

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

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Second Edition

Edited by Abiola Johnson

April 2004

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Rational Pharmaceutical Management Plus Program  
Center for Pharmaceutical Management  
Management Sciences for Health  
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## **About RPM Plus**

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (USAID) (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS and other infectious diseases, and family planning and in promoting appropriate use of health commodities in the public and private sectors.

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**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.

## **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 following RPM Plus staff members for providing a great deal of technical assistance and direction for this edition—Francis (Kofi) Aboagye-Nyame, Andy Barraclough, Charles Brimmer, Douglas Keene, Mandi Mayer, Julie McFadyen, Tom Moore, Marian Ryan, Sameh Saleeb, Leanne Sullivan, Belén Tarrafeta, and Helena Walkowiak.

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

## ACRONYMS

AIDS	acquired immunodeficiency syndrome
CA	cooperating agency
CDC	U.S. Centers for Disease Control and Prevention
CIF	cost, insurance, and freight
FDA	U.S. Food and Drug Administration
FOB	free on board
HIV	human immunodeficiency virus
IDA	International Dispensary Association
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
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
USD	U.S. dollar
WHO	World Health Organization

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

## GLOSSARY

<b>Cost, insurance, and freight (CIF)</b>	The seller covers all costs for a freight of goods to be shipped to a named destination port. Once the goods leave the ship, the risk and other costs become the responsibility of the buyer. The seller pays for insurance against loss or damage to goods on behalf of the buyer. This cost is passed on to the buyer.
<b>Efficacy</b>	<b>Efficacy</b> is the ability of a drug or pharmaceutical product to produce a particular effect as determined by scientific methods.
<b>Ex-works</b>	The seller's only obligation is to provide goods at his/her premises for collection by the buyer. It is the buyer's responsibility and obligation to load the goods and transport them to the buyer's destination.
<b>FDA approval</b>	<b>FDA approval</b> 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.
<b>Free on board (FOB)</b>	The carriage of goods is arranged by the buyer, and the risks and costs transfer from the seller to the buyer at final port of entry.
<b>Origin</b>	The <b>origin</b> of a pharmaceutical product is the country in which it was produced.
<b>Pharmaceutical products</b>	For the purposes of USAID procurement regulations, <b>pharmaceutical products</b> 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).
<b>Quality</b>	The <b>quality</b> of a pharmaceutical product is determined by its identity, purity, potency, uniformity of dosage form, bioavailability, and stability.
<b>Safe medical product</b>	The FDA defines a <b>safe medical product</b> as one that poses reasonable risks given the magnitude of the benefit expected and the alternatives available.
<b>Sensitivity</b>	The <b>sensitivity</b> 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.
<b>Source</b>	The <b>source</b> 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.
<b>Specificity</b>	The <b>specificity</b> 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 negatives decreases.





# INTRODUCTION

## Objective and Background

Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus (RPM Plus) Program is pleased to present the second edition of the *HIV Test Kits Listed in the USAID Source and Origin Waiver: Procurement Information Document*. This update replaces the first edition, which was printed in 2002. The preparation of this document has been funded by the Office of HIV/AIDS (OHA) of the U.S. Agency for International Development (USAID).

The objective of this document is to facilitate the process of procuring the HIV tests listed in Tab 1 (Approved List of Testing Kit Products and Manufacturers) of the USAID Source and Origin Waiver for HIV Test Kits, included in Annex 1 of this document. These HIV tests are acquired by USAID Missions and USAID-funded cooperating agencies (CAs), and this document is intended to assist the USAID Missions and CAs to identify manufacturers, international agencies, and suppliers. This document also contains additional information to assist Missions and CAs with planning for procurement, including information on prices, shelf life on delivery, and the source and origin of the product. Also included is the test kit procurement information for the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) and HIV test kit donation programs managed by the Axios Foundation.

In 2000, USAID's Division of HIV/AIDS (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*.<sup>1</sup> 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 some USAID-funded CAs. In January 2001, the USAID Administrator approved a source and origin waiver for HIV/AIDS diagnostic materials (test kits) to facilitate the process of procuring these HIV test kits.

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 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 countries are not available from U.S. sources and are not of U.S. origin; very few are approved by the U.S. Food and Drug Administration (FDA).

The USAID Source and Origin Waiver for HIV Test Kits was approved to facilitate the complex process of preparing requests for approval to procure HIV test kits in view of the "Buy America"

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<sup>1</sup> 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.

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.

## **Methodology**

To develop the first edition of this document, RPM Plus surveyed the manufacturers of the HIV test kits listed in Tab 1 of the USAID Source and Origin Waiver. Some international procurement agencies and suppliers were also surveyed. The same process has been used for this second edition. It is important to point out that inclusion on this list does not imply that the supplier/agency is endorsed by USAID or MSH/RPM Plus or preferred over any other international supplier/agency.

## **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 in Tab 1 of the USAID Source and Origin Waiver for HIV Test Kits 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 international 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 update the 2002 edition as necessary 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 second edition will be posted on the RPM Plus Web site ([www.msh.org/rpmpplus](http://www.msh.org/rpmpplus)). An interactive Web version is also being created.

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

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### **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*<sup>2</sup> to provide information on how to apply for approval to procure USAID-funded pharmaceutical products.

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<sup>2</sup> 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

The USAID Source and Origin Waiver for HIV Test Kits was amended in October 2001 to include additional test kits. These test kits have been reviewed by USAID and found to meet all the necessary suitability and price criteria for approval of a source/origin waiver. USAID periodically reviews the source/origin waiver and the continued need for the kits. The CDC has also reviewed the listed kits for safety and efficacy and recommends their use in resource-constrained settings. The list will be revised if U.S.-manufactured test kits or new 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, as amended in October 2001, lists the following kits—

- Bionor™ HIV-1&2 (Bionor)
- Capillus™ HIV-1/HIV-2 (Trinity Biotech)
- Determine™ HIV-1/2 (Abbott Laboratories)
- DoubleCheck™ HIV 1&2 (Orgenics, Ltd.)
- Genie II HIV-1/HIV-2 (Bio-Rad Laboratories)
- Hema-Strip™ HIV (Saliva Diagnostic Systems)
- HIVCHEK System 3™ (Ortho-Clinical Diagnostics/EY Laboratories)<sup>3</sup>
- HIVSav 1&2 Rapid SeroTest™ (Sayvon Diagnostics)
- HIV SPOT™ (Genelabs Diagnostics)<sup>4</sup>
- MultiSpot HIV-1/HIV-2 (Bio-Rad Laboratories)<sup>5</sup>
- OraQuick® Rapid HIV-1 Antibody Test (OraSure Technologies)
- SeroCard™ HIV (Trinity Biotech)
- Sero-Strip™ HIV (Saliva Diagnostic Systems)
- Uni-Gold™ HIV (Trinity Biotech)

This chapter presents general information on each test kit, cross-referenced with manufacturer information. Information on international procurement agencies and suppliers is presented in Chapter 2. The procurement information for the manufacturer of each HIV test kit listed is intended to be used as an initial reference for identifying manufacturers and planning for procurement. Prices are given as an indicator only and may vary according to 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 HIV test kits. Inclusion in this document does not imply that the product or the manufacturers are endorsed by USAID or MSH/RPM Plus or preferred over any other product or manufacturer.

