	USD 1.60 per test; USD 57.60 per kit (EXW, Yavne, Israel)
Additional pricing information	Special pricing consideration is given for large orders. Special prices may also be considered for developing countries (contact the manufacturer for additional information).
Donation programs	No information provided
Available from U.S. sources	No
Minimum order from manufacturer	1 kit
Average minimum shelf life on delivery	12–14 months
Stock on hand	The manufacturer has a large stock available but may manufacture extra batches on demand, depending on quantities ordered.
Average time to fill order	If the order quantity is in stock, it is dispatched immediately. If it is a special manufacture, the order takes 2–3 weeks.
Quality issues	The company has a recall procedure for suspected defective products. In case of manufacturing problems, there is a Material Review Board. This forum convenes weekly or as needed. If required, the Troubleshooting Laboratory reworks the out-of-specification material. Any deviation from existing procedures is approved by the Material Review Board before implementation.
Payment method to manufacturer	Telegraphic bank transfer
Available from	Crown Agents, IDA Foundation, Tri-Med Group, UNICEF, and the WHO Bulk Procurement Scheme (see Chapter 2).



Photo appears courtesy of EY Laboratories

InstantCHEK™ HIV 1+2

Manufactured by EY Laboratories, Hong Kong

For further information, please contact:
Eileen Chu, Director International Accounts

EY Laboratories

*107 N. Amphlett Boulevard
San Mateo, CA 94401*

USA

Tel: +1-650-342-3296

Fax: +1-650-342-2648

E-mail: orders@eylabs.com

Website: <http://www.eylabs.com>

Information current as of October 2006

Technical Information

InstantCHEK™ HIV 1+2 is a rapid, qualitative in vitro test for the detection of HIV-1 and HIV-2 antibodies in human serum, plasma, or whole blood. It has 100 percent sensitivity⁴⁵ and 99.89 percent specificity for HIV-1 and HIV-2 antibodies.⁴⁶

Product Information

Number of tests per kit	20, 40, or 100
Items included in kit	Lyophilized stable controls, wash solution, sample and reagents, pipettes, lyophilized colloidal gold reagent, reconstitution solution, WBT (whole blood/urine/saliva filter tube)
Additional items required but not included	None
FDA approved	No
Approved by other regulatory agency	State Food and Drug Administration (SFDA) (China)
Shelf life of the HIV test kit	12 months
Language of package insert	English and Chinese (other languages can be provided on request)
Recommended storage conditions	5–25°C (41–77°F)

⁴⁵ Based on Boston Biomedica, Inc., panel and internal positive and negative sample study.

⁴⁶ Correspondence with manufacturer.

Weight/dimensions/volume for one kit (100 tests) Weight: 0.81 kg (1.78 lb)
Dimensions: 28 × 16 × 14 cm (11 × 6.3 × 5.5 in)
Volume: 6,072 cm³ (0.006072 m³) (370.5 cu in [0.2144 cu ft])

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	1–10 kits, USD 1.20 per test; per 20-test kit, USD 24; per 40-test kit, USD 48; per 100-test kit, USD 120 (FOB, Hong Kong)
Additional pricing information	Special prices are offered to developing countries. An organization/agency can get the lowest price depending on the volume ordered and length of contract with the company. It can be lower than USD 0.50 per test depending on the volume.
Donation programs	Open for discussion with the manufacturer
Available from U.S. sources	Yes, but not for domestic use in the United States
Minimum order from manufacturer	Subject to negotiation to suit the customer's needs and depending on the quantity ordered
Average minimum shelf life on delivery	Less than 12 months
Stock on hand	Some stock is available; kits are manufactured on demand when more than 100 kits are ordered.
Average time to fill order	Small orders can be filled within 1–3 days. Large orders of more than 10,000 tests require 1 week to 1 month, depending on the quantity ordered.
Quality issues	The company has Good Manufacturing Practices (GMP) and ISO 9002. The company has a recall procedure.
Payment method to manufacturer	Net 30 days; alternatives available for negotiation
Available from	Crown Agents, IDA Foundation, UNICEF, and the WHO Bulk Procurement Scheme (see Chapter 2 for more details).



Photo appears courtesy of BioLytical Laboratories

INSTI™ HIV-1/HIV-2 Rapid Antibody Test

Manufactured by BioLytical Laboratories in Canada

For further information, please contact:

Richard Galli, Chief Science Officer

BioLytical Laboratories

1208-13351 Commerce Parkway

Richmond, BC

Canada

V6V 2XY

Tel: +1-604-204-6784

Fax: +1-604-244-8399

E-mail: rgalli@biolytical.com

Website: <http://www.biolytical.com>

Information current as of December 2006

Technical Information

The INSTI™ HIV-1/HIV-2 Rapid Antibody Test is a single use, rapid (60 seconds), membrane-based flow-through in vitro qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human EDTA-whole blood, fingerstick blood, serum or EDTA-plasma. The device also contains a built-in IgG capture control to ensure proper sample addition. In large-scale national and international clinical trials sensitivity ranged from 99.4–100 percent with positive predictive values of 97.9–100 percent and specificity of 99.3–100 percent with negative predictive values of 99.6–100 percent. The test is intended for use by trained personnel in medical facilities, clinical laboratories, emergency care situations, testing and counseling and point-of-care settings, and physicians' offices as a diagnostic test.⁴⁷

Product Information

Number of tests per kit	1 or 24 per pack
Items included in kit	Single-use lancets, alcohol swab, transfer pipette
Additional items required but not included	No
FDA approved	No
Approved by other regulatory agency	Medical Devices Bureau, Health Canada
Shelf life of the HIV test kit	15 months
Language of package insert	English (other languages available on request)

⁴⁷ Correspondence with manufacturer.

Recommended storage conditions	15–30°C (59–86°F)
Weight/dimensions/volume for one kit (100/500 tests)	Weight: 0.5 kg (1.1 lb) Dimensions: 10 × 15 × 25 cm (4 × 6 × 10 in) Volume: not stated

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	USD 3.85–4.35 per test (FOB, Vancouver)
Additional pricing information	Special prices are available for developing countries. Contact the company directly for additional information
Donation programs	Donation programs are available through the INSTI™ Foundation (contact the company directly for additional information).
Available from U.S. sources	No
Minimum order from manufacturer	500 single tests or 20 kits of 24 tests each
Average minimum shelf life on delivery	12 months
Stock on hand	Limited stock is maintained but larger orders are produced on demand
Average time to fill order	6–8 weeks
Quality issues	These are addressed through the documented ISO 9001-2000 and ISO 13485 quality system program in place at bioLytical. There is a recall procedure for HIV test kits.
Payment method to manufacturer	50 percent of payment of total order is required upfront, 50 percent is required after the order has been fulfilled.
Available from	Crown Agents



Photo appears courtesy OraSure Technologies, Inc.

OraQuick® ADVANCE™ Rapid HIV-1/2 Test

Manufactured by OraSure Technologies, Inc., Thailand

For further information, please contact:

Lee Ann Smolick

*Government & International Affairs
Coordinator*

OraSure Technologies, Inc.

220 East First Street

Bethlehem, PA 18015

USA

Tel: +610-882-1820 Ext. 3810

Fax: +610-814-3406

E-mail: lsmolick@orasure.com

Website: <http://www.orasure.com>

Information current as of February 2007

Technical Information

The OraQuick® ADVANCE™ Rapid HIV 1/2 Test is a single-use, qualitative immunoassay to detect antibodies to HIV-1 and HIV-2 in oral fluid, fingerstick whole blood, venipuncture whole blood, and plasma specimens. The OraQuick ADVANCE Rapid HIV 1/2 Test is intended for use as a point of care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is read visually and results are read between 20 and 40 minutes. Sensitivity is 100 percent and the specificity is 99.87 percent.⁴⁸

Product Information

Number of tests per kit	25 or 100
Items included in kit	25 count kit: 25 devices, 25 loops, 5 stands, 25 subject information pamphlets, 1 customer letter, and 1 package insert 100 countt kit: 100 devices, 100 loops, 10 stands, 100 subject information pamphlets, 1 customer letter, and 1 package insert
Additional items required but not included	OraQuick ADVANCE Rapid HIV 1/2 Test Kit Controls are also available and sold separately. Timer or watch capable of timing 20 to 40 mins. Clean disposable absorbent workplace cover. Biohazard waste container. Lancet if used for blood.

⁴⁸ Correspondence with manufacturer.

FDA approved	Yes
Approved by other regulatory agency	Information not available
Shelf life of the HIV test kit	6 months
Language of package insert	English and Spanish (Portuguese is available on request)
Recommended storage conditions	2–27°C (36–80°F) ⁴⁹
Weight/dimensions/volume for one kit (25 tests) / (100 tests)	Weight: 0.907 kg (2 lb) / 3.175 kg (7lb) Dimensions: 23 × 23 × 18 cm (9 × 9 × 7 in) / 40 × 33 × 23 cm (16 × 13 × 9 in) Volume: 9344.6 cm ³ (0.00934 m ³) [0.33 cu ft] (1,745.28 cu in) / 31, 149 cm ³ (0.0311 m ³) [1.10 cu ft]

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/ price for one kit	USD 18.85 per kit (for both the 25 and 100-test kits) (EXW, Bethlehem, PA, USA)
Additional pricing information	Special prices are available to government agencies (currently USD 10.95 per kit). Special prices are also available for developing countries and are determined at the time of request, based on volume
Donation programs	Donation programs are considered and approved on an as needed basis at the time of the request
Available from U.S. sources	Yes
Minimum order from manufacturer	1 kit (25 tests)
Minimum average shelf life on delivery	Less than 6 months from the date of manufacture
Stock on hand	Stock is maintained at the company warehouse.
Average time to fill order	2 business days
Quality issues	There is a quality assurance system in place as well as a corrective and preventative action procedure to handle product-related issues. Stability studies are conducted on selected manufacturing batches

⁴⁹ If refrigerated storage is used, ensure that the divided pouch is brought to operating temperature (15–37°C [59–99°F]) before opening.

to ensure that product meets the established specifications over the assigned shelf life. There is a recall procedure for the HIV test kit.



Photo appears courtesy OraSure Technologies, Inc.

OraQuick® HIV-1/2 Rapid Antibody Test

Manufactured by OraSure Technologies, Inc., Thailand

For further information, please contact:

Lee Ann Smolick

Government Affairs Department

OraSure Technologies, Inc.

220 East First Street

Bethlehem, PA 18015

USA

Tel: +1-610-882-1820 Ext. 3810

Fax: +1-610-814-3406

E-mail: lsmolick@orasure.com

Website: <http://www.orasure.com>

Information current as of October 2006

Technical Information

OraQuick® HIV-1/2 Rapid Antibody Test is a qualitative in vitro immunoassay. It detects antibodies to HIV-1 and HIV-2 in human oral fluid, whole blood, serum, or plasma.⁵⁰ A WHO evaluation reported that the time taken to perform the assay is 21 minutes and a sensitivity of 98.1 percent and specificity of 100 percent (serum samples).⁵¹

Product Information

Number of tests per kit	100 or 500
Items included in kit	In the 100-test kit: 100 devices, 10 reusable test stands, 1 pack of 5 specimen collection loops, and 1 package insert. In the 500-test kit: 500 devices, 20 reusable test stands, 25 collection loops, and 1 package insert.
Additional items required but not included	Quality controls are available for purchase from the manufacturer. Each kit control contains a package insert and three vials (one HIV-1 positive control, one HIV-2 positive control, and one negative control). Other items needed are gloves, sterile lancet to obtain finger-stick or materials to obtain venipuncture whole blood sample, timer or watch, antiseptic wipe, sterile gauze pad, biohazard waste container, phlebotomy materials, and disposable

⁵⁰ Correspondence with manufacturer.

