



HIV TEST KIT FACT SHEET

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

MANUFACTURER

Trinity Biotech plc (Headquarters)
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Bray, Co. Wicklow, Ireland
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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: 95.7–100%
- Specificity: 99.3–100%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 7 minutes

PACKAGING INFORMATION

- 100 tests per kit
- Up to 200 kits per shipping carton (20,000 tests).

TEST KIT PACKAGE

- Dimensions: 9 x 14 x 24 cm
- Volume: 3,024 cm³
- Weight: 490 g.

SHIPPING CARTON

Size of carton is tailored to the number of kits ordered. Maximum carton size (Eurocarton) holds 200 kits.

- Dimensions: 120 x 80 x 80 cm
- Volume: 768,000 cm³
- Weight: 135 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: 20 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 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 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.\$1.40–2.79 per test.
- Price varies depending on the quantity being procured.



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HIV TEST KIT FACT SHEET

DETERMINE HIV-1/2 (RAPID TEST KIT)

MANUFACTURER

Abbott Japan Co., Ltd.
Diagnostics Division
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.abbott.com

KIT CONTENTS

- 10 tests per card
- 10 cards
- Whole blood assay requires 1 additional bottle of chase buffer (2.5 ml)

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

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

SHIPPING CARTON

No standard shipping carton. Quantity is tailored to 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.
- 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 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.\$1.00–1.30 per test
- Price varies depending on the quantity being procured.



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HIV TEST KIT FACT SHEET

DOUBLECHECK™ HIV 1&2 (RAPID TEST KIT)

MANUFACTURER

Orgenics Ltd.
North Industrial Zone
P. O. Box 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 biotinylated 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%

TYPES OF SAMPLES

- Serum and plasma

RUN TIME OF TEST

12 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: 1.035 kg

SHIPPING CARTON

- Dimensions: 59 x 45 x 54 cm
- Volume: 143,370 cm³
- Weight: Approximately 18.6 kg

STORAGE CONDITIONS

- Storage temperature is 4–8°C.
- Do not freeze test kits or 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.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- Shelf life is 15 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

- Each test result is validated by an internal control.

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

- biohazard waste containers
- timer or stopwatch
- disposable gloves.

ESTIMATED PRICE

- Cost is approx. U.S.\$1.20 per test.
- Price varies depending on the quantity being procured.



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HIV TEST KIT FACT SHEET

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

MANUFACTURER

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

- The 192 test kit contains 2 plates of 96 tests.
- The 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: 98.7–100%

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: 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 1,000 µL)

ESTIMATED PRICE

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



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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)
- 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: 1.01 kg

SHIPPING CARTON

Size of carton is tailored to the number of kits ordered. Maximum carton size holds 8 kits.

- Dimensions: 61 x 41 x 29 cm
- Volume: 72,529 cm³
- Weight: 8.7 kg

STORAGE CONDITIONS

- Storage temperature: 2–8°C
- 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

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

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Disposable pipettes

ESTIMATED PRICE

- Approximately U.S.\$3.00–5.00 per test
- Price varies depending on the quantity being procured.





HIV TEST KIT FACT SHEET

HEMA-STRIP™ HIV (RAPID TEST KIT)



MANUFACTURER

Saliva Diagnostics Systems (SDS)
3661 Horseblock Road
Suite E
Medford, NY 11763 USA
Tel: +1 917-853-6440
Fax: +1 212-937-3801
Email: info@salv.com
www.salv.com

KIT CONTENTS

Each pouch contains:

- sampler with a test strip
- 1 buffer vial attached to a sampler
- 1 lancet
- 1 bandage
- 1 desiccant (drying agent).

PERCENT ACCURACY

- Sensitivity: >99%
- Specificity: >99%

TYPES OF SAMPLES

- Whole blood

RUN TIME OF TEST

- 15 minutes

PACKAGING INFORMATION

- 25 pouches, 1 product insert per kit
- 25 kits per carton (625 tests)

TEST KIT PACKAGE

- Dimensions: 24.1 x 15.9 x 8.3 cm
- Volume: 3,162 cm³
- Weight: approximately 45.3 g

SHIPPING CARTON

- Dimensions: 53.3 x 43.2 x 3.2 cm
- Volume: 99,453 cm³
- Weight: 11.8 kg

STORAGE CONDITIONS

- Storage temperature is 20–33°C
- If the test is stored below 20°C, bring it to room temperature before use.
- 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 is 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 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 is an internal procedural control. A clear background in the test area is an internal negative procedural control.

