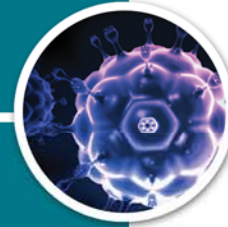


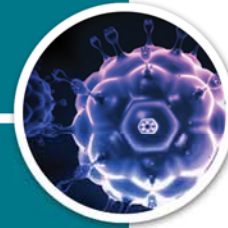
OraQuick *ADVANCE*[®] Rapid HIV-1/2 Antibody Test



OraSure Technologies, Inc.

OraQuick
ADVANCE[®] **HIV-1/2**

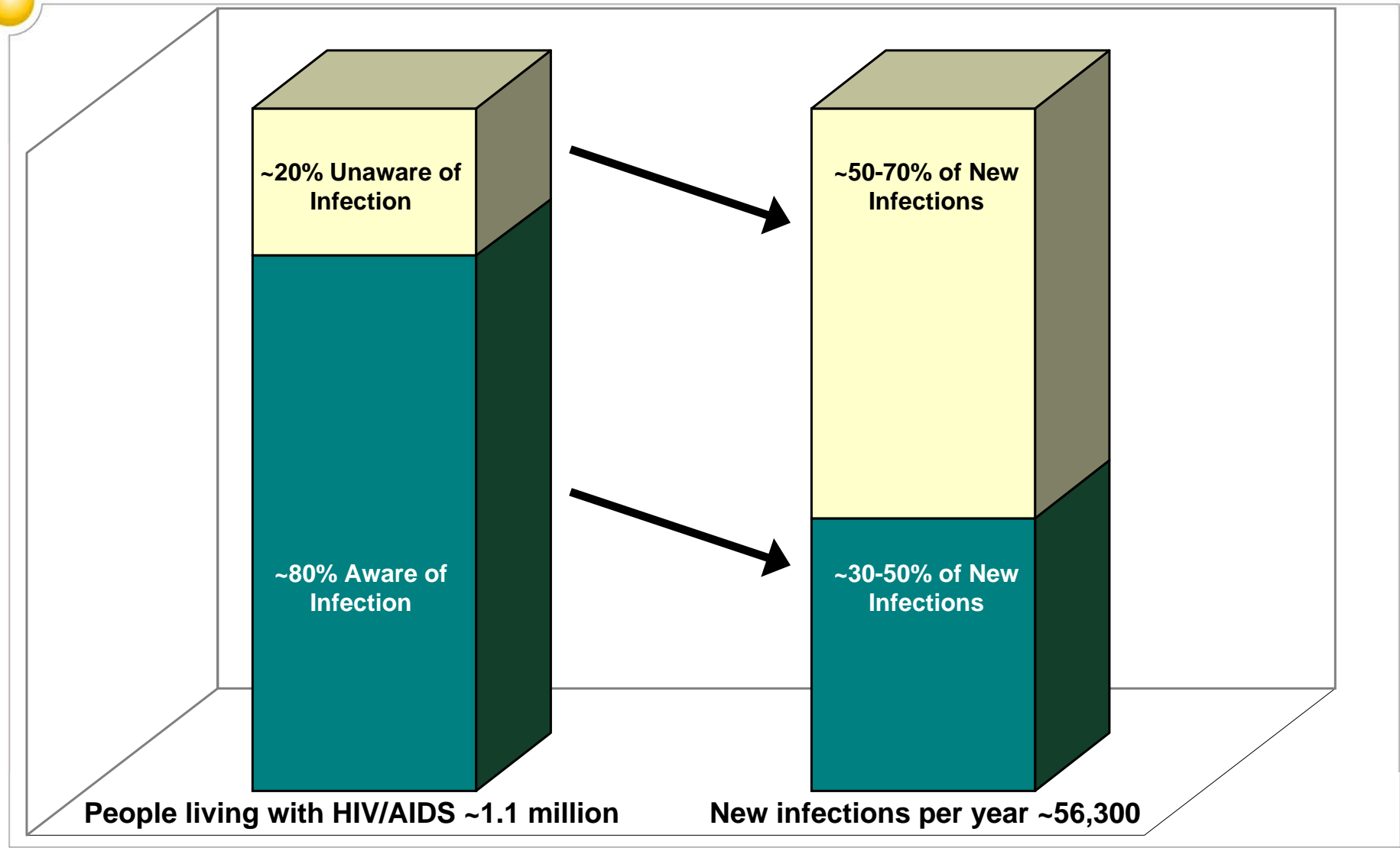
The Importance of Routine Rapid HIV Testing



OraSure Technologies, Inc.

OraQuick
ADVANCE® HIV-1/2

While approximately 1 in 5 people who are HIV+ do not know it, they cause over 50% of new infections

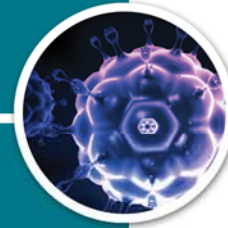


OraQuick ADVANCE[®] Rapid HIV-1/2 Antibody Test

- **Simple**
 - Rapid HIV-1/2 antibody testing with oral fluid collection – results in 20 minutes
- **Accurate**
 - Results with >99% sensitivity and specificity across all specimen types
- **Versatile**
 - Testing platform suitable for both clinical and non-clinical settings using several specimen types
- **Deliver Rapid Results and Identify More HIV+ Individuals at the Point-of-Care**



Overview of the OraQuick *ADVANCE*[®] Rapid HIV-1/2 Antibody Test



OraSure Technologies, Inc.