⁵¹ World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2004. *HIV Assays: Operational Characteristics (Phase I). Report 14: Simple/Rapid Tests*. Geneva: WHO.

	absorbent workspace cover.
FDA approved	No
Approved by other regulatory agency	Information not available
Shelf life of the HIV test kit	6 months
Language of package insert	English (Portuguese, French and Spanish available upon request)
Recommended storage conditions	2–30°C (36–86°F)
Weight/dimensions/volume for one kit (100/500 tests)	Weight: 5 kg (11 lb)/20 kg (44 lb) Dimensions: 35 × 39 × 21 cm (14 × 15 × 8 in)/44 × 59 × 44 cm (17 × 23 × 17 in) Volume: 28,600 cm ³ (0.0286 m ³) (1,745.28 cu in [1.01 cu ft])/114,117 cm ³ (0.114117 m ³) (6,963.84 cu in [4.03 cu ft])

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	USD 4–5 per test (for both the 100- and 500-test kits) (EXW, Thailand)
Additional pricing information	Special prices can be negotiated based on the volume of test kits ordered.
Donation programs	Product donations are considered on a case by case basis.
Available from U.S. sources	Yes
Minimum order from manufacturer	1 kit (100-count case)
Average minimum shelf life on delivery	Less than 6 months
Stock on hand	Kits are manufactured on demand, depending on the order quantity.
Average time to fill order	4–5 weeks
Quality issues	There is a recall procedure for faulty test kits. Stability studies are conducted on selected manufacturing batches each year to ensure that the product meets the established specifications over the assigned shelf life.
Payment method to manufacturer	Wire transfer of funds (there is an additional USD 25 fee for this). Letters of credit and credit card payments are also accepted.

Available from

Crown Agents, Medical Export Group, Missionpharma A/S, UNFPA, UNICEF, and the WHO Bulk Procurement Scheme (see Chapter 2 for more details).



Photo appears courtesy MedMira, Inc.

Reveal™ G3 Rapid HIV-1 Antibody Test

Manufactured by MedMira in Canada

For further information, please contact:

Paul Phillips, Director of Global Sales

MedMira Laboratories Inc

155 Chain Lake Drive, Suite 1

Halifax, Nova Scotia B3S 1B3

Canada

Tel: +1-902-450-1588

Fax: +1-902-450-1580

E-mail: info@medmira.com

Website: <http://www.medmira.com>

Information current as of November 2006

Technical Information

The *Reveal™* G3 Rapid HIV-1 Antibody Test is a single use, qualitative immunoassay intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1. It detects antibodies to HIV-1 in human serum or plasma. It is a manually performed, visually interpreted rapid immunoassay. It is comprised of a single-use cartridge containing an immunoreactive test membrane comprised of a combination of synthetic peptides corresponding to conserved regions of HIV structural proteins coated onto a membrane matrix, which functions to capture anti-HIV-1 antibodies present in human serum or plasma when a drop of specimen is applied. The run-time for the test is approximately three minutes. The test has a sensitivity of 99.8 percent and a specificity of 99.1 percent for serum specimens and 98.6 percent for plasma specimens.⁵²

Product Information

Number of tests per kit	30
Items included in kit	Universal buffer and test control package
Additional items required but not included	None
FDA approved	Yes
Approved by other regulatory agency	Health Canada and SFDA (China)
Shelf life of the HIV test kit	12 months
Language of package insert	English

⁵² Correspondence with manufacturer.

Recommended storage conditions	2–30°C (36–86°F)
Weight/dimensions/volume for 1 kit (30 tests)	Weight: 0.91 kg (2 lb) Dimensions: 23 × 18 × 18 cm (9 × 7 × 7 in) Volume: 7,362 cm ³ (449 cu in [0.01 m ³])

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	USD 15.00–16.00 per test or USD 450–480 per kit (FOB, Halifax)
Additional pricing information	Special pricing consideration is offered to developing country clients who contact MedMira directly. Price will depend on the volume.
Donation programs	No information available
Available from U.S. sources	Yes, from Cardinal Health through MedMira’s distribution partner (American Health Partners)
Minimum order from manufacturer	1,000 tests
Average minimum shelf life on delivery	The company will not ship any product that has less than 75 percent of shelf life on it unless agreed by the customer
Stock on hand	HIV tests are manufactured on demand
Average time to fill order	Three weeks
Quality issues	No information provided
Payment method to manufacturer	For the first three orders, half of the total payment is required up-front
Available from	Crown Agents, Cardinal Health through MedMira’s distribution partner (American Health Partners)



Photo appears courtesy of Trinity Biotech, Plc

Uni-Gold™ HIV

**Manufactured by Trinity Biotech, Plc
Ireland**

For further information, please contact:
*Fidelma Loftus, International Product
Manager
Trinity Biotech, Plc
IDA Business Park
Bray, Co. Wicklow
Ireland*

Tel: +353-1-276 9800

Fax: +353-1-276 9888

Email: fidelma.loftus@trinitybiotech.com

Website: <http://www.trinitybiotech.com>

Information current as of October 2006

Technical Information

Uni-Gold™ HIV is a single reagent assay that uses the immunochromatographic sandwich principle for the detection of antibodies to HIV-1 and HIV-2 in serum, plasma, or whole blood. It has been evaluated by a number of independent organizations. The test is estimated to produce results in 11 minutes.⁵³ The WHO evaluation recorded 100 percent sensitivity and 100 percent specificity for the product (whole blood samples).⁵⁴

Product Information

Number of tests per kit	20
Items included in kit	Devices, wash buffer, and disposable pipettes
Additional items required but not included	Timer or stopwatch, disposable gloves, biohazard bags, blood collection equipment, and disinfectant
FDA approved	No
Approved by other regulatory agency	Approved by regulatory agencies in a number of countries (contact manufacturer for additional information).
Shelf life of the HIV test kit	15 months
Language of package insert	English (other languages can be provided on request)
Recommended storage	2–27°C (36–81°F)

⁵³ World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2002. *HIV Assays: Operational Characteristics (Phase 1). Report 12: Simple/Rapid Tests, Whole Blood Specimens*. WHO/BCT/02.07. Geneva: WHO.

⁵⁴ Trinity Biotech PLC. n.d. *Uni-Gold™ HIV Catalogue No: 1206502 Package Insert*. Wicklow, Ireland: Trinity Biotech.

conditions

Weight/dimensions/volume for one kit (20 tests) Weight: 0.2 kg (0.44 lb)
Dimensions: 23.5 × 14 × 8 cm (9.25 × 5.5 × 3.15 in)
Volume: 3,360 cm³ (0.00336 m³) (205.04 cu in [0.118657 cu ft])

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/
price for one kit USD 1.50 per test; USD 30 per kit (EXW, Ireland)

Additional pricing
information No handling charges are added, but shipping and insurance are extra. Prices may vary by quantity and region. Concessionary prices are offered to WHO, other UN agencies, and major international procurement agencies. Discounts from the listed price can be negotiated on a case-by-case basis either directly through the manufacturer or through local distributors.

Donation programs There are currently no donation programs for this HIV test kit.

Available from U.S.
sources Yes, but not for domestic use in the United States

Minimum order from
manufacturer 5 kits (100 tests)

Average minimum shelf life
on delivery 10–11 months (kits are usually delivered with 75 percent of their shelf life remaining)

Stock on hand Stocks are held, but levels vary with demand.

Average time to fill order 6 weeks

Quality issues Any quality problem with the product is investigated through the in-house quality control system. If a product problem is confirmed, replacement product or product notes are issued. The manufacturer does not have a specific recall procedure for the HIV test kit, but it has implemented SOPs for the management of postmarketing activities including customer complaint handling, adverse event reporting, and product recalls. These SOPs have been developed in accordance with all relevant ISO, EU, and FDA requirements.

Payment method to
manufacturer Up-front payments for three orders, after which credit terms can be established. Credit card orders may be accepted.

Available from Crown Agents, Durbin PLC, IDA Foundation, Joint Medical Stores (Uganda), Medical Export Group, MEDS (Kenya), Missionpharma A/S, UNICEF, UNFPA, and the WHO Bulk Procurement Scheme (see Chapter 2 for more details). The manufacturer has exclusive/non-exclusive local suppliers in a large number of countries (contact the manufacturer for additional information).

Uni-Gold™ Recombigen®

Manufactured by Trinity Biotech, Plc Ireland

For further information, please contact:

Fidelma Loftus, International Product

Manager

Trinity Biotech, Plc

IDA Business Park

Bray, Co. Wicklow

Ireland

Tel: +353-1-276 9800

Fax: +353-1-276 9888

Email: fidelma.loftus@trinitybiotech.com

Website: <http://www.trinitybiotech.com>

Information current as of April 2007

Technical Information

Uni-Gold™ Recombigen® HIV is a single-use rapid immunoassay for the qualitative detection of antibodies to HIV-1 in serum, plasma, and whole blood (venipuncture and fingerstick). The sensitivity of the test is 100 percent and the specificity of the test is 99.7 percent. Test results are available after 10 minutes.⁵⁵

Product Information

Number of tests per kit	20
Items included in kit	Wash solution, 20 disposable finger-stick sample collection and transfer pipettes.
Additional items required but not included	Timer or stopwatch, blood collection devices (for testing of venipuncture whole blood, serum, or plasma), biohazard disposal container, disposable gloves. For fingerstick samples the following additional materials are required: adhesive bandages, lancet capable of producing a 50µl droplet, sterile wipes, and sterile gauze pads.
FDA approved	Yes
Approved by other regulatory agency	
Shelf life of the HIV test kit	12 months
Language of package insert	English

⁵⁵ Correspondence from the manufacturer.

Recommended storage conditions	2–27°C (36–81°F). Do not freeze.
Weight/dimensions/volume for one kit (20 tests)	Weight: 0.4 kg (0.8 lb) Dimensions: 24 × 14.5 × 10 cm (9.5 × 5.7 × 3.9 in) Volume: 3,480cm ³ (0.00348 m ³) (212.36 cu in [0.122 cu ft])

Procurement Information

USAID Missions and CAs can purchase the kit directly from the manufacturer.

Average price for one test/price for one kit	USD 16.50 per test; USD 330.00 per kit (EXW)
Additional pricing information	Special pricing is also given to developing countries. Please contact the manufacturer directly for more information.
Donation programs	Humanitarian pricing is available through a number of organizations. Please contact the manufacturer for additional information.
Available from U.S. sources	Yes ⁵⁶
Minimum order from manufacturer	None
Average minimum shelf life on delivery	6 months
Stock on hand	Some stock is held
Average time to fill order	1–2 weeks
Quality issues	Quality issues are handled through an official customer complaints process. There is a recall procedure for faulty test kits.
Payment method to manufacturer	Bank transfer
Available from	The product is available directly from the manufacturer and from local distributors (contact the manufacturer for a list of distributors).

⁵⁶ The Trinity Biotech U.S. Office supplies the U.S. customer base. For shipments of the product to regions outside of the U.S., please contact the office in Ireland. See website for contact information.

CHAPTER 2: PROCUREMENT AGENCIES AND SUPPLIERS

Chapter 2 contains HIV test kit procurement information from selected procurement agencies and suppliers (both national and international).

A supplier maintains a warehouse and sends items directly to customers. The following international suppliers responded to this survey—

- Action Medeor
- IDA Foundation
- Orbi-Pharma

Also included in this fourth edition are national suppliers who procure and supply pharmaceuticals and other commodities for programs within countries or regions. The following national suppliers responded to the survey—

- Joint Medical Stores (JMS), Uganda
- MEDS, Kenya
- Medical Stores Department (MSD), Tanzania

A procurement agency negotiates prices and places purchase orders for clients and may often order from a vendor. An agency usually charges a fee for its services over and above the CIF price of the product or test kit. The following international procurement agencies responded to the survey—

- Crown Agents
- Durbin PLC
- Medical Export Group
- Missionpharma A/S
- Tri-Med Group

Some of the international procurement agencies and suppliers listed in the 2005 edition of MSH's *International Drug Price Indicator Guide*⁵⁷ were surveyed, but not all responded.

Also featured in this section are three UN agencies that have been involved in the procurement of HIV test kits: UNICEF, UNFPA, and WHO. UNFPA assists countries to procure HIV test kits for general use, while UNICEF assists countries to procure HIV test kits for their PMTCT programs. WHO directs and manages the HIV Test Kit Bulk Procurement Scheme for several other UN agencies and civil society organizations involved in programs that require test kits.

