Protocol for Providing HIV Antibody Oral Fluid Testing: Division of Public Health Designated HIV CTR Agencies & 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 test that is currently FDA approved is known by the brand name *OraSure**.

*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.

Blood on the collection pad will not affect accuracy of the test, not will other oral conditions, medications or diseases.

Use in the WI HIV Counseling, Testing, and Referral (CTR) Program

The WI Division of Public Health (DPH) will make the oral fluid test available to DPH-designated HIV CTR agencies and local health departments involved in conducting PCRS activities. Staff using the test must be trained in use of the device and have completed the WI HIV CTR new provider training. The WI HIV CTR Coordinator must approve the use of the device for a specific CTR agency or PCRS site orders being placed from the WI State Laboratory of Hygiene (WSLH).

The oral fluid test generally takes longer to detect HIV antibodies after infection than the serum (blood) test used in the program. The serum test used by the WI HIV CTR Program—the Abbott HIV-1/HIV-2 Combination EIA – 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 6 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 6 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.

The benefits of oral fluid testing include:

- portability/ease for field testing,
- greater acceptance from clients who are reluctant to have their blood drawn,
- easier testing for clients with compromised venous access or vasovagal response, and
- safer specimen collection in non-clinical settings—given oral fluid testing does not require the use of syringes, thereby preventing blood exposure.

The WI HIV CTR Program will use oral fluid testing in the following circumstances:

- field testing by staff doing HIV CTR outreach or partner counseling and referral services,
- clinical settings when staff are unable to obtain a blood sample from a client,
- clinical or outreach settings when staff are not trained in phlebotomy, and
- as a back-up to rapid HIV testing in an outreach setting where the temperature falls outside the allowable 59 to 80 degree Fahrenheit range.

Storing and Transporting *OraSure* Devices

Sites must establish practices to ensure proper storage and transportation of *OraSure* devices, including:

- devices and specimens can be stored at temperatures between 39-98 degrees Fahrenheit,
- 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, and
- when testing outside a clinic setting in cold weather months, avoid allowing the devices to drop below the 39 degree Fahrenheit limit by transporting them in a protected container and not leaving them in an automobile for long periods of time.

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

Pre-Test Counseling: Informed Consent

The protocol for oral fluid testing is essentially the same as serum testing. The test is provided in conjunction with client-centered counseling. Informed consent is obtained prior to testing. Data is obtained through use of the a questionnaire and is recorded on a scannable form (see *WI Division of Public Health-AIDS/HIV Program HIV Counseling, Testing, and Referral Protocol* and *Protocol for Completion of Scannable HIV Counseling, Testing, and Referral Data Form*).

When obtaining informed consent for oral fluid testing the following additional pieces of information should be provided and explained to the client in a simple manner:

- specimen collection process and use of the device,
- oral fluid test is not a saliva test,
- oral fluid test, similar to other tests, checks for antibodies which are produced by the body to fight HIV-1, and
- time frame for accurately identifying HIV infection.

In addition, the FDA requires all clients who receive oral fluid testing be given the leaflet entitled "*Testing for HIV Antibodies with OraSure*" 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 client.

It is not necessary to explain the difference between HIV-1 and HIV-2 to all clients. Less than 100 cases of HIV-2 have been identified in the U.S. However, staff should assess whether the client may be at risk for HIV-2 to determine whether the HIV-1/HIV-2 combination blood test is advisable. HIV-2 is most prevalent in West Africa. Clients who are from West Africa should be advised to consider serum testing.

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 discolored or clear, dispose of the entire packet.
- The client should not smoke, chew gum, eat, drink (including water), or rinse their mouth five minutes prior to specimen collection.

The decision whether to use gloves should be made on the agency level. Oral fluid is not considered a biohazard. Although early studies have shown that low amounts of HIV can be found in oral fluid, especially when visible blood is present, 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 sanitizers is recommended.

Specimen Collection

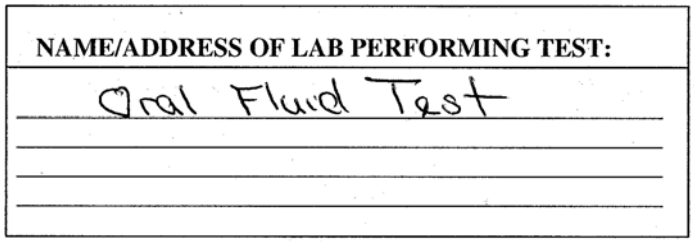
- Open the exterior packet slowly (where indicated by arrows) to avoid the possibility of the contents falling out of the packet. (Keep the preservative vial in the plastic tray until the specimen has been collected.)
- Open the interior packet containing the collection device slowly immediately prior 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 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 at least 3-4 minutes. If the device is left in place less than this time, there may be insufficient quantity of OMT to accurately process the test. 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. Or, 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 briefly to moisten the collection pad with the preservative.
- Some clients experience a salty taste that lingers after specimen collection. As a courtesy, staff may want to offer water or hard candy after specimen collection.