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<sup>3</sup> This product may have been discontinued in August 1997, according to personal communication with a representative of Ortho-Clinical Diagnostics; however, the details were unable to be determined.

<sup>4</sup> The manufacture of this product has been discontinued by the company.

<sup>5</sup> Based on a recent e-mail communication with a representative of Bio-Rad Laboratories, it was learned that the company has discontinued production of this product.

## **What Is in This Section?**

The following information is provided for each test kit—

- Technical information, including a basic description
- Product information
- Procurement information
- Information on donation programs (for those companies that indicated they have a donation process in place)

### ***Technical Information***

This section contains a brief description of the product, including sensitivity,<sup>6</sup> specificity,<sup>7</sup> the test principle,<sup>8</sup> 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. The level of complexity of the tests may be determined by the items included in the kit. <sup>9</sup>
Additional items required but not included	Usually standard laboratory equipment is sufficient, but some test kits have special requirements (e.g., reagents, gloves, centrifuges).
Shelf life from the date of production	The shelf life is the length of time (for rapid test kits, usually months) for which a product can be safely used and accurate results can be expected. Shelf life assumes that the storage conditions specified by the manufacturer are met.
Language of package insert	This lists the languages included in the standard package insert. Special language requirements must be negotiated and included in the procurement contract.

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<sup>6</sup> See the Glossary for a definition of sensitivity.

<sup>7</sup> See the Glossary for a definition of specificity.

<sup>8</sup> Current rapid tests are based on one of four test principles: particle agglutination, immunodot (dipstick), immunofiltration (flow-through testing), or immunochromatography (lateral-flow device).

<sup>9</sup> The Joint United Nations Programme on HIV/AIDS (UNAIDS) and WHO define four levels of complexity of HIV test kits:

- Level 1: No additional equipment or laboratory equipment needed
- Level 2: Reagent preparation or multistep process required
- Level 3: Specific skills such as diluting required
- Level 4: Equipment and laboratory technicians required

Storage conditions	Manufacturer-recommended storage conditions. These recommendations need to be adhered to during shipping, storage, and delivery to ensure that the quality and performance of the product are not compromised.
Weight/dimensions/volume of kits or tests	This information will assist programs to plan for storage. Planning is particularly important when refrigeration is required.

### ***Procurement Information***

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

Price for one kit	Prices are given as an indicator 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 of the time that may have passed between the time the manufacturers were contacted and 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.
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.
Available from U.S. sources	This 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 quantity from manufacturer	Unless otherwise specified, the minimum order quantity is one kit.
Minimum average 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's 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 addresses the issue of whether stock is maintained or the kit is manufactured on demand. If stock is kept on hand, the order lead time is generally less. However, having the kits manufactured on receipt of an order has the advantage of giving the longest shelf life.

Average time to fill order	This information assists programs in planning for procurement to ensure that orders are placed in sufficient time to prevent stock-outs.
Quality issues	This section 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 or specific related information.
Available from	This 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).

### ***Information on Donation Programs***

Over the past few years, some manufacturers have set up donation programs to provide HIV test kits for relevant programs in resource-constrained settings. Information on available donation programs and how to access them is included in this section.



## **Bionor™ HIV-1&2**

**Manufactured by Bionor A/S, Norway**

For further information, please contact:

*Gunnar Flatten*

*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.flatten@bionor.no](mailto:gunnar.flatten@bionor.no)*

*Web site: <http://www.bionor.no>*

Information current as of February 2002

### **Technical Information**

Bionor™ HIV-1&2 is a rapid enzyme immunoassay (EIA) that uses synthetic peptides to detect antibodies to HIV-1 and HIV-2. The sensitivity (tested on 263 samples) was found to be 100 percent, and the specificity (of 332 samples) was found to be 98.8 percent.<sup>10</sup> It is estimated that this test can produce results in 30 minutes.

### **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	A rocking platform with magnets, aspirator, lamp, and waste container. The product is supplied with four strips and a lid that can be operated on 115 or 230 volts (V) or on a 12V solar or car battery. The dimensions of the testing station are 35 × 20 × 12 cm (13.8 × 7.9 × 4.7 in). Disposable gloves, biohazard bags, blood collection equipment, and disinfectant are also required.
Shelf life from the date of production	12 months
Language of package insert	English (but for larger orders, other languages can be provided)
Storage conditions	Store kit at 2–8°C (32–46°F). If stored at room temperature, shelf life is reduced to four to six months. Do not leave kits in strong heat or light.
Weight/dimensions/volume for four 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 cm <sup>3</sup> (0.0041 m <sup>3</sup> ) (251 cu in [0.15 cu ft])

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<sup>10</sup> World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2002. *HIV Simple/Rapid Assays: Operational Characteristics (Phase 1): Report 12, Whole Blood Specimens*. WHO/BCT/02.07. Geneva: WHO.

**(Bionor, cont.)**

**Procurement Information**

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

Price for one kit	Varies from 300 U.S. dollars (USD) to USD 825 ex-works. <sup>11</sup> Prices may vary according to quantities ordered and whether supplied directly or through the distributor.
FDA approved	No
Available from U.S. sources	No
Minimum order from manufacturer	Four kits
Minimum average 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 three to four weeks if a new batch is manufactured.
Quality issues	Quality problems are resolved by replacing the kit. Bionor A/S 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, Missionpharma A/S, and Orbi-Pharma. The product is also available through the WHO Bulk Procurement Scheme. (See Chapter 2 for more details.)

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.

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<sup>11</sup> See Glossary for a definition of ex-works.

The manufacturer reports using the following distributors—

In Uganda: Achelis Ltd., Kampala  
James Segawa  
Tel: +256-41-344-442  
E-mail: [achelis@infocom.co.ug](mailto:achelis@infocom.co.ug)

In South Africa: The Scientific Group, Johannesburg  
Mike Thomson  
Tel: +27-11-652-4000  
E-mail: [miket@scientificgroup.com](mailto:miket@scientificgroup.com)

Worldwide: Martin James Medical, UK  
Brian Hobbs  
Tel: +44-1326-280-776  
E-mail: [bhobbs@martinjames.com](mailto:bhobbs@martinjames.com)



*Photo appears courtesy of  
Trinity Biotech Plc*

## **Capillus™ HIV-1/HIV-2**

**Manufactured by Trinity Biotech, Ireland**

For further information, please contact:

*Marie McCarthy, Group Product Manager*

*Trinity Biotech Plc*

*IDA Business Park*

*Bray, Co. Wicklow, Ireland*

*Tel: +353-1-276 9800*

*Fax: +353-1-276 9888*

*E-mail: [mmccarthy@trinitybiotech.ie](mailto:mmccarthy@trinitybiotech.ie)*

*Web site: <http://www.trinitybiotech.com>*

Information current as of November 2003

### **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 tests conducted on 80 and 170 samples showed results of 100 percent each. It is estimated that the test can produce results in three minutes.<sup>12</sup>

### **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
Shelf life from the date of production	15 months
Language of package insert	English (however, other languages can be provided on request)
Storage conditions	Optimum storage is at 2–8°C (32–46°F). Stable for short periods (up to four weeks) at 25°C (77°F). 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.
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 <sup>3</sup> (0.00246 m <sup>3</sup> ) (150.3 cu in [0.09 cu ft])

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

## **Procurement Information**

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

Price for one kit	Price varies from USD 150 to USD 175 ex-works (purchaser picks up at warehouse). No additional handling charges are added, but shipping and insurance are extra. Prices may vary by quantity and region.
FDA approved	No
Available from U.S. sources	No
Minimum order from manufacturer	Five kits (500 tests)
Minimum average shelf life on delivery	9–10 months
Stock on hand	Some stock is held, but levels vary according to demand.
Average time to fill order	Six 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.
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, and Missionpharma A/S. The product is also available from UNICEF and through the WHO Bulk Procurement Scheme. (See Chapter 2 for more details.)



