

Test Menu

TOPIC	DESCRIPTION
Test Name	HIV-1 EIA (OraSure screening), and HIV-1/2 supplemental IA
Other Name (s)	HIV-1 oral fluid testing
Analyte(s)	HIV-1
Test Code	0520
Lab location	Jacksonville location
Department	Retrovirology (HIV)
Prior Authorization	none
Required Forms	none
Specimen Source	OraSure Collection Devices® manufactured by Orasure Technologies, Inc (OTI).
Supplemental Information- Special Specimen Preparation	OraSure Collection Devices® manufactured by Orasure Technologies, Inc (OTI). Each OraSure Collection Device has an expiration date, displayed as “year (20xx)/month (xx)”. Please make sure the device has NOT expired prior to use. Expired devices cannot be tested at the BPHL.
Minimum Volume	Device pre-set
Storage Conditions	Collected OraSure specimens may be stored at 2°– 37°C for a maximum of 21 days (including the time for shipping and testing). Despite the substantial storage limit, we recommend sending the OraSure specimens within 3-4 days post-collection to allow for laboratory testing and reporting prior to the Patient’s scheduled follow up visit.
Collection Media	OraSure Collection Devices®
Specimen Labeling	Specimen must be labeled with at least two unique patient identifiers (first and last name, unique ID# or DOB) plus the date of collection. A single unique ID is acceptable for anonymous testing only. Electronic lab order preferred, HMS, etc. Information on the specimen must match the requisition
Packaging and Shipping Instructions and Handling	OraSure specimens may be shipped overnight, 2-day delivery or hand-delivered Monday-Friday at 2-37°C, using cold packs as needed. Specimen needs to be received at the lab within 21 days of collection.
Test Methodology	Enzyme Immunoassay (EIA)
Turnaround Time	2 - 3 days
Result Indicator	Laboratory interpretation: Positive, Negative, or Inconclusive for HIV-1
Unsatisfactory Specimen	1) Quantity not sufficient (QNS) 2) No ID on OraSure device 3) Information on specimen does not match requisition/test order 4) Expired collection device was used for specimen collection 5) Leaked in transit 6) Laboratory Accident 7) No specimen received 8) Specimen rec’d >21 days post-collection 9) Patient age is not appropriate for testing
Interferences and Limitations	See FDA approved OraSure® Collection Device IFU
Additional Information & Notes	OraSure Collection Device is intended for person ≥13 years of age
Reference Range	HIV-1 Negative
Reference Lab	none
Reflex testing	Request blood redraw if HIV-1 antibody Inconclusive

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis
Governor

Joseph A. Ladapo, M.D., Ph.D.
State Surgeon General

Vision: To be the **Healthiest State** in the Nation

BUREAU OF PUBLIC HEALTH LABORATORIES

Guidelines for Submission of OraSure® Collection Devices for HIV-1 Antibody Screening and Confirmation

The Florida Bureau of Public Health Laboratories (BPHL), Jacksonville, offers HIV-1 antibody screening and confirmation testing services for the OraSure Collection Device, manufactured by OraSure Technologies Inc. This alternative specimen type is appropriate for detecting antibodies to HIV-1 in persons with suspected established (non-acute disease stage) HIV-1 infections. This specimen collection device is NOT suggested for suspect HIV-2 infections.

- Collected OraSure specimens may be stored at 2°– 37°C for a maximum of 21 days (including time for shipping and testing). Despite the substantial storage limit, we recommend sending OraSure specimens within 3-4 days post-collection to allow for laboratory testing and reporting prior to the patient's scheduled follow up visit.
- Specimen must be labeled with **at least two unique patient identifiers** (first and last name, unique ID# or DOB) and **the date of collection**. A single unique ID is acceptable for anonymous testing only. Electronic lab order preferred, HMS, etc. **Information on the specimen must match the requisition.**
- OraSure specimens may be shipped overnight, 2-day delivery or hand-delivered Monday-Friday at ambient temperature or on cold packs.
- Each OraSure Collection Device has an expiration date, displayed as "year (xxxx)/month (xx)". Please make sure the device has NOT expired prior to use. Expired devices cannot be tested at the BPHL.
- OraSure HIV-1 antibody testing may be electronically ordered through HMS or the DOH HIV portal (MOVE IT), test order #0520

Should you need additional information or clarification please contact Ms. Imelda Ignacio-Hernando at (904) 791-1531, or Mr. Berry Bennett at (904) 791-1527.

BB/IIH 6/20/24