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

- 1 clock, watch, or other timing device
- rack for holding buffer vials upright
- lab pipette to deliver 2.5 µL sample (for serum and plasma samples only).

ESTIMATED PRICE

- Cost is approximately U.S.\$3.00 per test.
- Price varies depending on the quantity being procured.



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HIV TEST KIT FACT SHEET

MIRAWELL™ HIV FLEX RAPID HIV TEST

MANUFACTURER

MedMira Laboratories, Inc.
155 Chain Lake Drive, Suite 1
Halifax, Nova Scotia
Canada, B3S 1B3
Tel: 902-450-1588
www.medmira.com

KIT CONTENTS

- 50 test cartridge pouches contain test cartridge with blue specimen filtration unit, 1 green conjugate cap
- 1 bag with 1 30-mL buffer solution
- 1 pouch with negative and positive test controls
- 1 bag with 50 diluent buffer vials
- 1 bag with 50 disposable pipettes.

PERCENT ACCURACY

Sensitivity: 99.7%
Specificity: 99.7%

TYPES OF SAMPLES

- Whole blood, serum, or plasma

RUN TIME OF TEST

- 3 minutes

PACKAGING INFORMATION

- 50 tests per package

TEST KIT PACKAGE

- Dimensions: 27 x 37 x 9 cm

SHIPPING CARTON

Dimensions of shipping carton dependent on quantity of tests ordered.

STORAGE CONDITIONS

- Store at 2–30°C.
- Do not freeze.
- Keep test components in sealed pouches until ready to use.
- 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.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- 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

- Built-in reagent and procedural control demonstrates the validity of the testing procedure and reagent function.

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 waste disposal bags
- disinfectant solution
- discard container
- centrifuge (for serum/plasma preparation).

ESTIMATED PRICE

- Cost is approximately U.S.\$1.50–2.75 per test.
- Price varies depending on the quantity being procured.

NOTE

The MiraWell HIV Flex Rapid HIV Test is volume packaged for use in clinical facilities and testing programs. Its sister test, the MiraWell HIV SOLO Rapid HIV Test, has individually packaged tests and is intended for physicians' offices, mobile clinics, and other situations that require a small number of tests. Please see the SOLO Rapid HIV Test Kit Fact Sheet for more information.





HIV TEST KIT FACT SHEET

MIRAWELL™ HIV SOLO RAPID HIV TEST

MANUFACTURER

MedMira Laboratories, Inc.
155 Chain Lake Drive, Suite 1
Halifax, Nova Scotia
Canada, B3S 1B3
Tel: 902-450-1588
www.medmira.com

KIT CONTENTS

Each box contains 20-test-cartridge Mylar pouches.

- 1 test cartridge with filtration unit
- 1 1-mL universal buffer solution
- 1 conjugate cap
- 1 lancet
- 1 alcohol swab
- 1 bandage
- 1 disposable pipette.

PERCENT ACCURACY

Sensitivity: 99.7%

Specificity: 99.7%

TYPES OF SAMPLES

- Whole blood

RUN TIME OF TEST

- 3 minutes

PACKAGING INFORMATION

- 20 tests per package

TEST KIT PACKAGE

Dimensions: 17.5 x 33 x 5 cm

SHIPPING CARTON

Dimensions of shipping carton are dependent on quantity of tests ordered.

STORAGE CONDITIONS

- Store at 2–30°C.
- Do not freeze.
- Keep test components in sealed pouches until ready for use.
- 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.
- Kit components are stable until expiration date.
- DO NOT use any component after expiry date.

SHELF LIFE AND DISPOSAL

- 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

Unknown

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 waste disposal bags
- disinfectant solution
- discard container
- centrifuge (for serum/plasma preparation).

ESTIMATED PRICE

- Cost is approximately U.S.\$2.00–3.25.
- Price varies depending on the quantity being procured.

NOTE

The MiraWell HIV SOLO Rapid HIV Test includes individually wrapped test kit packages, and is designed for physicians' offices, mobile clinics, and other situations that require a small number of tests. Its sister test, the MiraWell HIV Flex Rapid HIV Test, is volume packaged for use in clinical facilities and testing programs. Please see the Flex Rapid HIV Test Kit Fact Sheet for more information.