The information in this chapter is current as of July 2007 and is intended to be used as an initial reference for identifying procurement agencies and suppliers and for procurement planning.

⁵⁷ Management Sciences for Health (MSH), in collaboration with the World Health Organization. 2005. *International Drug Price Indicator Guide, Guía Internacional de Indicadores de Precios de Medicamentos, Indicateur de Prix Internationaux des Médicaments* (updated annually). Boston, MA: MSH.

Inclusion in this document does not imply that the supplier or agency is endorsed by USAID or MSH/RPM Plus or preferred over any other supplier or agency.

Prices are given as an indication only and may vary according to quantities ordered and with fluctuations on the international market or in currency exchange rates. Additional handling and shipping charges may apply. Due to the time-sensitive nature of the procurement information included in this guide, the supplier or agency should be contacted to verify the information, particularly with regard to price and availability, prior to placing an order or preparing a request for USAID approval to procure HIV test kits.

What Is in This Section?

To obtain relevant information on the HIV test kits listed in the USAID Source and Origin Waiver, surveys were sent to the procurement agencies and suppliers of the HIV test kits. The responses from these agencies and suppliers provide the information that appears in this section. Also noted is whether a representative of the U.S. Government can purchase test kits from the specified procurement agency or supplier. The information included for each company is as follows, with some exceptions—

Product(s) supplied	Names of the test kits listed in the Source and Origin Waiver that the procurement agency or supplier stocks or supplies.
Listed price (range) and terms and suggested retail price	Prices are given as an indication only. The supplier or agency should be contacted to verify the information.
Additional pricing information	Additional procurement information is listed here, such as whether the manufacturer provides special discounts for nonprofits or other organizations working on certain programs.
Minimum order quantity	This lists the minimum order quantity required, if any.
Average minimum shelf life on delivery	The remaining time (usually months) for which a product can be safely used and accurate results can be expected after purchase from the manufacturer. Assuring that the shelf life can be maintained as stated on the product packaging is dependent on the product being stored and handled according to the conditions specified by the manufacturer. These instructions must be included in every package, carton, and/or shipping unit. The minimum accepted shelf life on delivery must be negotiated and included in the procurement contract.
Stock on hand	Specifies whether stock is maintained or if the kit is manufactured on demand. If stock is held, the lead time is generally shorter. However, having the kits manufactured on receipt of the order has the advantage of a longer shelf life.

Average time to fill an order	This information assists programs in planning for procurement to ensure that orders are placed in sufficient time to avoid product unavailability.
Delivery information	Details the delivery locations the company serves, if applicable.
Payment method	Any general requirements for method of payment are given in this section. These requirements are often country-, program-, or quantity-specific. The procurement agency or supplier may need to be contacted for additional information.
Quality issues	Information on the company's policy if the customer experiences problems with the quality of the test kits.
Additional information	Other information that might be useful in the procurement of HIV test kits is given here, if any.

Action Medeor

International Aid Organization

For further information, please contact:

Christoph Bonsmann, Pharmacist, Head of Quality Control

Action Medeor

St. Töniser Str. 21

D-47918, Tönisvorst

Germany

Tel: +49-21-56-97-88-0

Fax +49-21-56-97-88-88

E-mail: christoph.bonsmann@medeor.org

Website: <http://www.medeor.org>

Information current as of November 2006

USAID Missions and CAs can purchase kits directly from this supplier.

Products supplied	Determine™ HIV-1/2
Listed price (range) and terms and suggested retail price	For developing countries: USD 80 for 100 tests For other countries: USD 92 for 100 tests (EXW, Germany)
Additional pricing information	Prices do not depend on the quantity ordered. Company is only licensed to sell to nonprofit organizations.
Minimum order quantity	None
Average minimum shelf life on delivery	12 months
Stock on hand	No stock is maintained. According to a special arrangement with Abbott Laboratories, deliveries are ready within 3–5 working days.
Average time to fill an order	Less than 2 weeks
Delivery information	Delivery is made to facilities within a country.
Payment method	For established customers, payment is expected within 30 days. For new customers, a prepayment is required
Quality issues	The company has a Quality Management System (QMS) which foresees a number of standard operations starting with informing the manufacturer to recalling products from the market. Batch-recording is done.

Crown Agents

International Procurement Agency

For further information, please contact:

Judy MacLeod, Purchasing Manager

Crown Agents

St. Nicholas House,

St. Nicholas Road

Sutton, Surrey

SM1 1EL, U.K.

Tel: +44-20-8710-6297

Fax: +44-20-8770-9719

E-mail: judy.macleod@crowagents.co.uk

Website: <http://www.crownagents.com>

Information current as of January 2007

USAID Missions and CAs can purchase kits directly from this agency.

Products supplied	Aware™ HIV 1/2 BSP Bioline HIV 1/2 3.0 Bionor™ HIV-1&2 Bundi Rapid HIV 1/2 Capillus™ HIV-1/HIV-2 CareStart™ HIV 1-2-O Determine™ HIV-1/2 DoubleCheck™ HIV 1&2 DoubleCheck Gold™ HIV 1&2 First Response® HIV 1-2.0	Genie II HIV-1/HIV-2 HIVSav 1&2 Rapid SeroTest™ HIV 1/2 Stat-Pak™ Assay HIV 1/2 Stat-Pak™ Dipstick ImmunoComb™ HIV 1&2 InstantCHEK™ HIV 1+2 INSTI™ HIV Antibody OraQuick® HIV-1/2 Rapid Antibody Test <i>Reveal™</i> Rapid HIV-1 Uni-Gold™ HIV
Listed price (range) and terms and suggested retail price	Kit prices (negotiated directly with manufacturers), together with shipping/insurance charges, are available upon application. There is no handling charge.	
Additional pricing information	The price for each kit is available to all customers, irrespective of the type of organization. Prices are not dependent upon the quantity ordered but large or long-term contracts would attract a negotiated discount.	
Minimum order quantity	None	
Average minimum shelf life on delivery	Procurement of freshly manufactured products is done to maximize shelf life at delivery.	
Stock on hand	Stock is not maintained, and kits are ordered on demand.	

Average time to fill an order	Usually 1–2 weeks from order to shipment and may be up to 6 weeks depending upon the manufacturer. Scheduled deliveries to meet the client’s requirements can be arranged.
Payment method	The preferred method is payment at order placement. However, other options are negotiable.
Quality issues	Quality problems are resolved according to the nature of the problem and the preferred solution of the customer. For example, the replacement of the damaged product, or a refund.

Durbin PLC

International Procurement Agency

For further information, please contact:

Anthony Varela, Marketing Manager

Durbin PLC.

180 Northolt Road

South Harrow

Middlesex, HA2 0LT

United Kingdom

Tel: +44-20-8869-6500

Fax: +44-20-8869-6565

E-mail: a.varela@durbin.co.uk

Website: <http://www.durbin.co.uk>

Information current as of December 2006

USAID Missions and CAs can purchase kits directly from this supplier.

Product(s) supplied	Capillus™, Determine™, and Uni-Gold™ HIV (additional HIV test kits available on request)
Listed price (range) and terms and suggested retail price	Prices are currently being reviewed and usually depend on the quantity ordered and include EXW. They include DDU or CIF (according to country regulations).
Minimum order quantity	None
Average minimum shelf life on delivery	No information available
Stock on hand	No information available
Average time to fill an order	Contact company directly
Payment method	Contact company directly
Quality issues	Contact company directly

IDA Foundation

International Supplier

For further information, please contact:

Nienke Gruppelaar, Product Manager

IDA Foundation

Slochterweg 35

1027 AA Amsterdam

The Netherlands

Tel: +31-20-40-33-051

Fax: +31-20-40-31-854

E-mail: info@ida.nl

Website: <http://www.ida.nl>

Information current as of November 2006

USAID Missions and CAs can purchase kits directly from this supplier.

Products supplied	Capillus™ Determine™ Double Check Gold™ First Response™ Genie II HIV 1/2 Stat-Pak™ Assay HIV 1/2 Stat-Pak™ Dipstick ImmunoComb™ InstantCHEK™ Uni-Gold™	
Listed price (range) and terms and suggested retail price ⁵⁸	Capillus™ Determine™ Double Check Gold™ First Response™ Genie II HIV 1/2 Stat-Pak™ Assay HIV 1/2 Stat Pak™ Dipstick InstantCHEK™ Uni-Gold™ HIV	EUR 178.25 (USD 234.14) for 100 tests EUR 75.30 (USD 98.90) for 100 tests EUR 112.70 (USD 147.99) for 100 tests EUR 19.55 (USD 25.66) for 30 tests EUR 106.95 (USD 140.46) for 40 tests EUR 29.65 (USD 38.92) for 20 tests EUR 29.90 (USD 29.90) for 20 tests Price for 100 tests available on request EUR 19.55 (USD 25.66) for 20 tests

Prices are EXW, Amsterdam; transportation and insurance are extra charges. Prices are indicative only and may vary based on volume and destination. The latest prices and complete product range can be found at <http://www.ida.nl>.

⁵⁸ Please note that prices were provided in euros (EUR) and subsequently converted to U.S. dollars (USD).

Average minimum shelf life on delivery	This varies per kit; customers are given detailed information beforehand.
Stock on hand	Stock levels are kept low due to short shelf life, but lead time is short.
Average time to fill an order	On average, orders are shipped 2–3 weeks after order confirmation.
Payment method	Goods are usually shipped on a prepayment basis. For large orders and tenders, the company will accept letters of credit.
Quality issues	Quality problems are resolved according to the nature of the problem and the preferred solution of the customer.

Joint Medical Stores (JMS)

National Supplier

For further information, please contact:

Donna Kusmererwa, General Manager

Joint Medical Stores

P.O. Box 4501

Kampala

Uganda

Tel: +256-41-510-096/7

Fax: +256-41-510-098

E-mail: donnak@jms.co.ug

Website: <http://www.jms.co.ug>

Information current as of October 2006

USAID Missions and CAs can purchase kits directly from this supplier.

Products supplied	Capillus™ (available only on request), Determine™ HIV-1/2, HIV 1/2 Stat-Pak™ Dipstick and Uni-Gold™ HIV
Listed price (range) and terms and suggested retail price	Capillus™ USD 159.10 per kit Determine™ USD 153.00 per kit HIV 1/2 Stat-Pak™ Dipstick USD 22.06 per kit Uni-Gold™ USD 35 per kit (CIF, Kampala, Uganda)
Additional pricing information	A 5 percent discount is available to church health facilities accredited by the Catholic or Protestant Medical Bureau.
Minimum order quantity	None
Average minimum shelf life on delivery	6 months
Stock on hand	Stock is maintained, but some orders are manufactured on demand. Slight delays can occur during times of high demand.
Average time to fill an order	Depends on the size of the order.
Payment method	Cash and carry
Quality issues	No information provided
Additional information	Orders are collected from the company's warehouse.

Medical Export Group (MEG)

International Procurement Agency

For further information, please contact:

Guido Ranselaar, Area Manager

Medical Export Group

Papland 16 P.O. Box 598

4200 AN Gorinchem

The Netherlands

Tel: +31-183-356-100

Fax: +31-183-356-122

E-mail: info@meg.nl

Website: <http://www.meg.nl>

Information current as of December 2006

USAID Missions and CAs can purchase kits directly from this supplier.

Product supplied	Bionor, Capillus™, Determine™, Genie II, OraQuick, and Uni-Gold™	
Listed price (range) and terms and suggested retail price	Bionor	USD 807.16 for 250 tests
	Capillus™	USD 317.49 for 100 tests
	Determine™	USD 129.04 for 100 tests
	Genie II	USD 214.43 for 40 tests or USD 258.97 for 96 tests
	OraQuick	USD 6.60 for 1 test
	Uni-Gold™	USD 60.14 for 20 tests
	FCA, Gorinchem MEG can supply other test kits upon request.	
Additional pricing information	For orders with a value of less than EUR 1,000 a handling charge of EUR 75.00 is applied.	
Minimum order quantity		
Average minimum shelf life on delivery	In general, MEG supplies goods with a shelf life of at least 75 percent.	
Stock on hand	Stock is not maintained.	
Average time to fill an order	Delivery time depends on availability.	
Payment method	30 days net	

Medical Stores Department (MSD)

National Supplier

For further information, please contact:

*Christopher Msemo, Director, Pharmaceutical
& Technical Services*

Medical Stores Department (MSD)

Off Nyerere Road, Keke Mwanga

P.O. Box 9081

Dar es Salaam

Tanzania

Tel: +255-22-286-0890

Fax: +255-22-286-5814

E-mail: info@msd.or.tz

Website: <http://www.msd.or.tz>

Information current as of March 2005

USAID Missions and CAs can purchase kits directly from this supplier.

