OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test - Whole Blood Technical Procedure 3402
OraSure Technologies, Inc.

Principle

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 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick whole blood, venipuncture whole blood and plasma specimens. At UCDHS, only EDTA whole blood samples will be tested. The OraQuick® *ADVANCE* Rapid HIV-1/2 antibody test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.

THIS TEST (using only whole blood EDTA specimens) IS RESERVED ONLY FOR BODY FLUID EXPOSURE INCIDENTS INVOLVING UCD HEALTH GROUP PATIENTS, O.B. UNSCREENED MOTHERS, DONOR MOTHERS WHOSE BREAST MILK WAS FED TO THE WRONG INFANT, NEONATES WHOSE MOTHER'S HIV STATUS IS UNKNOWN (MOTHER UNAVAILABLE OR REFUSES TESTING), SHRINERS HOSPITAL PATIENTS, "REVERSE TRANSMISSION" EXPOSURE INCIDENTS (PATIENT IS EXPOSED TO EMPLOYEE BLOOD), AND SPECIAL EMERGENCY CASES REQUIRING INFECTIOUS DISEASE DIVISION REQUEST/CHEMISTRY DIRECTOR APPROVAL.

Clinical Significance

Using a rapid HIV test increases the number of HIV infected persons who may be diagnosed. The Centers for Disease Control and Prevention (CDC) estimates that nearly one third of the estimated 900,000 HIV-infected persons in the United States do not know their HIV status. As a result, they cannot benefit from early intervention with effective antiviral therapy. Rapid HIV testing is instrumental in the decision to initiate treatment for health care workers after accidental exposures to body fluids from infected individuals. In the U.S., it is estimated that 600,000 to 1,000,000 "needlestick injuries" occur each year. Critical decisions about treatment depend on the availability of accurate, rapid HIV test results.

Summary and Explanation

Acquired Immune Deficiency Syndrome (AIDS), AIDS related complex (ARC) and pre-AIDS are thought to be caused by the Human Immunodeficiency Virus (HIV). The first AIDS-related virus, HIV-1 (also known as HTLV-III, LAV-1 and ARV) has been isolated from patients with AIDS and from healthy persons at high risk for AIDS. (1,2) Genetic analysis of HIV-1 isolates has documented the existence of subtypes. To date, eight HIV-1 subtypes (A through H), designated as group M, have been identified worldwide in addition to the highly divergent HIV-1 isolates from AIDS patients in Cameroon, designated as Group O. (3) A closely related but distinct second type of pathogenic human immunodeficiency retrovirus, designated HIV-2 (formerly LAV-2), has been isolated from West African patients with AIDS. HIV-2 has been shown to share a number of conserved sequences with HIV-1, but serological cross-reactivity between HIV-1 and HIV-2 has been shown to be highly variable from sample to sample.

HIV is known to be transmitted by sexual contact, by exposure to blood (including sharing contaminated needles and syringes), or by contaminated blood products, or it may be transmitted from an infected mother to her fetus during the prenatal period. Individuals infected with HIV produce antibodies against the HIV viral proteins. Testing for the presence of antibodies to HIV in bodily fluids (e.g., blood, oral fluid, and urine) is an accurate aid in the diagnosis of HIV infection. However, the implications of seropositivity must be considered in a clinical context. For example, in neonates, the presence of antibodies to HIV is indicative of exposure to HIV, but not necessarily of HIV infection, due to the acquisition of maternal antibodies that may persist for up to eighteen months. Conversely, absence of antibody to HIV cannot be taken as absolute proof that an individual is free of HIV infection or incapable of transmitting the virus. An antibody response to a recent exposure may take several months to reach detectable levels. HIV has been isolated from asymptomatic, seronegative individuals presumably before seroconversion following exposure.

The standard laboratory HIV testing algorithm used in the United States consists of screening with an enzyme immunoassay (EIA) and confirmation of repeatedly reactive EIAs using the Western blot test. Results are typically reported within 48 hours to 2 weeks, making these standard screening and supplemental tests inadequate to meet the need for rapid HIV diagnosis. The OraQuick® *ADVANCE* Rapid HIV-1/2 antibody test is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

Rapid HIV testing for pregnant women who do not know their status at the time of delivery permits therapy to be initiated for these mothers during labor, and to their infants post partum, substantially reducing the chance that the infants will become infected with HIV. Likewise, rapid HIV testing is instrumental in the decision to initiate treatment for healthcare workers after accidental exposures to body fluids from infected individuals. In the U.S., it is estimated that 1,000,000 “needlestick injuries” occur each year. Critical decisions about treatment depend on the availability of accurate, rapid HIV test results.

Methodology

The OraQuick® *ADVANCE* Rapid HIV-1/2 antibody test is a manually performed, visually read, 20 minute immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in human oral fluid, fingerstick or venipuncture whole blood specimens and plasma. The OraQuick® *ADVANCE* rapid test is comprised of a single-use test device and a single-use vial containing a pre-measured amount of a buffered developer solution. Each component is sealed in separate compartments of a single pouch to form the test. The OraQuick® *ADVANCE* rapid test utilizes a proprietary lateral flow immunoassay procedure. The plastic housing device holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and the platform for indication of the test results.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test (T) zone and the Control (C) zone, respectively.

An oral fluid specimen is collected using the flat pad on the test device, followed by the insertion of the test device into the vial of developer solution. A fingerstick or venous whole blood or plasma specimen is collected and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it re-hydrates the protein-A gold colorimetric reagent contained in the device. As the specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of anti- bodies to HIV-1 and/or HIV-2 in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen.

Further up the assay strip, the sample will encounter the C zone. This built-in procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the C zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HIV-1 and/or HIV-2 (refer to the *Test Result* and *Interpretation of Test Result* section).

The test results are interpreted after 20 minutes but not more than 40 minutes after the introduction of the test device into the developer solution containing the test specimen. No precision pipeting, predilutions, or specialized instrumentation are required to perform the Oraquick® ADVANCE Rapid HIV-1/2 Antibody Test.

Specimen

Acceptable Sample Containers

13 x 75 Purple Top BD tubes (EDTA)
Purple Top BD microtainers (EDTA)

Unacceptable Specimens

Samples other than venous whole blood with designated anticoagulants or from a fingerstick are unacceptable. Unacceptable anticoagulants are Lithium Heparin (green top) and Sodium Fluoride (gray top). Oral fluid samples are unacceptable.

Notify the appropriate person in charge of the patient and request a new specimen. Document specimen information in the LIS.

Specimen Processing, Storage and Stability

Prior to testing, mix the blood tube gently by inversion several times to ensure a homogenous sample.

