



LOGISTICS FACT SHEETS:

HIV TEST KITS



JULY 2008

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LOGISTICS FACT SHEETS:

HIV TEST KITS

USAID | DELIVER PROJECT, Task Order 1

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Abstract

The HIV fact sheets include information critical to the selection, forecasting, procurement, and inventory management of the 16 brands of HIV tests.

USAID | DELIVER PROJECT

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HIV TEST KIT FACT SHEET

AWARE™ HIV-1/2 BSP TEST (RAPID TEST KIT)

MANUFACTURER

Calypte Biomedical Corporation
5 CentrepoinTE Drive
Lake Oswego OR 97035
Tel: +1 971 204 0282
Fax: +1 971 204 0284
www.calypte.com

KIT CONTENTS

- The 25 test kit contains 25 foil pouches, 25 Specimen Collection Loops, 25 Specimen Dilution Tubes.
- The 50 test kit contains 50 foil pouches, 50 Specimen Collection Loops, 50 Specimen Dilution Tubes.
- Both contain 2 dropper bottles of Blood Sample Buffer (5ml each),
- Each foil pouch contains one device (assay test strip), and a dessicant.

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 100%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 20 minutes
- Do not interpret the result after 45 minutes of beginning test.

PACKAGING INFORMATION

- 25 or 50 tests per kit

TEST KIT PACKAGE

- 25 tests per kit:
- Dimensions: 14 x 14 x 10 cm
 - Volume: 1,960 cm³
 - Weight: 400 g

50 tests per kit

- Dimensions: 14 x 18 x 13 cm
- Volume: 3,276 cm³
- Weight: 700 g

SHIPPING CARTON

25 tests per kit, 20 kits per carton:

- Dimension = 45 x 55 x 45 cm
- Volume = 111,375 cm³
- Weight = 9.4 kg
- 50 tests per kit, 18 kits per carton
- Dimension = 45 x 55 x 45 cm
- Volume = 111,375 cm³
- Weight = 14 kg

STORAGE CONDITIONS

- Storage temperature: 2–30°C (36–86°F)
- Do not open the foil pouch containing assay test strip until you are ready to perform test.
- Do not store for prolonged periods; or close to hot radiator, motor, or other source of heat.
- Do not freeze the test kits or reagents.
- Expiration date is based on ideal storage conditions.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- Shelf life: 18 months
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- A procedural control is incorporated in the device. A control line in the Control Zone indicates a valid result. If the control line does not appear in the Control Zone, the test result is invalid, and the sample should be retested.
- Positive and negative kit controls should be run at the beginning of each shift. They should also be run whenever changing to a different lot of tests, or whenever testing conditions change (e.g., new location, lighting, temperature, etc.).

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 manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- Watch or timer
- Sterile lancet or blood collection system
- Antiseptic wipe
- Sterile gauze pads
- Disposable gloves
- Biohazard disposal container

- Calypste® Aware™ HIV-1/2 BSP controls are sold separately.

ESTIMATED PRICE

- Approximately U.S.\$1.30–1.70 per test
- Price varies depending on the quantity being procured.

REGULATORY AGENCY APPROVAL

- Kenya, Malaysia, South Africa, Uganda, Zimbabwe

HIV TEST KIT FACT SHEET

BUNDI™ HIV-1/2 (RAPID TEST KIT)

MANUFACTURER

Bundi International Diagnostics Ltd.
157 Cameroun Rd, Aba, Abia State, Nigeria.
Tel: + 234 822 323 94 ,+234 82 501700
Fax: + 234 822 32406

KIT CONTENTS

- Test cassettes in sealed pouch
- Plastic 20 µL pipette
- Bottled buffer solution
- Safety lancet (available in the single kits only)
- Sterile alcohol wipe (available in the single kits only)

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.5%

TYPES OF SAMPLES

Serum, plasma, or whole blood

RUN TIME OF TEST

- 10 minutes
- Do not interpret the result after 20 minutes.

