

**Protocol for Providing HIV Antibody Oral Fluid Testing:
Division of Public Health Designated HIV CTR Agencies and PCRS Sites**

Overview

The oral fluid test detects the HIV-1 antibody in a fluid known as oral mucosal transudate (OMT). OMT is not saliva. It is a fluid which is drawn from the cheek and gums and is rich in antibodies, including, if present, HIV-1 antibodies. OMT is collected by a device that consists of a treated absorbent cotton fiber pad affixed to a nylon stick. After collection, the pad is placed in preservative solution in a plastic vial. The specimen is sent to the laboratory and tested for HIV using an enzyme immunoassay (EIA) and the Western Blot if the EIA is repeatedly reactive. The only oral fluid collection device that is currently FDA approved is known by the brand name OraSure™. Testing an OraSure™ HIV-1 specimen for HIV-1 antibodies is highly accurate; however, testing a blood specimen is more accurate.

- Studies show that for every 100 people with HIV antibodies in their blood, tests using OraSure™ HIV-1 oral fluid specimens may miss 1 or 2 people.
- Studies show that for every 100 people with HIV antibodies in their blood, tests using OraSure™ HIV-1 oral fluid specimens may give an indeterminate test result to 2 or 3 people instead of a positive test result.

Note: OraSure™ is not FDA-approved for use with persons under the age of 13 years and should not be used for this population.

Additional Information

Testing with OraSure™ is generally painless. However, since the specimen collection pad contains sodium chloride, individuals with sores or abrasions in their mouth may experience a stinging reaction. The collection pad also contains a trace amount of gelatin that acts as a binding and blocking agent. There have been rare allergic reactions to gelatin documented in medical literature.

Small amounts of blood on the collection pad will not affect accuracy of the test, nor will other conditions, medications or diseases.

Use in the WVDHHR/BPH/OEPS/HIV Counseling, Testing, and Referral (CTR) Program

The HIV Prevention Program will make the oral fluid test available to designated HIV Counseling, Testing, and Referral agencies for CTR activities. Staff using the test must be trained in the proper use of the device, completed training/certification by attending the HIV Prevention CTR two day course and be recertified every three years.

The OraSure™ test will also be available:

- **By request** for Outreach testing events targeting adults (18 years and older) identified as high risk and/or the African American populations.
- Local health departments with sub recipient agreements will also be given the option of oral fluid testing on a limited basis. At these sites, the OraSure™ collection device will only be used on individuals identified by the specimen submitter as difficult to draw blood for an EIA test.

The oral fluid test generally takes longer to detect HIV antibodies after infection than the serum (blood) test used in the program. The EIA serum test used by the HIV Prevention CTR Program detects antibodies for HIV-1 and HIV-2, and may identify them as early as 3 weeks after initial infection. The oral fluid test generally detects HIV-1 antibodies at least six weeks after infection. At six weeks after infection the oral fluid test can accurately identify HIV-1 antibodies in approximately 50% of people with HIV infection. By 12 weeks after infection, the test will identify the majority of individuals with HIV-1 infection. Both tests may take up to six months to identify infection in some individuals.

Since the oral fluid test does not identify HIV-2 antibodies and typically has a longer window period, the serum test remains the preferred test in the CTR program—in particular, for identifying early infection.

When to Use the OraSure™ Collection Devices

The approved HIV Prevention CTR Program facilities will use oral fluid testing in the following circumstances:

- outreach testing by staff performing HIV CTR outreach or partner counseling and referral services
- outreach or other HIV CTR settings when staff are not trained in phlebotomy
- Clinical setting when staff is unable to obtain a blood sample from a client due to a “difficult stick” situation.
- as a confirmatory test to a positive rapid HIV test

Obtaining Devices

Approved facilities may obtain oral fluid collection devices by submitting a “Requisition Form for Specimen Mailing Kits” to the WV Office of Laboratory Services (OLS). This form can be found on the OLS website at www.wvdhhr.org/labservices/shared/docs/Serology/1stform.pdf. Instructions for filling out this form are also located at the website. Please note that each Oral Fluid Kit contains four collection devices and four plastic bags.

- Local Health Departments will be allowed to have four collection devices on hand at their facilities.
- Other CTR sites can order no more than 7 kits (28 collection devices) without prior approval from the Office of Laboratory Services.
- Outreach events are to be arranged by contacting the program at 1-304-558-3530. An outreach event form will be sent to the facility to complete and return to the program. More information on outreach events can be obtained by calling the number listed above.

Storing and Transporting OraSure™ Devices

Sites must establish practices to ensure proper storage and transportation of OraSure™ devices as listed below:

- devices and specimens must be stored at temperatures between 64-77° Fahrenheit or 18°-25°C
- when testing outside a clinic setting, keep devices out of direct sunlight and place them in a cooler on warm days—this avoids break down and/or evaporation of the specimen preservative fluid
- when testing outside a clinic setting in cold weather months, avoid allowing the devices to drop below the 64°F/18°C limit by transporting them in a protected container and not leaving them in an automobile for long periods of time

Note: Dispose of any devices that have not been stored or transported under the above-described conditions.

Pre-Test Counseling: Informed Consent

The protocol for oral fluid testing is essentially the same as for serum testing. The test is provided in conjunction with client-centered counseling. Informed consent is obtained prior to testing. Data is obtained through the completion of the CDC HIV testing form and the laboratory submission form.