If specimens are not tested at the time of collection, the whole blood may be stored at 2° - 18°C for up to 30 hours.

Test Request Procedure

General policy:

The exposure program will produce a “Priority One” rapid HIV lab slip to test the source patient only. Hand written Exposure forms are only to be used in the event of a printer failure to the on-line program. Tests ordered on the source patient are HBsAg hepatitis B surface antigen, Hepatitis C antibody and the Rapid HIV test.

For donor mothers whose breast milk was fed to the wrong infant, a miscellaneous lab form will be filled out, printed with the Cost Center 9628, and “Breast Milk” will also be printed on the request slip. Samples drawn from the donor mother will be tested for HIV (Rapid HIV test), Hepatitis B (HBSag) and Hepatitis C (HCV).

For unscreened OB mothers or neonates whose mother's HIV status is unknown, the rapid HIV test will be ordered in EMR and qualifying reason will be denoted when ordered. The routine HIV test performed in Special Chemistry should not be ordered concomitantly.

For reverse transmission exposures, an Employee Health exposure form printed with the Account number 12300286 will be filled out. The referring physician’s name (Neil F. Speth, M.D.) will also be printed on the request slip. Samples drawn from the employee will be tested for HIV (Rapid HIV test), Hepatitis B (HBSag) and Hepatitis C (HCV).

For special cases involving emergency department patients with or without Infectious Disease Division request, Chemistry Director approval is required. Collect the following information (in addition to the patient information):

a. name and contact information for the Infectious Disease physician requesting the test, if applicable
b. name and contact information for the Emergency Department physician managing the patient

Reagents

Materials Provided

OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test Kits are available in the following packaging configurations: 100 Count; 25 Count:

Kit Size	100 count	25 count
Divided Pouches, each containing: Test Devise (1) Absorbent Packet (1) Developer Solutions Vial (1) (each vial contains 1 mL of a phosphate buffered saline solution containing polymers and an antimicrobial agent)	100	25
Reusable Test Stands	10	5
Specimen Collection Loops	100	25
Subject Information Pamphlets	100	25
Package Insert	1	1
Customer Letter	1	1

DIVIDED POUCH WITH TWO CHANBERS

REUSABLE TEST STAND

SPECIMEN COLLECTION LOOP

DEVELOPER SOLUTION VIAL

TEST DEVICE WITH RESULT WINDOW AND FLAT PAD

DESSICANT PACKET

Materials Required and Available as an Accessory to the Kit

OraQuick ADVANCE Rapid HIV-1/2 Antibody Test Kit Controls – P/N 1001-0077

Contents:

- HIV-1 Positive Control Vial (0.2 ml) – black cap
- HIV-2 Positive Control Vial (0.2 ml) – red cap
- Negative Control Vial (0.2 mL) – white cap
- Package Insert

Store at 2° to 8°C (35° to 46°F)

CONTROL KIT

Materials Needed But not Supplied with Test Kit

Timer or watch capable of timing 20 - 40 minutes

Vinyl or nitrile disposable gloves

Biohazard waste container

Clean, disposable, absorbent workspace cover

Storage and Stability

Store unused OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Tests unopened at 2° - 27°C. These will be stored at ambient temperature at UCDMC SESP Chemistry lab. Unopened tests are stable until the expiration date listed on the packaging. Do not open the Divided Pouch until you are ready to perform a test.

Store OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test Kit Controls (external controls) at refrigerated temperature in the walk-in refrigerator. These do not have to be brought to room temperature before use. Unopened controls are stable until the expiration date listed on the packaging. Once opened controls are only stable for eight weeks.

Warnings - For in vitro Diagnostic Use

Read the procedure completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.

Before performing testing, all operators MUST be familiar with Universal Precautions for the Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings.(5)

FDA has approved this kit for use with oral fluid, venipuncture whole blood (EDTA, Sodium Heparin, Sodium Citrate, and ACD Solution A), fingerstick whole blood and plasma samples only. Use of this kit with specimen types other than those specifically approved for use with this device may result in inaccurate test results. At UCDHS, only EDTA whole blood samples will be tested.

This test should be performed at ambient temperature, 15° - 37°C. If stored refrigerated, ensure that the Divided Pouch is brought to ambient temperature before performing testing. Kits will be stored at ambient temperature at UCDMC SESP Chemistry lab.

If the test kit is stored at temperatures outside of ambient temperature (2° - 27°C), or used outside of the operating temperature (15° - 37°C), use the Kit Controls to ensure performance of the test.

Individuals infected with HIV-1 and/or HIV-2 who are receiving highly active anti-retroviral therapy (HAART) may produce false negative results.

Precautions - Safety Precautions

Handle specimens and materials contacting specimens as if capable of transmitting infectious agents.

Do not drink, eat, or smoke in areas where specimens are being handled or testing is being performed.

Wear disposable gloves while handling specimens and performing tests. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.

Oral fluid is not considered potentially infectious unless it contains blood.(8)

Dispose of all test specimens and materials used in the test procedure in a biohazard waste container.

Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant.(4) If a bleach solution is used, the bleach solution should be made fresh each day.

For additional information on biosafety, refer to “Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings”(5) and “Updated U.S. Public Health Service Guidelines for the Management of Occupatioanl Exposures to HBV, HCV, and HIV and Recommendations for Post exposure Prophylaxis”.(8)

Handling Precautions

Use all Specimen Collection Loops, Test Devices, and Developer Solution Vials only once and dispose of properly (see Safety Precautions). Do not reuse any of these test components.

Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.

Do not interchange Test Devices and Developer Solution Vials from kits with different lot numbers.

Avoid microbial contamination and exercise care in handling the kit components.

To ensure accurate results, the Test Device must be inserted into the Developer Solution Vial within 60 minutes after introducing the blood sample.

When collecting oral fluid specimens the test device must be inserted into the Developer Solution Vial within 10 minutes of collection.

Adequate lighting is required to read a test result.

Reagent Documentation

Document lot numbers of all reagent kits and external controls on reagent log sheet. Also document on containers the date opened, and the expiration date for controls.

Calibration

None required.

Quality Control

Built-in Control Features

The OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test has a built-in procedural control that demonstrates assay validity. A reddish-purple line in the Control ("C") area of the Result Window indicates that a specimen was added and that the fluid migrated appropriately through the Test Device. The Control line will appear on all valid tests, whether or not the sample is Reactive or Non-reactive. (Refer to *Test Result and Interpretation of Test Result* section below.)