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HIV TEST KIT FACT SHEET

MULTISPOT™ HIV-1/HIV-2 RAPID TEST

MANUFACTURER

Bio-Rad Laboratories
3, Bd Raymond Poincaré
92430 Marnes la Coquette
France
Tel: 33-1-47-95-6000
Fax: 33-1-47-41-9133
www.bio-rad.com

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

KIT CONTENTS

- 50 test cartridges
- 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)
- 60 disposable transfer pipettes

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.91%

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

Size of carton is tailored to the number of kits ordered. The maximum carton size, holding 4 kits is:

- Dimensions: 61 x 41 x 29 cm
- Volume: 72,529 cm³
- Weight: 5.67 kg

STORAGE CONDITIONS

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

QUALITY CONTROL

- Run the positive and negative control provided with the kit 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 manufacture date)
- missing contents
- leakage or stains
- improper storage conditions.

MATERIALS REQUIRED BUT NOT PROVIDED

- disposable glass or plastic test tubes to prepare diluted specimens (e.g., 12 75-mm tubes)
- test tube racks
- absorbent pads or paper towels
- biohazard bags with closures
- bleach or other disinfectant
- disposable gloves
- precision pipettors that deliver 10 ml and 90 ml.

ESTIMATED PRICE

- Cost is approximately U.S.\$6.00–10.00 per test.
- Price varies depending on the quantity being procured.



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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

- The 100 test kit contains 100 test devices, 5 loops, 10 test stands, 1 product insert, 100 information pamphlets, and 1 customer letter.
- The 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.

PERCENT ACCURACY

Sensitivity: 99.5%

Specificity: 99.87%

TYPES OF SAMPLES

- Fingertstick whole blood

RUN TIME OF TEST

- 20 minutes

PACKAGING INFORMATION

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

TEST KIT PACKAGE

- Dimensions:
35 x 39 x 21 cm (100 tests)
44 x 59 x 44 cm (500 tests)
- Volume: 28,665 cm³ (100 tests)
114,224 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: 5–6 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

ESTIMATED PRICE

- Approximately U.S.\$3.30/test for bulk purchases outside the U.S.
- Price varies depending on the quantity being procured.



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HIV TEST KIT FACT SHEET

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

MANUFACTURER

Standard Diagnostics, Inc.
156-68, Hagal-ri, Giheung-eup,
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 (4 mL), and 1 package insert. Optional: pipettes or capillary tubes and lancets, and alcohol swabs.
- 20 test kit package contains 20 test devices, assay diluent (4 mL), capillary tubes, lancets and alcohol swabs, and 1 package insert.

PERCENT ACCURACY

- Sensitivity: 100%
- Specificity: 99.9%

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 20 minutes:
 - Serum and plasma can be interpreted at 5–20 minutes.
 - Whole blood should be interpreted within 10 minutes; do not interpret after 10 minutes.

PACKAGING INFORMATION

- 30 tests per kit, 40 kits per carton
- 20 tests per kit, 54 kits per carton
- Other test packages available, such as a multi-cassette type, upon request.

TEST KIT PACKAGE

- Dimensions:
 - 22.2 x 12.7 x 7.3 cm (30 tests)
 - 18.5 x 12.5 x 7.3 cm (20 tests)
- Volume: 2,059 cm³ (30 tests)
1,689 cm³ (20 tests)
- Weight: 310 g (30 tests)
250 g (20 tests)

SHIPPING CARTON

- Dimensions:
 - 53 x 48 x 40 cm (30 tests)
 - 56.5 x 42 x 45 cm (20 tests)
- Volume: 101,760 cm³ (30 tests)
106,785 cm³ (20 tests)
- Weight:
 - (310 g x 40 box) +1.5 kg (30 tests)
 - (250 g x 54 box) +1.5 kg (20 tests)

STORAGE CONDITIONS

- Store at 1–30°C.
- Can withstand short periods (up to 4 weeks) at up to 30°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.\$0.85–1.10 per test.
- Price varies depending on the quantity being procured and can be negotiated on a case-by-case basis.



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HIV TEST KIT FACT SHEET

SEROCARD™ HIV (RAPID TEST KIT)

MANUFACTURER

Trinity Biotech plc
IDA Business Park
Bray, Co. Wicklow, Ireland
Tel: +353-1-276-9800
Fax: +353-1-276-9888
www.trinitybiotech.com
Free phone: +1-800-603-8076

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

Trinity Biotech USA
2823 Girts Road
P. O. Box 1059
Jamestown, NY 14702-1059
Tel: +1 716-483-3851
Fax: +1 716-488-1990
Email: sales@trinityusa.com
Free phone: +1-888-864-4653

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%
- Specificity: >99%

TYPES OF SAMPLES

- Whole blood, serum, or plasma

RUN TIME OF TEST

- 5 minutes

PACKAGING INFORMATION

- 40 tests per kit
- Shipping cartons contain up to 150 kits of 100 tests (15,000 tests).

