Capillus HIV-1/HIV-2 Rapid Test Kit

**Kit Contents**
- Latex reagent (4 ml or 2 x 6.3 ml)
- Positive control (0.4 ml)
- Negative control (0.4 ml)
- 20/100 disposable pipette tips
- 1 pipette
- 1 Interpretation station

**Percent Accuracy**
- Sensitivity: 98.6–99.9%
- Specificity: 98.2–99.6%

**Types of Samples**
- Serum, plasma, or whole blood

**Run Time of Test**
- 7 minutes

**Packaging Information**
- 100 tests per kit
- 30 kits per carton of 100 tests (3,000 tests)

**Test Kit Package**
- Dimensions: 7.8 x 13.5 x 22 cm
- Volume: 2,316.6 cm³
- Weight: 550g

**Shipping Carton**
- Dimensions: 7.8 x 13.5 x 22 cm
- Volume: 69,498 cm³
- Weight: 16.5 kg

**Storage Conditions**
- Storage temperature: 2–8°C
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

**Shelf Life and Disposal**
- Shelf life: 9–12 months
- Disposal Methods:
  - Autoclave @ 121°C for 60 minutes
  - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

**Brand and Manufacturer**
- Capillus HIV-1/HIV-2 Rapid Test Kit
- Trinity Biotech
  - P.O. Box 1059
  - Jamestown, NY 04702-1059
  - USA
  - Tel: +1 716-483-3851
  - Fax: +1 716-488-1990
  - www.trinitybiotech.com

**Quality Control**
- The positive and negative controls should be run at least once per test day.

**Indicators of Potential Quality Problems**
- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer’s name; lot and batch numbers; and expiration and/or manufacturer’s date)
- Missing contents
- Leakage or stains
- Improper storage conditions

**Materials Required but Not Provided**
- Disposable gloves
- Biohazard discard bags
- Blood collection devices

**Estimated Price**
- Approximately U.S.$1.10–2.79 per test
- Price varies according to the quantity being procured.

February 2003
DETERMINE HIV–1/2 RAPID TEST KIT

Brand and Manufacturer

Abbott Laboratories
Diagnostics Division
100 Abbott Park Road
Abbott Park, IL  60064-3500
USA
Tel: +1 847-937-6100
www.abbott.com

Kit Contents

- 100 tests per card
- Serum/plasma assay contains 10 cards
- Whole blood assay contains 10 cards and 1 bottle of chase buffer (2.5 ml)

Percent Accuracy

- Sensitivity: 97.9–100%
- Specificity: 100%

Types of Samples

- Serum/plasma kit
- Whole blood kit

Run Time of Test

- 15 minutes

Packaging Information

- 100 tests per kit
- Kits of 20 tests are available in some countries.

Test Kit Package

Dimensions: 27 x 16 x 1 cm
Volume: 432 cm³
Weight: 500 g

Shipping Carton

There is no standard shipping carton. The quantity is tailored to the customer’s needs.
Volume: 432 cm³ x number of kits
Weight: 500 g x number of kits

Storage Conditions

- Storage temperature: 2–30°C
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.
- Kit components are stable until expiration date.

Shelf Life and Disposal

- Shelf life: 12–18 months

- Disposal Methods:
  - Autoclave @121°C for 60 minutes
  - Incinerate

- Dispose of all specimens, used devices, and pipettes as though they are capable of transmitting infection.

Quality Control

A procedural control is incorporated in the device. If the control bar does not turn red by assay completion, the test result is invalid and the sample should be retested.

Indicators of Potential Quality Problems

- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Protective wrappers torn or discolored
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer’s name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage
- Improper storage conditions

Materials Required but Not Provided

- Serum/Plasma Assay
  - Pipette
  - Pipette tips
- Whole Blood Assay
  - Lancets
  - EDTA capillary tubes

Estimated Price

- Approximately U.S.$1.20–1.50 per test
- The price varies according to the quantity being procured.

