INSTRUCTIONS FOR THE COLLECTION AND PACKAGING OF ORASURE®
ORAL FLUID SPECIMENS FOR HIV-1 AND HIV-2

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE COLLECTING SPECIMEN

In order to comply with postal regulations, ensure the safety of laboratory personnel and those involved in the transport of specimens, and to maintain integrity of the sample, the VT Department of Health Laboratory (VDHL) will accept for testing only those specimens that are packaged according to the instructions below.

The kit should contain:

- VDHL Clinical Microbiology Request Forms (Micro 220)
- OraSure Collection Devices
- Zip-loc bags
- Absorbent Material
- Padded envelope

Storage:

Store unused OraSure HIV Oral Specimen Collection Devices at room temperature (18-25°C/64-77°F). Exposure to higher temperatures should be avoided. Protect from prolonged exposure to direct sunlight.

Collection of Specimen:

1. Open the OraSure HIV package containing the Collection Pad and the Specimen Vial such that it allows for easy removal of the Collection Pad.
2. Without touching the contents, present the stick of the device to the client and instruct the client to pull it out of the packaging sleeve.
3. Instruct the client to place the Collection Pad inside his/her mouth (pad oriented down) between the lower cheek and gum and gently rub the pad back and forth along the gum line until the pad is moist.
4. Begin timing for two (2) minutes.
5. Instruct the client to leave the pad stationary against the lower gum for a minimum of two (2) minutes, and a maximum of five (5) minutes.
6. Remove the Specimen Vial from the package and print or affix client name or sample ID # and date of collection on the Specimen Vial.
7. Open the vial in an upright position (with the cap up, pointed tip down) by gently rocking the cap back and forth to avoid spilling the contents.
8. Give the opened vial to the client.
9. At the end of two minutes, instruct the client to remove the pad from the mouth and insert the pad into the blue liquid in the Specimen Vial, and push the pad all the way to the bottom of the vial.
10. Instruct the client to break the nylon stick of the pad by snapping it against the side of the vial and in a direction away from yourself and other personnel (the stick is scored to facilitate breakage).
11. Take the vial from the client and replace the vial cap, ensuring it is tight. The cap will "snap" into place when secure.

12. Once collected, place the labeled specimen into a zip-loc bag with absorbent material (one specimen per bag) and seal.

13. Collected specimens may be stored at 4 - 37°C for a maximum of 21 days (including the time for shipping and testing). Please ship as soon as possible, but within 14 days of collection, so that testing may be completed within 21 days of collection.

14. Fill out the Vermont Department of Health "Clinical Microbiology Request Form" (Micro 220) completely. The following information is required to ensure accurate and efficient processing of the specimen and reporting of test results:

   ♦ Name, address and phone number of health care provider
   ♦ Patient's Name or ID #
   ♦ Date of specimen collection
   ♦ OraSure test checked on requisition form

15. Fold the requisition form and place within the padded envelope along with the specimen.

16. Mail or deliver the envelope to the VT Department of Health Laboratory at the above address.

THE LABORATORY WILL DECONTAMINATE AND DISCARD ANY SPECIMEN WHICH IS IMPROPERLY PACKAGED AND MAY PRESENT A RISK TO PERSONNEL.

The specimen may be rejected if:

• Patient Name or ID is missing on the specimen and form
• Medical provider name/address is missing on the form
• Specimen container is leaking
• Date of collection is missing on the form
• Specimens are greater than 21 days old.

Additional VDHL packaging components may be obtained by calling the VDHL at 1-800-660-9997 and pressing 6, or by calling 802-338-4724.

If you have any comments or questions regarding these instructions, please call one of the telephone numbers listed on the front of this form. Thank you.