External Quality Control

Oraquick® *ADVANCE* Rapid HIV-1/2 Antibody Test Kit Controls are available separately for use only with the Oraquick® ADVANCE Rapid HIV-1/2 Antibody Test. The Kit Controls are specifically formulated and manufactured to ensure performance of the Test, and are used to verify your ability to properly perform the test and interpret the results. The HIV-1 and HIV-2 Positive Controls will produce a Reactive test result and have been manufactured to produce a very faint Test ("T") line. The Negative control will produce a Non-Reactive test result. (Refer to *Test Result and Interpretation of Test Result* section below.)

Positive and **Negative** external controls should be run in the following circumstances:

1. Daily when a patient specimen is tested. Controls do not need to be run if a specimen is not received. If a rapid HIV specimen is received and external controls have already been run on that calendar day, they do not need to be run again.
2. When opening a new test kit lot.
3. Whenever a new shipment of test kits is received.
4. If the temperature of the test kit storage area falls outside of 2° - 27°C
5. If the temperature of the testing area falls outside of 15° - 37°C (59° – 99°F)

Document external QC results on the QC log.

External Control Storage and Stability

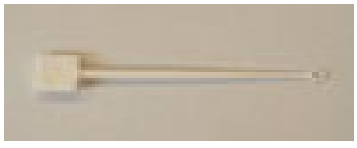
The External Controls are stable until the expiration date printed on the label when stored unopened at 2-8°C.

After opening, they are stable for 8 weeks when stored at 2-8°C.

Testing Procedure

1. Prior to testing, mix the blood tube gently by inversion several times to ensure a homogenous sample.
2. Pick up an unused Specimen Collection Loop by the thick "handle" end (picture 1). Put the "rounded" end of the Loop in the tube of blood (picture 2). Make sure the Loop is completely filled with blood (picture 3).

   If the loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container, get a new loop and start over.



PICTURE 1

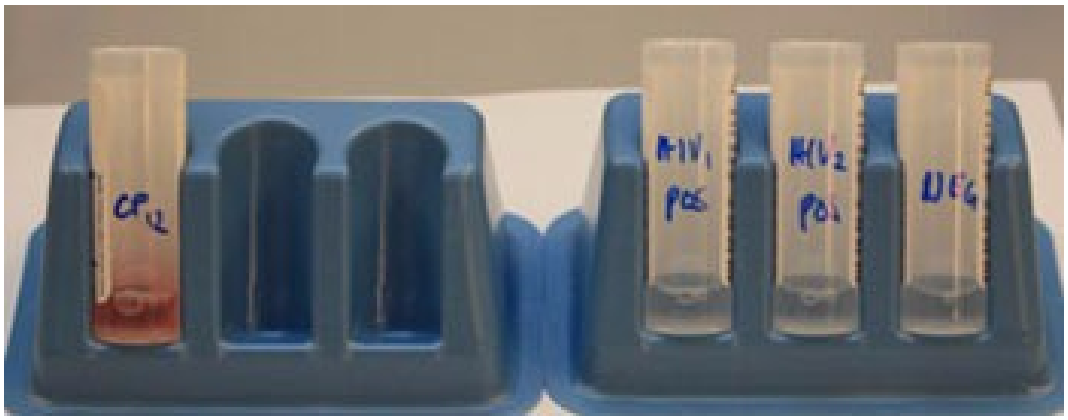
PICTURE 2

PICTURE 3

3. Immediately insert the blood-filled end of the loop all the way into the Vial. Use the Loop to stir the blood sample in the Developer Solution. Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.

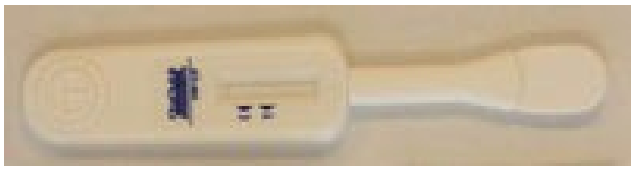
4. Check the Solution to make sure that it appears pink. This means that the blood was correctly mixed into the Solution (see picture 4, left side) If the Solution is not pink, discard all test materials in a biohazard waste container. Start the test over. Use a new Pouch and a new blood sample.

   NOTE: External control specimens will not turn the Solution pink. Be sure the Loop is completely filled with QC material (see picture 4, right side).



[PATIENT] **PICTURE 4** [CONTROLS]

5. Remove the Device from the Pouch. Do not touch the Flat Pad (see picture 5). Check to make sure that an Absorbent Packet is included with the Device (see picture 6). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.



PICTURE 5 [FLAT PAD] **PICTURE 6**

6. Insert the Flat Pad of the Device all of the way into the Vial containing the blood sample. Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you. (see picture 6)

7. Set a timer for 20 minutes. Do not remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. (see picture 7) The pink fluid will gradually disappear as the test develops. Read the results after **20 minutes** but not more than **40 minutes** in a fully lighted area.

PICTURE 7

8. Refer to the *Test Result and Interpretation of Test Result* section.

Test Result and Interpretation of Test Results

Refer to the Result Window on the Test Device.

NON-REACTIVE

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”. See image below.

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**.

REDDISH-PURPLE LINE IN CONTROL ZONE

NO LINE IN THE TEST ZONE

REACTIVE

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”. One of these lines may be darker than the other.

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**.

REDDISH-PURPLE LINE IN CONTROL ZONE

FAINT RED LINE IN THE TEST ZONE

ALL REACTIVE PATIENT RESULTS MUST BE REPEATED.

INVALID

A test is **INVALID** if:

No reddish-purple line appears next to the triangle labeled “C” or a red background in the result window makes it difficult to read the result after 20 minutes or if any of the lines are NOT inside the “C” or “T” triangle areas.

An Invalid test result means that there was a problem running the test, either related to the specimen or to the Test Device. An Invalid result cannot be interpreted. Repeat the test with a new Divided Pouch and/or new sample. Contact Orasure Technologies’ Customer Service if you are unable to get a valid test result upon repeat testing.

NO REDDISH-PURPLE LINES IN CONTROL ZONE OR TEST ZONE

Calculations

None required

Limitations

1. The OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test must be used in accordance with the instructions in the package insert to obtain an accurate result.
2. Reading test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.
3. The FDA has approved this kit for use with fingerstick whole and venipuncture whole blood specimens and oral fluid only. Use of this kit with specimen types other than those specifically approved for use with this device may result in inaccurate test results.
4. Individuals infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may pro- duce false negative results.
5. Clinical data has not been collected to demonstrate the performance of the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody test in persons under 12 years of age.
6. A Reactive result using the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test suggests the presence of HIV-1 and/or HIV-2 antibodies in the specimen. The OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.
7. For a Reactive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
8. A Non-Reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
9. A person who has antibodies to HIV-1 or HIV-2 is presumed to be infected with the virus, except

that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.