*Photo appears courtesy of  
Abbott Laboratories*

## **Determine™ HIV-1/2**

**Manufactured by Abbott Laboratories, Japan**

For further information, please contact:

*Friedah Nehmadi, Senior Product Manager*

*Abbott Laboratories*

*100 Abbott Park Road*

*Abbott Park, Illinois 60064-3500 USA*

*Tel: +1-847-937-6100*

*Fax: +1-847-937-2776*

*E-mail: [friedah.nehmadi@abbott.com](mailto:friedah.nehmadi@abbott.com)*

*Web site: <http://www.abbottdiagnostics.com>*

*Information current as of January 2004*

### **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.<sup>13</sup> It is estimated that the test can produce results in 17 minutes.<sup>14</sup>

### **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
Shelf life from the date of production	14 months
Language of package insert	English, French, German, Portuguese, Spanish
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 <sup>3</sup> (0.000432 m <sup>3</sup> ) (26.36 cu in [0.015 cu ft])

<sup>13</sup> Abbott Laboratories. 2001. *Determine™ HIV-1/2 Package Insert*. Abbott Park, IL: Abbott Laboratories.

<sup>14</sup> World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2002. *HIV Simple/Rapid Assays: Operational Characteristics (Phase 1): Report 12, Whole Blood Specimens*. WHO/BCT/02.07. Geneva: WHO.

## **Procurement Information**

USAID Missions and CAs can purchase kits directly from the manufacturer or from an Abbott country office.<sup>15</sup>

Price for one kit	Suggested retail price per kit (100 tests) is USD 120, free on board (FOB) for nonprofit organizations for 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.
FDA approved	No
Available from U.S. sources	No
Minimum order from manufacturer	One kit
Minimum average shelf life on delivery	Usually about 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 the kit will be tested to verify whether there is a defect. 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.
Available from	Action Medeor, Crown Agents, International Dispensary Association (IDA), Missionpharma A/S, Orbi-Pharma, and Tri-Med Ltd. The product is also available from UNICEF and through the WHO Bulk Procurement Scheme. (See Chapter 2 for more details.)

## **Information on Donation Programs**

Abbott Laboratories established a donation program in mid-2002. Kits are available for programs specifically targeted for the prevention of mother-to-child transmission (PMTCT).<sup>16</sup> (For more details, see Annex 3 on donation programs.)

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<sup>15</sup> Abbott has offices in 150 countries.

<sup>16</sup> Abbott Laboratories. 2004. "Global Citizenship: Global Care & Product Access Programs/Determine HIV Test Donation Program." <<http://abbott.com/citizenship/access/pmtct.shtml>> (accessed January 2004).



*Photo appears courtesy of Orgenics, Ltd.*

## **DoubleCheck™ HIV 1&2**

**Manufactured by Orgenics, Ltd., Israel**

For further information, please contact:

*Rosanne Tzuk, Export Manager*

*Orgenics, Ltd.*

*North Industrial Zone*

*P.O. Box 360*

*70650 Yavne, Israel*

*Tel: +972 8 942 9206*

*Fax: +972 8 943 8758*

*E-mail: [rosanne@orgenics.co.il](mailto:rosanne@orgenics.co.il)*

*Web site: <http://www.orgenics.com>*

Information current as of January 2004

### **Technical Information**

DoubleCheck™ HIV 1&2 is a dual-recognition enzyme immunoassay (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 108 HIV-positive and 179 HIV-negative individuals revealed a sensitivity and specificity of 100 percent.<sup>17</sup> It is estimated that the test will produce results in 11 minutes.<sup>18</sup>

### **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
Shelf life from the date of production	15 months
Language of package insert	English, French, Portuguese, Russian, Spanish
Storage conditions	Store the kit at 4–8°C (39–46°F). Do not freeze.
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: 6916 cm <sup>3</sup> (0.0069 m <sup>3</sup> ) (421.9 cu in [0.244 cu ft])

<sup>17</sup> Orgenics, Ltd. n.d. “DoubleCheck™ HIV 1&2 Package Insert.” <<http://www.orgenics.com>> (accessed January 2004).

<sup>18</sup> World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2002. *HIV Simple/Rapid Assays: Operational Characteristics (Phase 1): Report 12, Whole Blood Specimens*. WHO/BCT/02.07. Geneva: WHO.



**Procurement Information**

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

Price for one kit	USD 40 per kit (ex-works); special consideration for large orders
FDA approved	No
Available from U.S. sources	No
Minimum order from manufacturer	One kit
Minimum average 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 quantities are in stock, the orders are dispatched immediately. If it is a special manufacture, the order takes two to three weeks.
Quality issues	The company has a recall procedure for suspected defective products, but no information on the procedure was available.
Payment method to manufacturer	Telegraphic bank transfer
Available from	Crown Agents and Missionpharma A/S. The product is also available from UNICEF. (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, Area Manager (Africa)*

*Bio-Rad Laboratories*

*3 Boulevard Raymond Poincaré  
92430 Marnes-la-Coquette, France*

*Tel: +33-1-47 95-6000*

*Fax: +33-1-47 41-9133*

*E-mail: [stephane\\_garcia@bio-rad.com](mailto:stephane_garcia@bio-rad.com)*

*Web site: <http://www.bio-rad.com>*

Information current as of February 2004

### **Technical Information**

Genie II HIV-1/HIV-2 is a rapid enzyme immunoassay (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.<sup>19</sup> The sensitivity and specificity of the test are 99.5 percent and 99.1 percent, respectively.<sup>20</sup>

### **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
Shelf life from the date of production	12 months
Language of package insert	English, French
Storage conditions	Store the kit at 2–8°C (32–46°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 (10.3 × 7.3 × 5.5 in) Volume: 6,700 cm <sup>3</sup> (0.0067 m <sup>3</sup> ) (423.0 cu in [0.245 cu ft])

<sup>19</sup> Bio-Rad Laboratories. 2000. *Genie II HIV-1/HIV-2 Package Insert*. Hercules, CA: Bio-Rad Laboratories.

<sup>20</sup> World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2002. *HIV Simple/Rapid Assays: Operational Characteristics (Phase 1): Report 12, Whole Blood Specimens*. WHO/BCT/02.07. Geneva: WHO.