Specimen Processing and Shipping

- Place a scannable form ID sticker on the vial. Do not cover the expiration date.
- Each vial should be wrapped in an absorbent and placed in the plastic bag provided in WI State Laboratory of (WSLH) it (one vial per bag). Note: the specimen is not a biohazard.
- A completed lab requisition slip (part B of the scannable form) should be placed in the pocket of the bag. **Note:** on the Part B lab slip write "oral fluid collection" under "NAME/ADRESS OF LAB PERFORMING TEST:" See **Figure 1** below.
- Oral fluid specimens may be sent to WSLH in the same mailer as blood specimens.
- Specimens should be submitted to the WSLH **as soon as possible** after collection. Specimens must be tested within 21 days of collection.
- Seal the mailer with clear packing tape and affix the WSLH address label.
- If you have specimens to mail on a Friday or Saturday and know that they may sit in a mailbox in the extreme **heat** or cold over a weekend, particularly a long weekend, wait to send them out. They can be stored at room temperature in the clinic.

Figure 1



Test Results

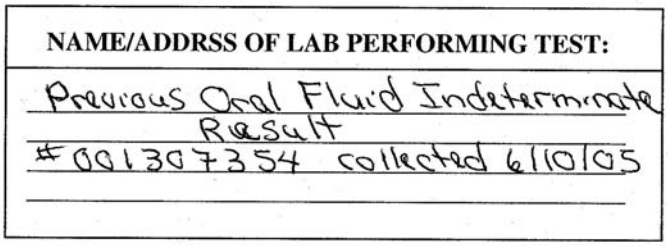
- WSLH will provide test results in approximately 2 weeks. Results are sent to1 or 2 contact people designated by your clinic or agency.
- The WSLH cannot guarantee that results will be available in two weeks for specimens received more than 5 days after collection. Specimens received more than 5 days after collection will be reported by the WSLH to the HIV CTR Coordinator.
- There are three possible interpretations for an oral fluid antibody test. Be certain to read through the results to the **Final Interpretation:**
    - ✓ **Positive:** Indicates HIV infection. As with blood test, individuals testing positive for the first time should be re-tested. This can be done after referral to HIV specialty medical care.
    - ✓ **Negative:** 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.

- ✓ **Inconclusive:** Indicates a final interpretation could not be determined at this time. Persons with initial inconclusive test results should be immediately re-tested using a blood test. If the agency does have phlebotomy services, this should be done through a previously established referral source.

Repeat Testing
If oral fluid test results are indeterminate, the test should be repeated using a blood test.

When submitting a serum specimen following an indeterminate, staff should submit a **new** scannable form, including documentation of the date of previous test result and the identification number of the previous scannable form; if the blood test is being performed by a referral source the agency will need to provide this information to referral agency. This information should be noted (as illustrated in **Figure 2** below) on part "B" of the scannable form in the bottom area designated for "NAME/ADDRESS OF LAB PERFORMING TEST:"

Figure 2



If the second test is inconclusive, the client should have a third, preferably blood, test in 30 days. If this test remains inconclusive, the person is considered NEGATIVE.

Obtaining Devices
An agency must be approved by the HIV CTR Coordinator to use the *OraSure* oral fluid device. Once approved, the site can order devices and shipping materials from the WSLH.

- Contact WSLH Clinical Orders Department at 1.800.862.1088 (or, in Madison at 265.2966).
- Order oral fluid kit number **22C-Bulk**. Indicate the number of collection devices you will need for a six month supply. You will receive absorbent wrap (for the specimen vial), a biobag, and the brochure *Testing for HIV Antibody with OraSUre* for each collection device you order.
- You must also order mailers and labels. Estimate the number of mailers you will need based on your expectations of how many specimens you will collect and how often specimens will be mailed to WSLH. A mailer will hold 10 oral fluid specimens. When ordering indicate you want the "**MRX**" mailer and label **22A** (Retrovirus Laboratory). Smaller mailers are available. Inquiry about them at the same number.