Standard Reporting Format

Results are reported as **Non-reactive** or **Reactive**.

Reference Interval: Non-Reactive.

Notification: UCDMC Rapid HIV 1/2 results

O.B. Unscreened Mothers:

NON-REACTIVE
Result is reported in the LIS. No verbal notification is required. Disregard comments in the LIS regarding verbal reporting.

REACTIVE
Result is verbally reported to the patient's physician. Document this in the LIS with the result.

Neonates whose mother's HIV status is unknown, or whose mother is unavailable or refuses testing:

NON-REACTIVE
Result is reported in the LIS. No verbal notification is required. Disregard comments in the LIS regarding verbal reporting.

REACTIVE
Result is verbally reported to the patient's physician. Document this in the LIS with the result.

Donor Mothers from accidental feeding of breast milk to the wrong infant:

NON-REACTIVE or **REACTIVE**
Result is verbally reported to the patient's physician or Nurse Practitioner. Document this in the LIS with the result.

Special Emergency Department Cases with Prior Chemistry Director Approval:

NON-REACTIVE
Result is verbally reported to the patient's physician; also request that the patient have a blood specimen drawn for follow-up testing via HIV AG/AB COMBO SCREEN. Document the rapid HIV result in the LIS.

REACTIVE
Result is verbally reported to the patient's physician (Emergency Medicine physician and/or Infectious Disease physician as appropriate). Document this in the LIS with the result.

Incidents involving Reverse Transmission exposure

NON-REACTIVE or **REACTIVE**

Monday - Friday, 0730 to 1600:
Result should be reported to the Blood-borne Pathogen Exposure Surveillance Nurse in Employee Health Services, **pager# 816-3081**. If no response is received within 15 minutes, page the Employee Health Services Nurse Practitioner, **pager# 816-7236**.

Monday - Friday, 1600 to 0730, weekends and holidays:
Result should be reported to the Infectious Disease Fellow (call hospital operator for pager number).

Incidents involving Bloodborne pathogen exposure (splash, needlestick, etc.)

Result is reported verbally. Results are reported according to employee's place of employment.

U.C. Davis Health System

NON-REACTIVE

Monday - Friday, 0730 to 1600:
Result should be reported to the Blood-borne Pathogen Exposure Nurse in Employee Health Services, **pager# 816-3081**. If no response is received within 15 minutes, page the Employee Health Services Nurse Practitioner, **pager# 816-7236**.

Monday - Friday, 1600 to 0730, weekends and holidays:
Result should be reported to the Nursing Supervisor, **pager # 816-5364**.

REACTIVE

Monday - Friday, 0730 to 1600:
Result should be reported to the Blood-borne Pathogen Exposure Surveillance Nurse in Employee Health Services, **pager# 816-3081**. If no response is received within 15 minutes, page the Employee Health Services Nurse Practitioner, **pager# 816-7236**.

Monday - Friday, 1600 to 0730, weekends and holidays:
Result should be reported to the Infectious Disease Fellow (call hospital operator for pager number).

Shriners Hospital for Children - Northern California (SHCNC):

NON-REACTIVE

All hours
Report result to the SHCNC Infection Control/Employee Health Manager, **phone# 453-2026** or **pager# 590-6086**. If the manager is not available, call the SHCNC House Supervisor, **phone# 453-2146** or **pager# 523-9311**.

REACTIVE

Monday - Friday, 0730 to 1600:
Report result to the SHCNC Infection Control/Employee Health Manager, **phone# 453-2026** or **pager# 590-6086**. If the manager is not available, call the SHCNC House Supervisor, **phone# 453-2146** or **pager# 523-9311**.

Monday - Friday, 1600 to 0730, weekends and holidays:
Report result to the SHCNC Infection Control/Employee Health Manager, **phone# 453-2026** or **pager# 590- 6086**. If the manager is not available, call the SHCNC House Supervisor, **phone# 453-2146** or **pager# 523-9311**.

Prehospital Personnel Exposure

NON-REACTIVE

Monday - Thursday, 0700 to 1600:
Result should be reported to the Prehospital Care Coordinator, **pager# 816-0578**. If no response is received within 15 minutes, contact the Nursing Supervisor, **pager # 816-5364**.

Monday - Thursday, 1600 to 0700, Fridays, weekends and holidays:
Result should be reported to the Nursing Supervisor, **pager # 816-5364**.

REACTIVE

Monday - Thursday, 0700 to 1600:
Result should be reported to the Prehospital Care Coordinator, **pager# 816-0578**. If no response is received within 15 minutes, contact the Nursing Supervisor, **pager # 816-5364**.

Monday - Thursday, 1600 to 0700, Fridays, weekends and holidays:
Result should be reported to the Nursing Supervisor, **pager # 816-5364**

ALL VERBAL RESULTS MUST BE DOCUMENTED IN THE LIS USING THE "RESULT ENTRY BY SPECIMEN" FUNCTION INTO THE HIV RAPID TEST FIELD (WHICH HAS A CF PREFIX).

LIS Result Entry

1. The specimen has a CF prefix (for confidential). These results are only viewable with certain passwords.
2. Results are placed in the LIS via Result Entry:
   a. If non-reactive, enter "**N**" (**Nonreactive** will be resulted in the LIS).
   b. If Reactive, enter "**R**" (**REACTIVE – SEE NOTE** will be resulted in the LIS). These specimens will have the HIV AG/AB COMBO SCREEN and the HIV-1, HIV-2 CONFIRMATION test reflexively ordered for testing in the Special Chemistry department.
3. Reactive results will have the following note attached to the result:

   Note: The rapid HIV 1/2 antibody screening test is REACTIVE. Rare false positive results may occur. See HIV AG/AB COMBO SCREEN and HIV-1, HIV-2 CONFIRMATION results for confirmation of HIV antibody status. Rapid screening test is performed using the OraQuick ADVANCE Rapid HIV 1/2 antibody test.

4. Reactive results will flag as "**A**" for abnormal.
5. Patients from 29 days old to 12 years of age will have the following comment attached to the result:

   Note: The OraQuick ADVANCE Rapid HIV 1/2 antibody test is not FDA approved for use in patients less than 12 years of age and has not been validated in this population. Performance characteristics including positive and negative predictive values are unknown. Results should be interpreted with caution.

6. Patients less than 29 days old will have the following comment attached to the result:

   Note: The OraQuick ADVANCE Rapid HIV 1/2 antibody test is not FDA approved for use in patients less than 12 years of age and has not been validated in this population. Performance characteristics including positive and negative predictive values are unknown. In high risk neonates, testing should be supplemented by HIV viral load (EPIC Order LABCF0005) on whole blood and maternal antibody testing, if possible. Results should be interpreted with caution.