PACKAGING INFORMATION

- 1 or 25 tests per kit

TEST KIT PACKAGE

- 1 test per kit:
- Dimensions: 14 x 8.5 x 2 cm
- Volume: 238 cm³
- Weight: 50 g

25 tests per kit with all kit contents:

- Dimensions: 24 x 13 x 7 cm
- Volume: 2,184 cm³
- Weight: 430 g

SHIPPING CARTON

- Dimensions 47 x 37 x 32.5cm
- Volume: 56,517.5 cm³
- Weight: 840 g x number of kits

STORAGE CONDITIONS

- Storage temperature: 4–30°C
- Store away from extreme heat.
- Do not store for prolonged periods; or close to hot radiator, motor, or other source of heat.
- Do not freeze the test kits or reagents.
- Expiration date is based on ideal storage conditions.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- Shelf life: 18 months
- Disposal methods:
 - Autoclave @121°C for 60 minutes
 - Incinerate
 - Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

A procedural control is incorporated in the device. If a red control bar does not appear in the

control region “C” on 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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- None

ESTIMATED PRICE

- Approximately U.S.\$1.50–2.50 per test
- Price varies depending on the quantity being procured.

REGULATORY AGENCY APPROVAL

- Nigeria (NAFDAC)

HIV TEST KIT FACT SHEET

CAPILLUS™ HIV-1/HIV-2 (RAPID TEST KIT)

MANUFACTURER

Trinity Biotech plc (Headquarters)
IDA Business Park
Bray, Co. Wicklow, Ireland
Tel: +353 1-276-9800
Fax: +353 1-276-9888
Free phone: +1800 603 8076
www.trinitybiotech.com

KIT CONTENTS

- Latex reagent (2 x 6.3 mL)
- Positive control (0.4 mL)
- Negative control (0.4 mL)
- 100 plastic slides
- 100 disposable pipette tips
- 1 pipette
- 1 interpretation station
- 1 package insert

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.7%

TYPES OF SAMPLES

Serum, plasma, or whole blood

RUN TIME OF TEST

- 3–7 minutes

PACKAGING INFORMATION

- 100 tests per kit
- Up to 196 kits per shipping carton (19,600 tests)

TEST KIT PACKAGE

- Dimensions: 22 x 14 x 8 cm
- Volume: 2,464 cm³
- Weight: 500 g

SHIPPING CARTON

Size of carton is tailored to the number of kits ordered. Maximum carton size holds 196 kits.

- Dimensions: 120 x 80 x 80 cm
- Volume: 768,000 cm³
- Weight: 136 kg

STORAGE CONDITIONS

- Store at 2–8°C.
- Can withstand short periods (up to 4 weeks) at up to 25°C.
- Store away from extreme heat.
- Do not store for prolonged periods; or close to hot radiator, motor, or other source of heat.
- Do not freeze the test kits or reagents.
- Expiration date is based on ideal storage conditions.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- Shelf life: 18 months
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- The positive and negative controls should be run at least once each 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 manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Biohazard discard bags
- Blood collection devices

ESTIMATED PRICE

- Cost is approximately U.S.\$1.10–2.70 per test.
- Price varies depending on the quantity being procured.

REGULATORY AGENCY APPROVAL

Many countries (not FDA)

HIV TEST KIT FACT SHEET

CLEARVIEW[®] COMPLETE HIV 1 / 2 (RAPID TEST KIT)

MANUFACTURER

Inverness Medical
Priory Business Park
Bedford, MK 44 3UP
United Kingdom
Tel: +44 1234 835000
Fax: +44 1234 835009
www.abbott.com

KIT CONTENTS

- 25 pouches containing:
 - sampler with a test strip
 - buffer vial
 - sterile lancet
 - bandage
 - desiccant packet
- 1 disposable rack
- 1 product insert

PERCENT ACCURACY

- Sensitivity: 99.7%
- Specificity: 99.9%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 15 minutes
- Do not interpret the result after 20 minutes.

PACKAGING INFORMATION

- 25 tests per kit

TEST KIT PACKAGE

- Dimensions: 24 x 9.5 x 16 cm
- Volume: 3,648 cm³
- Weight: 600 g

SHIPPING CARTON

Contact manufacturer for details.