OraQuick
ADVANCE[®] HIV-1/2

Intended Use

- The OraQuick *ADVANCE*[®] Rapid HIV-1/2 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 and 2 (HIV-1/2) in oral fluid, venipuncture whole blood, fingerstick whole blood, and plasma specimens.
- For *in vitro* diagnostic use.
- This is a restricted device.

Clinical Laboratory Improvement Amendments (CLIA)

- The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA)
- The objective of the CLIA program is to ensure quality laboratory testing.
- CLIA requires all entities that perform even one test to meet certain federal requirements
- CLIA regulations are based on the complexity of the test method; the more complicated the test, the more stringent the requirements.
 - **Three categories of tests have been established: waived complexity, moderate complexity, and high complexity**

More information at www.cms.hhs.gov/clia

NOTE – Individual state requirements may vary

OraQuick *ADVANCE*[®] is a CLIA-Waived Test

- OraQuick *ADVANCE*[®] Rapid HIV-1/2 Antibody Test is CLIA-Waived for the following samples:
 - Oral fluid
 - Fingerstick whole blood
 - Venipuncture whole blood

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test



- Single-use testing device with built-in procedural control
- Single-use test developer solution vial
- Reusable test stand
- Disposable single-use specimen collection loop



OraQuick *ADVANCE*® Clinical Features

Operating Principle

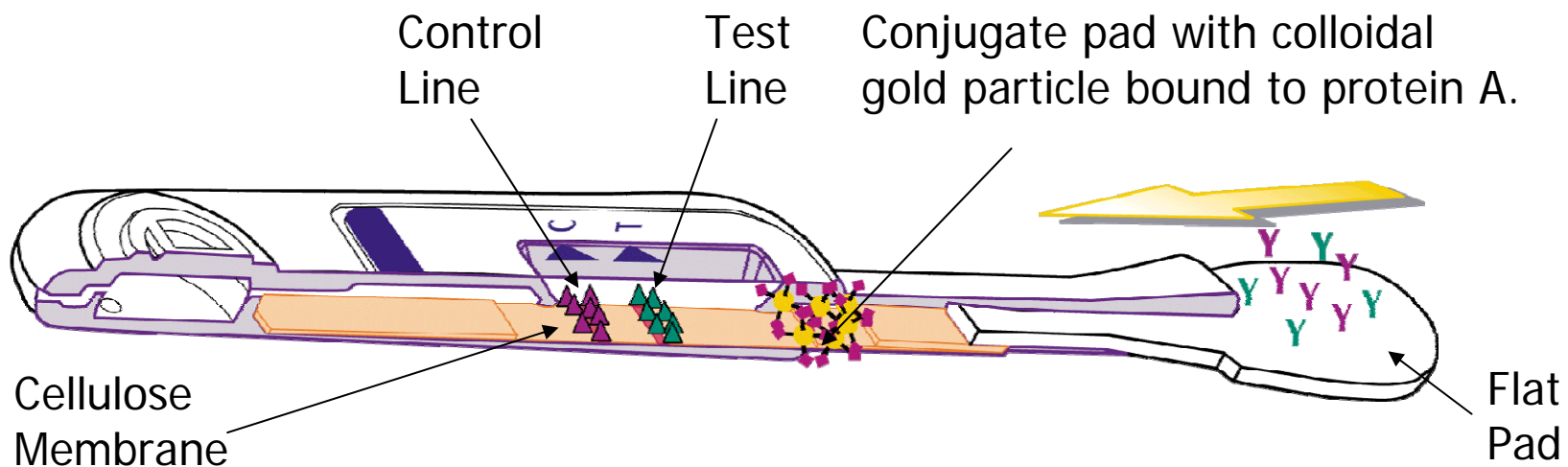
▲ Anti-Human Antibody

Colloidal Gold
Conjugated
to Protein A

Y Human Antibodies

▲ HIV Antigen

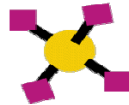
Y HIV-1/2 Antibodies



Using a lateral flow process, a sample specimen is wicked up by the flat pad of the device and transferred to the cellulose membrane. Human antibodies and HIV antibodies (if present) bind to the colloidal gold particles.