## **Procurement Information**

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

Price for one kit	Fewer than 75 kits: USD 138 per kit 75–200 kits: USD 125 per kit More than 200 kits: USD 111 per kit
FDA approved	No
Available from U.S. sources	No
Minimum order from manufacturer	Minimum order value of USD 280
Minimum average shelf life on delivery	Six to nine months
Stock on hand	The manufacturer has stock available to cover an average of one and a half months' worth of sales; large quantities may be staggered or need to be ordered at least two months in advance.
Average time to fill order	Nine days; can be longer for unexpected orders
Quality issues	Complaints should be addressed to Bio-Rad's technical support staff in France. Complaints are usually investigated, and if the quality problem is justified, the product is either replaced or a credit note is issued.
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 and Missionpharma A/S. The product is also available through the WHO Bulk Procurement Scheme. (See Chapter 2 for more details.)

## **Hema-Strip™ HIV**

**Manufactured by Saliva Diagnostic Systems, USA**

For further information, please contact:

*Leo Ehrlich, President*

*Saliva Diagnostic Systems*

*2294 Nostrand Ave.*

*Brooklyn, NY 11210, USA*

*Tel: +1-917-853-6440*

*Fax: +1-212-937-3801*

*E-mail: [leo@salv.com](mailto:leo@salv.com)*

*Web site: <http://www.salv.com>*

Information current as of November 2003

### **Technical Information**

Hema-Strip™ HIV is a single-use test that analyzes a whole blood specimen for the detection of antibodies to HIV-1 and HIV-2. Finger-stick samples can be used. The test produces results in minutes. The sensitivity and specificity of the test are both 99 percent.<sup>21</sup>

### **Product Information**

Number of tests per kit	25
Items included in kit	Sampler, reagents, lancet, bandage, buffer vial, and rack
Additional items required but not included	Timer or stopwatch, rack for holding buffer vials upright (optional), pipette and pipette tips, blood collection equipment as necessary, disposable gloves, biohazard bags, and disinfectant
Shelf life from the date of production	15 months
Language of package insert	English, French, Portuguese
Storage conditions	Store the kit at 20–33°C (68–91°F).
Weight/dimensions/volume for 20 kits (500 tests)	Weight: 11.3 kg (25 lb) Dimensions: 53.3 × 43.2 × 43.2 cm (21 × 17 × 17 in) Volume: 99,470 cm <sup>3</sup> (0.1 m <sup>3</sup> ) (6,067.7 cu in [3.5 cu ft])

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<sup>21</sup> Saliva Diagnostic Systems. 2000. "Hema-Strip HIV." <<http://www.salv.com/>> (accessed November 2003).

**Procurement Information**

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

Price for one kit	Fewer than 10,000 kits: USD 50 per kit More than 10,000 kits: determined by manufacturer
FDA approved	No
Available from U.S. sources	Yes
Minimum order from manufacturer	20 kits (500 tests)
Minimum average shelf life on delivery	10 months
Stock on hand	The manufacturer reports keeping stock on hand.
Average time to fill order	Two to three days; for a specially manufactured batch, two to four weeks. The company recommends a two- to four-week lead time for delivery.
Quality issues	Complaints should be addressed to the company's Quality Assurance/Quality Control Manager.
Payment method to manufacturer	U.S. Government purchase orders are accepted. Other purchasers must prepay or set up an open letter of credit.
Available from	The company is responsible for distribution of this product. Deliveries are direct to the customer. This product is for export only from the United States. Certain documents are required from the importing countries.



*Picture appears courtesy of Savyon Diagnostics*

## **HIVSav™ 1&2 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](mailto:elana@savyondiagnosics.com)*

*Web site: <http://www.savyondiagnosics.com>*

*Information current as of November 2003*

### **Technical Information**

HIVSav™ 1&2 Rapid SeroTest is an immunoassay that detects antibodies directed against HIV-1 and HIV-2 in serum or plasma. Results from clinical studies demonstrate a specificity and sensitivity greater than 99.9 percent.<sup>22</sup>

### **Product Information**

Number of tests per kit	25 or 50 tests per kit
Items included in kit	Cassettes, reagents, controls, and pipettes
Additional items required but not included	Disposable gloves, biohazard bags, blood collection equipment, and disinfectant
Shelf life from the date of production	12 months
Language of package insert	English (but other languages can be arranged)
Storage conditions	Store the kit at 4–8°C (39–46°F).
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 (7.5 × 6.3 × 4.3 in)/same Volume: 3,344 cm <sup>3</sup> (0.0033 m <sup>3</sup> ) (204.0 cu in [0.12 cu ft])/same

<sup>22</sup> Savyon Diagnostics. n.d. "HIVSav 1&2 Rapid SeroTest." <<http://www.savyondiagnosics.com>> (accessed November 2003).

## **Procurement Information**

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

Price for one kit	USD 1.50 FOB; 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.
FDA approved	No
Available from U.S. sources	No
Minimum order from manufacturer	One kit
Minimum average 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 four 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 and Missionpharma A/S (see Chapter 2 for more details).

The manufacturer also has a number of distributors in several countries that can supply the test kit. The distributors are Applied Biodiagnostics and OSB Agencies (India), Beta Medico Trading (Macedonia), Biocare (Philippines), Biomeca (Cyprus), Bio-Nuclear SA and BioMedica SA (Dominican Republic), Brassora (Argentina), CPEI (Brazil), DBA (Bolivia), Distrilabo (Côte d'Ivoire), Exadactylos (Greece), Gamidor (Turkey), Glanson Laboratories and R.L. Upright (Nigeria), Hass Scientific and Lancet Laboratories (Kenya), Immunochem (Peru), OCD SA (Venezuela), Rapport (Thailand), Setema (Ethiopia), and Trade Medica Diagnosticos (Brazil).



*Photo appears courtesy of  
OraSure Technologies*

## **OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test**

**Manufactured by OraSure Technologies, USA**

For further information, please contact:

*Ron Ticho, Director of Marketing*

*OraSure Technologies, Inc.*

*220 East First Street*

*Bethlehem, PA 18015 USA*

*Tel: +1-610-882-1820*

*Fax: +1-610-882-3572*

*E-mail: [rticho@orasure.com](mailto:rticho@orasure.com)*

*Web site: <http://www.orasure.com>*

Information current as of December 2003

### **Technical Information**

OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test is a finger-stick and venipuncture whole blood test that uses a lateral-flow immunoassay principle to detect the presence of HIV-1 antibodies. Results from a large, controlled clinical trial revealed the sensitivity and specificity to be 99.6 percent and 100 percent, respectively. It can produce results in about 20 minutes.<sup>23</sup>

### **Product Information**

Number of tests per kit	25 or 100
Items included in kit	Reusable test stand, specimen collection loops, subject information pamphlet, package insert, and customer letter
Additional items required but not included	Gloves, sterile lancet to obtain finger-stick or materials required to obtain venipuncture whole blood sample, timer or watch, antiseptic wipe, sterile gauze pad, biohazard waste container, phlebotomy materials, and disposable absorbent workspace cover
Shelf life from the date of production	Seven months
Language of package insert	English, Spanish
Storage conditions	Store the kit at 2–27°C (32–81°F).
Weight/dimensions/volume for one kit	Information not provided

<sup>23</sup>OraSure Technologies. 2003. "OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test Package Insert." <http://www.orasure.com/uploaded/346.pdf?134&sec=2&subsec=2> (accessed November 2003).