TEST KIT PACKAGE

- Dimensions: 20 x 10 x 14 cm
- Volume: 2,940 cm³
- Weight: 400 g

SHIPPING CARTON

Size of the carton is tailored to the number of kits ordered. Maximum carton size (Eurocarton), which holds 168 kits is:

- Dimensions: 120 x 80 x 80 cm
- Volume: 768,000 cm³
- Weight: 92 kg

STORAGE CONDITIONS

- Store at 2–8°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.
- Kit components are stable until expiration date.
- 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

- The SeroCard assay has a nonspecific 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
- 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 (pos/neg control result, control band presence, etc.).

MATERIALS REQUIRED BUT NOT PROVIDED

- timer or stopwatch
- blood collection devices
- disposable gloves.

ESTIMATED PRICE

- Cost is approximately U.S.\$1.50–1.75 per test.
- Price varies depending on the quantity being procured.



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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 5 µL sample loops
- 1 instruction leaflet

PERCENT ACCURACY

- Sensitivity: 99.7%
- Specificity: 97.9–99.5%

Summary data, based on multiple evaluations and studies, are available upon request

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 10 minutes

PACKAGING INFORMATION

- 20 tests per kit
- 37 kits per shipping carton (740 tests)

TEST KIT PACKAGE

- Dimensions: 16.51 x 12.7 x 8.89 cm
- Volume: 1,864 cm³
- Weight: 293.9 g

SHIPPING CARTON

- Dimensions: 53.3 x 43.2 x 43.2 cm
- Volume: 99,450 cm³
- Weight: 10.9 kg

STORAGE CONDITIONS

- Storage temperature is 8–30°C.
- If the test is stored below 20°C it should be allowed to come 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: 18 months
- Disposal methods:
 - autoclave at 125°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 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.

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 finger stick blood samples only).

ESTIMATED PRICE

- Cost is approximately U.S.\$1.20-1.45 per test.
- Price varies depending on the quantity being procured.





HIV TEST KIT FACT SHEET

SURE CHECK™ HIV

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:

- 25 pouches.

Each pouch contains:

- 1 sampler with a test strip
- 1 buffer vial attached to a sampler
- 1 lancet
- 1 bandage
- 1 desiccant (drying agent)
- 1 disposable rack per kit.

PERCENT ACCURACY

- Sensitivity: 99.63%
- Specificity: 100%

Summary data, based on multiple evaluations and studies, are available upon request.

TYPES OF SAMPLES

- Serum, plasma, or whole blood

RUN TIME OF TEST

- 15 minutes

PACKAGING INFORMATION

- 25 pouches and 1 product insert per kit
- 1 rack for holding buffer vials upright
- 20 kits per carton (500 tests).

TEST KIT PACKAGE

- Dimensions: 24.1 x 15.9 x 8.3 cm
- Volume: 3,162 cm³
- Weight: approximately 499 g.

SHIPPING CARTON

- Dimensions: 53.3 x 43.2 x 3.2 cm
- Volume: 99,453 cm³
- Weight: 11.8 kg

STORAGE CONDITIONS

- Store at 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 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: 18 months
- Disposal methods:
 - autoclave at 125°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 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.

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

- 1 clock, watch, or other timing device
- lab pipette to deliver 2.5 µL sample (for serum and plasma samples only).

ESTIMATED PRICE

- Cost is approximately U.S.\$1.75–2.00 per test.
- Price varies depending on the quantity being procured.



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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
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

PACKAGING INFORMATION

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

TEST KIT PACKAGE

- Dimensions: 24 x 14 x 10 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 (Eurocarton), holding 150 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 (pos/neg 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.\$1.15–2.25 per test.
- Price varies depending on the quantity being procured.



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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, 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

- 2 hours and 4 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

- Dimensions:
 - 27 x 23.5 x 6.6 cm (192 tests);
 - 27 x 23.5 x 9.6 cm (576 tests)
- Volume:
 - 4,188 cm³ (192 tests);
 - 6,091.2 cm³ (576 tests)
- Weight:
 - .975 kg (192 tests);
 - 1.550 kg (576 tests).

SHIPPING CARTON

The shipping carton will hold a maximum of:

- 192 tests—8 kits
- 576 tests—6 kits.
- Dimensions: 50 x 29 x 32 cm
- Volume: 46,400 cm³
- Weight:
 - 192 tests—7.8 kg
 - 576 tests—9.3 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

- microplate washer, microplate reader, 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

- Cost is approximately U.S.\$0.75–1.56 per test.
- Price varies depending on the quantity being procured.



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