STORAGE CONDITIONS

- Storage temperature: 8–30°C
- Store away from extreme heat.
- Do not store for prolonged periods; or close to hot radiator, motor, or other source of heat.
- Do not freeze the test kits or reagents.
- Expiration date is based on ideal storage conditions.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- Shelf life: 24 months
- Disposal methods:
 - autoclave @121°C for 60 minutes
 - incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- A procedural control is incorporated in the device. If a pink/purple control bar does not appear in the control area, 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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock, watch, or other timing device
- Pipettor, 2.5µL (for other than fingerstick whole blood specimens)
- Disposable gloves
- Sterile gauze
- Antiseptic wipes
- Biohazard disposal container
- Collection devices for samples other than fingerstick whole blood specimens

ESTIMATED PRICE

- Approximately U.S.\$0.75–3.00 per test

REGULATORY AGENCY APPROVAL

- USA (FDA)

HIV TEST KIT FACT SHEET

DETERMINE™ HIV-1/HIV-2 (RAPID TEST KIT)

MANUFACTURER

Manufactured for Inverness Medical
Japan Co., Ltd
By Abbott Japan Co., Ltd
Roppongi First Building, 4th Floor
9-9, Roppongi 1-Chome
Minato-ku, Tokyo 106-8535
Japan
Tel: 81 3 3589 9441
Fax: 81 3 3589 9591
www.determinetest.com

KIT CONTENTS

- Test card
- 10 cards (10 tests per card)
- Whole blood assay requires chase buffer. One bottle (2.5 ml) is sufficient for 100 tests. If chase buffer is required this must be ordered. (Cat. No. 7D2243).

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.75%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 15 minutes

PACKAGING INFORMATION

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

TEST KIT PACKAGE

- 100 tests:
- Dimensions: 27 x 16 x 1 cm
 - Volume: 432 cm³
 - Weight: 156 g

SHIPPING CARTON

- 50 kits per carton:
- Dimensions: 46 x 34 x 27 cm
 - Weight (full kits): 8.6kg

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.
- Do not freeze the test kits or reagents.
- Expiration date is based on ideal storage conditions.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- Shelf life: 14 months
- Disposal methods:
 - autoclave @121°C for 60 minutes
 - incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- Serum/plasma and whole blood (venipuncture preferred) assay
 - pipette
 - pipette tips
- Whole blood (fingerstick) assay
 - lancets
 - EDTA capillary tubes

ESTIMATED PRICE

- Approximately U.S.\$0.66–1.20 per test
- Price varies depending on the quantity being procured.

HIV TEST KIT FACT SHEET

ENZYGNOST[®] ANTI-HIV 1/2 PLUS (ELISA TEST KIT)

MANUFACTURER

Dade Behring GmbH Hoechst
Strasse 70, 65835 Liederbach,
Germany
www.dadebehring.com

KIT CONTENTS

- 192 test kit contains 2 plates of 96 tests.
- 960 test kit contains 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.

PERCENT ACCURACY

- Sensitivity: 99.6–100%
- Specificity: 99.1–100%

TYPES OF SAMPLES

- Serum and plasma (must separate from whole blood)

RUN TIME OF TEST

- 30 minutes

PACKAGING INFORMATION

- Kits of 192 or 960 tests
- 25 kits per carton

TEST KIT PACKAGE

- Dimensions: 18 x 17.5 x 11.5 cm (192 tests)
- Volume: 3,622.5 cm³ (192 tests); 18,112.5 cm³ (960 tests)

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.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- Shelf life: approximately 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 (biohazardous waste).

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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- Piston-type pipettes (25, 100, and 1,000µL)

ESTIMATED PRICE

- Approximately U.S.\$0.75–0.99 per test
- Price varies depending on the quantity being procured.