## **Procurement Information**

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

Price for one kit	USD 8–12, but can be negotiated based on the volume of test kits ordered
FDA approved	Yes
Available from U.S. sources	Yes
Minimum order from manufacturer	One kit
Minimum average shelf life on delivery	Information not given
Stock on hand	Stock is maintained, and kits are also manufactured on demand, depending on the order quantity.
Average time to fill order	Four to six weeks
Quality issues	There is a recall procedure for faulty test kits. All production batches undergo quality control release testing in accordance with established procedures. The devices must fill requirements and are evaluated for physical attributes/defects and performance using a standardized quality control panel representing various levels of HIV-antibody reactivity. Stability studies are also 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	Payment is required 30 days from receipt of the invoice. Most international clients do a 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	None of the international procurement agencies or suppliers surveyed indicated that they supply this product.



*Photo appears courtesy of Trinity Biotech Plc*

## **SeroCard™ HIV**

**Manufactured by Trinity Biotech, Ireland**

For further information, please contact:

*Marie McCarthy, Group Product Manager*

*Trinity Biotech Plc*

*IDA Business Park*

*Bray, Co. Wicklow, Ireland*

*Tel: +353-1-276 9800*

*Fax: +353-1-276 9888*

*E-mail: [mmccarthy@trinitybiotech.ie](mailto:mmccarthy@trinitybiotech.ie)*

*Web site: <http://www.trinitybiotech.com>*

Information current as of November 2003

### **Technical Information**

The Trinity Biotech SeroCard™ HIV is a rapid test that uses the lateral-flow membrane principle<sup>24</sup> for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma, or whole blood. The specificity and sensitivity were determined by the analysis of 4,882 samples by several independent international laboratories; both the sensitivity and specificity were over 99 percent.<sup>25</sup> The estimated time expected for one test activity is nine minutes.<sup>26</sup>

### **Product Information**

Number of tests per kit	40
Items included in kit	Test cards, reagents, and disposable pipettes
Additional items required but not included	Timer or stopwatch, disposable gloves, biohazard bags, blood collection equipment, and disinfectant
Shelf life from the date of production	15 months
Language of package insert	English (but other languages are available on request)
Storage conditions	Store the kit at 2–8°C (32–46°F).
Weight/dimensions/volume for one kit (40 tests)	Weight: 0.5 kg (1.1 lb) Dimensions: 20 × 10 × 14 cm (7.9 × 3.9 × 5.5 in) Volume: 2,800 cm <sup>3</sup> (0.003 m <sup>3</sup> ) (170.8 cu in [0.10 cu ft])

<sup>24</sup> World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 1999. *Operational Characteristics of Commercially Available Assays to Determine Antibodies to HIV-1 and/or HIV-2 in Human Sera: Report 11*. WHO/BTS/99.1, UNAIDS/99.5. Geneva: WHO.

<sup>25</sup> Trinity Biotech Plc. n.d. "HIV-1/2 IgG Antibodies Package Insert." <http://www.trinitybiotech.com/EN/index.asp> (accessed January 2004).

<sup>26</sup> World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 1999. *Operational Characteristics of Commercially Available Assays to Determine Antibodies to HIV-1 and/or HIV-2 in Human Sera: Report 11*. WHO/BTS/99.1, UNAIDS/99.5. Geneva: WHO.

## **Procurement Information**

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

Price for one kit	USD 60–70 per kit (40 tests). Prices are ex-works (purchaser picks up at the warehouse). There are no extra charges for handling, but shipping and insurance are extra. Prices may vary by quantity and region.
FDA approved	No
Available from U.S. sources	No
Minimum order from manufacturer	Five kits (200 tests)
Minimum average shelf life on delivery	9–13 months
Stock on hand	The manufacturer has stock available, but levels vary according to demand.
Average time to fill order	Four weeks
Quality issues	A quality problem with a product is investigated through the in-house quality control system. If a product problem is confirmed, replacement products or credit notes are issued.
Payment method to manufacturer	The required payment method for orders is three up-front payments, after which credit terms can be established. Credit card orders can be accepted.
Available from	Crown Agents and Missionpharma A/S (see Chapter 2 for more details).

## **Sero-Strip™ HIV**

**Manufactured by Saliva Diagnostic Systems, USA**

For further information, please contact:

*Leo Ehrlich, President*

*Saliva Diagnostics Systems*

*2294 Nostrand Ave.*

*Brooklyn, NY 11210 USA*

*Tel: +1-917-853-6440*

*Fax: +1-212-937-3801*

*E-mail: [leo@salv.com](mailto:leo@salv.com)*

*Web site: <http://www.salv.com>*

Information current as of November 2003

### **Technical Information**

Sero-Strip™ is a test strip that uses the capillary-flow membrane principle for the detection of antibodies to HIV-1 and HIV-2 in human serum and plasma. The sensitivity of 263 samples was 98.9 percent, and the specificity of 332 samples was 100 percent. The test produces results in three minutes.<sup>27</sup>

### **Product Information**

Number of tests per kit	30
Items included in kit	Test strips and buffer and transfer loops
Additional items required but not included	Timer or stopwatch, tubes for holding buffer/specimen mixture (1 mL sampling tubes and disposable cardboard rack available at additional cost), disposable gloves, biohazard bags, blood collection equipment, and disinfectant
Shelf life from the date of production	12 months
Language of package insert	English, Spanish
Storage conditions	Store the kit at 20–33°C (68–91°F).
Weight/dimensions/volume for 60 kits (1,800 tests)	Weight: 9.5 kg (21 lb) Dimensions: 45.7 × 40.6 × 35.6 cm (18 × 16 × 14 in) Volume: 66,052 cm <sup>3</sup> (0.07 m <sup>3</sup> ) (4029.2 cu in [2.3 cu ft])

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<sup>27</sup> World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 1999. *Operational Characteristics of Commercially Available Assays to Determine Antibodies to HIV-1 and/or HIV-2 in Human Sera: Report 11*. WHO/BTS/99.1, UNAIDS/99.5. Geneva: WHO.

## **Procurement Information**

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

Price for one kit	The listed price for 10,000 tests or fewer is USD 1.25 per test and for more than 10,000 tests is USD 1.00 per test (prices listed are per test, not per kit). Prices vary according to the quantity ordered and customer/user.
FDA approved	No
Available from U.S. sources	Yes
Minimum order from manufacturer	10 kits (300 tests)
Minimum average shelf life on delivery	10 months
Stock on hand	The manufacturer has substantial stock.
Average time to fill order	Two to three days; for a specially manufactured batch, two to four weeks. The company recommends a two- to four-week lead time for delivery.
Quality issues	Complaints should be addressed to the company's Quality Assurance/Quality Control Manager.
Payment method to manufacturer	U.S. Government purchase orders are accepted. Other purchasers must prepay or set up an open letter of credit.
Available from	The company is responsible for distribution of this product. Deliveries are direct to the customer. Based on the FDA's export regulations, this product cannot be shipped to a purchaser within the United States. Certain documents are required from the importing countries.