In addition, the FDA requires all clients who receive oral fluid testing be given the leaflet entitled “What You Should Know about the OraSure™ HIV-1 Oral Specimen Collection Device Prior to Providing an Oral Specimen” prior to specimen collection. If the client cannot read or has a reading level lower than language used in the leaflet, staff should discuss basic information within the leaflet with the client.

Preparing for Specimen Collection

Prior to oral fluid specimen collection:

- Check the expiration date on the device packet and specimen vial prior to testing. If the device is expired, dispose of the entire packet.
- Check to ensure the fluid in the specimen vial is blue. If it is discolored or clear, dispose of the entire packet.
- The client should not smoke, chew gum, eat, drink (including water), or rinse their mouth for at least five minutes prior to specimen collection

Despite the fact that Oral fluid is not considered a biohazard, the program recommends the use of gloves and adherence to all universal precautions. Early studies have shown that low amounts of HIV can be found in oral fluid, especially when visible blood is present; however there have been no cases of HIV transmission clearly attributed to saliva or oral fluids.

As with other medical procedures it is advisable to wash hands before and after specimen collection to decrease transmission of oral/respiratory viruses. If hand washing facilities are not available, use of instant hand sanitizer is recommended.

Specimen Collection

- Open the **exterior** packet slowly (where indicated by arrows) to avoid the possibility of the contents falling out of the packet. (Keep the preservative vial in the plastic tray until the specimen has been collected).
- Open the **interior** packet containing the collection device slowly immediately prior to collecting the sample. Avoid contamination of the pad and preservative. Do not touch the pad or top area of the opened preservative vial. The collection device should not touch any surface prior to sample collection. If the device touches a surface, dispose of the entire packet and use a new device.
- Touching only the blue nylon stick, hand the device to the client and direct them to place it in their mouth between their lower cheek and gums. **DO NOT** have the client rub the device back and forth against their gum as this may cause abrasions.
- The device should remain in place for a full 5 minutes. If the device is left in place less than this time, there may be insufficient quantity of OMT to accurately process the test causing “Verify Dispense Errors” and no patient results can be given. The device should not be left in the mouth longer than 5 minutes.
- Grip the lower portion of the preservative vial and remove the cap by gently rocking it and pulling up (the cap does not screw off or on).
- Grip the cap by its top **being careful not to touch the portion that will be inserted back in the vial**. It is also acceptable to place the cap on its top on a clean, dry surface.
- Take the device out of the client’s mouth and insert the cotton pad into the preservative in the vial.
- Break off the nylon stick by applying gentle pressure against the vial wall and away from your face. Recap the vial by pushing gently until you hear a snap. The snap indicates the cap and vial are secure.
- Gently shake the vial back and forth to moisten the collection pad with the preservative.
- Write the clients name on the OraSure™ Collection tube.
- Complete the submission form.

Note: A copy of the newest version of the submission form can be accessed on the internet at <http://www.wvdhhr.org/labservices/shared/docs/Serology/DI%20Request%20Form.pdf>

Specimen Processing and Shipping

- Place the collection tube in the specimen collection bag provided by the laboratory and seal (one vial per bag).
- The completed lab submission form should be placed around the outside of the internal canister and placed into the shipping canister. For additional information on the collection, submission form and mailing of HIV specimens, use the following link <http://www.wvdhhr.org/labservices/shared/docs/Serology/HIV%20instructions.pdf>
- Specimens should be submitted to the Office of Laboratory Services as soon as possible after collection.
- Specimens must be tested within 21 days of collection or the specimen is considered unsatisfactory.

Final Test Results and Interpretations

- Upon completion of the test, results are sent to the HIV contact person designated by the clinic or facility.
- **NOTE: Delaying shipment of specimens means a delay in receiving results. Sites that routinely hold specimens five days or more before shipping will be reported by OLS to the HIV CTR Coordinator.**
- Be certain to read through the results to the Final Interpretation:
 - HIV-1/2 +O
 - **Nonreactive:** Indicates no HIV infection or insufficient presence of HIV-1 antibodies. Person with risk of recent exposure should have follow-up testing three months after exposure.
 - **Reactive:** Indicates HIV antibodies have been detected. It is part of laboratory protocol to retest the specimen in duplicate and for all three results to agree before a Reactive result is reported. As with blood test, Reactive specimens are automatically confirmed with a Western Blot test.
 - HIV-1 Western Blot
 - **Nonreactive:** No viral bands are present
 - **Indeterminate:** Less than two diagnostic bands are present, or non-viral specific bands are present. Another specimen should be submitted to the lab for testing within one to three months.
 - **Reactive:** Consistent with the presence of antibodies to the HIV-1 virus. Another specimen (preferably blood) should be submitted to the lab for testing as soon as possible. **Note:** The report will also include the individual band numbers that are reactive for the patient. This information is of additional help to the clinicians evaluating the patient's status.

Most Common Reasons for Rejected Specimens

- Verify Dispense Errors – Specimens containing low levels of protein cause this type of error.
 - How to help prevent this error:
 - Patient should not smoke, chew gum or mints, eat, drink (including water or alcohol), or rinse their mouth for a minimum of five minutes before the specimen is collected.
 - Collection device should remain in patient's mouth for the full five minutes.
- Witness or patient signature is missing from the submission form.
 - These signatures are currently required by the CTR program for OLS to complete the test.
- No name on the collection device or the names on collection device and submission form do not match.
 - Federal law requires a unique identifier be present on the collection device and submission form at the time that the laboratory receives the

specimen. The unique identifier must be the same on the collection device and submission form.