Product supplied	Capillus™ HIV-1/HIV-2
Listed price (range) and terms and suggested retail price	USD 197 per kit
Additional pricing information	None
Minimum order quantity	None
Average minimum shelf life on delivery	No information provided
Stock on hand	Stock is maintained.
Average time to fill an order	Orders are dispatched immediately. Orders may be delivered either to facilities within the country or to a single address/warehouse, as the customer requests.
Payment method	Cash and carry or advance payment
Quality issues	No information provided

Mission for Essential Drugs and Supplies (MEDS)

Regional Supplier

For further information, please contact:

Ruth Njoroge, Projects Manager

Mission for Essential Drugs and Supplies (MEDS)

P.O. Box 78040

Viwandani

00507, Nairobi

Kenya

Tel: +254-20-551633

Fax: +254-20-551653

E-mail: mnjoroge@meds.or.ke

Website: <http://www.meds.or.ke>

Information current as of March 2005

USAID Missions and CAs can purchase kits directly from this supplier.

Products supplied	Capillus™ HIV-1/HIV-2 Determine™ HIV-1/2 Uni-Gold™ HIV
Listed price (range) and terms and suggested retail price	Capillus™ USD 322 per kit Determine™ USD 101 per kit Uni-Gold™ USD 54 per kit (CIF, Nairobi, Kenya)
Additional pricing information	Prices do not depend on quantity ordered or on the type of organization that the HIV test kits are being supplied to. Although one price is offered to all customers, large contracts are negotiable.
Minimum order quantity	None
Average minimum shelf life on delivery	75 percent of remaining shelf life
Stock on hand	Stock is maintained.
Average time to fill an order	Four days (for locations in Kenya). Company sometimes has problems filling orders when its suppliers are out of stock.
Payment method	Cash for facilities within the country and telegraphic transfer for facilities outside the country.
Quality issues	The company reports that it has not had any quality issues.

Missionpharma A/S

International Procurement Agency

For further information, please contact:
*Laurent Lombart, Director, Sales Processes
& Strategic Marketing
Missionpharma A/S
Vassingerøedvej 9
DK-3540 Lyngø, Denmark
Tel: +45 48 163200
Fax: +45 48 163248*

E-mail: info@missionpharma.com

Website: <http://www.missionpharma.com>

Information current as of March 2005

USAID Missions and CAs can purchase kits directly from this agency.

Products supplied	Capillus™ Determine™ DoubleCheck™ Genie II HIV 1/2 Stat-Pak™ OraQuick® Uni-Gold™ HIV
Listed price (range) and terms and suggested retail price	Capillus™ ~USD 198 for 100 tests Determine™ ~USD 91 for 100 tests DoubleCheck™ ~USD 90 for 100 tests Genie II ~USD 269 (~EUR 200) for 40 tests HIV 1/2 Stat-Pak™ ~USD 32 for 20 tests OraQuick® ~USD 480 for 100 tests Uni-Gold™ ~USD 55 for 20 tests

All prices are EXW (Denmark).

Additional pricing information	Prices are based on quantities ordered. The company does not have a standard discount rate, and there are no handling charges. Humanitarian organizations get a lower price. For an organization/agency to get a lower price the agency requires sufficient time to prepare a quote; therefore, such an order must be planned farther ahead of time (for example, 6 months).
--------------------------------	--

Minimum order quantity	None
Average minimum shelf life on delivery	Shelf life varies according to the product.
Stock on hand	Stock is not maintained because of the short shelf life of the products.

Average time to fill an order	Varies according to the manufacturer; usually 1–2 weeks but up to 4–5 weeks.
Delivery information	The company can deliver to facilities within a country or to only a single address/warehouse, according to the customer’s request.
Payment method	A percentage of payment is required (depending on the relationship with the client) before delivery.
Quality issues	Kits with quality problems will be replaced or a refund will be issued, depending on the customer’s preference. The Quality Assurance/Quality Control Department is responsible for visual control of samples from each consignment and for verifying each certificate of analysis. The company adheres to WHO GMP rules.

Orbi-Pharma

International Supplier

For further information, please contact:

Chantal Dauw, Account Manager

Orbi-Pharma

Molenberglei, 18

B-2627 Schelle

Belgium

Tel: +32-3-880-6366

Fax: +32-3-888-7481

E-mail: info@orbi-pharma.be

Website: <http://users.online.be/orbipharma>

Information current as of December 2006

USAID Missions and CAs can purchase kits directly from this supplier.

Product supplied	Determine™ HIV-1/2
Listed price (range) and terms and suggested retail price	For Congo (DRC) only: USD 123.20 (EUR 92.63) for 100 tests with blood chase buffer & EDTA capillary 100 pcs (EXW, Belgium) For other African countries: USD 183.47 (EUR 137.95) for 100 tests. Price is reduced to USD 17.29 for 100 tests for orders greater than 5 kits. Blood chase buffer for 100 tests: USD 7.04 EDTA capillary 100 pcs: USD 21.63 (All EXW Belgium)
Additional pricing information	Price varies according to quantity ordered.
Minimum order quantity	1 kit
Average minimum shelf life on delivery	6 months
Stock on hand	Stock is usually held in a warehouse (the European Distribution Center in Delkenham, Germany) by the manufacturer (Abbott Laboratories).
Average time to fill an order	Depends on the quantity. Ordinary orders take 2–4 weeks.
Payment method	International bank transfer (SWIFT)
Quality issues	Quality problems are handled according to the complaint; kits with problems are usually recalled and replaced.

Tri-Med Group

International Procurement Agency

For further information, please contact:

Peter Smith, Director

Tri-Med Ltd.

1 Ossian Mews

London N4 4DT

United Kingdom

Tel: +44-20-8348-4666

Fax: +44-20-8348-5666

E-mail: smith@tri-med.com

Website: <http://www.tri-med.com>

Information current as of December 2006

USAID Missions and CAs can purchase kits directly from this supplier.

Product(s) supplied	Bioline HIV 1/2 3.0 DoubleCheck™ DoubleCheck Gold™ HIV 1/2 Stat-Pak™ Assay HIV 1/2 Stat-Pak™ Dipstick ImmunoComb™ HIV 1&2
Listed price (range) and terms and suggested retail price	Prices vary according a number of factors including the quantity ordered as well as the customer's final delivery destination. Each order is undertaken on a cost and handling charge. The terms are DDU or CIF (according to country regulations).
Minimum order quantity	None
Average minimum shelf life on delivery	80 percent of shelf life
Stock on hand	Kits are ordered on demand. A small amount of stock is held.
Average time to fill an order	4–14 days
Payment method	For frequent customers payment is expected within 30 days of delivery. For non-frequent customers other arrangements are made.
Quality issues	Kits with quality problems are referred to the manufacturer who operate appropriate quality assurance procedures

UNFPA

International Aid Agency

For further information, please contact:

Ann Janssens, Procurement Specialist

UNFPA

Midtermolen 3

DK-2100 Copenhagen

Denmark

Tel: +45-35-46-7368

Fax: +45-35-46-7018

E-mail: janssens@unfpa.org

Website: <http://www.unfpa.org>

Information current as of October 2006

UNFPA procures HIV test kits that have been evaluated by the World Health Organization and sends the HIV test kits to various countries.

Products supplied	Capillus™ HIV-1/HIV-2, Determine™ HIV-1/2, Genie II HIV-1/HIV-2, OraQuick® HIV-1/2 and Uni-Gold™ HIV
Source of products	Products are purchased directly from the manufacturers.
Stock on hand	HIV test kits are procured on demand.
Minimum order quantity	Depends on the manufacturer.
Average time to fill an order	4 weeks
Delivery information	HIV test kits are delivered to facilities in the country or directly to the program that requires them, depending on the customer's preference.
Quality issues	The agency reports that it has not had any specific quality problems.

UNICEF

International Aid Agency

For further information, please contact:

Hélène Möller, Field Support Officer HIV/AIDS, PMTCT

PMTCT and HIV/AIDS Technical Services Centre

UNICEF Supply Division/UNICEF Plads

Freeport, DK 2100

Copenhagen 8

Denmark

Tel: +45-35-273527

Fax: +45-35-269421

E-mail: hmoller@unicef.org

Website: <http://www.unicef.org/supply>

Information current as of October 2006

UNICEF can procure HIV test kits for any least developed or middle income country on request and has provided this service to more than 50 countries in the last 12 months. All HIV test kits procured by UNICEF are evaluated by the World Health Organization.

Products supplied	Bioline HIV 1/2 3.0 Capillus™ Determine™ Double Check™ First Response® HIV 1-2.0 Genie II HIV 1/2 Stat-Pak™ Assay HIV 1/2 Stat-Pak™ Dipstick ImmunoComb™ InstantCHEK™ OraQuick® Uni-Gold™ HIV
Source of products	HIV test kits are purchased directly from the manufacturers.
Stock on hand	HIV test kits are procured as needed.
Average time to fill an order	2–3 weeks depending on the supplier
Average minimum shelf life on delivery	UNICEF requires 80 percent remaining shelf life on delivery; in most cases, freshly manufactured batches are sent to fill orders.
Delivery information	Kits are delivered to facilities within a country or to particular programs, depending on the situation. UNICEF also provides assistance with distribution plans.

Payment method	Payment requirements are often country-, program-, or quantity-specific.
Quality issues	The standard procedure is for quality problems to be handled in the UNICEF Quality Assurance department. Complaints are dealt with in collaboration with WHO to exclude program weaknesses.
Additional information	Problems have been encountered in procuring HIV test kits in terms of poor supply performance by the manufacturing company and extremely long lead times. For this reason, according to the contract, companies which do not perform up to standard will be required to pay penalties

World Health Organization

International Aid Agency

For further information, please contact:

Ahmed Bellah, Procurement Officer,

Contracting and Procurement Services

World Health Organization

Avenue Appia 20

1211 Geneva 27

Switzerland

Tel: +1-41-22-791-1254

Fax: +1-41-22-791-4196

E-mail: bellaha@who.int

Website: <http://www.who.int/en>

Information current as of November 2006

In 1988–1989, WHO’s Global Program on AIDS started a scheme to assess commercially available HIV test kits.⁵⁹ The HIV Test Kit Bulk Procurement Scheme was set up to enable national governments and agencies to get high-quality HIV test kits at a reduced price and to assist in identifying those kits that are appropriate for the requirements of the program where they will be used. It is not the mandate of WHO to provide accreditation or licensing; rather, this is the mandate of the National Regulatory Authorities in each country. WHO assesses the performance of diagnostic tests, and if they meet the criteria that WHO has set, they are eligible to tender for procurement through the UN system. U.S. Government representatives can purchase kits directly from WHO.

Products supplied⁶⁰

Bioline HIV 1/2 3.0
Capillus™
Determine™
DoubleCheck™
DoubleCheck™ Gold
First Response® HIV 1-2.0
Genie II
HIV 1/2 Stat-Pak™ Assay
HIV 1/2 Stat-Pak™ Dipstick
ImmunoComb HIV 1&2
InstantCHEK™ HIV 1+2
OraQuick® HIV-1/2 Rapid Antibody Test
Uni-Gold™ HIV

Listed price (range) and terms and suggested retail

WHO negotiates prices directly with the manufacturers for all the HIV test kits in the Bulk Procurement Scheme; this allows WHO

⁵⁹ World Health Organization (WHO). 2002. *WHO HIV Test Kit Bulk Procurement Scheme*. Flyer. Geneva: WHO. <http://www.who.int/diagnostics_laboratory/procurement/en/> (accessed November 2006).