OraQuick ADVANCE[®] Clinical Features Operating Principle

▲ Anti-Human Antibody

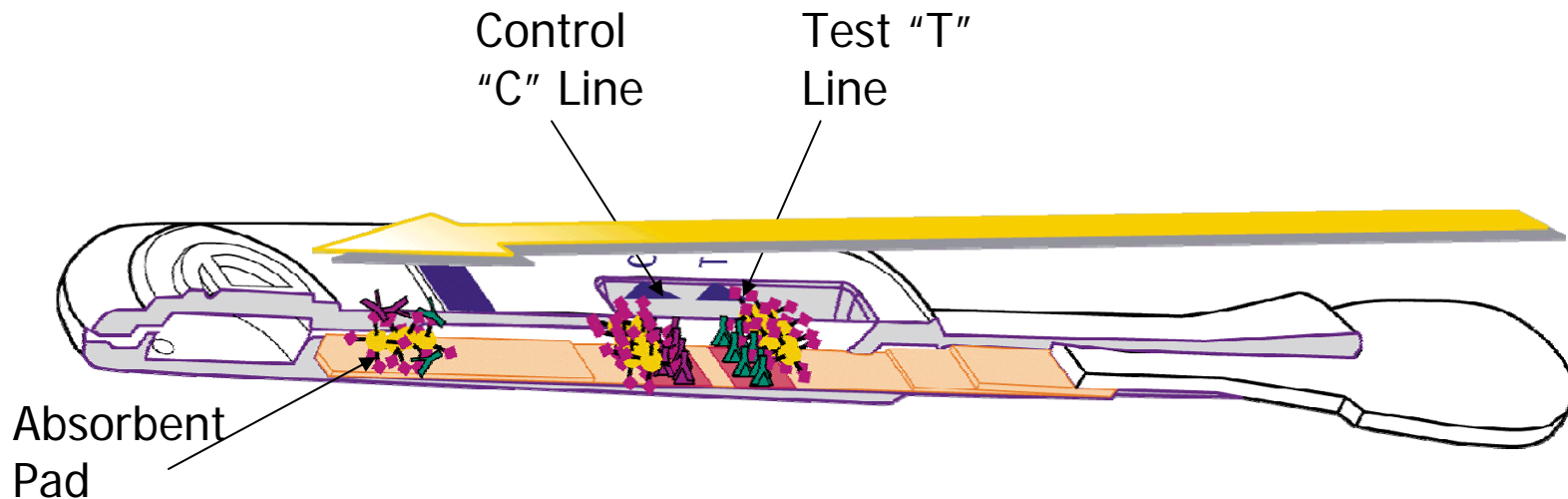


Colloidal Gold
Conjugated
to Protein A

Y Human Antibodies

▲ HIV Antigen

Y HIV-1/2 Antibodies



Colloidal gold particles containing HIV antibodies bind to the HIV antigen "T" line forming a visible red band. Colloidal gold particles containing Human antibodies bind to the Anti-Human Antibodies "C" line forming a visible red band. Any remaining colloidal gold particles are captured and retained by the absorbent pad.

Clinically Proven with >99% Accuracy

- What defines accuracy?

Sensitivity: The ability to detect a true positive.

Specificity: The ability to detect a true negative

Clinically Proven with >99% Accuracy

| Claim | Sensitivity | Specificity |
|----------------------------|-------------|-------------|
| HIV-2* | 100.0% | - |
| Oral Fluid | 99.3% | 99.8% |
| Fingerstick Whole Blood | 99.6% | 100.0% |
| Plasma | 99.6% | 99.9% |

*HIV-2 (Based on >800 banked serum/plasma specimens. In addition, FSWB and OF tests were done on 3 HIV-2 infected individuals). Specificity not reported. Sensitivity and specificity for venipuncture whole blood not reported.

Tips to Avoid False Positive and False Negative Results

- In order to ensure accurate results are obtained, specimen collection is important. The following may cause inaccurate results:
 - Improper oral fluid specimen collection (over or under swabbing)
 - Not following proper fingerstick collection procedures
- Failure to test in well lit area can make results more difficult to read
- If you wear eyeglasses to read, it is important that you wear them while interpreting results

Test Kit - Available Packaging

| Kit Size | 100 Count | 25 Count |
|-------------------------------|---|-----------|
| Item No. | 1001-0078 | 1001-0079 |
| Reusable Test Stand | 10 | 5 |
| Specimen Collection Loops | 100 | 25 |
| Subject Information Pamphlets | 100 | 25 |
| Package Insert | 1 | 1 |
| Customer Letter | 1 | 1 |
| Shelf Life | 30 Months from Date of Manufacture | |
| Storage Requirements | 2—27°C (36 —80°F) | |
| Operating Requirements | 15—37°C (59 —99°F) | |
| CLIA Complexity | Waived (Moderate Plasma Only) | |
| Test Sample Type(Size) | Oral Fluid, Venipuncture and Fingertick Whole Blood, Plasma | |
| Test Type | Qualitative Immunoassay | |
| CPT Code | 86703 / G0435 HIV-1/2 | |

Additional Materials Required and Available as an Accessory Kit



OraQuick *ADVANCE*[®] Kit Controls Positive Controls

- **Black-capped vial** - inactivated human plasma positive for antibodies to HIV-1
- **Red-capped vial** - inactivated human plasma positive for antibodies to HIV-2

Negative Control

- White-capped vial - human plasma negative for antibodies to HIV-1 and HIV-2
- Sufficient volume to perform 25 tests

Additional Materials Required



- Timer or Watch
- Biohazard Waste Container
- Disposable, Absorbent Workspace Cover



Additional Required Phlebotomy Materials (WB, Plasma):



- Disposable Gloves
- Sterile Lancet
- Phlebotomy materials
- Centrifuge
- Antiseptic Wipe
- Sterile Gauze Pads