July 2002
**DoubleCheck HIV 1&2 Rapid Test Kit**

**Brand and Manufacturer**
- **DoubleCheck HIV 1&2 Rapid Test Kit**
- **Orgenics Ltd.**
  - North Industrial Zone
  - POB 360, 70650
  - Yavne, Israel
  - Tel: 972-8-9429201
  - Fax: 972-8-9438758
  - www.orgenics.com

**Kit Contents**
- 40 test devices
- 42 disposable pipettes
- 42 microtubes
- 1 bottle specimen diluent (5 ml)
- 1 bottle HIV antigens (15 ml)
- 1 bottle conjugate (5 ml)
- 1 bottle chromogenic substrate (50 ml)
- 1 bottle DoubleCheck Enhancer (5 ml)
- 1 bottle stop solution (50 ml)
- 1 vial positive control (1.5 ml)
- 1 vial negative control (1.5 ml)

**Percent Accuracy**
- Sensitivity: 100%
- Specificity: 99.3–100%

**Types of Samples**
- Serum and plasma

**Run Time of Test**
- 10 minutes

**Packaging Information**
- 40 tests per kit
- 18 kits per carton (720 tests)

**Test Kit Package**
- Dimensions: 26 x 19 x 14 cm
- Volume: 6,916 cm³
- Weight: 0.8 g

**Shipping Carton**
- Dimensions: 59 x 45 x 54 cm
- Volume: 143,370 cm³
- Weight: approximately 14.4 kg

**Storage Conditions**
- Storage temperature: 4–8°C
- Do not freeze.
- Do not store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.
- Kit components are stable until expiration date.

**Shelf Life and Disposal**
- Shelf life: 12–15 months
- Dispose in a biohazardous waste container.
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

**Materials Required but Not Provided**
- Biohazard waste containers
- Timer or stopwatch
- Disposable gloves

**Estimated Price**
- Approximately U.S.$1.35 per test
- Price varies according to the quantity being procured.

Indicators of Potential Quality Problems
- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer’s name; lot and batch numbers; and expiration and/or manufacturer’s date)
- Missing contents
- Leakage or stains
- Improper storage conditions

July 2002
**Enzygnost Anti-HIV 1/2 Plus: ELISA Test Kit**

### Brands and Manufacturer
- **Enzygnost Anti-HIV 1/2 Plus**
- **Dade Behring Inc.**
  1717 Deerfield Rd.
  Deerfield, Illinois 60015 USA
  Tel: +1 847-267-5300
  Fax: +1 847-267-1066
  www.dadebehring.com

### Kit Contents
- Kits of 192 tests contain 2 plates of 96 tests.
- Kits of 960 tests contain 10 plates of 96 tests.
- Kits of 960 tests contain:
  - Test plates
  - HIV Ag/POD conjugate
  - Sample buffer
  - Control serum, positive
  - Control serum, negative
  - Washing solution
  - Buffer substrate
  - Chromogen
  - Stopping solution
  - Adhesive foils
  - Polyethylene bag
- Enzygnost TMB reagent supplies are not included with the 192 test kit, and need to be ordered separately. The reagent kit includes washing solution, buffer/substrate, chromogen, and stopping solution. One reagent kit is sufficient for 4 kits of 192 tests.

### Sensitivity
- Sensitivity: 99.6–100%

### Specificity
- Specificity: 98.7–100%

### Types of Samples
- Serum and plasma (must separate from whole blood)

### Run Time of Test
- 30 minutes

### Packaging Information
- 192 or 960 tests per kit
- 25 kits per carton

### Test Kit Package
**Dimensions:**
- 18 x 17.5 x 11.5 cm (192 tests)
- 18 x 17.5 x 11.5 cm (960 tests)
**Volume:**
- 3,622.5 cm³ (192 tests)
- 18,112.5 cm³ (960 tests)
**Weight:**

### Shipping Carton
**Dimensions:**

**Volume:**

**Weight:**

### Storage Conditions
- Storage temperature: 2–8°C
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.
- Kit components are stable until expiration date.

### Shelf Life and Disposal
- Shelf life: 5 months
- Disposal Methods:
  - Autoclave @ 121°C for 60 minutes
  - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

### Materials Required but Not Provided
- Piston-type pipettes (25, 100, and 1000 µL)

### Quality Control
- 6 per test run

### Indicators of Potential Quality Problems
- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage
- Improper storage conditions

### Estimated Price
- Approximately U.S.$0.45–0.80 per test
- Price varies according to the quantity being procured.
**Genie II HIV1/HIV2**