7. If the patient has already had an HIV test done within a specified time frame, those results must be called and documented. You do not need to redo the rapid HIV test.

Specimen Saves and Follow-up:

All EDTA specimens collected for Rapid HIV testing will be stored in the SESP specimen walk-in refrigerator for one month.

If the Rapid HIV test results are REACTIVE, the SST sample(s) collected is/are routed to Special Chemistry for follow-up testing and storage. The HIV AG/AB COMBO SCREENS are done M - F, 0800-1630.

These samples will be sent by courier to the STC starting as early as 0600 every morning. Samples can be put in the "Out" basket for delivery. From 1600 to 0600, samples should be put in the "STC Specimens" drawer in the Specimen Processing refrigerator. These samples will be delivered to Special Chemistry on the first courier run at 0600 the next day.

Further Result Inquiry:

Any other requests for results will not be given out by the lab. Inquiries will be directed to the blood/body fluid exposure hotline at 4-7585.

Procedure Notes

Test cartridges and reagents should be handled as if capable of transmitting infection. Wipe all spills with a 10% dilution of common liquid household bleach or other appropriate disinfectant.

No dilution of specimens is required.

Specimen must be accompanied with a copy of the Uniform Needlestick Injury Report Form.

LIS ordering mnemonic is "NEEDLE". There will then be a prompt to order HCV, HBSAG, and HIVR, generating "SC" labels for the hepatitis C antibody and the HBSAG, and "CF" labels for the HIVR results. (Be sure and send specimens to Special Chemistry for HCV and HBSAG).

Performance Characteristics

Sensitivity

Detection of antibodies to HIV-1 in specimens from individuals infected HIV-1 Plasma

A sensitivity study was performed at eleven clinical trial sites using EDTA-plasma specimens collected from 891 individuals reported to be infected with HIV-1. Of the 891 specimens that were identified as seropositive using licensed confirmatory testing, 887 gave a Reactive result on the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test. The results of this study are shown in Table 1.

A separate study was performed at six clinical trial sites using EDTA-plasma specimens collected from populations at high-risk for HIV-1 infection. The results of this study are also shown in Table 1. All of the 14 specimens that were identified as seropositive using licensed confirmatory testing, were reactive using the OraQuick® *ADVANCE* HIV-1/2 Antibody Test.

Table 1 - Detection of Antibody to HIV-1 in Plasma Specimens from HIV-1 Seropositive Individuals.

Test Group	Total Samples	OraQuick® ADVANCE Reactive	Licensed EIA Repeatedly Reactive	True Positive1
Known HIV-1 Positive	891	887	891	891
High-Risk	533	14[2]	14	14
TOTAL	1424	901	905	905

[1] Confirmation performed by licensed HIV-1 Western blot, confirmation of indeterminate Western blot results by radioimmunoprecipitation assay (RIPA) or licensed IFA.
[2] One additional specimen was OraQuick® ADVANCE false positive (see table 5)

Combining the number of OraQuick® *ADVANCE* reactive results obtained from the study of confirmed positives with the number of OraQuick® *ADVANCE* reactive results obtained from the study of high-risk populations, the sensitivity of the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test in these studies was calculated to be 901/ 905 = 99.6% (95%C.I. = 98.9% - 99.8%).

Reactivity with HIV-1 Specimens from Various Geographic Regions

To assess the sensitivity of the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test for HIV-1 variants from various geographic regions, 215 confirmed HIV-1 antibody-positive serum/plasma specimens were obtained from various parts of the world. Of these 215 specimens, 214 were reactive using the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test. One confirmed HIV-1 antibody positive specimen from China was non-reactive using the OraQuick® *ADVANCE* test. An additional 13 specimens representing HIV-1 Subtypes A,B,C,D,F and G, and Group O were tested and reactive on OraQuick® *ADVANCE.*

Reactivity with HIV-1 Seroconversion Panels

Eleven HIV-1 seroconversion panels were tested in comparison with licensed anti-HIV EIA tests. Each panel consisted of sequential serum/plasma specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of 69 specimens. The results of this study are shown in Table 2. In this study, OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test was demonstrated to be capable of detecting seroconversion similar to currently available FDA licensed EIAs

Table 2 - Comparison of the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test and Licensed Anti-HIV EIA Tests Using Seroconversion Panels

Specimen Information			**Licensed Anti-HIV EIA Tests**				
Panel	Relative Day of Bleed	OraQuick® ADVANCE Test	EIA#1	EIA#2	EIA#3	EIA#4	EIA#5
K	1	NR	NR	NR	NR	NR	NR
	7	NR	NR	NR	NR	NR	NR
	9	NR	NR	NR	NR	NR	NR
	14	R	NR	RR	NR	NR	NR
	16	R	NR	RR	NR	NR	NR
	21	R	NR	RR	NR	RR	RR
	23	R	RR	RR	RR	RR	RR
	30	R	RR	RR	RR	RR	RR
	34	R	RR	RR	RR	RR	RR
	37	R	RR	RR	RR	RR	RR
N	1	R	RR	RR	NR	NR	NR
	5	R	RR	RR	NR	RR	NR
	8	R	RR	RR	NR	RR	NR
	26	R	RR	RR	RR	RR	RR
	32	R	RR	RR	RR	RR	RR
Q	1	NR	NR	NR	NR	NR	NR
	54	NR	NR	NR	NR	NR	NR
	58	NR	NR	NR	NR	NR	NR
	61	NR	NR	RR	NR	NR	NR
	66	R	NR	RR	NR	NR	NR
	68	R	RR	RR	NR	RR	RR
	73	R	RR	RR	RR	RR	RR
R (M)	3	NR	NR	RR	NR	NR	NR
	8	NR	NR	RR	NR	NR	NR
	14	R	RR	RR	RR	RR	RR
	16	R	RR	RR	RR	RR	RR
	22	R	RR	RR	RR	RR	RR
S	1	NR	NR	NR	NR	NR	NR
	10	R	RR	RR	NR	NR	NR
	12	R	RR	RR	NR	RR	NR
W	1	NR	NR	NR	NR	NR	NR
	8	NR	NR	NR	NR	NR	NR
	13	NR	NR	NR	NR	NR	NR
	15	NR	NR	NR	NR	NR	NR
	29	NR	NR	NR	NR	NR	NR
	31	NR	NR	NR	NR	NR	NR
	36	NR	NR	NR	NR	NR	NR
	38	NR	NR	NR	NR	NR	NR

