

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	Patient name, DOB, Collection date and time
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 need 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	<ol style="list-style-type: none"> 1) Quantity not sufficient (QNS) 2) No ID on OraSure device 3) Mismatch hx/specimen 4) OraSure device expired 5) Leaked in transit 6) Laboratory Accident 7) No specimen received 8) OraSure device rec’d >21 days post-collection
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.
- OraSure specimens may be shipped overnight, 2-day delivery or hand-delivered Monday-Friday at 2 - 37°C, using cold packs as needed.
- 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
6/15/23