REGULATORY AGENCY APPROVAL

EC (European Conformity)

HIV TEST KIT FACT SHEET

FIRST RESPONSE[®] HIV CARD TEST I-2.0 (V.3) (RAPID TEST KIT)

MANUFACTURER

Premier Medical Corporation Ltd.
259 Amherst Ave
Colonia, NJ 07067, USA
Tel: +1 732 815 0462
Fax: +1 530 869 7966
www.premiermedcorp.com

KIT CONTENTS

- Test device
- Dropper
- Assay diluent
- Instructions

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.18%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 5–15 minutes

PACKAGING INFORMATION

- 1, 5, 10, 30, or 60 tests per kit
- 50 kits per carton

TEST KIT PACKAGE

- 30 test kit:
- Dimensions: 12 x 7 x 22 cm
 - Volume: 3681 cm³
 - Weight: 315 g

SHIPPING CARTON

- Carton contains 50 kits:
- Dimensions: 75 x 42 x 43 cm
 - Weight: 22 kg

STORAGE CONDITIONS

- Storage temperature: 4–30°C
- Store away from extreme heat.
- Do not store for prolonged periods; or close to hot radiator, motor, or other source of heat.
- Do not freeze the test kits or reagents.
- Expiration date is based on ideal storage conditions.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- Shelf life: 20–22 months
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- A procedural control is incorporated in the device. If the control line does not appear at “C” 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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- Lancet
- Disposable gloves

ESTIMATED PRICE

- Approximately U.S.\$0.55–0.95 per test
- Price varies depending on the quantity being procured.

HIV TEST KIT FACT SHEET

GENIE II HIV-1/HIV-2 (RAPID TEST KIT)

MANUFACTURER

Bio-Rad Laboratories
3, Bd Raymond Poincaré
92430 Marnes la Coquette
France
Tel: +33-1-4795-6000
Fax: +33-1-4741-9133
www.bio-rad.com

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) with separate drop dispenser
- 1 vial positive control (0.5 ml)
- 1 vial negative control (0.5 ml)

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.8–100%

TYPES OF SAMPLES

- Serum or plasma

RUN TIME OF TEST

- 10 minutes

PACKAGING INFORMATION

- 40 tests per kit

TEST KIT PACKAGE

- Dimensions: 26 x 18.5 x 14 cm

- Volume: 6,700 cm³
- Weight: 1,010 g

SHIPPING CARTON

Cartons containing 10 kits of 40 tests:

- Dimensions: 60 x 40 x 43 cm
- Volume: 103,200 cm³
- Weight: 11.3 kg

Cartons containing 16 kits of 40 tests:

- Dimensions: 74 x 30 x 48 cm
- Volume: 106,560 cm³
- Weight: 19.2 kg

STORAGE CONDITIONS

- Storage temperature: 2–8°C
- Can travel at room temperature if transit time does not exceed 5 days.
- Do not freeze the test kits or reagents.
- 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 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 of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- A procedural control is incorporated in the device. An internal control spot indicates a valid result. If the spot does not appear the test result is invalid and the test should be repeated.
- Run the positive and negative controls provided with the kit each day the test is performed, and/or whenever changing to a different lot of tests.

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 manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Disposable pipettes and pipette tips
- Biohazard bags
- Blood collection equipment
- Disinfectant

ESTIMATED PRICE

- Approximately U.S.\$1.88–3.52 per test
- Price varies depending on the quantity being procured.

REGULATORY AGENCY APPROVAL

USA (FDA), Mexico, Brazil, Romania,
Ghana, Nigeria

HIV TEST KIT FACT SHEET

INSTANTCHEK™ HIV 1+2 (RAPID TEST KIT)

MANUFACTURER

EY Laboratories, manufactured in
Hong Kong
107 N. Amphlett Boulevard
San Mateo, CA 94401
Tel: +1 650 342 3296
Fax: +1 650 342 2648
www.eylabs.com

KIT CONTENTS

- Lyophilized stable controls
- Wash solution
- Sample and reagents
- Pipettes
- Lyophilized colloidal gold reagent
- Reconstitution solution
- WBT filter tube (whole blood/urine/saliva)

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.89%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 2 minutes

PACKAGING INFORMATION

- 40 or 100 tests per kit

TEST KIT PACKAGE

- 100 tests per kit
- Dimensions: 28 x 16 x 14 cm
 - Volume: 6,272 cm³
 - Weight: 810 g

SHIPPING CARTON

One carton contains 16 kits (100 tests per kit) with 16 WBT (whole blood tube):

- Dimensions: 63 x 43 x 60 cm
- Volume: 162,540 cm³
- Weight: 18.56 kg

STORAGE CONDITIONS

- Storage temperature: 2–25°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.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry 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 (biohazardous waste).