**Brand and Manufacturer**
- **Genie II HIV1/HIV2 Rapid Enzyme Immunoassay**
- **Bio-Rad Laboratories**
  Clinical Diagnostics
  4000 Alfred Nobel Drive
  Hercules, CA 94547 USA
  Tel: 1-800-2-BIORAD
  Fax: +1 510-741-6373
  www.bio-rad.com

**Packaging Information**
- 40 tests per kit

**Test Kit Package**
- **Dimensions:** 26 x 18.5 x 14 cm
- **Volume:** 6,700 cm³
- **Weight:** 1.01 kg

**Shipping Carton**
- No standard carton. Carton size will be chosen depending on the number of kits to delivered.

**Quality Control**
- Internal control spot for validation of the test procedure.
- Positive and negative controls for validation of an assay series.
- Run the positive and negative controls provided with the kit each day the test is performed, and/or when a new kit number is used.

**Indicators of Potential Quality Problems**
- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacturer's date)
- Missing contents
- Leakage or stains
- Improper storage conditions

**Materials Required but Not Provided**
- Disposable gloves

**Estimated Price**
- Approximately U.S.$3.00–5.00 per test
- Price varies according to the quantity being procured.

**Kit Contents**
- 40 Genie II HIV-1/HIV-2 Reaction Devices
- 42 microtubes for diluting specimens
- 1 bottle specimen diluent (7 ml)
- 1 bottle Streptavidin/AP conjugate (7 ml)
- 1 bottle washing solution (50 ml)
- 1 bottle chromogenic substrate (5 ml)
- 1 bottle stop solution (50 ml)
- 1 vial positive control (0.5 ml)
- 1 vial negative control (0.5 ml)

**Percent Accuracy**
- **Sensitivity:** 97.8–100%
- **Specificity:** 99.7–100%

**Types of Samples**
- Serum or plasma

**Run Time of Test**
- 10 minutes

**Storage Conditions**
- Storage temperature: 2–8°C
- Do not freeze test kits.
- Prior to testing bring all reagents, reaction devices, and samples to room temperature (3 hours at 22–26°C or 15 minutes at 37°C).
- After testing, return remaining control solutions, reagents, and the instructions for use to the original kit box and return to cold storage (2–8°C).
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

**Shelf Life and Disposal**
- Shelf life: 12 months
- Dispose in a biohazardous waste container.
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.
**Hema-Strip HIV-1/2 Rapid Test Kit**

<table>
<thead>
<tr>
<th>Brand and Manufacturer</th>
<th>Packaging Information</th>
<th>Quality Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hema-Strip HIV-1/2 Rapid Test Kit</strong></td>
<td>25 pouches and 1 product insert per kit</td>
<td>A pink/purple colored line should always appear in the control area if the test has been performed correctly and the device is working properly. It serves as an internal procedural control. A clear background in the test area is an internal negative procedural control.</td>
</tr>
<tr>
<td><strong>Saliva Diagnostics Systems (SDS)</strong></td>
<td>25 kits per carton (625 tests)</td>
<td></td>
</tr>
<tr>
<td>3661 Horseblock Road</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suite E</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medford, NY 11763 USA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tel: +1 917-853-6440</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: +1 212-937-3801</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email: <a href="mailto:info@salv.com">info@salv.com</a></td>
<td></td>
<td></td>
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<tr>
<td><a href="http://www.salv.com">www.salv.com</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kit Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each pouch contains:</td>
</tr>
<tr>
<td>- 1 sampler with a test strip</td>
</tr>
<tr>
<td>- 1 buffer vial attached to a sampler</td>
</tr>
<tr>
<td>- 1 lancet</td>
</tr>
<tr>
<td>- 1 bandage</td>
</tr>
<tr>
<td>- 1 desiccant (drying agent)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Percent Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity:</strong> 99.2%</td>
</tr>
<tr>
<td><strong>Specificity:</strong> 100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Types of Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum, plasma, or whole blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Run Time of Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 minutes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Storage temperature:</strong> 20–33°C</td>
</tr>
<tr>
<td>If the test is stored below 20°C it should be allowed to come to room temperature prior to use.</td>
</tr>
<tr>
<td>Store away from extreme heat.</td>
</tr>
<tr>
<td>Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.</td>
</tr>
<tr>
<td>Expiration date is based on ideal storage conditions.</td>
</tr>
<tr>
<td>DO NOT use any component after expiry date.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shelf Life and Disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shelf life:</strong> 15 months</td>
</tr>
<tr>
<td>Disposal Methods:</td>
</tr>
<tr>
<td>- Autoclave @121°C for 60 minutes</td>
</tr>
<tr>
<td>- Incinerate</td>
</tr>
<tr>
<td>Dispose of all specimens, used devices, and pipettes, as though they could transmit infection.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indicators of Potential Quality Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical damage to shipping carton, inner box, or test kits</td>
</tr>
<tr>
<td>Presence of foreign matter inside unit package</td>
</tr>
<tr>
<td>Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer’s name; lot and batch numbers; and expiration and/or date of manufacture)</td>
</tr>
<tr>
<td>Missing contents</td>
</tr>
<tr>
<td>Leakage or stains</td>
</tr>
<tr>
<td>Improper storage conditions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Materials Required but Not Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 clock, watch, or other timing device</td>
</tr>
<tr>
<td>Rack for holding buffer vials upright</td>
</tr>
<tr>
<td>Lab pipette to deliver 2.5µL sample (for serum and plasma samples only)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Estimated Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approximately U.S.$3.00 per test</td>
</tr>
<tr>
<td>Price varies according to the quantity being procured.</td>
</tr>
</tbody>
</table>
**MedMira MiraWell Rapid HIV Test Kit**