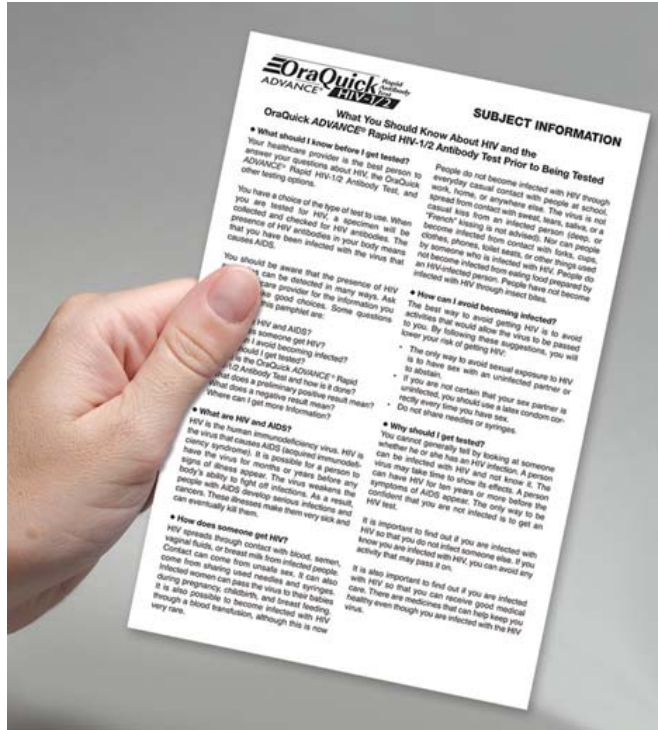
Test Preparation



OraSure Technologies, Inc.

OraQuick
ADVANCE[®] **HIV-1/2**

Prior to Testing



- Remember to observe “Universal Precautions” at all times.
- Read product instructions *first*.
- Gather testing materials.
- Let test come to operating temperature.
- Set up workspace cover and reusable Test Stand on a flat level surface.
- Put on disposable gloves if working with blood or plasma specimens.
- Provide the “Subject Information” pamphlet to the person being tested.



General Test Preparation



- Check expiration date on OraQuick *ADVANCE*[®] Pouch.
- Open two chambers of Divided Pouch by tearing at the notches.
- Leave the Test Device in the Pouch.
- Remove the Developer Vial. Gently rock the cap back and forth to remove.
- Slide the Vial into the top of one of the slots of the Stand. Make sure it is seated.

General Test Preparation

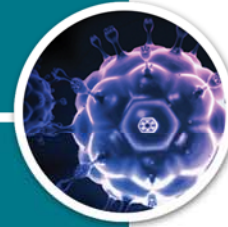


- Remove test device from Pouch. **DO NOT** touch the flat pad.
- Label device with subject information. **DO NOT** block holes on back of device.

NOTE: Test Device must be inserted into vial within 30 minutes of sample introduction.

- Make sure an Absorbent Packet is present. If no Absorbent Packet is present, discard Device; obtain a new Pouch for testing.

Specimen Collection and Test Initiation



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OraQuick
ADVANCE[®] **HIV-1/2**

Universal Precautions

Handling of Potentially Infectious Human Samples

- Before handling any specimens please refer to your facility's procedures on universal precautions.
- Universal guidelines stress that all patients should be assumed to be infectious for blood-borne diseases such as AIDS and hepatitis.
- Barriers are used for protection against occupational exposure to blood and certain body fluids.
 - These barriers consist of:
 - Personal protective equipment (PPE)
 - Engineering controls
 - Work practice controls
- **FOR COMPLETE INFORMATION REFER TO THE CDC WEBSITE AT: <http://www.cdc.gov/HAI/prevent/prevention.html>**

Prior to Oral Fluid Specimen Collection

- Ensure prior to testing that the subject has not had anything to eat, drink (including water) or has chewed gum for at least 15 minutes.
- Have the subject wait for at least 30 minutes prior to testing if they have used any oral care products.

Oral Fluid – Specimen Collection



- Place the flat pad above above the teeth against the outer gum.
 - Gently swab completely around the outer gums, both upper and lower, one time around, using the Flat Pad.
 - **DO NOT** swab the roof of the mouth, the inside of the cheek or the tongue.
- NOTE: It is okay to use both sides of the Flat Pad during this procedure.

If Device is transported prior to testing



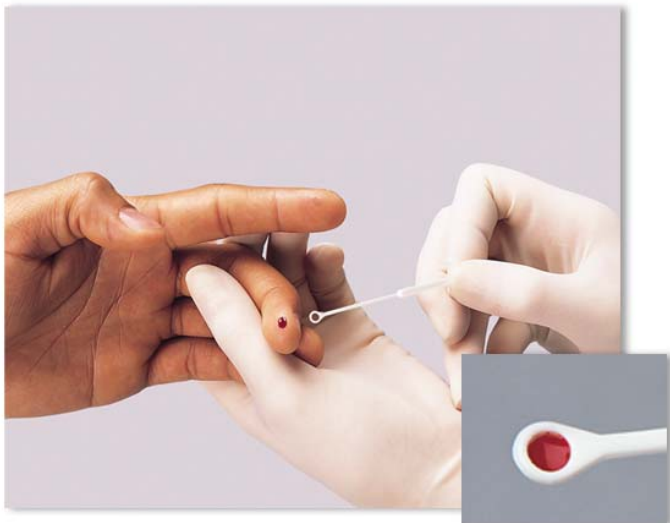
- **NOTE:** When collecting oral fluid specimens, the Test Device must be inserted into Developer Solution vial within 30 minutes of collection
 - Blood and plasma insertion within 60 minutes
- A test device containing an oral fluid specimen that is not inserted into the vial within 10 minutes of collection should be either stored on a flat surface or returned to the pouch after the desiccant has been removed.
- For a 10-30 minute delay in insertion, return the device to the pouch after desiccant has been removed
- Ensure that the pouch containing the device is kept in a horizontal position until the device is inserted into the developer solution vial.