Table 2 continued

W	48	NR	NR	RR	NR	NR	NR
	85	R	RR	RR	RR	RR	RR
	87	R	RR	RR	RR	RR	RR
	146	R	RR	RR	RR	RR	RR
	162	R	RR	RR	RR	RR	RR

Specimen Information			**Licensed Anti-HIV EIA Tests**				
Panel	Relative Day of Bleed	OraQuick® ADVANCE Test	EIA#1	EIA#2	EIA#3	EIA#4	EIA#5
AB	1	NR	NR	NR	NR	NR	NR
	29	NR	NR	RR	NR	NR	NR
	34	R	RR	RR	NR	NR	NR
	36	R	RR	RR	NR	NR	RR
	41	R	RR	RR	RR	RR	RR
AC	1	NR	NR	NR	NR	NR	NR
	112	NR	NR	RR	NR	NR	NR
	121	R	RR	RR	RR	RR	RR
	126	R	RR	RR	RR	RR	RR
	131	R	RR	RR	RR	RR	RR
AE	1	NR	NR	NR	NR	NR	NR
	4	NR	NR	NR	NR	NR	NR
	8	NR	NR	RR	NR	NR	NR
	11	NR	RR	RR	NR	RR	NR
AF	1	NR	NR	NR	NR	NR	NR
	3	NR	NR	NR	NR	NR	NR
	8	NR	NR	NR	NR	NR	NR
	10	NR	NR	NR	NR	NR	NR
	16	NR	NR	NR	NR	NR	NR
	29	R	NR	RR	NR	NR	NR
	34	R	RR	RR	NR	RR	RR
	36	R	RR	RR	RR	RR	RR
	43	R	RR	RR	RR	RR	RR
AI	1	NR	NR	NR	NR	NR	NR
	8	R	RR	RR	NR	NR	RR
	12	R	RR	RR	NR	RR	RR

NR = Non-Reactive, R = Reactive, RR = Repeatedly Reactive

Reactivity with HIV-1 Low Titer Panels

Two low titer HIV-1 antibody panels were tested in comparison with the licensed anti-HIV EIA tests. The low titer antibody panels consisted of 30 serum/plasma specimens. The results of this study are shown in Table 3. In this study, the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test was demonstrated to be capable of detecting antibodies to HIV-1 similar to currently available FDA licensed EIAs.

Table 3 – Comparison of the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test and Licensed Anti-HIV EIA Tests Using Low Titer HIV-1 Antibody Panels

Specimen Information			Licensed Anti-HIV EIA Tests				
Panel	Member	OraQuick® *ADAVANCE* Test	EIA#1	EIA#2	EIA#3	EIA#4	EIA#5
LT106	1	R	RR	RR	RR	RR	RR
	2	NR	NR	RR	NR	NR	NR
	3	R	RR	RR	RR	RR	RR
	4	R	RR	RR	RR	RR	RR
	5	R	RR	RR	RR	RR	RR
	6	NR	NR	NR	NR	NR	NR
	7	R	RR	RR	RR	RR	RR
	8	NR	RR	RR	NR	NR	NR
	9	R	RR	RR	RR	RR	RR
	10	R	RR	RR	RR	RR	RR
	11	R	RR	RR	NR	NR	RR
	12	R	RR	RR	NR	NR	RR
	13	R	RR	RR	RR	RR	RR
	14	R	RR	RR	RR	RR	RR
	15	R	RR	RR	RR	RR	NR
LT107	1	NR	NR	RR	RR	NR	NR
	2	R	NR	RR	RR	RR	NR
	3	R	NR	RR	NR	NR	NR
	4	R	RR	RR	RR	RR	NR
	5	NR	NR	NR	NR	NR	NR
	6	R	RR	RR	RR	RR	NR
	7	NR	NR	RR	RR	NR	NR
	8	NR	NR	RR	NR	RR	NR
	9	NR	NR	RR	NR	NR	NR
	10	R	RR	RR	RR	RR	RR
	11	R	RR	RR	RR	RR	RR
	12	NR	NR	RR	NR	NR	NR
	13	NR	NR	RR	RR	NR	NR
	14	R	RR	RR	RR	RR	RR
	15	R	RR	RR	RR	RR	RR

Interfering Substances and Unrelated Medical Conditions

To assess the impact of unrelated medical conditions or interfering substances on the sensitivity of the Ora-Quick® *ADVANCE* Rapid HIV-1/2 Antibody Test, 200 serum/plasma specimens from a variety of medical conditions unrelated to HIV-1 infection and 125 specimens with interfering substances were spiked with an HIV-1 positive specimen to give a level of reactivity in the low positive range (see list of medical conditions and interfering substances in Table 4). All spiked specimens gave reactive results.

In addition, a study was performed to assess the potential effect of anticoagulants on assay sensitivity. Venipuncture whole blood (collected from 20 subjects in each of 4 tubes containing one of four anticoagulants (EDTA, sodium heparin, sodium citrate, and ACD Solution A) was spiked with an HIV-1 positive specimen to give a level of reactivity in the low positive range. The samples were then aliquoted and stored either refrigerated (2°-8°C) or at room temperature (18°C) and tested over a 7-day period. There was no anticoagulant-specific effect observed on assay performance with samples held up to 30 hours at 2°-18°C.

Table 4 – OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test Reactivity with Specimens from Individuals with Potentially Interfering Medical Conditions and Specimens with Interfering Substances.

Medical condition (n-321)	**OraQuick® *ADVANCE* Results**	
	Reactive	**Non-Reactive**
Multiparous women	1[2]	14
Anti-nuclear antibody (ANA)	0	17
Lupus	0	15
Rheumatoid factor	1[2]	17
Cytomegalovirus (CMV)	0	15
Epstein Barr virus (EBV)	1[2]	14
Hepatitis A virus (HAV)	3[1]	17
Hepatitis B virus (HBV)	1[2]	16
Hepatitis C virus (HCV)	0	15
Human T-cell Lymphotropic virus Type I (HTLV-I)	0	15
Human T-cell Lymphotropic virus Type II (HTLV-II)	0	15
Rubella	0	15
IgG gammopathies	0	13
IgM gammopathies	0	12
Syphilis	0	15
Toxplasmosis	0	15
Tuberculosis	0	15
Influenza	0	10
Multiple transfusions	0	10
Hemophiliac	0	10
Herpes Simplex virus	0	5
Cirrhosis	0	5
Dialysis patient	0	4
Colon cancer	0	4
HTLV I/II	0	2
Chlamydia	0	3
Anti-scl or anti-rnp antibody	0	3
Breast cancer	0	1
Anti-DNA antibody	0	1
Gonorrhea	0	1

Table, continued	**OraQuick® *ADVANCE* Results**	
	Reactive	**Non-Reactive**
Interfering Substances (n=199)		
Elevated Bilirubin	0	20
Elevate Hemoglobin	0	20
Elevated Triglycerides	0	20
Elevated Protein	0	20
Bacterially contaminated	0	25
Visual Hemolysis (hemolytic)	0	5
Icteric	0	5
Lipemic	0	4
Sodium Heparin[3]	0	20
EDTA[3]	0	20
Sodium Citrate[3]	0	20
ACD Solution A[3]	0	20

[1] A total of 3 of the 20 HAV specimens were Oraquick® ADVANCE falsely reactive. Two of the 3 specimens were Oraquick® ADVANCE non-reactive at the 20-25 minute read time and reactive at the 55-60 minute read time. The remaining specimen was reactive at both read times.