### Brand and Manufacturer
- **MedMira MiraWell Rapid HIV Test Kit**
- **MedMira Inc.**
  155 Chain Lake Drive, Suite 1
  Halifax, Nova Scotia B3S 1B3
  Canada
  Tel: 1+902-450-1588
  Fax: 1+902-450-1580
  www.medmira.ca

### Packaging Information
- 50 tests per kit
- 10 kits per carton (500 tests)

### Test Kit Package
- **Dimensions:** 37.5 x 28.8 x 10 cm
- **Volume:** 10,800 cm³
- **Weight:** 1.05 kg

### Shipping Carton
- **Dimensions:** 55 x 37.5 x 50 cm
- **Volume:** 103,125 cm³
- **Weight:** 10.55 kg

### Storage Conditions
- **Storage temperature:** 2–30°C
- **Do not freeze.**
- **Keep test components in sealed pouches until ready to be used.**
- **Store in a dry area protected from direct sunlight, heat, and moisture.**
- **Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.**
- **Expiration date is based on ideal storage conditions.**
- **DO NOT use any component after expiry date.**
- **Kit components are stable until expiration date.**

### Shelf Life and Disposal
- **Shelf life:** 12 months
- **Disposal Methods:**
  - Autoclave @121°C for 60 minutes
  - Incinerate
- **Dispose of all specimens, used devices, and pipettes as though they could transmit infection.**

### Estimated Price
- **U.S.$10.00 per test (30% discount for end-users in developing countries).**
- **Price varies according to the quantity being procured.**

### Indicators of Potential Quality Problems
- **Physical damage to shipping carton, inner box, or test kits**
- **Presence of foreign matter inside unit package**
- **Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer’s name; lot and batch numbers; and expiration and/or manufacturer’s date)**
- **Missing contents**
- **Leakage or stains**
- **Improper storage conditions**

### Materials Required but Not Provided
- **Disposable gloves**
- **Biohazard waste disposal bags**
- **Disinfectant solution**
- **Discard container**
- **Centrifuge (for serum/plasma preparation)**

### Quality Control
- **Each test result is validated by an internal control.**
- **Additionally, one set of controls is recommended for every 10 tests done. However, if testing more than 50 specimens per session, controls should be run at least twice for each of the 50-test packs used.**

### Percent Accuracy
- **Sensitivity:** 99.75–100%
- **Specificity:** 99.31%

### Types of Samples
- Serum, plasma, and whole blood

### Run Time of Test
- 3 minutes

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**MedMira MiraWell Rapid HIV Test Kit**

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**MedMira Inc.**
155 Chain Lake Drive, Suite 1
Halifax, Nova Scotia B3S 1B3
Canada
Tel: 1+902-450-1588
Fax: 1+902-450-1580
www.medmira.ca

---

**The test kit is available in two formats: one for serum/plasma specimens and another for whole blood specimens.**

Each test kit contains:

- 1 large foil pack containing 50 test cartridges. (Cartridges for the whole blood test format contain a pre-fitted filter unit for whole blood separation.)
- 1 small foil pack containing 50 colloidal gold-protein A conjugate caps.
- 30 ml squeeze bottle of Universal Buffer solution.
- 50 disposable transfer pipettes.
- 200 µ positive control.
- 200 µ negative control.