Oral Fluid – Test Procedure



- Insert Flat Pad of device into the bottom of Developer Vial.
- Start timing test.
- Pink fluid will travel up Result Window. Fluid disappears as test develops. **DO NOT** remove device while test is running.
- Read results after 20 minutes but **not more** than 40 minutes. Adequate lighting must be available.

Fingerstick – Specimen Collection



- Use an antiseptic wipe; clean finger of person being tested. **Dry completely.**
- Use sterile lancet, puncture skin off center of finger pad.
- **WIPE** first droplet with gauze. Hold the hand downward for new droplet. Gently apply pressure to express if needed.
- With new Specimen Collection Loop, touch to droplet.
- *Make sure Loop is completely filled with blood.*
- [Fingerstick whole blood collection Video](#)

Fingerstick – Mixing Specimen



- Insert blood-filled end of Loop into the vial.
Be careful not to touch the sides of the vial.
- Use Loop to stir sample in Vial. Dispose of used loop in biohazard waste container.
- Check Solution to make sure it appears pink in color if using whole blood.

Fingerstick – Test Procedure



- Insert Flat Pad of device into the bottom of Developer Vial.
- Start timing test.
- Pink fluid will travel up Result Window. Fluid disappears as test develops.
DO NOT remove device while test is running.
- Read results after 20 minutes but **not more** than 40 minutes.
Adequate lighting must be available.

Whole Blood – Specimen Collection



- Use standard phlebotomy procedures, collect whole blood sample with one of the following collection tubes:
 - EDTA, Sodium Heparin, or Sodium Citrate.
- Mix blood tube by inversion.
- With new Specimen Collection Loop, dip loop into test tube.
- Visually inspect the Loop to make sure that it is completely filled with a specimen.

Whole Blood – Mixing Specimen



- Insert blood-filled end of Loop into the vial.
Be careful not to touch the sides of the vial.
- Use Loop to stir sample in Vial.
Dispose of used loop in biohazard waste container.
- Check Solution to make sure it appears pink in color if using whole blood.

Whole Blood – Test Procedure



- Insert Flat Pad of device into the bottom of Developer Vial.
- Start timing test.
- Pink fluid will travel up Result Window. Fluid disappears as test develops. **DO NOT** remove device while test is running.
- Read results after 20 minutes but **not more** than 40 minutes. Adequate lighting must be available.

Plasma – Specimen Collection



- Collect a whole blood sample in a blood collection tube containing an anticoagulant.
- Centrifuge the blood to separate cells from plasma.
- With new Specimen Collection Loop, dip loop into the plasma specimen.
- Visually inspect the Loop to make sure that it is completely filled with a specimen.

Plasma – Mixing Specimen



- Insert plasma-filled end of Loop into the vial.
Be careful not to touch the sides of the vial.
- Use Loop to stir sample in Vial.
Dispose of used loop in biohazard waste container.

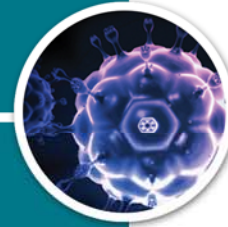


Plasma – Test Procedure



- Insert Flat Pad of device into the bottom of Developer Vial.
- Start timing test.
- Pink fluid will travel up Result Window. Fluid disappears as test develops. **DO NOT** remove device while test is running.
- Read results after 20 minutes but **not more** than 40 minutes. Adequate lighting must be available.

Test Interpretation



OraSure Technologies, Inc.

OraQuick
ADVANCE[®] **HIV-1/2**

Test Reading & Interpretation

- Non-reactive result
- Reactive result
- Invalid

Reading a Non-Reactive Test



A test is **NON-REACTIVE** if:

- A reddish-purple line appears next to the triangle labeled “C” **and** no line appears next to the triangle labeled “T”.

Interpreting a Non-Reactive Test

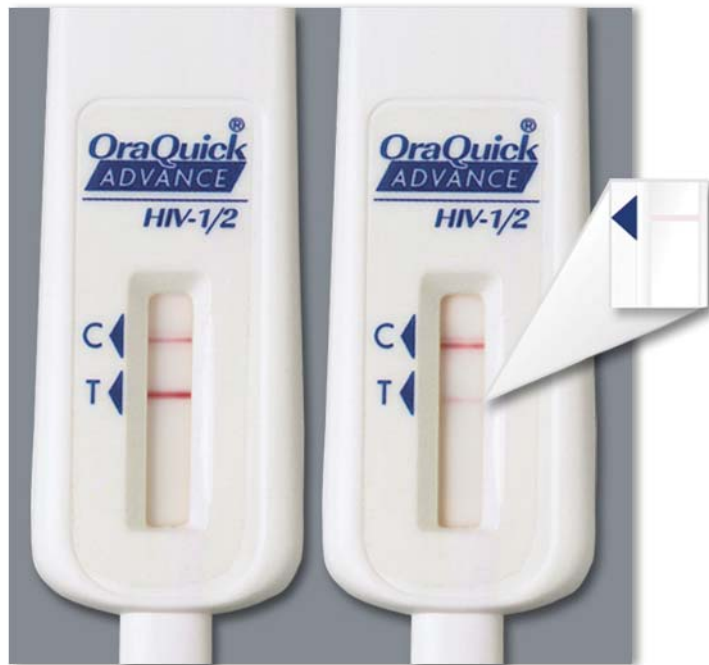


A **Non-Reactive** test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen.