⁶⁰ All the HIV test kits available through the Bulk Procurement Scheme have been evaluated by WHO.

price	to offer a price per test that is approximately half the open market price.
Who can benefit	The HIV Test Kit Bulk Procurement Scheme accepts purchase requests from WHO programs and UN agencies (Category A); WHO Member States and NGOs that have a working relationship with WHO (Category B); and donor-supported AIDS projects and regulatory bodies (Category C ⁶¹).
Purchase procedure	<p>The Procurement Services Division at WHO purchases the requested kits. Information required for purchase is—</p> <ul style="list-style-type: none">• Name of the requesting program• Contact person’s name and telephone number• Test kit name and manufacturer• Order code (which appears on the WHO Bulk Procurement List)• Number of test kits required (indicate number of tests per kit where necessary) <p>This information should be submitted along with the request to—</p> <ul style="list-style-type: none">• For Category A: WHO headquarters in Geneva or a WHO Regional Office• For Category B: A WHO Regional Office, WHO Country Representative, or UNAIDS Representative• For Category C: UNAIDS Representative or Ministry of Health
Minimum order quantity	None
Stock on hand	Stock is not maintained because of the limited shelf life of the HIV test kits. WHO recommends that bulk orders have staggered delivery times.
Average time to fill an order	3–4 weeks
Delivery information	WHO ships the goods to the airport of destination; the consignee is responsible for customs clearance and delivery of goods. Kits can be delivered to a variety of programs or NGOs in a country.
Problems procuring/ supplying HIV test kits	Manufacturers sometimes have production-related quality problems.
Payment method	Payment will be debited from the accounts of WHO programs and UN agencies; pro forma invoices are issued to WHO Member States, NGOs, donor-supported AIDS projects, and regulatory bodies.

⁶¹ Please note that USAID-sponsored projects and programs fall under Category C.

Quality issues

If the HIV test kits have quality problems, WHO should be informed by the end user. WHO will then verify the problem and, if required, a formal complaint is filed with the manufacturer/supplier.

REFERENCES

- Abbott Laboratories. 2006. *Determine™ HIV-1/2 Package Insert*. Abbott Park, IL: Abbott Laboratories.
- AccessBio, Inc. n.d. *CareStart™ HIV 1-2-O Human Immunodeficiency Virus Rapid Test Device (Serum/Plasma/Whole blood) Package Insert*. Monmouth Jct., NJ: AccessBio, Inc.
- Bionor AS Bionor™. 2004. *HIV-1 and HIV-2 Rapid EIA Test Kit Package Insert*. Skien, Norway.
- Calypte Biomedical. 2005. *Aware HIV-1/2 BSP Package Insert*. Rockville, MD: Calypte Biomedical Corporation. available online at http://www.calypte.com/PRODUCTS/INSERTS/pi_aware_bsp_english.pdf
- Chembio Diagnostics Systems, Inc. 2006. HIV 1/2 STAT-PAK™ Assay Catalog #HIV101. Medford, NY.
- Chembio Diagnostics Systems, Inc. 2006. HIV 1/2 STAT-PAK™ DIPSTICK Assay Catalog #HIV302. Medford, NY.
- EY Laboratories, Inc. 2002. *InstantCHEK™ HIV 1+2 Package Insert*. Hong Kong.
- OraSure Technologies, Inc. 2006. *OraQuick® HIV-1/2 – Rapid HIV1/2 Antibody Test Package Insert*. Bethlehem, PA.
- Organics Limited. 2004. *DoubleCheck™ HIV 1&2 Package Insert*. Yavne, Israel.
- Organics Limited. 2005. *Immunocomb® II HIV 1 &2 BiSpot Package Insert*. Yavne, Israel.
- Organics Limited. 2006. *DoubleCheckGold™ HIV 1&2 Package Insert*. Yavne, Israel.
- PMC Medical (India) PVT, Ltd. n.d. *First Response™ HIV Card Test 1-2.0 Package Insert*. Daman, India.
- Savyon® Diagnostics Ltd. 2006. *HIVSav 1/2/0 Rapid SeroTest™ Instruction Manual*. Ashdod Israel.
- Trinity Biotech PLC. n.d. *Capillus™ HIV-1/HIV-2 Catalogue Number 6048G Package Insert*. Wicklow, Ireland.
- Trinity Biotech PLC. n.d. *Uni-Gold™ HIV Catalogue No: 1206502 Package Insert*. Wicklow, Ireland.

World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2002. *HIV Assays: Operational Characteristics (Phase I). Report 12: Simple/Rapid Tests, Whole Blood Specimens*. WHO/BCT/02.07. Geneva: WHO.

WHO/UNAIDS. 2004. *HIV Assays: Operational Characteristics (Phase I). Report 14: Simple/Rapid Tests*. Geneva: WHO.

ANNEX 1. USAID SOURCE AND ORIGIN WAIVER FOR HIV/AIDS DIAGNOSTIC MATERIALS

This annex section contains the list of all the USAID source and origin waiver related documents and AAPDs issued since January 2001 starting with the most recent.



Acquisition & Assistance Policy Directive (AAPD)

From the Director, Office of Acquisition & Assistance Issued: , 2006

AAPD 06 -

Procurement of HIV-AIDS Test Kits from Code 935 Countries

Subject Category: *Assistance, Acquisition Management*
Type: *Policy and Procedure*

AAPDs provide information of significance to all agency personnel and partners involved in the Acquisition and Assistance process. Information includes (but is not limited to): advance notification of changes in acquisition or assistance regulations; reminders; procedures; and general information. Also, AAPDs may be used to implement new requirements on short-notice, pending formal amendment of acquisition or assistance regulations.

AAPDs are EFFECTIVE AS OF THE ISSUED DATE unless otherwise noted in the guidance below; the directives remain in effect until this office issues a notice of cancellation.

This AAPD: Is New Replaces/ Amends CIB/AAPD No: 05-01

<p>Applicable to:</p> <p><input checked="" type="checkbox"/> Existing awards; <input type="checkbox"/> Modification required</p> <p><input type="checkbox"/> No later than</p> <p><input type="checkbox"/> As noted in guidance below</p> <p><input checked="" type="checkbox"/> RFPs/RFAs issued on or after the effective date of this AAPD; all other Pending Awards, i.e., 8(a), sole source, IQC</p> <p><input type="checkbox"/> Other or N/A</p>	<p>Precedes change to:</p> <p><input type="checkbox"/> AIDAR Part(s) Appendix</p> <p><input checked="" type="checkbox"/> USAID Automated Directives System (ADS) Chapters 302, 303</p> <p><input type="checkbox"/> Code of Federal Regulations</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> No change to regulations</p>
--	---

Michael F. Walsh, Director

AAPD 06-xx-- Procurement of HIV-AIDS Test Kits from Code 935 Countries

PURPOSE:

1. This AAPD replaces AAPD 05-01.
2. The USAID List of Approved HIV/AIDS Test Kits has been updated.
3. The AAPD confirms that OAA “restricted commodity” approval under ADS 312.5.3c is not required for the test kits on the list.
4. AA/M no longer approves test kits; the authority has been delegated to Director of the Office of HIV/AIDS, Bureau for Global Health (GH/OHA). GH/OHA establishes the technical requirements and issues technical guidance for test kits. The List, technical requirements, technical guidance and points of contact are at http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html
5. Under contracts and agreements in effect prior to the issuance of this AAPD, Contracting and Agreement officers (COs and AOs) are encouraged to give advance approval for procurement of approved test kits under the source/origin or “restricted commodity” provisions of the Mandatory Standard Provisions for U.S., Nongovernmental Recipients "USAID Eligibility Rules For Goods And Services", the AIDAR provision 752.225-70, "Source, Origin and Nationality Requirements", or similar provisions. For contracts and agreements obligated after the issuance of this AAPD, COs and AOs should include language in the schedule or elsewhere that indicates that CO/AO approval is not needed for procurement of approved test kits under the above clauses or similar provisions.
- 56 CO’s may give advance approval for procurements of test kits in excess of the simplified acquisition threshold and any other consent required under FAR clause 52.244-2 or comparable provisions in the implementing instrument.

ACTION REQUIRED: COs/AOs, in coordination with Cognizant Technical Officers (CTOs), amend current agreements and include language in new agreements to implement AAPD, as appropriate.

BACKGROUND: On January 11, 2001, the Administrator of USAID authorized the procurement of certain listed test kits from Geographic Code 935 countries. In an Action Memorandum dated September 26, 2006 the Administrator modified the basis for the waiver and delegated the authority to approve test kits to the Director of the Office of HIV/AIDS, Bureau for Global Health.

GUIDANCE:

- a. The “USAID List of Approved HIV/AIDS Test Kits” is at http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html.
- b. **Office of Acquisition and Assistance (OAA) and Contracting and Agreement Officer (CO/AO) Approval.**

1. OAA approval under ADS 312.5.3c is not required for approved test kits.

2. Under contracts and agreements in effect prior to the issuance of this AAPD, COs and AOs may and are encouraged to give advance approval for procurement of approved test kits under the source/origin or “restricted commodity” provisions of the Mandatory Standard Provisions for U.S., Nongovernmental Recipients "USAID Eligibility Rules For Goods And Services", the AIDAR provision 752.225-70, "Source, Origin and Nationality Requirements", or similar provisions. For contracts and agreements obligated after the issuance of this AAPD, COs and AOs should include language in the schedule or elsewhere that indicates that CO/AO approval is not needed for procurement of approved test kits under the above clauses or similar provisions.

3. COs are encouraged to give advance approval to procurements of approved test kits in amounts in excess of the simplified acquisition threshold and any other consent required under FAR clause 52.244-2 or comparable provisions in the implementing instrument.

b. Technical Requirements and Considerations.

AA/M no longer approves test kits; that is now done by GH/OHA. GH/OHA establishes the technical requirements and issues technical guidance for test kits. The technical requirements, technical guidance and points of contact are at http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html.

POINT OF CONTACT: Please direct questions about the AAPD to Diane Howard, M/OAA/P, Phone (202) 712-0206. For points of contact on questions about test kits see the website, http://www.usaid.gov/our_work/global_health/aids/TechAreas/scms/scms.html.



Acquisition & Assistance Policy Directive (AAPD)

From the Director, Office of Acquisition & Assistance
Issued: February 10, 2005

AAPD 05-01

Procurement of HIV-AIDS Test Kits from Code 935 Countries

Subject Category: *Assistance, Acquisition Management*
Type: Policy and Procedure

AAPDs provide information of significance to all agency personnel and partners involved in the Acquisition and Assistance process. Information includes (but is not limited to): advance notification of changes in acquisition or assistance regulations; reminders; procedures; and general information. Also, AAPDs may be used to implement new requirements on short-notice, pending formal amendment of acquisition or assistance regulations.

AAPDs are EFFECTIVE AS OF THE ISSUED DATE unless otherwise noted in the guidance below; the directives remain in effect until this office issues a notice of cancellation.

This AAPD: Is New Replaces/ Amends CIB/AAPD No: 01-04

<p>Applicable to:</p> <p><input checked="" type="checkbox"/> Existing awards; <input type="checkbox"/> Modification required</p> <p><input type="checkbox"/> No later than</p> <p><input type="checkbox"/> As noted in guidance below</p> <p><input checked="" type="checkbox"/> RFPs/RFAs issued on or after the effective date of this AAPD; all other Pending Awards, i.e., 8(a), sole source, IQC</p> <p><input type="checkbox"/> Other or N/A</p>	<p>Precedes change to:</p> <p><input type="checkbox"/> AIDAR Part(s) Appendix</p> <p><input checked="" type="checkbox"/> USAID Automated Directives System (ADS) Chapters 302, 303</p> <p><input type="checkbox"/> Code of Federal Regulations</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> No change to regulations</p>
<p><input type="checkbox"/> New Provision/Clause Provided Herein: If checked, scheduled update to Prodoc:</p>	

(signed copy on file)

Kimberly Triplett, Acting Director

AAPD 05-01 -- Procurement of HIV-AIDS Test Kits from Code 935 Countries

PURPOSE: The purpose of this AAPD is to update the list of Testing Kits included in Contract Information Bulletin (CIB) 01-04 that were approved for purchase for HIV/AIDS programs from Geographic Code 935 countries (any country or area excluding foreign policy restricted countries). The updated list is included in the GUIDANCE section below and may be revised and updated yearly or as necessary by the Office of HIV/AIDS (OHA), Bureau for Global Health, with the approval of AA/M, and issued through an amendment to this AAPD.