QUALITY CONTROL

- A procedural control is incorporated in the device. If a small red control dot does not appear toward the bottom of the circle 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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- None

ESTIMATED PRICE

- Approximately U.S.\$0.57–1.20 per test
- Price varies depending on the quantity being procured.

REGULATORY AGENCY APPROVAL

China (SFDA)

HIV TEST KIT FACT SHEET

NEW LAV BLOT I (CONFIRMATORY TEST KIT)

MANUFACTURER

Bio-Rad Laboratories
3, Bd Raymond Poincaré
92430 Marnes la Coquette
France
Tel: +33-1-4795-6000
Fax: +33-1-4741-9133
www.bio-rad.com

KIT CONTENTS

- 18 strips in 3 trays (6 cells each).
- 1 vial of buffer solution (100 mL)
- 1 vial of negative control (0.2 mL)
- 1 vial of positive control (0.2 mL)
- 1 vial of conjugate (40 mL)
- 1 vial of color development solution (BCIP/NBT) (40 mL)

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 100%

TYPES OF SAMPLES

- Serum and plasma

RUN TIME OF TEST

- At least 4 hours

PACKAGING INFORMATION

- Each kit contains enough reagents for 18 determinations.

TEST KIT PACKAGE

- Dimensions: 13 x 14 x 21.1 cm
- Volume: 3,840 cm³
- Weight: 580 g

SHIPPING CARTON

Size of the carton is tailored to the number of kits ordered.

STORAGE CONDITIONS

- Store at 4–8°C.
- Ship at room temperature.
- 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: 4 to 12 months
- Disposal methods:
 - autoclave at 121°C for 60 minutes
 - incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- 4–5 per test run
- The control supplied should be tested in parallel with patient samples for each test run. The positive control is required to validate the test and correctly interpret the bands.
- Use the positive control to locate and identify the shown antibodies and check that the internal control band is present on each test strip.

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 manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions
- Quality control criteria not achieved

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled or demineralized water
- 100mL, 250mL, and 500mL graduated cylinders
- 2mL graduated pipettes
- Automatic or semi-automatic pipettes (20µL)
- Disposable gloves
- Liquid jet vacuum pump with safety bottle
- Sodium hypochlorite (bleach)
- Absorbent paper
- Tweezers
- 1, 2, or 3 dimensional shaker
- Container for biohazardous waste
- Protective glasses

ESTIMATED PRICE

- Cost is approximately
U.S.\$17.10–17.70 per test.
- Price varies depending on the
quantity being procured.

HIV TEST KIT FACT SHEET

ORAQUICK® RAPID HIV-I ANTIBODY TEST

MANUFACTURER

OraSure Technologies, Inc.
150 Webster Street
Bethlehem, PA 18015 USA
USA Sales

Tel: +1-800-869-3538

Fax: +1-610-882-2275

International Sales

Tel: +84-90-33-65-712

Fax: +84-8-845-7251

www.orasure.com

The information provided on this sheet pertains to non-U.S. manufactured tests.

KIT CONTENTS

- 100 test kit contains 100 test devices, 5 loops, 10 test stands, 1 product insert, 100 information pamphlets, and 1 customer letter.
- 500 test kit contains 500 test devices, 25 loops, 6 test stands, 1 product insert, 25 information pamphlets, and 1 customer letter.
- Test kit controls are required to conduct the test and need to be ordered separately. The positive and negative controls are packaged in 0.2 ml vials.
- Loops and test stands can be ordered separately.
- If required more loops will be included free of charge.
- OraQuick® Rapid HIV-I test kit Controls are sold separately.

