

Test Menu

TOPIC	DESCRIPTION
Test Name	HIV-1/HIV-2 antigen/antibody (Ag/Ab) screening (Immunoassay - IA) and HIV-1/2 Ab Supplemental IA
Other Name (s)	HIV-1/2 Combo IA and HIV-1/2 antibody confirmation
Analyte(s)	HIV-1/HIV-2
Test Code	0500 or 0590
Lab location	Jacksonville and Miami locations
Department	Retrovirology (HIV)
Prior Authorization	none
Required Forms	none
Specimen Source	Plasma or Serum
Supplemental Information- Special Specimen Preparation	Centrifuge PPT or SST bloods within 8 hours of collection and refrigerate until shipment . Submit centrifuged PPT or SST bloods via overnight delivery at 2-37°C, ice packs as needed or frozen with dry ice.
Minimum Volume	At least 2.5mL plasma or serum
Storage Conditions	N/A
Collection Media	Collect a "pearl top" Plasma Preparation Tube (PPT) (preferred) or a "red/tiger top" Serum Separator Tube (SST) (acceptable).
Specimen Labeling	Specimen must be labeled with at least two unique patient identifiers (first and last name, unique ID# or DOB) and the date of collection . Electronic lab order preferred, HMS, etc. Information on the specimen must match the requisition.
Packaging and Shipping Instructions and Handling	Ship for overnight delivery at 2-37°C, ice packs as needed or frozen on dry ice to be shipped at ≤-20°C. Bloods shipped at 2-8°C must be received within 7 days post-collection Bloods shipped at 8-37°C must be received within 72 hours post-collection
Test Methodology	Chemiluminescent immunoassay (CIA)
Turnaround Time	2 - 3 days
Result Indicator	Laboratory interpretations: Positive or Negative
Unsatisfactory Specimen	1) Quantity not sufficient (QNS) 2) No ID on specimen 3) Information on specimen does not match requisition/test order 4) Grossly hemolyzed 5) Leaked in transit 6) Laboratory Accident 7) No specimen received 8) Bloods rec'd 2-8°C >7 days post-collection 9) Bloods rec'd 8-37°C >72 hours post-collection 10) Expired collection device used for specimen collection 11) Patient age is not appropriate for testing
Interferences and Limitations	Not recommended for use with <2 years of age
Additional Information & Notes	See quick reference guide
Reference Range	HIV-1/2 Negative
Reference Lab	none
Reflex testing	Discordant cases reflex to HIV-1 RNA testing

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 Serum or Plasma Specimens for HIV-1/2 Antigen/Antibody Screening

The Florida Bureau of Public Health Laboratories (BPHL), Miami and Jacksonville PHLs offer HIV-1/2 antigen (Ag)/antibody (Ab) combo testing for initial laboratory-based diagnostic screening. The HIV-1/2 Ag/Ab Combo test is a chemiluminescent immunoassay for the simultaneous qualitative detection of HIV-1 p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2 in human serum or plasma. The assay is intended as an aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute or primary HIV-1 infection. Because HIV-1 p24 antigen is not as stable as HIV-1/2 antibodies in human serum and plasma, please adhere to the following collection, storage, and shipping guidelines to maximize antigen detection sensitivity.

Recommended Specimen Storage and Shipping (access to centrifugation required):

1. Collect whole blood in a plasma preparation tube (PPT) (preferred) or serum separator tubes (SST). **Centrifuge (10-15 minutes at 1000xg) within 8 hours of collection and refrigerate until a shipment is prepared.** Specimen must be labeled with **at least two unique patient identifiers** (first and last name, unique ID# or DOB) and **the date of collection**. Electronic lab order preferred, HMS, etc. **Information on the specimen must match the requisition.**
2. Bloods collected Monday-Thursday must be centrifuged and shipped overnight priority or hand-delivered by next day at room temperature, ice packs, or frozen. Bloods collected on Fridays must be centrifuged and shipped overnight, designate as "Saturday Delivery" or hand-deliver at least one hour before laboratory closing on Fridays. If not feasible, please centrifuge and refrigerate specimens until the following Monday, then send overnight priority or hand-deliver at room temperature, ice packs, or frozen.
3. Bloods collected on weekends should be centrifuged within 8 hours of collection and refrigerate until the following Monday, then send overnight priority or hand-deliver at room temperature, ice packs, or frozen.
4. To preserve HIV-1 Ag sensitivity and acceptable reporting turn-around-time for post-test appointments, please send **at least 2-3 overnight shipments or hand-deliveries per week. If for some reason, a blood sample may not be delivered to the laboratory within 7 days of collection, it must be frozen prior to and at delivery.**
5. The HIV-1/2 Ag/Ab diagnostic algorithm may be electronically ordered through HMS or the DOH HIV portal (MOVE IT), test order #0500.

Acceptable Specimen Storage and Shipping (no access to centrifugation):

1. Collect whole blood in red tops, purple tops (EDTA), SSTs or PPTs. **Whole bloods must be hand-delivered to the laboratory on the date of collection, Monday through Friday at room temperature or on ice packs. Whole bloods must be delivered at least one hour before laboratory closing.**

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 6/15/24