The test result is interpreted as **NEGATIVE for HIV-1 and HIV-2 antibodies.**

Follow CDC Guidelines to inform subject of test result and interpretation.

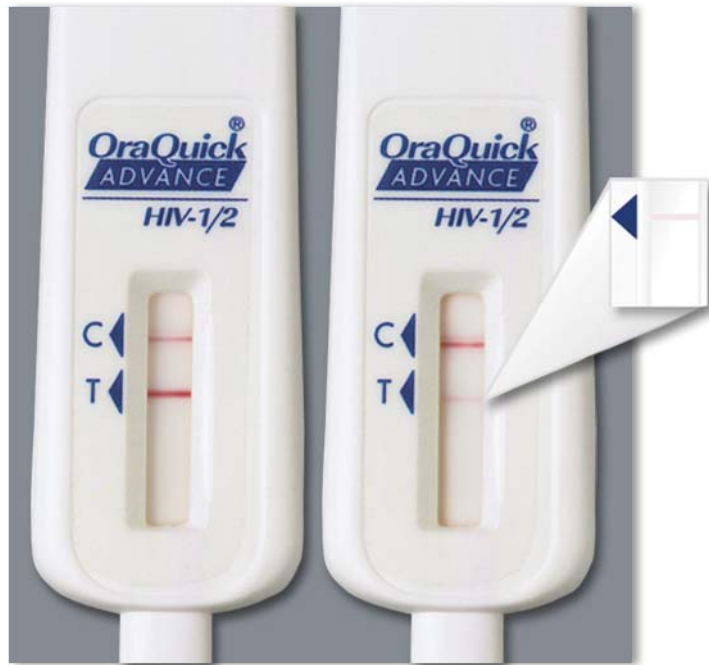
Reading a Reactive Test



A test is **REACTIVE** if:

- A reddish-purple line appears next to the triangle labeled “C” **and** a reddish-purple line appears next to the triangle labeled “T”. Lines may vary in intensity.
- **NOTE:** The test is reactive if a complete reddish-purple line appears next to the “T” triangle **and** next to the “C” triangle, no matter how faint.

Interpreting a Reactive Test

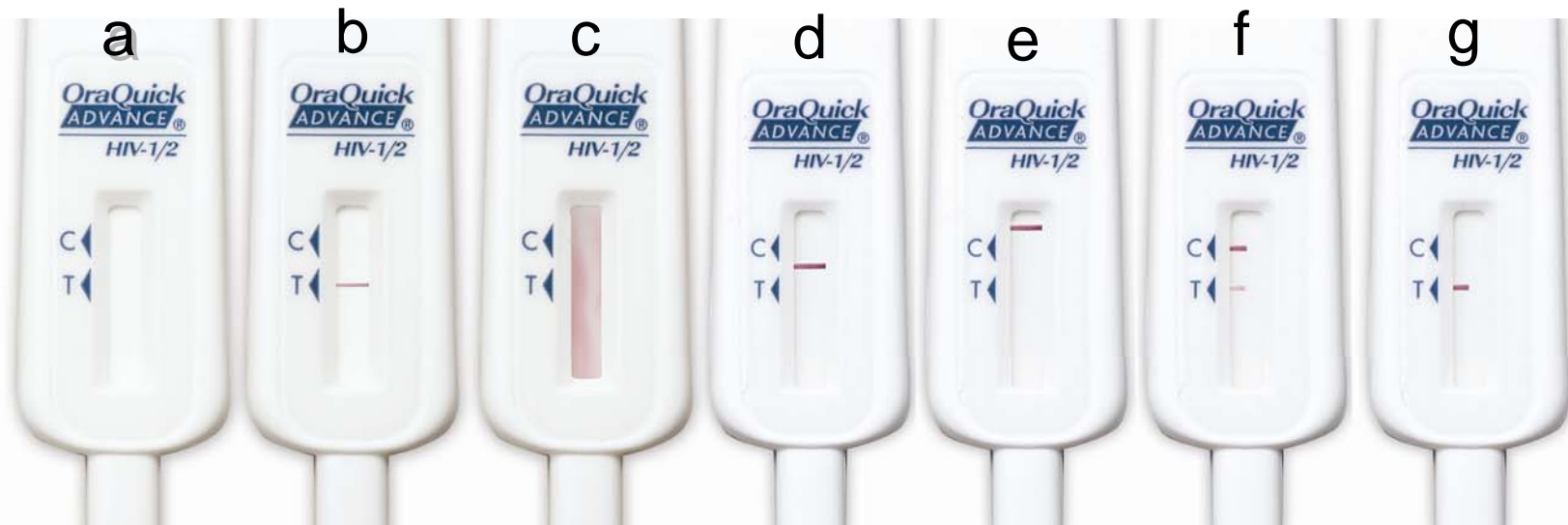


A Reactive test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen.

The test result is interpreted as **PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies.**

Follow CDC Guidelines to inform subject of test result and interpretation.