---

**Sensitivity:** 99.75–100%
**Specificity:** 99.31%

---

**Serum, plasma, and whole blood**

---

**3 minutes**

---

**Disposal Methods:**
- Autoclave @121°C for 60 minutes
- Incinerate

---

May 2003
# Multispot HIV-1/HIV-2 Rapid Test Kit

## Brand and Manufacturer
- **Multispot HIV-1/HIV-2 Rapid Test Kit**
- **Bio-Rad Laboratories**
  Clinical Diagnostics
  4000 Alfred Nobel Drive
  Hercules, CA 94547 USA
  Tel: 1-800-2-BIORAD
  Fax: +1 510-741-6373
  www.bio-rad.com

## Kit Contents
- 1 test cartridge (50 tests)
- 1 bottle positive control (1 ml)
- 1 bottle negative control (1 ml)
- 1 bottle specimen diluent (25 ml)
- 1 bottle conjugate reagent (9.5 ml)
- 2 bottles wash solution (2 x 85 ml)
- 1 bottle development reagent (8.5 ml)
- 1 bottle stop solution (55 ml)
- 50 disposable transfer pipettes

## Percent Accuracy
- Sensitivity: 99.3–100%
- Specificity: 98.5–100%

## Types of Samples
- Serum or plasma

## Run Time of Test
- 10 minutes

## Packaging Information
- 50 tests per kit

## Test Kit Package
### Dimensions:
- 14.5 x 20.4 x 19.5 cm
### Volume:
- 5,768 cm³
### Weight:
- 1.265 kg

## Shipping Carton
### Dimensions:
- **Volume:**
- **Weight:**

## Storage Conditions
- Storage temperature: 2°–8°C
- Bring all reagents and test components to room temperature (20–30°C) before use. Return the entire kit to 2–8°C when not in use.
- Do not freeze test components.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

## Shelf Life and Disposal
- **Shelf life:** 12 months
- **Disposal Methods:**
  - Autoclave @121°C for 60 minutes
  - Disposable materials may be incinerated.
  - Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

## Quality Control
- The positive and negative control provided with the kit should be run each day the test is performed and/or when a new kit lot number is used.

## Indicators of Potential Quality Problems
- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing or illegible labeling (especially product, brand, or manufacturer’s name; lot and batch numbers; and expiration and/or manufacturer's date)
- Missing contents
- Leakage or stains
- Improper storage conditions

## Materials Required but Not Provided
- Disposable glass or plastic test tubes to prepare diluted specimens (ex. twelve 75 mm tubes)
- Test tube racks
- Absorbent pads or paper towels
- Biohazard bags with closures
- Bleach or other disinfectant
- Disposable gloves

## Estimated Price
- Approximately U.S.$4.00 per test
- Price varies according to the quantity being procured.

---

**John Snow, Inc.**

1616 N. Fort Myer Drive
11th Floor
Arlington, Virginia 22209 USA
Tel: 703-528-7474
Fax: 703-528-7480
Web: deliver.jsi.com

August 2002

Funded by USAID
OraQuick Rapid HIV–1 Antibody Test

**Brand and Manufacturer**
- OraQuick® Rapid HIV–1 Antibody Test
- OraSure Technologies, Inc.
  150 Webster Street
  Bethlehem, PA 18015 USA
  Tel: +1 800-869-3538
  Fax: +1 610-882-2275
  www.orasure.com

**Kit Contents**
- The 100 test kit contains 100 test devices, 105 loops, 10 test stands, 1 product insert, 100 information pamphlets, and 1 customer letter.
- The 25 test kit contains 25 test devices, 30 loops, 6 test stands, 1 product insert, 25 information pamphlets, and 1 customer letter.
- Test kit controls are required to conduct the test and are available separately. The positive and negative controls are packaged in 0.2 mL vials.

**Percent Accuracy**
- Sensitivity: 99.6%
- Specificity: 100%

**Type(s) of Samples**
- Fingerstick whole blood

**Run Time of Test**
- 20 minutes

**Packaging Information**
- Tests are packaged in individual pouches. Each pouch contains one test.
- Tests are available in quantities of 25 and 100.