PERCENT ACCURACY

- Sensitivity: 99.6%
- Specificity: 100%

TYPES OF SAMPLES

- Fingerstick whole blood

RUN TIME OF TEST

- 20 minutes
- Do not interpret after 40 minutes after running the test.

PACKAGING INFORMATION

- Tests are packaged in individual pouches. Each pouch contains 1 test and 1 chase buffer.

TEST KIT PACKAGE

- Dimensions: 35 x 39 x 21 cm (100 tests); 44 x 59 x 44 cm (500 tests)
- Volume: 28,600 cm³ (100 tests); 114,117 cm³ (500 tests)
- Weight: 5 kg (100 tests); 20 kg (500 tests)

STORAGE CONDITIONS

- Storage temperature: 2–27°C
- If the test is refrigerated, bring the pouch 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: 6 months
- Dispose of in a biohazardous waste container.
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- 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.

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 manufacture 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
- Test kit controls are available separately

ESTIMATED PRICE

- Approximately U.S. \$4–5/test for bulk purchases outside the U.S.
- Price varies depending on the quantity being procured.

HIV TEST KIT FACT SHEET

SD BIOLINE HIV-1/HIV-2 3.0 (RAPID TEST KIT)

MANUFACTURER

Standard Diagnostics, Inc.
156-68, Hagal-dong, Giheung-gu,
Yongin-si, Kyonggi-do, Korea
Tel: 82-31-899-9700
Fax: 82-31-899-9740
e-mail: taylor@standardia.com
www.standardia.com

KIT CONTENTS

- 30 test kit package contains 30 test devices, assay diluent (5mL), and 1 package insert. Optional: pipettes or capillary tubes and lancets, and alcohol swabs.
- 25 test kit package contains 25 test devices, assay diluent (5mL), capillary tubes, lancets and 1 package insert. Optional: alcohol swabs.

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.8%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 5 - 20 minutes
- Do not interpret after 20 minutes.

PACKAGING INFORMATION

- 30 tests per kit, 40 kits per carton
- 25 tests per kit, 45 kits per carton
- Other test packages available, such as a multi-cassette type, upon request.

TEST KIT PACKAGE

- Dimensions: 22.2 x 12.5 x 7.1 cm (30 tests); 18.3 x 12.5 x 7.3 cm (20 tests)
- Volume: 1,970 cm³ (30 tests)
1,670 cm³ (25 tests)
- Weight: 310 g (30 tests)
270 g (25 tests)

SHIPPING CARTON

- Dimensions: 53 x 48 x 40 cm (30 tests); 53 x 48 x 40 cm (25 tests)
- Volume: 101,760 cm³ (30 tests);
101,760 cm³ (20 tests)
- Weight: (310 g x 40 box) +1.5 kg (30 tests); (270 g x 45 box) +1.5 kg (25 tests)

STORAGE CONDITIONS

- Store at 1–30°C.
- The unopened kit is stable for 4 weeks in accelerated temperatures (55°C).
- Store away from extreme heat and humidity.
- Do not freeze the test kits or reagents.
- Expiration date is based on ideal storage conditions.
- Kit components are stable until expiry date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- Shelf life: 24 months
- Disposal methods:
 - autoclave at 121°C for 60 minutes
 - incinerate

- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- A procedural control is incorporated in the device. If the control bar does not turn purple 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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- disposable tips
- latex gloves
- timer

ESTIMATED PRICE

- Cost is approximately U.S.\$0.47–0.96 per test.
- Price varies depending on the quantity being procured, and can be negotiated on a case-by-case basis.

**REGULATORY AGENCY
APPROVAL**

Korea (KFDA)

HIV TEST KIT FACT SHEET

HIV 1/2 STAT-PAK (RAPID TEST KIT)

MANUFACTURER

Chembio Diagnostic Systems, Inc.
3661 Horseblock Rd.
Medford, NY 11763 USA
Tel: +1 631-924-1135
Fax: +1 631-924-6033
Email: info@chembio.com
www.chembio.com

KIT CONTENTS

Each kit contains the items to perform 20 tests:

- 20 test devices, each containing a cocktail of antigens of HIV 1/2 and gold conjugate
- 1 buffer vial
- 20 disposable 5µL sample loops
- 1 instruction leaflet