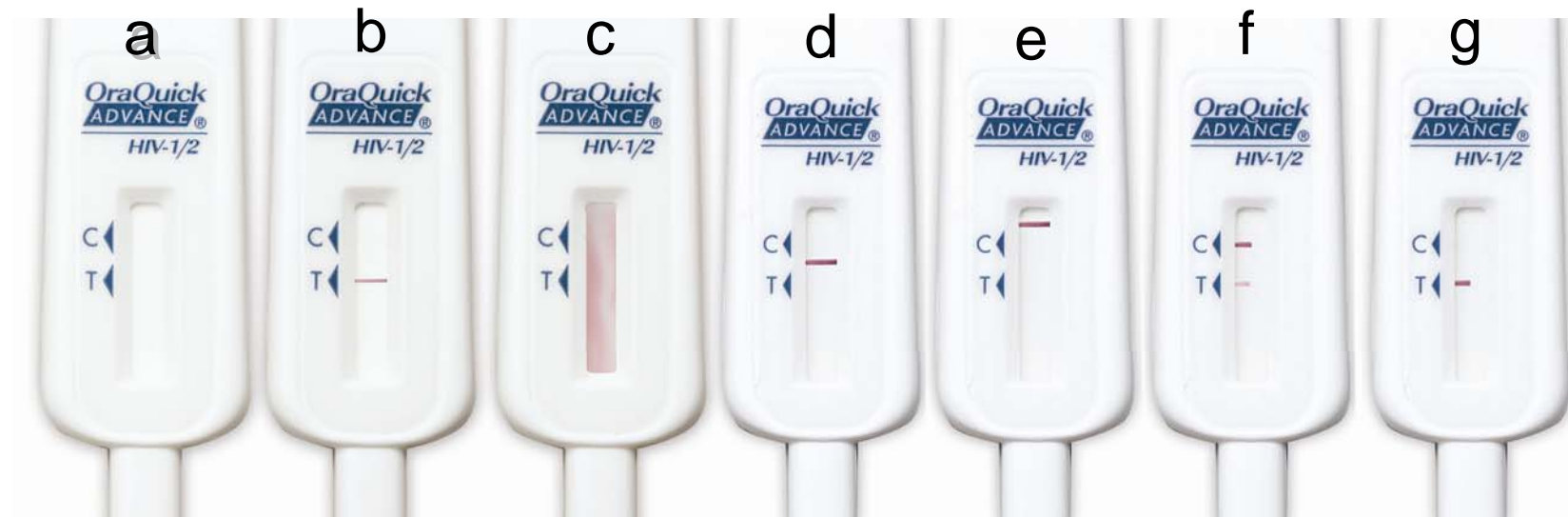
Reading an Invalid Test



A test is **INVALID** if:

- No reddish-purple lines appears next to the triangle labeled “C” (see picture a and b), **or**
- A red background in the Results Window makes it difficult to read the result after 20 minutes (picture c), **or**
- If any of the lines are **NOT** inside the “C” or “T” triangle areas (picture d or e).
- If any of the lines are **partially developed** on either side of the “C” or “T” zones (pictures f and g)

Interpreting an Invalid Test



An **Invalid** test result means that there was a problem running the test, either related to the specimen or to the Device.

IT CANNOT BE INTERPRETED.

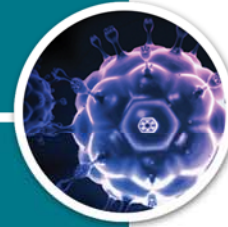
Repeat test with a new Pouch and a new oral fluid, fingerstick or venipuncture whole blood, or plasma sample.

General Test Clean Up



- Dispose of the used test materials in a biohazard waste container.
- When using gloves, change your gloves between each test to prevent contamination. Throw away the used gloves in a biohazard waste container.
- Use a freshly prepared 10% solution of bleach to clean up any spills.

Quality Assurance



OraSure Technologies, Inc.

OraQuick
ADVANCE[®] HIV-1/2

Quality Control

- Positive and Negative Kit Controls provide:
 - Quality Control to:
 - Assure test performance
 - Provide for user proficiency
- Positive Controls
 - Are calibrated specifically to a very low assay reactivity level (challenge line).
 - Low assay performance reaffirms assay functionality (assay chemistry).
 - Provide better training tool for user proficiency.



Test Kit - Kit Controls



Positive Controls

- **Black-capped vial** - inactivated human plasma positive for antibodies to HIV-1
- **Red-capped vial** - inactivated human plasma positive for antibodies to HIV-2

Negative Control

- White-capped vial - human plasma negative for antibodies to HIV-1 and HIV-2
- Sufficient volume to perform 25 tests

Test Kit Control Contents

| #1001-0077 Test Kit Control | |
|---|--|
| Positive HIV-1 Control Vial (1) (Black Cap) | 0.2 mL |
| Positive HIV-2 Control Vial (1) (Red Cap) | 0.2 mL |
| Negative Control Vial (1) (White Cap) | 0.2 mL |
| Package Insert | 1 |
| Storage Requirements | 2—8°C (35—46°F)* |
| Shelf-Life | 1 Year from manufacture date or 8 weeks After Initial Opening of Packaging |

***Kit Controls do not have to be brought to operating temperature prior to performing testing.**

Performing Kit Controls



Run one positive HIV-1 control (+), one positive HIV-2 control (+), and one negative control (-) for:

- Each new operator,
- Each new lot of test kits,
- Each new shipment of test kits,
- Test kit storage temperature falls outside 2-27°C; 35-80°F,
- Testing area temperature falls outside of 15-37°C; 59-99°F, and
- At periodic intervals dictated by user facility.