BACKGROUND: On January 11, 2001, the Administrator of USAID authorized the procurement of certain listed test kits from Geographic Code 935 countries. Test kits eligible for this procurement were listed in Tab 1 to that waiver. The waiver also delegated authority to AA/M to amend the list at Tab 1 to the waiver, to add new testing kits which could be determined to meet the same criteria. This waiver was included in CIB 01-04.

GUIDANCE:

a. Procurement in Geographic Code 935 countries is authorized for the test kits listed below.

Approved List of Testing Kit Products and Manufacturers as of February 2005

Product	Source Country	Manufacturer
Bioline	South Korea	Standard Diagnostics
Bionor	Norway	Bionor A/S
Capillus	Ireland	Trinity Biotech*
Determine	Japan	Abbott Laboratories*
DoubleCheck	Israel	Orgenics
First Response	India	Premier Medical Corporation
Genie II	France	BioRad
Hema-Strip	Singapore	Saliva Diagnostic Systems, Ltd.*
HIVsav 1&2	Israel	Sayvon Diagnostics Ltd.
HIV 1 / 2 Stat-Pak	USA	ChemBio Diagnostics, Inc.
Immunocomb	Israel	Orgenics
Instant Screen	Germany	GAIFAR GmbH
InstantCHEK	USA	EY Laboratories
OraQuick	Singapore	OraSure Technologies
SeroCard	Ireland	Trinity Biotech*
Sero-Strip	Israel	Saliva Diagnostic Systems, Ltd.*
SureCheck HIV	USA	ChemBio Diagnostics, Inc.
Unigold	Ireland	Trinity Biotech
* Parent Company is a United States based firm		

b. Choosing test kits for country programs

While purchase of kits on the approved list is authorized, different kits are appropriate for different countries and testing situations. We recommend that kits be evaluated in country for their performance as part of a national testing algorithm. Guidance on HIV rapid test kit evaluation is available at <http://www.phppo.cdc.gov/dls/pdf/HIV%20Test%20Guidelines%20Africa.pdf> .

c. Adding additional test kits to the list

For an HIV/AIDS test kit to be added to the list of those approved for procurement from Geographic Code 935 countries, the following information regarding such test kit must be submitted to OHA:

1. Whether it has FDA-approval;
2. Whether its producer has FDA-approval;
3. Whether the facility and production site where it is manufactured has FDA-approval;
4. Whether the test kit, producer, or production site has approval of a stringent regulatory authority⁶²; and
5. Why the proposed test kit is necessary and appropriate for the country/countries concerned.

Alternatively, OHA will accept notification from the Department of Health and Human Services Centers for Disease Control and Prevention (“CDC”) that they have evaluated the test kit and find that it meets the attached criteria.

⁶² A stringent regulatory authority is a drug regulatory body that closely resembles FDA in standards utilized in its operations. Currently, countries that participate in the International Conference on Harmonization (ICH) are considered as stringent regulatory authorities. The ICH regulatory bodies include: the U.S. FDA; the Japanese Ministry of Health, Labor, and Welfare; the European Agency for the Evaluation of Medicinal Products (EMA) centralized procedure; and the European Free Trade Area (represented by the Swiss Medic). The Canadian drug regulatory authority, the Therapeutic Products Directorate, Health Canada, is an observer to the ICH and is also considered a stringent regulatory authority. Other countries may be considered having a stringent regulatory body if they have implemented ICH guidelines and resemble the U.S. FDA in operation, but would be considered on a case-by-case basis. It should be noted that the World Health Organisation (WHO) has a pre-qualification program for procurement purposes. The WHO is not a regulatory authority, and acceptance of a manufacturer or product by the WHO pre-qualification program would not be considered equivalent to approval of a product by a stringent regulatory authority.

1. Attachment: RAPID HIV TEST KIT TECHNICAL REQUIREMENTS

POINT OF CONTACT: Please direct any questions pertaining to the test kits to Katharine Kripke, GH/OHA/TLR, Phone: (202) 712-1452, e-mail: kkripke@usaid.gov. Please direct questions about the AAPD to Diane Howard, M/OAA/P, Phone (202) 712-0206.

Attachment to AAPD 05-01 -- Procurement of HIV-AIDS Test Kits from Code 935 Countries

2. RAPID HIV TEST KIT TECHNICAL REQUIREMENTS

1. HIV Rapid Test Kits:

HIV rapid tests are defined as assays for detection of antibodies to HIV-1, HIV-2, or both, from which test results can be read directly, within 30 minutes of the time specimen is applied to the device, without calibration, interpretation, or calculations. Qualifications for HIV rapid test kits are listed below. The only acceptable kits are those meeting the test characteristics described below. Acceptable kits may change periodically as evaluation data on kit performance is updated.

A. Test Characteristics:

- i. Documentation from manufacturer studies that test has sensitivity of at least 99% and specificity of at least 98% for detection of HIV-1 in each sample matrix for which the test is designed (e.g., whole blood, serum, plasma, oral fluid or urine). Data should be based on at least 500 HIV negative and 500 HIV-1 positive specimens. If test claims to detect both HIV-1 and HIV-2, sensitivity for HIV-2 should be demonstrated with evaluation of 50 HIV-2 positive specimens, and must be at least 99%.
- ii. One or more credible evaluations by internationally recognized independent institutions validating that sensitivity and specificity of the tests are within 95% +/- 2% confidence interval of that demonstrated in manufacturer's studies (criterion i.). Approximately 200 HIV-positive and 200 HIV-negative specimens are needed to provide 95% confidence intervals of less than $\pm 2\%$ for both the estimated sensitivity and specificity. A document that describes the process of such an evaluation can be found at:

<http://www.phppo.cdc.gov/dls/pdf/HIV%20Test%20Guidelines%20Africa.pdf>

- iii. Presence of a normal internal control or other failure alert mechanism to notify the operator if the assay malfunctions. Also, having external controls that assure the presence of functional test antigens in the test platform will be very useful.

B. Performance Characteristics:

- 1). Use direct, unprocessed specimens (e.g., unprocessed whole blood or oral fluid) or samples that require minimal processing (e.g., serum or plasma).
- 2). All reagents including diluents are included in kit, and require no technique-dependent reagent manipulation (e.g., no reconstitution)
- 3). No operator intervention or procedural steps during the analysis after initial addition of specimen and reagents.
- 4). No requirements for assay-specific equipment.
- 5). Kits and all reagents stored at temperatures recommended by manufacturers shall have a minimum 1-year shelf life when received by contractors.

C. Manufacturing Characteristics:

The HIV rapid test kits must be purchased from manufacturers of those kits that meet the test characteristics and performance characteristics, described in sections A. and B., and manufacturing characteristics described below. As the list of tests is updated, the eligible manufacturers may change.

Eligible manufacturers must have:

- i. Documented production capacity to provide the number of kits needed by USG programs for current and projected assay usage (e.g., 200,000 – 500,000 test kits needed annually), and ability to deliver a minimum of 45,000 test kits within 90 days of order.
- ii. Availability of data to document reproducible performance across different lots of assay.
- iii. Ability to ship to international sites.
- iv. Documentation of export certificate, when required.

ACTION MEMORANDUM

TO: AA/M, John Marshall

FROM: AA/GH, E. Anne Peterson



SUBJECT: The HIV/AIDS and Infectious Disease Initiatives:
Update of Source and Origin Waiver for HIV/AIDS
Diagnostic Materials (testing kits)

ISSUE FOR DECISION

Whether to authorize the amendment of the approved and updated list of HIV rapid test kits that can be procured under the January 2001 source and origin waiver

ESSENTIAL FACTORS

In a January 11, 2001 action memorandum (Tab 2), the former Administrator approved the source and origin waiver from Geographic Code 000 to Code 935 for the procurement of rapid HIV test kits (Tab 1). To meet the requirements of safety and efficacy, this authority was limited to a list of approved products, based on review and evaluation by the Centers for Disease Control (CDC). The January 11, 2001 memorandum delegated authority to AA/M to amend the approved list from time to time to add new code 935 testing kits when they meet the same criteria.

RECOMMENDATION

We recommend that, based on the findings above, you authorize the amendment of the list of HIV test kits approved for procurement under the January 11, 2001, source and origin waiver

Approve _____



Disapprove _____

Date

Dec 6 2001

Attachments:

Tab 1 - Contains an updated list of testing kits that have been reviewed internally and found to meet all the necessary suitability and price criteria in the applicable waiver regulations cited above. CDC has reviewed and approved the items on the list for safety and efficacy.

Tab 2 - Original Waiver, January 11, 2001. Note that the former Administrator delegated authority to Assistant Administrator of the Management Bureau.

CLEARANCE PAGE FOR ACTION MEMORANDUM requesting a source and origin waiver for HIV/AIDS diagnostic testing kits for the HIV/AIDS and Infectious Disease Initiative.

Clearances:

BGH/HIV/AIDS: PDelay	<u>draft</u>	Date	<u>11/27/07</u>
GH/HN: BBrown	<u>draft</u>	Date	<u>11/27/07</u>
AAA/GH: JHolfeld	<u>[Signature]</u>	Date	<u>12/03/01</u>
A-DAA/GH: DGillespie	<u>[Signature]</u>	Date	<u>12/03/01</u>
A-DAA/GH: Llion	<u>[Signature]</u>	Date	<u>12/04/01</u>
AA/PDS: BTUMER	<u>[Signature]</u>	Date	<u>[Signature]</u>
AA/GH: HPeterson	<u>[Signature]</u>	Date	<u>[Signature]</u>

Draft:GH:Kcrawford: x24409: 11/19/01:
P/GH.Shared/ExecutiveCorrespondence/WaiverKits

M096

DAA/M:RNygard	<u>[Signature]</u>	Date	<u>12/8/11</u>
M/AA:DJohnson	<u>[Signature]</u>	Date	<u>12/6/01</u>

Tab 1 Approved List of Testing Kit Products and Manufacturers as of October 15, 2001⁶³

Product	Price in Dollars	Source Country	Manufacturer
Bionor	NA	Norway	Bionor A/S
Capillus	\$1.50	Ireland	Trinity Biotech*
Determine	\$3.80	Japan	Abbott Laboratories*
DoubleCheck	\$1.35	Israel	Orgenics
HIVCHEK System 3	NA	USA	Ortho-Clinical Diagnostics Systems* ⁶⁴
Genie II	NA	France	Sanofi Diagnostics Pasteur* ⁶⁵
Hema-Strip	\$3.00	USA	Saliva Diagnostics, Ltd.*
HIV Spot ⁶⁶	\$1.20	Singapore	Genelabs Diagnostics*
HIVSav 1&2	NA	Israel	Sayvon Diagnostics Ltd.
MultiSpot ⁶⁷	\$4.00	France	Sanofi Diagnostics Pasteur
Ora Quick HIV 1&2	NA	USA	OraSure Technologies ⁶⁸
SeroCard	\$1.80	Ireland	Trinity Biotech*
Uni-Gold	\$2.25	Ireland	Trinity Bio-Tech plc
Sero-Strip	\$1.50	USA	Saliva Diagnostic Systems, Ltd.*

*Parent Company is a United States-based firm

⁶³ Changes that have been made to Tab 1 since its approval in October 2001 are indicated in footnotes.

⁶⁴ The product is manufactured by EY Laboratories for Ortho-Clinical Diagnostics Systems; however, the product may have been discontinued in August 1997, according to personal communication with a representative of Ortho-Clinical Diagnostics Systems. The details were unable to be determined.

⁶⁵ Bio-Rad Laboratories acquired Sanofi Diagnostics Pasteur in 1999.

⁶⁶ The manufacture of this product has been discontinued by the company.