PERCENT ACCURACY

- Sensitivity: 99.7%
- Specificity: 99.3–99.9%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 10 minutes
- Do not read results after 20 minutes

PACKAGING INFORMATION

- 20 tests per kit
- 48 kits per shipping carton

TEST KIT PACKAGE

- Dimensions: 16.5 x 12.7 x 7 cm
- Volume: 1,467 cm³
- Weight: 283 g

SHIPPING CARTON

- Dimensions: 51 x 40.6 x 40.6 cm
- Volume: 84,066 cm³
- Weight: 14.3 kg

STORAGE CONDITIONS

- Storage temperature is 8–30°C.
- If the test is stored below 20°C, bring it to room temperature before use.
- Store away from extreme heat.
- Do not freeze test kits.
- 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: 24 months (guarantee a minimum of 12 months on receiving)
- Disposal methods:
 - autoclave at 121°C for 60 minutes
 - incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- A pink/purple colored line in the control area indicates 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.

- Kit controls should be run once per shift, and whenever changing to a different lot of tests.

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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions

MATERIALS REQUIRED BUT NOT PROVIDED

- 1 clock, watch, or other timing device
- Sterile single-use lancets (for finger stick blood samples only)
- Sterile alcohol swabs (for fingerstick blood samples only)
- pipette 5µL (for non-fingerstick blood samples only)
- Chembio HIV Reactive and Nonreactive controls are available separately.

ESTIMATED PRICE

- Cost is approximately U.S. \$0.65–1.60 per test.
- Price varies depending on the quantity being procured.

REGULATORY AGENCY APPROVAL

USA (FDA), 35 other countries
(contact manufacturer)

HIV TEST KIT FACT SHEET

UNI-GOLD™ HIV TEST



MANUFACTURER

Trinity Biotech plc
IDA Business Park
Bray, Co. Wicklow, Ireland
Tel: +353-1-276-9800
Fax: +353-1-276-9888
<http://www.trinitybiotech.com/>
Free phone: +1-800-603-8076
The information provided on this sheet pertains to non-U.S.-manufactured tests.

KIT CONTENTS

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

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.7–100%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 10 minutes
- Do not read results after 20 minutes.

PACKAGING INFORMATION

- 20 tests per kit
- up to 150 kits per carton.

TEST KIT PACKAGE

- Dimensions: 23.5 x 14 x 8 cm
- Volume: 3,360 cm³
- Weight: 200 g

SHIPPING CARTON

- Size of the carton is tailored to the number of kits ordered. The maximum carton size holds 224 kits is:
- Dimensions: 120 x 80 x 80 cm
- Volume: 768,000 cm³
- Weight: 52.5 kg

STORAGE CONDITIONS

- Store at 2–27°C.
- Do not freeze test kits/reagents.
- 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: 15 months
- Disposal methods:
 - autoclave at 121°C for 60 minutes
 - incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

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

- 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 manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions
- Quality control criteria not achieved (positive/negative control result, control band presence, etc.).

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch
- Blood collection devices (i.e., lancets, capillary tubes/test tubes)

ESTIMATED PRICE

- Cost is approximately U.S.\$1.50–2.34 per test.
- Price varies depending on the quantity being procured.

HIV TEST KIT FACT SHEET

VIRONOSTIKA® HIV UNI-FORM II PLUS O (ELISA TEST KIT)

MANUFACTURER

BioMérieux
F-69280 Marcy l'Etoile
France
Tel: (+33) (04) 78 87 20 00
Fax: (+33) (04) 78 87 20 90
www.biomerieux.com
The information provided on this
sheet pertains to non-U.S.-
manufactured tests.

KIT CONTENTS

- 192 test kit package contains 2 plates of 96 tests
- 576 test kit package contains 6 plates of 96 tests
- 12 strips per plate, each with 8 wells
- Can break strips in half and use as 4-well strips
- Each kit contains sufficient control serum, specimen diluent, phosphate buffer concentrate, TMB solution, urea peroxide solution, plate sealers, clamp and rod, and sheets of labels.