**Test Kit Package**
- Dimensions: 15.2 x 16.5 cm
- Weight: 17 g

**Shipping Carton**
- Dimensions: 41 x 31 x 23 cm (100 tests) 31 x 23 x 15 cm (25 tests)
- Volume: 29,223 cm³ (100 tests) 10,695 cm³ (25 tests)
- Weight: 2.54 kg (100 tests) 0.907 kg (25 tests)

**Storage Conditions**
- Storage temperature: 2–27°C
- If the test is refrigerated, ensure that the pouch is brought to ambient temperature (15–27°C) before opening.
- Do not open the pouch until you are ready to perform a test.
- Store away from extreme heat. Do not store close to radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

**Shelf Life and Disposal**
- Shelf life: 7 months
- Dispose of in a biohazardous waste container.
- Dispose of all specimens, used devices, and pipettes, as though they could transmit infection.

**Indicators of Potential Quality Problems**
- A control line in the ‘C’ area of the result window indicates a valid result. The control line will appear on all valid tests, whether or not the result is reactive.
- Kit controls should be run once per shift and whenever changing to a different lot of tests.
- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacturer's date)
- Missing contents
- Leakage or stains
- Improper storage conditions

**Materials Required but Not Provided**
- Timer or watch
- Antiseptic wipes
- Sterile lancets
- Sterile gauze pads
- Disposable gloves
- Biohazard disposal container

**Estimated Price**
- U.S.$3.00/test for bulk purchases outside the U.S.
- Prices will vary according to the quantity being procured.

Note: OraQuick was approved by the FDA in November 2002. This fact sheet contains the current specifications of the FDA approved product. Prior to FDA approval, OraQuick was sold with different specifications for shelf life and types of samples. It is expected that specifications of the FDA approved product will be expanded as the results of ongoing tests are confirmed.
SEROCARD HIV RAPID TEST KIT

Brand and Manufacturer
- SeroCard HIV Rapid Test Kit
- Trinity Biotech
  P.O. Box 1059
  Jamestown, NY 04702-1059
  USA
  Tel: +1 716-483-3851
  Fax: +1 716-488-1990
  www.trinitybiotech.com

Kit Contents
- 20 packages, each containing 2 test cards (40 tests)
- Enzyme conjugate reagent (5 ml)
- BCIP substrate reagent (8 ml)
- Wash reagent (24 ml)
- 40 disposable pipettes

Percent Accuracy
- Sensitivity: 99.8–100%
- Specificity: 97.9–99.5%

Types of Samples
- Whole blood, serum, or plasma

Run Time of Test
- 5 minutes

Packaging Information
- 40 tests per kit

Test Kit Package
- Dimensions:
  - Volume: cm³
  - Weight:

Shipping Carton
- Dimensions:
  - Volume: cm³
  - Weight:

Storage Conditions
- Storage temperature: 2–8°C
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.
- Kit components are stable until expiration date.

Shelf Life and Disposal
- Shelf life: 9 months
- Disposal Methods:
  - Autoclave @ 121°C for 60 minutes
  - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

Quality Control
- The SeroCard assay has a non-specific binding reaction port to confirm that only HIV specific antibodies are present.

Indicators of Potential Quality Problems
- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Protective wrappers torn or discolored
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer’s name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage
- Improper storage conditions

Materials Required but Not Provided
- Timer or stopwatch
- Blood collection devices

Estimated Price
- Approximately U.S.$1.80
- Price varies according to the quantity being procured.
**Uni-gold HIV Test**

### Brand and Manufacturer
- Uni-Gold HIV Rapid Test Kit
- Trinity Biotech
  P.O. Box 1059
  Jamestown, NY 04702-1059
  USA
  Tel: +1 716-483-3851
  Fax: +1 716-488-1990
  www.trinitybiotech.com

### Kit Contents
- 20 test devices
- Wash reagent (2 ml)
- 20 disposable pipettes
- 1 package insert

### Packaging Information
- 20 tests per kit
- 100 or 150 kits per carton (2,000 or 3,000 tests)

### Test Kit Package
- Dimensions: 23 x 14 x 10.5 cm
- Volume: 3,381 cm³
- Weight: approximately 300 g

### Shipping Carton
- Dimensions:
  - 120 x 80 x 60 cm (100 kits)
  - 120 x 80 x 80 cm (150 kits)
- Volume:
  - 576,000 cm³ (100 kits)
  - 768,000 cm³ (150 kits)
- Weight:

### Quality Control
- A built-in procedural control on the test device indicates that the test is functioning correctly. A pink/red band should always appear in the control window.