⁶⁷ A recent e-mail communication with a representative of Bio-Rad Laboratories indicated that the company has discontinued production of this product.

⁶⁸ On June 17, 2002, OraSure Technologies (created when Epitepe, Inc., merged with STC Technologies in September 2000) announced that it had entered into an agreement with Abbott Laboratories for the co-exclusive distribution of OraQuick tests in the United States.

[Approved by J. Brady Anderson, USAID Administrator, on January 11, 2001 and effective from this date.]

January 11, 2001

ACTION MEMORANDUM

TO: The Administrator
FROM: A-AA/G Barbara Turner /s/
SUBJECT: The HIV/AIDS and Infectious Disease Initiatives:
Source and Origin and Waiver for HIV/AIDS Diagnostic
Materials (testing kits)

ISSUE FOR DECISION

Whether to authorize the procurement of testing kits from Code 935 countries (any country or area excluding foreign policy restricted countries).

ESSENTIAL FACTORS

In a December 19, 2000, Action Memorandum (See Tab 2) you approved certain waivers and expedited procedures to acquire services and commodities for the Agency's HIV/AIDS and Infectious Diseases Initiatives. While the December 19th Memorandum authorizes expedited procurement procedures for testing kits, it does not waive source and origin requirements because more research was required on their availability in the United States and the efficacy and cost of offshore testing kits.

Having completed this research, we are seeking your approval of a source and origin waiver from Geographic Code 000 (United States) to Geographic Code 935 for specific testing kits identified in Tab 1. Consistent with the December 19th Memorandum, your approvals below will be in effect through the year 2007 and apply to all sources of funds including prior year funds. Records will be kept on all uses of the waiver authorities. Annual reviews will determine the adequacy of the waiver authorities and their continuing need. The list at Tab 1 will be revised and updated should U. S. manufactured testing kits, or new or improved testing kits from Code 935 sources become available that meet USAID program requirements.

Effective counseling and testing for HIV is a critical component of any HIV/AIDS strategy. While testing provides information to

individuals regarding their HIV status, it also provides information regarding the extent of the epidemic among target groups and indicates where additional resources may be needed. We anticipate that between one million to three million testing kits will be purchased annually over the seven-year life of the HIV/AIDS initiative. At an estimated average cost of \$3 per test, the aggregate procurement value will be approximately 45 to 55 million dollars. However, this amount will be substantially reduced if, as expected, the average cost per testing kits is reduced as new products come on stream.

The applicable statute and regulations covering USAID's "buy America" requirements (including testing kits) appear in section 604 (a) of the Foreign Assistance Act, ADS section 312.5.3c (2), and in 22CFR 228. Taken together, these sometimes overlapping regulations provide that pharmaceuticals be purchased outside of the United States only if information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the Food and Drug Administration (FDA) or other U.S. controlling authority. ADS Section E312.5c (3) adds a further requirements that patent laws be honored. Such items may be purchased in Geographic Code 935 countries if you determine that: 1) the items are not produced or available in the United States, or if available , they cost more than 50 percent of comparable items, or 2) offshore procurement is necessary to promote efficiency in the use of foreign assistance resources and avoid impairment of foreign assistance objectives. While the United States Centers for Disease Control (CDC) is not controlling authority, approval by CDC is good evidence that may be used as a basis for authorizing non-U.S. procurement of products that are not approved by the FDA.

With respect to test kits, the criteria supporting a waiver are met. The most commonly available United States testing kits are based on the Elisa Reader method. The cost per test of these kits is approximately \$20. This cost is more than 50 percent higher than the cost of offshore alternatives. Further, these products require high quality lab facilities and highly trained personnel that are not widely available in target countries. Even where this kind of physical and human infrastructure is available in urban centers, there are insurmountable logistical problems in transporting thousands of blood specimens to and from rural sites to urban laboratories. It takes days or weeks to obtain tests results using Elisa Reader method. This is too long, given that in some target countries more than 30 percent of clients tested by these systems fail to return for the test results.

Recently, a new "simple-rapid" type pf HIV test costing \$1-3 per test has become available offshore. These tests are easy to use, no central laboratory is needed, and they deliver test results within a few hours instead of days to weeks. There is currently only one United States-manufactured HIV rapid test that is FDA approved. It costs about \$9 and the manufacturer has recently suspended production of this product.

Tab 1 contains a list of testing kits that have been reviewed internally and found to meet all the necessary suitability and price criteria in the applicable waiver regulations cited above. CDC has reviewed and approved the items on the Tab 1 list for safety and efficacy.

RECOMMENDATIONS

- A. We recommend that, based on the findings above, you authorize the procurement in Code 935 countries of testing kits identified in Tab 1

Approve _____

Disapprove_____

Date_____

- B. We recommend that you delegate authority to AA/M to amend the Tab 1 approved list from time to time to add new Code 935 testing kits when they meet the same criteria

Approve _____

Disapprove_____

Date_____

Attachments:

Tab 1 - Approved List of Testing Kit Products and
Manufacturers

TAB 2 - December 19, 2000 Action Memo
[Omitted here]

CLEARANCE PAGE FOR ACTION MEMORANDUM requesting a source and origin waiver for HIV/AIDS diagnostic testing kits for the HIV/AIDS and Infectious Disease Initiative.

Clearances:

DAA/G/PHN: DGillespie <u>on waiver for</u>	Date <u>12/29/00</u>
S-DAA/G: LLion <u>LL (MS)</u>	Date <u>1/10/01</u>
A-AA/G: MSterne <u>a</u>	Date <u>1/9/00</u>
AA/LPA: JCrapa <u>AUC</u>	Date <u>1/10/01</u>
AA/PPC: TFox <u>KS on (see attached 2.msd)</u>	Date <u>1/10/00</u>
A-AA/M: RNygaard <u>RN</u>	Date <u>1/11/01</u>
GC: SMCAllister <u>OC (see back sheet), PR 1-11-01</u>	Date <u>1-4-01</u>
ES: RConroy <u>SM</u>	Date <u>1/11/01</u>
M: MWard <u>DRAFT (KH on)</u>	Date <u>1/5/01</u>

Draft: G/PHN: AGetson, RKirkland 12/20/00; Revised
 GC: RMeighan, MKitay 12/27/00
 P:\G.SHARED\Exec\PHN\HIV/AIDS WAIVER TESTING KITS 4-12-28-00.DOC

20010428

Tab 1 - Approved List of Testing Kit Products and Manufacturers

Product	Price in Dollars	Source Country	Manufacturer
Bionor	NA	Norway	Bionor A/S
Capillus	\$1.50	Ireland	Trinity Biotech*
Determine	\$3.80	Japan	Abbott Laboratories*
DoubleCheck	\$1.35	Israel	Orgenics
Genie II	NA	France	Sanofi Diagnostics Pasteur
Hema-Strip	\$3.00	Singapore	Saliva Diagnostics, Ltd.*
HIV Spot	\$1.20	Singapore	Genelabs Diagnostics*
HIVSav	NA	Israel	Sayvon Diagnostics Ltd.
MultiSpot	\$4.00	France	Sanofi Diagnostics Pasteur*
SeroCard	\$1.80	Ireland	Trinity Biotech*
Sero-Strip	\$1.50	Israel	Saliva Diagnostic Systems, Ltd.*

* Parent company is a United States based firm

ANNEX 2. USAID GEOGRAPHIC CODES

USAID Geographic Code	Description
Code 000 – The United States	The United States of America; any state of the United States; the District of Columbia; and areas of U.S.-associated sovereignty, including commonwealths, territories, and possessions.
Code 899 – Free World	Any area or country except the cooperating country itself and the following foreign policy–restricted countries: Libya, Cuba, Laos, Iraq, Iran, North Korea, and Syria.
Code 935 – Special Free World	Any area or country in the Free World including the cooperating country but excluding the foreign policy–restricted countries.
Code 941 – Selected Free World	The United States and any independent country in the Free World (excluding foreign policy–restricted countries), except the cooperating country itself and the following: Albania, Andorra, Angola, Armenia, Austria, Australia, Azerbaijan, Bahamas, Bahrain, Belgium, Bosnia and Herzegovina, Bulgaria, Belarus, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Gabon, Georgia, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Kazakhstan, Kuwait, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia,* Malta, Moldova, Monaco, Mongolia, Montenegro,* Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Romania, Russia, San Marino, Saudi Arabia, Serbia,* Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan,* Tajikistan, Turkmenistan, Ukraine, United Arab Emirates, United Kingdom, Uzbekistan, and Vatican City.

* Has the status of “geopolitical entity” rather than independent country.

ANNEX 3. SUMMARY LISTINGS FOR HIV TEST KITS

Table 1. Summary Listing by HIV Test Kit

	HIV Test Kit (Manufacturer, Country)	Number of Tests Per Kit	Manufacturer's Price Range		Shelf Life from Manufacturer	Storage Conditions	Language on Package Insert	Special Price for Developing Countries	FDA Approved
			Per Test	Per Kit					
1.	Aware [®] HIV-1/2 BSP Rapid Test (Calypte Biomedical Corporation, Thailand)	25 or 50	No information provided	No information provided	18 months	2–30°C (36–86°F)	English, French, Spanish, Portuguese, and Arabic	No information provided	No
2.	Bioline HIV 1/2 3.0 (Standard Diagnostics, Inc., South Korea)	30	USD 0.80– 0.85	USD 24.00– 25.50	24 months	1–30°C (34–86°F)	English, French, and Spanish	Yes	No
3.	Bionor [™] HIV-1&2 (Bionor A/S, Norway)	250	USD 1.20– 1.90		12 months	2–30°C (36–86°F). Additional shelf life can be obtained if the kit is stored at 2– 8°C (36–46°F).	English (other languages available on request)	No	No
4.	Bundi [™] HIV- 1/2(Bundi International Diagnostics Limited, Nigeria)	1 or 25		USD 1.50– 2.50	18 months	4–30°C (39– 86°F)	English, Yoruba, Hausa, and Ibo	Delivery is free to any location in Nigeria	No
5.	Capillus [™] HIV-1/HIV-2 (Trinity Biotech, Plc, Ireland)	100	USD 1.50– 1.75	USD 150– 175	15 months	Optimum storage is at 2–8°C (36– 46°F). Stable for	English (other languages available on request)	Yes	No

HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document

	HIV Test Kit (Manufacturer, Country)	Number of Tests Per Kit	Manufacturer's Price Range		Shelf Life from Manufacturer	Storage Conditions	Language on Package Insert	Special Price for Developing Countries	FDA Approved
			Per Test	Per Kit					
						short periods (up to 4 weeks) at 25°C (77°F).			
6.	CareStart™ HIV-1-2-0 (Access Bio Inc., South Korea and United States)	30	USD 0.55–.085	USD 16.50–25.50	18 months	2–30°C (36–86°F)	English	Yes	No
7.	Clearview® COMPLETE HIV 1/2 (Inverness Medical Innovations, United Kingdom)	25			24 months	8–30°C (47–86°F)	English (additional languages will be available in the next year)		Yes
8.	Determine™ HIV-1/2 (Abbott Laboratories, Japan)	100	USD 1.20	USD 120	14 months	30°C (86°F)	English, French, German, Portuguese, and Spanish	Yes	No
9.	DoubleCheck™ HIV 1&2 (Orgenics, Ltd. Israel)	40	USD 1.41	USD 56.45	15 months	4–8°C (39–46°F)	English, French, Portuguese, Spanish, and Russian	Yes	No
10.	DoubleCheck Gold™ HIV 1&2 (Orgenics, Ltd. Israel)	100	USD 0.79	USD 79.00	15 months	2–30°C (36–86°F)	English, French, and Spanish	Yes	No
11.	First Response® HIV 1-2.0 (Premier Medical Corporation, India)	1, 5, 10, 30, 60	USD 0.70–0.95		18 months	4–30°C (39–86°F)	English, French, Portuguese, and Spanish	Yes	No

HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document

	HIV Test Kit (Manufacturer, Country)	Number of Tests Per Kit	Manufacturer's Price Range		Shelf Life from Manufacturer	Storage Conditions	Language on Package Insert	Special Price for Developing Countries	FDA Approved
			Per Test	Per Kit					
12.	Genie II HIV-1/HIV-2 (Bio-Rad Laboratories, France)	40	<75 kits: USD 3.45; 75–200 kits: USD 3.12; >200 kits: USD 2.77	USD 138 USD 125 USD 111	12 months	2–8°C (36–46°F)	English and French	Yes	Yes
13.	HIVSav 1/2/0 Rapid SeroTest™ (Savyon Diagnostics, Israel)	25 or 50	USD 1.50	USD 37.50– 75.00	15 months	2–30°C (36–86°F)	English (other languages available on request)	Yes	No
14.	HIV 1/2 Stat-Pak™ Assay (Chembio Diagnostics Systems, Inc., United States)	20	USD 1.45– 1.60	USD 29.00– 32.00	24 months	8–30°C (46–86°F)	English	No	Yes
15.	HIV 1/2 Stat-Pak™ Dipstick (Chembio Diagnostics, Inc., United States)	30	USD 0.90– 1.05	USD 27.00– 31.50	18 months	8–30°C (46–86°F)	English (other languages available on request)	Yes	No
16.	ImmunoComb™ HIV 1&2 (Orgenics, Ltd., Israel)	36	USD 1.60	USD 57.60	15 months	2–8°C (36–46°F)	English, French, Russian, and Spanish	Yes	No
17.	InstantCHEK™ HIV 1+2 (EY Laboratories, Hong Kong)	20, 40, or 100	USD 1.20	USD 24– 120	12 months	5–25°C (41–77°F)	English and Chinese	Yes	No

HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document

	HIV Test Kit (Manufacturer, Country)	Number of Tests Per Kit	Manufacturer's Price Range		Shelf Life from Manufacturer	Storage Conditions	Language on Package Insert	Special Price for Developing Countries	FDA Approved
			Per Test	Per Kit					
18.	INSTI™ HIV-1/HIV-2 Rapid Antibody Test (Biolytical Laboratories, Canada)	1 or 24	USD 3.85–4.35		15 months	15–30°C (59–86°F)	English (other languages available on request)	Yes	No
19.	OraQuick® HIV-1/2 Rapid Antibody Test (OraSure Technologies, Inc., USA)	100 or 500	USD 4.00–5.00		6 months	2–30°C (36–86°F)	English (Portuguese, French, and Spanish available on request)	Yes	Yes
20.	Reveal™ Rapid HIV-1 Antibody (MedMira, Canada)	30	USD 15.00–16.00		12 months	2–30°C (36–86°F)	English	Yes	Yes
21.	Uni-Gold™ HIV (Trinity Biotech, Plc, Ireland)	20	USD 1.50	USD 30	15 months	2–27°C (36–81°F)	English (other languages available on request)	Yes	No
22.	Uni-Gold Recombigen® (Trinity Biotech, Plc, Ireland)	20	USD 16.50	USD 330	12 months	2–27°C (36–81°F)	English	Yes	Yes

Table 2. Summary Listing by Supplier

Name (Type of Supplier, Location, [Last Updated])	HIV Test Kits Supplied	Price Range	Stock on Hand	Payment Method
Action Medeor (International Aid Organization, Germany [November 2006])	Determine™ HIV-1/2	For developing countries— USD 80 for 100 tests For other countries— USD 92 for 100 tests (EXW Germany)	No stock is maintained. According to special arrangement with Abbott Laboratories deliveries are ready within 3–5 days.	For established customers, a payment is expected within 30 days. For new customers, a prepayment is required.
Crown Agents (International Procurement Agency, USA [January 2007])	Aware™ HIV 1/2 BSP, Bioline HIV 1/2 3.0, Bionor™ HIV-1&2, Bundi Rapid HIV 1/2, Capillus™ HIV-1/HIV-2, CareStart™ HIV 1-2-O, Determine™ HIV-1/2, DoubleCheck™ HIV 1&2, DoubleCheck Gold™ HIV 1&2, First Response® HIV 1-2.0, Genie II HIV-1/HIV-2, HIVSav 1&2 Rapid SeroTest™, HIV 1/2 Stat-Pak™ Assay, HIV 1/2 Stat-Pak™ Dipstick, ImmunoComb™ HIV 1&2, InstantCHEK™ HIV 1+2, INSTI™ HIV Antibody, OraQuick® HIV-1/2 Rapid Antibody Test, Reveal™ Rapid HIV-1, and Uni-Gold™ HIV	Kit prices (negotiated directly with manufacturers), together with shipping/insurance charges, are available upon application. There is no handling charge.	Stock is not maintained, and kits are ordered on demand.	The preferred method is payment at order placement. However, other options are negotiable.

HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document

Name (Type of Supplier, Location, [Last Updated])	HIV Test Kits Supplied	Price Range	Stock on Hand	Payment Method
Durbin PLC (International Procurement Agency, United Kingdom [December 2006])	Capillus™, Determine™, and Unigold™ HIV		Contact company directly	
IDA Foundation (International Supplier, The Netherlands [November 2006])	Capillus™ HIV-1/HIV-2, Determine™ HIV-1/2, Double Check Gold™ HIV 1&2, First Response™, Genie II HIV-1/HIV-2, HIV 1/2 Stat-Pak™ Assay, HIV 1/2 Stat-Pak™ Dipstick, ImmunoComb™ HIV 1&2, InstantCHEK™, and Uni-Gold™ HIV	<p>Capillus™: EUR 178.25 (USD 234.14) for 100 tests</p> <p>Determine™: EUR 75.30 (USD 98.90) for 100 tests</p> <p>Double Check Gold™: EUR 112.70 (USD 147.99) for 100 tests</p> <p>First Response™: EUR 19.55 (USD 25.66) for 30 tests</p> <p>Genie II HIV-1/HIV-2: EUR 106.95 (USD 140.46) for 40 tests</p> <p>HIV 1/2 Stat-Pak™ Assay: EUR 29.65 (USD 38.92) for 20 tests</p> <p>HIV 1/2 Stat Pak™: EUR 29.90 (USD 29.90) for 20 tests</p> <p>InstantCHEK™: Price for 100 tests available on request</p> <p>Uni-Gold™ HIV: EUR 19.55 (USD 25.66) for 20 tests</p> <p>Prices include EXW Amsterdam</p>	Stocks are kept low due to short shelf life, but lead time is short.	Goods are usually shipped on a prepayment basis. For large orders and tenders, the company will accept letters of credit.

HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document

Name (Type of Supplier, Location, [Last Updated])	HIV Test Kits Supplied	Price Range	Stock on Hand	Payment Method
Joint Medical Stores (JMS) (National Supplier, Uganda [October 2006])	Capillus™(available only on request), Determine™ HIV-1/2, HIV 1/2 Stat Pak™, Dipstick, and Uni-Gold™ HIV	Capillus™: USD 159.10 Determine™: USD 153 HIV1/2 Stat-Pak™ Dipstick: USD 22.06 Uni-Gold™: USD 35	Stock is maintained, but some orders are manufactured on demand. Slight delays can occur during times of high demand.	Cash and carry
Mission for Essential Drugs and Supplies (MEDS) (Regional Supplier, Kenya [March 2005])	Capillus™ HIV-1/HIV-2, Determine™ HIV-1/2, and Uni-Gold™ HIV	Capillus™: USD 322 Determine™: USD 101 Uni-Gold™: USD 54	Stock is maintained.	Cash for facilities within the country and telegraphic transfer for facilities outside the country
Medical Export Group (MEG) (International Procurement Agency, The Netherlands[December 2006])	Bionor, Capillus™, Determine™, Genie II, OraQuick, and Uni-Gold™	Bionor: USD 807.16 for 250 tests Capillus™: USD 317.49 for 100 tests Determine™: USD 129.04 for 100 tests Genie II: USD 214.43 for 40 tests or USD 258.97 for 96 tests OraQuick: USD 6.60 for 1 test Uni-Gold™: USD 60.14 for 20 tests	Stock is not maintained.	30 days net
Medical Stores Department (MSD) (National Supplier, Tanzania [March 2005])	Capillus™ HIV-1/HIV-2	USD 197	Stock is maintained.	Cash and carry or advance payment
Missionpharma A/S (International Procurement Agency, Denmark [March 2005])	Capillus™ HIV-1/HIV-2, Determine™ HIV-1/2, DoubleCheck™ HIV 1&2, Genie II HIV-1/HIV-2, HIV 1/2 Stat-Pak™, OraQuick® HIV-1/2 Rapid Antibody Test,	Capillus™: USD 198 for 100 tests Determine™: USD 91 for 100 tests DoubleCheck™: USD 90 for 100 tests	Stock is not maintained because of the short shelf life of the products.	A percentage of payment is required (depending on the relationship with the client) before delivery.

HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document

Name (Type of Supplier, Location, [Last Updated])	HIV Test Kits Supplied	Price Range	Stock on Hand	Payment Method
	Uni-Gold™ HIV	Genie II: USD 269 (~EUR 200) for 40 tests Hema-Strip™: USD 2 for 1 test HIV 1/2 Stat-Pak™: USD 32 for 20 tests OraQuick®: USD 480 for 100 tests Uni-Gold™: USD 55 for 20 tests		
Orbi-Pharma (International Supplier, Belgium [December 2006])	Determine™ HIV-1/2	Democratic Republic of Congo: USD 123.20 for set of 100 tests Other African countries: USD 183.47 for 100 tests	Stock is usually held in a warehouse (the European Distribution Center in Delkenham, Germany) by the manufacturer (Abbott Laboratories).	International bank transfer (SWIFT)
Tri-Med Group (International Procurement Agency, United Kingdom [December 2006])	Bioline HIV 1/2 3.0, DoubleCheck™ HIV 1&2, DoubleCheckGold™ HIV 1&2, HIV 1/2 Stat-Pak™ Assay, HIV 1/2 Stat-Pak™ Dipstick, and ImmunoComb™ HIV 1&2	Prices vary according to a number of factors including the quantity ordered as well as the customer's final delivery destination.	Kits are ordered on demand. A small amount of stock is held.	Preferred payment option is international bank transfer (SWIFT)
UNFPA (International Aid Agency, Denmark [October 2006])	Capillus™ HIV-1/HIV-2, Determine™ HIV-1/2, Genie II HIV-1/HIV-2, OraQuick® HIV-1/2 and Uni-Gold™ HIV	N/A	HIV test kits are procured on demand.	N/A

HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document

Name (Type of Supplier, Location, [Last Updated])	HIV Test Kits Supplied	Price Range	Stock on Hand	Payment Method
UNICEF (International Aid Agency, Denmark [October 2006])	Bioline HIV 1/2 3.0, Capillus™ HIV-1/HIV-2, Determine™ HIV-1/2, Double Check™ HIV 1&2, First Response® HIV 1-2.0, Genie II HIV-1/HIV-2, HIV 1/2 Stat-Pak™ Assay, HIV 1/2 Stat-Pak™ Dipstick, ImmunoComb™ HIV 1, InstantCHEK™ HIV 1+2, OraQuick® and Uni-Gold™ HIV	N/A	HIV test kits are procured as needed.	N/A
WHO (International Aid Agency, Switzerland)	Bioline HIV 1/2 3.0, Capillus™ HIV-1/HIV-2, Determine™ HIV-1/2, DoubleCheck™ HIV 1&2, DoubleCheck™ Gold HIV 1&2, First Response® HIV 1-2.0, Genie II HIV-1/HIV-2, HIV 1/2 Stat-Pak™ Assay, HIV 1/2 Stat-Pak™ Dipstick, ImmunoComb HIV 1&2, InstantCHEK™ HIV 1+2, OraQuick® HIV-1/2 Rapid Antibody Test, Uni-Gold™ HIV	WHO negotiates prices directly with the manufacturers for all the HIV test kits in the Bulk Procurement Scheme; this allows WHO to offer a price per test that is approximately half the open market price.	Stock is not maintained because of limited shelf life of the HIV test kits. WHO recommends that bulk orders have staggered delivery times.	Payment will be debited from the accounts of WHO programs and UN agencies; pro forma invoices are issued to WHO Member States, NGOs, donor-supported AIDS projects, and regulatory bodies.