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.92%

TYPES OF SAMPLES

- Serum and plasma

RUN TIME OF TEST

- 1 hour and 30 minutes

PACKAGING INFORMATION

- Kits must be identified by the catalogue number:

- 192 tests per kit—No. 284017
- 576 tests per kit—No. 284018

TEST KIT PACKAGE

- Volume: .044 m³ (192 tests); .065 m³ (576 tests)
- Weight: 0.958 kg (192 tests); 1.530 kg (576 tests)

SHIPPING CARTON

- The shipping carton: 192 tests—8 kits
- Dimensions: 39 x 39 x 29 cm
- Volume: 44,100 cm³
- Weight: 192 tests—7.7 kg

STORAGE CONDITIONS

- Store at 2–8°C.
- Allow the reagents, samples, and foil test pack to come to room temperature (15–30°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.

SHELF LIFE AND DISPOSAL

- Shelf life: 12 months
- Disposal methods:
 - autoclave at 121°C for 60 minutes
 - incinerate
- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- 4–5 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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions
- Quality control criteria not achieved

MATERIALS REQUIRED BUT NOT PROVIDED

- microwell plate washer, microwell plate reader, incubator, vortex mixer, microshaker, 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

- Cost is approximately U.S.\$0.75–2.50 per test.
- Price varies depending on the quantity being procured.

HIV TEST KIT FACT SHEET

VIRONSTIKA[®] HIV UNI-FORM II AG/AB (ELISA TEST KIT)

MANUFACTURER

BioMérieux
F-69280 Marcy l'Etoile
France
Tel: (+33) (04) 78 87 20 00
Fax: (+33) (04) 78 87 20 90
www.biomerieux.com

The information provided on this sheet pertains to non-U.S.-manufactured tests.

KIT CONTENTS

- 192 test kit package contains 2 plates of 96 tests
- 576 test kit package contains 6 plates of 96 tests
- 12 strips per plate, each with 8 wells
- Can break strips in half and use as 4-well strips
- Each kit contains sufficient control serum, specimen diluent, phosphate buffer concentrate, TMB solution, urea peroxide solution, plate sealers, clamp and rod, and sheets of labels.

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.8%

TYPES OF SAMPLES

- Serum and plasma

RUN TIME OF TEST

- 1 hour and 30 minutes

PACKAGING INFORMATION

- Kits must be identified by the catalogue number:

- 192 tests per kit—No. 284046
- 576 tests per kit—No. 284047

TEST KIT PACKAGE

- Volume: .044 m³ (192 tests); .065 m³ (576 tests)
- Weight: 0.963 kg (192 tests); 1.410 kg (576 tests)

SHIPPING CARTON

- The shipping carton: 192 tests—8 kits
- Dimensions: 39 x 39 x 29 cm
- Volume: 44,100 cm³ (192 tests)
- Weight: 192 tests—7.7 kg

STORAGE CONDITIONS

- Store at 2–8°C.
- Allow the reagents, samples, and foil test pack to come to room temperature (15–30°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.

SHELF LIFE AND DISPOSAL

- Shelf life: 12 months
- Disposal methods:
 - autoclave at 121°C for 60 minutes

- incinerate

- Dispose of all specimens, used devices, and pipettes as though they could transmit infection (biohazardous waste).

QUALITY CONTROL

- 4–5 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
- Incorrect, missing, or illegible labeling (especially product, brand, or manufacturer's name; lot and batch numbers; and expiration and/or manufacture date)
- Missing contents
- Leakage or stains
- Improper storage conditions
- Quality control criteria not achieved

MATERIALS REQUIRED BUT NOT PROVIDED

- Microwell plate washer, microwell plate reader, incubator, vortex mixer, microshaker, 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

- Price varies depending on the quantity being procured.

For more information, please visit deliver.jsi.com.

USAID | DELIVER PROJECT

John Snow, Inc.

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Arlington, VA 22209 USA

Phone: 703-528-7474

Fax: 703-528-7480

Email: deliver_project@jsi.com

Internet: deliver.jsi.com