### Indicators of Potential Quality Problems
- The presence of foreign matter inside unit package
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Physical damage to shipping carton, inner box, or test kits
- Missing contents
- Leakage
- Improper storage conditions

### Materials Required but Not Provided
- Timer or stopwatch
- Blood collection devices (i.e., lancets, capillary tubes/test tubes)

### Estimated Price
- Approximately U.S.$1.15–2.25 per test

### Materials Required but Not Provided
- Price varies according to the quantity being procured.

### Percent Accuracy
- Sensitivity: 99.6–100%
- Specificity: 98.7–100%

### Types of Samples
- Serum, plasma, or whole blood

### Run Time of Test
- 10 minutes

### Storage Conditions
- Storage temperature: 2–27°C
- Store away from extreme heat.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

### Shelf Life and Disposal
- Shelf life: 9–12 months
- Disposal Methods:
  - Autoclave @ 121°C for 60 minutes
  - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

### Estimated Price
- Approximately U.S.$1.15–2.25 per test

### Estimated Price
- Price varies according to the quantity being procured.

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May 2002
# Vironostika HIV Uni-Form II Plus O: ELISA Test Kit

## Brand and Manufacturer
- **Vironostika HIV Uni-Form II Plus O**
- **BioMérieux**
  - 69280 Marcy l’Étoile
  - France
  - Tel: +33 (0) 47-887-2000
  - Fax: +33 (0) 47-887-2090
  - [www.biomerieux.com](http://www.biomerieux.com)

## Packaging Information
- 192 or 576 tests per kit

## Quality Control
- 4–5 per test run

## Test Kit Package
### Dimensions:
- 27 x 23.5 x 6.6 cm  (192 tests)
- 27 x 23.5 x 9.6 cm  (576 tests)
### Volume:
- 3,948 cm³  (192 tests)
- 6,027.75 cm³  (576 tests)

## Shipping Carton
### Dimensions:
- Weight:

## Storage Conditions
- Storage temperature: 2–8°C
- Allow the reagents, samples, and foil test pack to come to room temperature (18–25°C) before testing.
- Do not store for prolonged periods or close to hot radiator, motor, or other source of heat.
- Expiration date is based on ideal storage conditions.
- Do NOT use any component after expiry date.

## Materials Required but Not Provided
- Washer
- Incubator
- Vortex mixer
- Microshaker
- Spectrophotometric reader
- Dispensing system and/or disposable tip pipettes
- Distilled/deionized water
- Sulfuric acid
- Disinfectant
- Absorbent tissue
- Disposable gloves
- Timer
- Reagent trough
- Disposable vial
- Biohazard waste containers

## Estimated Price
- Approximately U.S.$0.75–1.56 per test
- Price varies depending on the quantity being procured.

## Indicators of Potential Quality Problems
- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer’s name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage
- Improper storage conditions

## Types of Samples
- Serum and plasma

## Run Time of Test
- 2 hours and 4 minutes

## Shelf Life and Disposal
- **Shelf life: 12 months**
- **Disposal Methods:**
  - Autoclave @ 121°C for 60 minutes
  - Incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection.

## Percent Accuracy
- Sensitivity: 99.6–100%
- Specificity: 97.6–100%

## Indicators of Potential Quality Problems
- Physical damage to shipping carton, inner box, or test kits
- Presence of foreign matter inside unit package
- Labeling incorrect, missing, or illegible (especially product, brand, or manufacturer’s name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage
- Improper storage conditions

## Materials Required but Not Provided
- Washer
- Incubator
- Vortex mixer
- Microshaker
- Spectrophotometric reader
- Dispensing system and/or disposable tip pipettes
- Distilled/deionized water
- Sulfuric acid
- Disinfectant
- Absorbent tissue
- Disposable gloves
- Timer
- Reagent trough
- Disposable vial
- Biohazard waste containers

## Estimated Price
- Approximately U.S.$0.75–1.56 per test
- Price varies depending on the quantity being procured.