*Photo appears courtesy of  
Trinity Biotech Plc*

## **Uni-Gold™ HIV**

**Manufactured by Trinity Biotech, Ireland**

For further information, please contact:

*Marie McCarthy, Group Product Manager*

*Trinity Biotech Plc*

*IDA Business Park*

*Bray, Co. Wicklow, Ireland*

*Tel: +353-1-276 9800*

*Fax: +353-1-276 9888*

*E-mail: [mmccarthy@trinitybiotech.ie](mailto:mmccarthy@trinitybiotech.ie)*

*Web site: <http://www.trinitybiotech.com>*

Information current as of November 2003

### **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.<sup>28</sup> The specificity and sensitivity of 80 and 170 samples were both found to be 100 percent. The test is estimated to produce results in 11 minutes.<sup>29</sup>

### **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
Shelf life from the date of production	15 months
Language of package insert	English (but other languages are available on request)
Storage conditions	Store the kit at 2–27°C (32–81°F).
Weight/dimensions/volume for one kit (20 tests)	Weight: 0.2 kg (0.5 lb) Dimensions: 24 × 14 × 10 cm (9.4 × 5.5 × 3.9 in) Volume: 3,360 cm <sup>3</sup> (0.00336 m <sup>3</sup> ) (205.04 cu in [0.118657 cu ft])

<sup>28</sup> Trinity Biotech Plc. n.d. "Uni-Gold Recombigen HIV." <<http://www.trinitybiotech.com/EN/index.asp>> (accessed January 2004).

<sup>29</sup> World Health Organization (WHO)/Joint United Nations Programme on HIV/AIDS (UNAIDS). 2002. *HIV Simple/Rapid Assays: Operational Characteristics (Phase 1): Report 12, Whole Blood Specimens*. WHO/BCT/02.07. Geneva: WHO.

**Procurement Information**

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

Price for one kit	USD 30
FDA approved	No
Available from U.S. sources	Yes
Minimum order from manufacturer	Five kits (100 tests)
Minimum average shelf life on delivery	10 months
Stock on hand	Stocks are held, but levels vary with demand.
Average time to fill order	Six weeks
Quality issues	A problem with a product is investigated through the in-house quality control system. If a product problem is confirmed, replacement product or credit notes are issued.
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, Missionpharma A/S, and Orbi-Pharma. The product is also available through the WHO Bulk Procurement Scheme. (See Chapter 2 for more details.)





## CHAPTER 2: INTERNATIONAL PROCUREMENT AGENCIES AND SUPPLIERS

This chapter contains HIV test kit procurement information from selected international procurement agencies and suppliers. A supplier maintains a warehouse and sends items directly to customers. The following international suppliers responded to this survey—

- Action Medeor
- International Dispensary Association
- Missionpharma A/S
- Orbi-Pharma

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 cost, insurance, and freight (CIF) price of the product or test kit. The following international procurement agencies responded to the survey—

- Crown Agents
- Tri-Med Ltd.

All the international procurement agencies and suppliers listed in the 2002 edition of MSH's *International Drug Price Indicator Guide*<sup>30</sup> were surveyed, although not all responded. Crown Agents were also surveyed as a procurement source available under the USAID-funded DELIVER project. 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 international supplier or agency.

Also featured in this section are two United Nations (UN) agencies that have been involved in the procurement of HIV test kits: WHO and UNICEF. 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. UNICEF assists countries to procure HIV test kits for their PMTCT programs.

The information in this chapter is current as of January 31, 2004, and is intended to be used as an initial reference for identifying international procurement agencies and suppliers and for planning for procurement. Prices are given as an indicator 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. Please consult the following section as a guide to information contained in this chapter.

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<sup>30</sup> Management Sciences for Health, in collaboration with the World Health Organization. 2001. *International Drug Price Indicator Guide, Guía Internacional de Indicadores de Precios de Medicamentos, Indicateur de Prix Internationaux des Médicaments* (updated annually). Boston, MA: MSH.

## **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 international procurement agencies and suppliers of 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 the test kits from the specified international procurement agency or supplier.

Product(s) supplied	Names of the test kits listed in the Source and Origin Waiver that the international procurement agency or supplier stocks or supplies.
Listed price (range) and terms and suggested retail price	Prices are given as an indicator only. The supplier or agency should be contacted to verify the information. Additional procurement information may also be listed here, such as whether the manufacturer provides special discounts for nonprofits or other organizations working on certain programs.
Minimum order quantity	Unless otherwise specified, one kit is the minimum order quantity.
Minimum average 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's 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 addresses the issue of 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 a situation where the product is out of stock when the order is placed.
Delivery information	The delivery locations the company serves.
Payment method	Any general requirements for method of payment are given. These requirements are often country-, program-, or quantity-specific. The international 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.

## **Action Medeor**

### **International Supplier**

For further information, please contact:

*Dr. Ilse Schleiden-Schmid*

*Head of Pharmaceuticals Dept.*

*Action Medeor*

*St. Töniser Str. 21*

*D-47918, Tönisvorst, Germany*

*Tel: +49-21-56-97-88-92*

*Fax +49-21-56-97-88-99*

*E-mail: [Schleiden-Schmid@medeor.org](mailto:Schleiden-Schmid@medeor.org)*

*Web site: <http://www.medeor-order.org>*

*Information current as of January 2004*

The company is a nonprofit organization that supplies other nonprofit organizations. U.S. Government representatives can purchase kits directly from this supplier.

Products supplied <sup>31</sup>	Capillus™ HIV-1/HIV-2 and Determine™ HIV-1/2
Listed price (range) and terms and suggested retail price	Capillus™ HIV-1/HIV-2: 230 euro for 100 tests; Determine™ HIV-1/2: USD 92 for 100 tests <sup>32</sup> (depending on the USD/euro exchange rate). Prices are ex-works and are not dependent on quantity ordered. There is an additional processing fee for 1 percent of the value of the goods (minimum 50 euro).
Minimum order quantity	One kit
Minimum average shelf life on delivery	Six months (both products)
Stock on hand	A small stock of Capillus™ HIV-1/HIV-2 is maintained; otherwise, kits are ordered on demand.
Average time to fill an order	Capillus™ HIV-1/HIV-2: three weeks if supplied from stock, six to eight weeks otherwise. Determine™ HIV-1/2: three weeks. Delivery is made to facilities within a country.
Payment method	Upon receipt of invoice or up-front for first-time orders. Please contact the company for additional information.
Quality issues	If there is a problem with a test, Action Medeor informs the manufacturer immediately.

<sup>31</sup> The company supplies only test kits that have been evaluated by WHO.

<sup>32</sup> Please note that the price given for Determine™ is limited to least developed countries.

## **Crown Agents**

### **International Procurement Agency**

For further information, please contact:

*Jennifer Katzka, Vice President*

*Crown Agents*

*818 Connecticut Avenue NW, Suite 840*

*Washington, DC 20006 USA*

*Tel: +1-202-822-8052*

*Fax: +1-202-822-8064*

*E-mail: [jktazka@crowagents.com](mailto:jktazka@crowagents.com)*

*Web site: <http://www.crownagentsusa.com>*

*Information current as of December 2003*

U.S. Government representatives can purchase kits directly from the agency.