[2] One of the specimens was Oraquick® ADVANCE non-reactive at the 20-25 minute read time and reactive at the 55-60 minute read time.

[3] The Oraquick® *ADVANCE* assay maximum read time for these specimens was 40 minutes.

Detection of Antibodies to HIV-2 in Specimens from Individuals Infected with HIV-2

A total of 324 serum/plasma specimens reported to be HIV-2 antibody positive were obtained from various repository sources. Specimens were tested by licensed anti-HIV-1/2 EIA, licensed anti-HIV-2 EIA, licensed HIV-1 Western blot, an HIV-2 Western blot and HIV-2 specific PCR. A total of 6 specimens were not demonstrated to be positive for antibodies to HIV-1 or HIV-2, all of which were Oraquick® *ADVANCE* non-reactive. Two of the 6 negative specimens were repeatedly reactive by licensed anti-HIV-1/2 EIA, negative by licensed anti-HIV-2 EIA, and indeterminate by licensed HIV-1 Western blot and by an HIV-2 Western blot.

Of the remaining 318 specimens, 151 were positive on an HIV-2 Western blot and 50 were positive using an HIV- 2 specific PCR. One hundred and twenty-two specimens gave confirmatory results consistent with HIV-1 infection and were excluded from the analysis. One specimen was categorized as a dual infection based on additional testing by co-culture, and was not included in the sensitivity analysis. One specimen, while indeterminate on HIV-1 and HIV-2 Western blots, gave a positive result on an HIV-2 radioimmuno-precipitation assay (RIPA) and is also considered to be positive for antibodies to HIV-2. Oraquick® *ADVANCE* detected 201/201 (100%) of the specimens from individuals confirmed as positive for HIV-2 antibodies (see table 5).

In a separate study, a total of 499 plasma specimens collected from an HIV-2 endemic area (Ivory Coast) were prepared as contrived whole and tested by Oraquick® *ADVANCE*, licensed anti-HIV-1/2 EIA, licensed anti-HIV-2 EIA, licensed HIV-1 Western blot, and an HIV-2 Western blot. Table 4 shows a summary of the results. Oraquick® *ADVANCE* was reactive with all of the 27 specimens that were repeatedly reactive by licensed anti-HIV-1/2 EIA, licensed anti-HIV-2 EIA and positive on licensed HIV-1 Western blot, and with all three specimens that were confirmed as positive for HIV-2 only by an HIV-2 Western blot. Two specimens were Oraquick® ADVANCE false positive.

Table 5 - Detection of Antibody to HIV-2 in Samples from HIV-2 Seropositive Individuals and Individuals at High Risk of HIV-2 Infection

Test Group	Total Samples	Oraquick® ADVANCE Reactive	Licensed anti HIV-2 EIA Repeatedly Reactive or HIV-2 PCR Positive	True Negative[1]
Known HIV-2 Positive	324[2]	201	201[3]	201[4]
High-Risk	499	32	33	3
TOTAL	823	233	234	204

[1] Confirmation performed by HIV-2 Western blot, with RIPA confirmation of Indeterminate Western blot results.

[2] One hundred and twenty-two specimens gave confirmatory results consistent with HIV-1 infection and were excluded from the analysis. In addition, one specimen was categorized as a dual infection based on additional testing by co-culture, and was not included in the sensitivity analysis.

[3] 151 specimens were tested with an anti-HIV-2 EIA alone. HIV-2 DNA or RNA PCR was performed on the remaining 50 specimens instead EIA. All results were positive.

[4] One specimen was confirmed to be HIV-2 positive based on the positive results of an HIV-1 specific RIPA.

Combining the number of Oraquick® *ADVANCE* reactive results obtained from the study of confirmed positives with the number of Oraquick® *ADVANCE* reactive results obtained from the study of the high risk population, the sensitivity of the Oraquick® *ADVANCE* Rapid HIV-1/2 Antibody Test for the detection of antibodies to HIV-2 in these studies was calculated to be 204/204 = 100% (95% C.I. = 98.2% - 100%).

Specificity

A specificity study was performed at eight clinical trial sites using freshly obtained fingerstick whole blood samples from 1250 previously unscreened individuals at low risk for HIV-1 infection. In the course of this study, two specimens were confirmed to have antibodies to HIV-1 and were removed from the specificity calculation. All of the remaining specimens gave non-reactive results using the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test. In addition, all 608 HIV-1 antibody-negative specimens from the study sites that examined populations at high risk for HIV-1 infection also gave non-reactive results using the OraQuick® *ADVANCE* test. The results of this study are shown in Table 6.

Table 6 – Performance of the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test on Fingerstick Whole Blood Specimens from Individuals Presumed to be Negative for HIV Infection

Test Group	Total Samples	Oraquick® ADVANCE Non-Reactive	Licensed EIA Non-Reactive	True Negative[3]
Low-Risk	1250[1]	1248	1247[2]	1248
High-Risk	625	608	605	608
TOTAL	1875	1856	1852	1856

[1] Two specimens in the low-risk study that gave reactive results using the OraQuick® ADVANCE test, repeatedly reactive results using a licensed EIA, and positive results using a licensed Western blot were removed from the calculation of specificity.

[2] One specimen was EIA repeatedly reactive, Western blot negative.

[3] True negative status based on negative or indeterminate test results using a licensed Western blot.

Combining the number of OraQuick® *ADVANCE* non-reactive results obtained from the study of the low-risk populations with the number of OraQuick® *ADVANCE* non-reactive results obtained from the study of high-risk populations, the specificity of the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test in these studies was calculated to be 1856/1856 = 100% (95% C.I. = 99.7% - 100%).

Interfering Substances and Unrelated Medical Conditions

To assess the impact of unrelated medical conditions or interfering substances on the specificity of the OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test, 321 serum/plasma specimens from a variety of medical conditions unrelated to HIV-1 infection and 119 specimens with interfering substances were analyzed. The results of this study are shown in table 6. One specimen from subjects known to be positive for EBV, for HBV, or for rheumatoid factor, one from a multiparous woman, and three specimens from known HAV infected subjects gave false positive results.