Performing Kit Controls

- Getting Started
 - **Read the OraQuick *ADVANCE*[®] Kit Control Package Insert.**
 - Remember to observe “Universal Precautions” at all times.
 - Follow directions for inspecting and opening pouches.
 - Follow directions for setting up workspace.
 - Label devices for Negative, Positive-1 and Positive-2 Control.
DO NOT block holes on back of device.
DO NOT touch flat pad of device.

Performing Kit Controls



NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears cloudy or discolored.

- Open a Kit Control vial.
- Insert round end of a new Specimen Collection Loop into the reagent vial.
- Remember to use separate unused Loop for each control reagent.

Performing Kit Controls



- Immerse Loop into Developer Solution Vial.
- **DO NOT** touch side of vial.
- Use the loop to stir contents.
- Discard Loop in a Biohazard Waste Container.



Performing Kit Controls



- Retrieve correct labeled device.
- Insert Flat Pad of device into the bottom of Developer Vial.
- Start timing test.
- Pink fluid will travel up Result Window. Fluid disappears as test develops. **DO NOT** remove device while test is running.
- Read results after 20 minutes but **not more** than 40 minutes. Adequate lighting must be available.

Performing Kit Controls

Example of a
Non-Reactive
Result
(Negative)

Example of a
Reactive Result
(Preliminary
Positive)



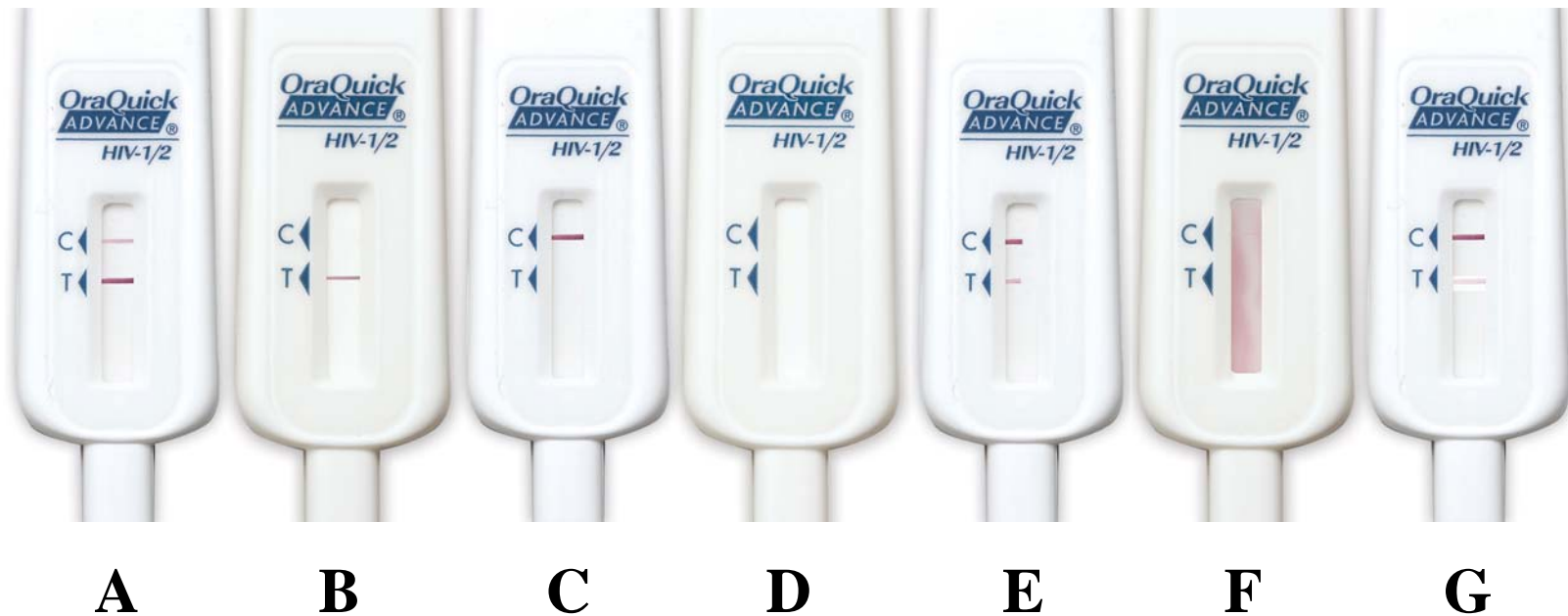
Expected Results:

- **Negative Control** will produce a **Non-Reactive** test result. A line should be present at “C” triangle in result window.
- **Positive Controls** will produce a **Reactive** test result specifically manufactured to produce a very faint (*Challenge Test*) “T” line.
- Lines should appear at “C” and “T” triangles in result window.

Kit Control Failure

- If test result does not perform as expected
 - Repeat test using new Test Device, Developer Solution Vial, and Control Specimen.
- If test result does not perform a second time
 - Discontinue testing and contact OraSure Technologies.

OraQuick ADVANCE[®] Interpretation Review



1-800-ORASURE • 1-800-672-7873

OraQuick ADVANCE[®] Interpretation Review

Reactive

Invalid

Non-Reactive

Invalid

Invalid

Invalid

Reactive



A

B

C

D

E

F

G

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