Products supplied	As an international procurement agency, the company does not stock test kits. It states that it is able to supply or procure any HIV test kit, including, but not restricted to, the kits listed on the USAID approved list. Under the company's current CDC global contract to supply HIV test kits, many of the kits listed in Tab 1 of the Source and Origin Waiver are regularly supplied.
Listed price (range) and terms and suggested retail price	Depends on the product. Includes all handling charges, but shipping and insurance charges are extra. There is also a procurement charge based on a sliding scale according to the value of the order. Scales are agreed on with individual clients. Commitment to a long-term agreement can lower prices. Discounts are negotiated for higher value orders. These discounts depend on the suppliers' policy. For some items, the supplier has already negotiated favorable prices for CAs. To get a reduced price, clients can provide details of their annual (or longer if possible) spending, upon which long-term contracts can be negotiated to reflect the total value of the requirement.
Minimum order quantity	One kit
Minimum average shelf life on delivery	The minimum average shelf life depends on the product; the company tries to procure more recently manufactured products in order 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	Two to six weeks from order to shipment. Delivery depends on the client's requirements.
Payment method	Payment is usually required at the time of order; however, other options can be discussed.
Quality issues	Quality problems are resolved with a refund or a replacement.

## **International Dispensary Association**

### **International Supplier**

For further information, please contact:

*Ron Wehrens, Sales and Marketing Support*

*International Dispensary Association*

*P.O. Box 37098*

*1030 AB Amsterdam*

*The Netherlands*

*Tel: +31 20 4033051*

*Fax: +31 20 4031854*

*E-mail: [rwehrens@ida.nl](mailto:rwehrens@ida.nl)*

*Web site: <http://www.ida.nl>*

Information current as of December 2003

U.S. Government representatives can purchase kits directly from the supplier.

Product supplied	Determine™ HIV-1/2
Listed price (range) and terms and suggested retail price	89 euro per kit (100 tests) FOB, shipping and insurance extra. Prices are available in printed and electronic catalogs on request and on the company's Web site; prices apply to all customers. The company is a nonprofit wholesaler, and discounts for large quantities are in the range of 1 or 2 percent. IDA supplies only to nonprofit customers (e.g., nongovernmental organizations [NGOs], governments).
Minimum order quantity	One kit. There is an additional handling fee of 1.5 percent of the value of the goods, with a minimum of 45 euro.
Minimum average shelf life on delivery	12 months
Stock on hand	Stocks of Determine™ HIV-1/2 are kept low due to the test's short shelf life, but lead time is short (usually a matter of days).
Average time to fill an order	On average, orders leave IDA two or three weeks after order confirmation. In special cases, such as emergencies, the company can provide overnight deliveries. Goods are usually sent to a single address. The company also provides a courier service when several addresses need to be supplied in a country.
Payment method	Goods are usually shipped on receipt of payment. 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.

## **Missionpharma A/S**

### **International Procurement Agency**

For further information, please contact:

*Jens V. Rasmussen, Area Sales Manager*

*Missionpharma A/S*

*Vassingerødvej 9*

*DK-3540 Lynge, Denmark*

*Tel: +45 48 163200*

*Fax: +45 48 163248*

*E-mail: [jr@missionpharma.com](mailto:jr@missionpharma.com)*

*Web site: <http://www.missionpharma.com>*

Information current as of January 2002

U.S. Government representatives can purchase kits directly from the agency.

Products supplied	As a procurement agency, the company does not stock test kits; procurement is done on receipt of an order.
Listed price (range) and terms and suggested retail price	Varies according to the product; shipping charges are extra. A commitment to a long-term agreement can result in lower prices. Most prices include handling charges.
Minimum order quantity	One kit
Minimum average shelf life on delivery	Shelf life varies according to the product.
Stock on hand	Products are ordered on demand.
Average time to fill an order	Varies according to the manufacturer; usually one to two weeks
Payment method	30 days from invoice
Quality issues	No information was provided.
Additional delivery information	Goods are usually sent to a single address; however, the company may use a courier to deliver to multiple addresses in a country.

## **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 6360*

*Fax: +32 3 888 7481*

*E-mail: [info@orbi-pharma.be](mailto:info@orbi-pharma.be)*

*Web site: <http://users.online.be/orbipharma>*

*Information current as of November 2003*

U.S. Government representatives can purchase kits directly from the supplier.

Product supplied	Determine™ HIV-1/2
Listed price (range) and terms and suggested retail price	Price varies according to quantities ordered. One kit: 99.48 euro for 100 tests (ex-works).
Minimum order quantity	One kit
Minimum average shelf life on delivery	Six 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 product and quantity. Ordinary orders take two to four weeks.
Payment method	The preferred payment option is international bank transfer (SWIFT).
Quality issues	Kits with quality problems are recalled and replaced.

**Tri-Med Ltd.**

**International Procurement Agency**

For further information, please contact:

*Neville Vickers*

*Tri-Med Ltd.*

*7 Hanson Street*

*London W1W 6TE UK*

*Tel: +44 20 7637 1601*

*Fax: +44 207255 1000*

*E-mail: [vickers@tri-med.com](mailto:vickers@tri-med.com)*

*Web site: <http://www.tri-med.com>*

Information current as of January 2002

U.S. Government representatives can purchase kits directly from the agency.

Product(s) supplied	Bionor™ HIV-1&2, Determine™ HIV-1/2
Listed price (range) and terms and suggested retail price	Prices vary according to many factors—quantity ordered, customer, final destination, required delivery time, terms of payment—but there are no strict policies. The price of the Bionor™ HIV-1&2 is ex-works (shipping is extra) and includes handling charges. The price of the Determine™ HIV-1/2 is ex-warehouse (shipping is extra). Although prices are dependent on quantities supplied, there are no fixed discounts for particular quantities. For Bionor™ HIV-1&2, service charges are included in the price; for Determine™ HIV-1/2, the handling charge is USD 20 per order. An organization can get a cheaper price by buying in bulk and shipping by sea-freight.
Minimum order quantity	One kit
Minimum average shelf life on delivery	Bionor™ HIV-1&2: 10 months Determine™ HIV-1/2: No information provided
Stock on hand	Kits are ordered on demand. A small amount of stock is held.
Average time to fill an order	Three to four days if supplied from stock, three to four weeks if specially manufactured (for large orders).
Payment method	The preferred payment option is international bank transfer (SWIFT).
Quality issues	Kits with quality problems are recalled and replaced.



## **UNICEF**

For further information, please contact:

*Hélène Möller, Technical Officer*

*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](mailto:hmoller@unicef.org)*

*Web site: <http://www.unicef.org/supply/>*

*Information current as of January 2004*

The UNICEF Supply Division focuses on providing medicines for PMTCT. In 2002, UNICEF assisted 35 countries (in Africa, Asia, Central Europe, and Latin America) in procuring HIV test kits. Any developing country that requests this service from UNICEF will be provided with HIV test kits. UNICEF procurement is limited to those test kits that are accredited by WHO.