In addition, a study was performed to assess the potential effect of anticoagulants on assay sensitivity. Venipuncture whole blood was collected from 20 HIV negative subjects, in each of 4 tubes containing one of the following anticoagulants: EDTA, sodium heparin, sodium citrate, and ACD Solution A. The samples were then aliquoted and stored either refrigerated (2-8°C) or at room temperature (18°C) and tested over a 7-day period. There was no anticoagulant-specific effect observed on assay performance with samples held up to 30 hours at 2- 18°C.

Reproducibility

The reproducibility of the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test was tested at 3 sites using 3 lots of the device on 3 different days with 9 operators (3 per site). A blind-coded panel was tested that consisted of 5 contrived blood specimens (4 antibody-positive and 1 antibody-negative). Test results were recorded at 20-25 minutes and at 55-60 minutes. A total of 405 tests were performed (135/site), with a total of 81 tests per panel member. The overall reproducibility of the OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test was 405/405 = 100%. Concordance between the specified assay read time limits was 99.8% (404/405); a single HIV-1 low positive panel member that was non-reactive at the 20-25 minute read time was reactive at the 55-60 minute read time.

Results of Untrained User Study

An “Untrained User” study was conducted in which participants were given only the test instructions and asked to perform testing of a blinded panel comprised of 6 randomized specimens of three different levels (Negative, Low Positive and High Positive OraQuick® *ADVANCE* test reactivity) consisting of human plasma. The participants were not given any training on the use of the test or the interpretation of the test results, nor were they allowed to observe the performance of the Kit Controls by the Study Coordinator. The study protocol stipulated that professionally trained medical laboratory personnel or persons with prior experience using the OraQuick® *ADVANCE* device were excluded from participation.

UCDMC Results

WSLH Proficiency Testing VeriSamp Results

Panel 01 (4 positive, 1 negative, 1 invalid), 100% agreement.
Panel 02 (4 positive, 1 negative, 1 invalid), 100% agreement.
Performed by 2 different technologists.

WSLH Remedial Anti-HIV Proficiency Testing

5/5 (100%) 9/8/03

Patient Comparisons:
Performed by two Technologists over 2 days, using 2 different lot numbers.

Specimen number	Microbiology EIA and Western Blot result	OraQuick® Rapid HIV-1 Antibody Test
061803:CF32	Positive	Positive
072303:CF36	Positive	Positive
073103:CF4	Positive	Positive
072803:CF14	Positive	Positive
080403:CF21	Positive	Positive
090403:CF2	Negative	Negative
090403:CF31	Negative	Negative
090403:CF29	Negative	Negative
090503:CF1	Negative	Negative
090503:CF2	Negative	Negative

Comparisons vs UCDMC HIV Viral load specimens

Specimen number (blinded specimens)	HIV Viral Load Result	OraQuick® Rapid HIV-1 Antibody Test
1	Positive	Positive
2	Positive	Positive
3	Positive	Positive
4	Positive	Positive
5	Positive	Positive
6	Negative	Negative
7	Negative	Negative
8	Negative	Negative
9	Negative	Negative
10	Negative	Negative

References

1. Gallo RC, Salahuddin SZ, Popovic M, et al. Frequent detection and isolation of cytopathic retroviruses (HTLV III) from patients with AIDS and at risk for AIDS. Science 1984; 224:500-3.
2. Curran JW, Morgan WM, Hardy AM, et al. The epidemiology of AIDS: current status and future prospects. Science 1985: 229:1352-7.
3. Clavel F, Guetard D, Brun-Vezinet F, et al. Isolation of a new human retrovirus from West African patients with AIDS. Science 1986: 233:343-6.
4. Sehulster LM, Hollinger FB, Dreesman GR, and Melnick JL. Immunological and biophysical alteration of hepatitis B virus antigens by sodium hypochlorite disinfection. Appl Env Microbiol 1981; 42:762-7.
5. CDC. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988: 37(24):377-388.
6. CDC. Approval of a New Rapid Test for HIV Antibody. MMWR 2002: 51(46):1051-1052 and Erratum 51(47):1075.
7. CDC: Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women. MMWR 2001: 50(19):32-35.
8. CDC: Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, HIV and Recommendations for Postexposure Prophylaxis. MMWR 2002: 50(RR-11):1-42.
9. OraSure Technologies, Inc., OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test Package Insert. OraSure Tech- nologies, Inc., Bethlehem, PA 18015. Item#3001-1215(rev. 10/07).

Prepared By	Date Adopted	Supersedes Procedure #
Michael Inn	11/01/2003	OraQuick Rapid HIV-1

Revision Date	Type of Revision	Revised by	Review/Annual Review Date	Reviewed By
08/10/1997	new	R. Becker	08/101997	Dr. J. Carlson
09/08/1997	revision	R. Becker	09/10/1997	Dr. J. Carlson
08/19/1998	revision	C. Jarvinen	09/10/1998	Dr. J. Carlson
			12/10/1999	L. Zeng
			10/27/2000	G. Kost
			12/28/2001	G. Kost
11/12/2002	revision	C. Jarvinen	11/13/2002	G. Kost
09/01/2003	Murex SUDS procedure			
11/01/2004	new-OraQuick HIV 1	C. Jarvinen	11/01/2003	Dr. J. Carlson
01/2004	revision	M. Inn		
			11/24/2004	G. Kost
			11/28/2005	G. Kost
01/04/2006	revision-OraQuick HIV-1/2	M. Inn		
			09/27/2006	G. Kost
08/01/2007	QC update	M. Inn		
			11/05/2007	G. Kost
			06/16/2008	G. Kost
06/03/2009	revision, std reporting format & notification update, control expiration	M.Inn		
			09/15/2009	G. Kost
			10/12/2010	G. Kost
03/02/2011	Update Specimen Saves and Follow up instructions	M.Inn	03/04/2011	G. Kost
03/28/2011	Added donor mothers breast milk given to wrong infant	M.Inn	11/16/2011	G. Kost
03/15/2012	Neonates whose mother's HIV status is unknown or refuses testing	M.Inn		G. Kost
03/15/2012	reporting format changed	M.Inn		G. Kost
03/15/2012	Result comments updated	M.Inn		G. Kost
03/15/2012	Update confirmation testing	M.Inn	03/31/2012	G. Kost/C.
			11/20/2013	G. Kost
05/22/2015	minor edit-update pager	kdagang		
			08/28/2016	J. Gregg
03/09/2017	add reverse transmission exposure, reformat	kdagang	05/04/2014	N.K. Tran