Products supplied	Capillus™ HIV-1/HIV-2, Determine™ HIV-1/2, Double Check™ HIV 1&2, Genie II HIV-1/HIV-2, and Uni-Gold™ HIV
Source of products	As a general rule, UNICEF purchases HIV test kits directly from the manufacturers. However, HIV test kits manufactured by Abbott Laboratories are available only through a South African distributor called Lucra Trading (this is the only exception).
Stock on hand	HIV test kits are procured as needed.
Storage information	Since HIV test kits often require refrigeration and have a short shelf life, the organization has a carefully managed supply planning scheme that involves reviewing order quantities and recommending split deliveries to ensure that countries receive fresh batches of supplies. Storage and distribution practice guidelines are strictly adhered to (e.g., kits are never shipped to arrive at their destination on a Friday afternoon).
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.
Payment method	Payment requirements are often country-, program-, or quantity-specific.
Quality issues	The standard procedure is for program and/or supply officers in the UNICEF Country Office to handle complaints. Complaints are then forwarded to quality assurance officers in the Supply Division. In the case of test kits, the whole supply chain will be investigated and the results will be reviewed (while taking into consideration the report from the quality assurance procedure).

## **World Health Organization**

For further information, please contact:

*Françoise Mas*

*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: [masf@who.int](mailto:masf@who.int)*

*Web site: <http://www.who.int/en/>*

Information current as of February 2004

In 1988, WHO's Global Program on AIDS started a program to assess commercially available HIV test kits.<sup>33</sup> The HIV Test Kit Bulk Procurement Scheme was set up in 1989 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 eventually be used. U.S. Government representatives can purchase kits directly from WHO.

Products supplied<sup>34</sup>

Bionor™ HIV-1&2, Capillus™ HIV-1/HIV-2, Determine™ HIV-1/2, Genie II HIV-1/HIV-2, Uni-Gold™ HIV

Listed price (range) and terms and suggested retail price

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.

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).

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<sup>33</sup> World Health Organization (WHO). 2002. *WHO HIV Test Kit—Bulk Procurement Scheme*. Flier. Geneva: WHO. <[http://www.who.int/bct/Main\\_areas\\_of\\_work/BTS/HIV\\_Diagnostics/Evaluation\\_reports/HIV%20Bulk%20PROC%20ENG.pdf](http://www.who.int/bct/Main_areas_of_work/BTS/HIV_Diagnostics/Evaluation_reports/HIV%20Bulk%20PROC%20ENG.pdf)> (accessed January 2004).

<sup>34</sup> All the HIV test kits available through the Bulk Procurement Scheme have been evaluated by WHO. The list of test kits procured is currently being revised, and new information should be available on the WHO Web site (<http://www.who.int/en/>) in the near future. (This information is based on personal communication with a representative of WHO Procurement Services in February 2004.)

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

How the purchase procedure works	<p>The Procurement Services division at WHO purchases the requested kits. Information required for purchase is—</p> <ul style="list-style-type: none"><li>• Name of the requesting program</li><li>• Contact person (name, telephone number)</li><li>• Test kit name and manufacturer</li><li>• Order code (which appears on the WHO Bulk Procurement List)</li><li>• Number of test kits required (indicate number of tests per kit where necessary)</li></ul> <p>This information should be submitted along with the request to—</p> <ul style="list-style-type: none"><li>• For Category A: WHO headquarters in Geneva or a WHO Regional Office</li><li>• For Category B: A WHO Regional Office, WHO Country Representative, or UNAIDS Representative</li><li>• For Category C: UNAIDS Representative or Ministry of Health</li></ul>
Average time to fill an order	No information available
Delivery information	WHO ships the goods to the airport of destination; the consignee is responsible for customs clearance and delivery of goods.
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.

**ANNEX 1: USAID SOURCE AND ORIGIN WAIVER  
FOR HIV TEST KITS**

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.

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

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>JH</u>	Date	<u>12/03/01</u>
A-DAA/GH: DGillespie	<u>DF</u>	Date	<u>12/03/01</u>
A-DAA/GH: Llion	<u>LL</u>	Date	<u>12/04/01</u>
<del>AA/PDS: BTUMER</del>		Date	
<del>AA/GH: HPeterson</del>		Date	

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

M096

DAA/M:RNygard	<u>RN</u>	Date	<u>12/8/11</u>
M/AA:DJohanson	<u>DJ</u>	Date	<u>12/6/01</u>

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

Tab 1 Approved List of Testing Kit Products and Manufacturers as of October 15, 2001<sup>35</sup>

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* <sup>36</sup>
Genie II	NA	France	Sanofi Diagnostics Pasteur* <sup>37</sup>
Hema-Strip	\$3.00	USA	Saliva Diagnostics, Ltd.*
HIV Spot <sup>38</sup>	\$1.20	Singapore	Genelabs Diagnostics*
HIVSav 1&2	NA	Israel	Sayvon Diagnostics Ltd.
MultiSpot <sup>39</sup>	\$4.00	France	Sanofi Diagnostics Pasteur <sup>39</sup>
Ora Quick HIV 1&2	NA	USA	OraSure Technologies <sup>40</sup>
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

<sup>35</sup> Changes that have been made to Tab 1 since its approval in October 2001 are indicated by footnotes 38–43.

<sup>36</sup> 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; however, the details were unable to be determined.

<sup>37</sup> Bio-Rad Laboratories acquired Sanofi Diagnostics Pasteur in 1999.

<sup>38</sup> The manufacture of this product has been discontinued by the company.

<sup>39</sup> A recent e-mail communication with a representative of Bio-Rad Laboratories indicated that the company has discontinued production of this product.

<sup>40</sup> 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. OraQuick tests were approved by the FDA on November 7, 2002.

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

[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 19<sup>th</sup> 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 19<sup>th</sup> 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



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

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.

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

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:

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

Tab 1 - Approved List of Testing Kit Products and  
Manufacturers

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

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

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

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 4/2-28-00.DOC

*20010428*

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

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, Vietnam, 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: DONATION PROGRAMS

### **Axios Foundation**

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Axios Foundation assists in the design of several donation and nonprofit programs for pharmaceutical companies that are willing to contribute to improving the health care of people in developing countries. Axios is also responsible for managing these programs for the companies. There are six donation programs in the Foundation's portfolio. The HIV test kit donation program managed by Axios is the Determine™ HIV-1/2 Testing Donation Program on behalf of Abbott Laboratories.

Specific Web sites have been designed to enable access to information, answers to questions, and online application requests. Completed application forms are reviewed by independent experts in the field who advise on whether to approve, request additional information, or refer the applicant to an institution that can help improve the request. Once the donation has been received, the Axios administrator maintains communication with the programs to monitor achievements and ensure the renewal and resupply of the donation.

The donation or nonprofit programs designed and administered by Axios currently include—

- The Viramune® and Determine™ Donation Programs for PMTCT. The programs offer Viramune® and Determine™ HIV-1/2 free of charge to developing countries for prevention of mother-to-child transmission of HIV-1. Axios is administering the program on behalf of Boehringer-Ingelheim and Abbott Laboratories (see [www.pmtctdonations.org](http://www.pmtctdonations.org)).
- Access to HIV Care. The program offers Determine™ HIV-1/2 tests at no profit to Abbott and two antiretrovirals (Norvir® and Kaletra™) below cost. Axios is managing the program on behalf of Abbott Laboratories (see [www.AccessstoHIVCare.org](http://www.AccessstoHIVCare.org)).

