

Test Menu

TOPIC	DESCRIPTION
Test Name	HIV-1 PrEP Monitoring
Other Name (s)	HIV-1 Pre-Exposure Prophylaxis (PrEP) Monitoring
Analyte(s)	HIV-1
Test Code	0580
Lab location	Jacksonville & Miami locations
Department	Retrovirology (HIV)
Prior Authorization	none
Required Forms	none
Specimen Source/s	Human plasma
Collection Media	PPT (Pearl top) or EDTA (Purple top)
Supplemental Information- Special Specimen Preparation	Centrifuge the PPT or purple top within 8 hours of collection. PPT is now ready to freeze until shipment is prepared. Purple tops will require decanting of plasma from cells into a sterile screw-top plastic tube then freeze.
Minimum Volume	2.5 mL plasma
Storage Conditions	Store centrifuged PPT or plasma frozen until shipment is prepared.
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	Send overnight Mon-Fri on Dry ice at $\leq -20^{\circ}\text{C}$ or 3-4 frozen refrigerant packs in Styrofoam cooler at $2-8^{\circ}$. Please label outside of cooler with "PrEP Monitoring".
Test Methodology	CMIA (HIV-1/2 Ag/Ab) and TMA (HIV-1 RNA)
Turnaround Time	2-3 days
Result Indicator	Laboratory Interpretation: Positive, Negative, Inconclusive, Quantitative values expressed in RNA copies/ml blood
Unsatisfactory Specimen	<ol style="list-style-type: none"> 1) Quantity not sufficient (QNS) 2) No ID on specimen 3) Information on the specimen does not match the requisition/test order 4) Grossly hemolyzed 5) Leaked in transit 6) Laboratory Accident 7) No specimen received 8) Plasma rec'd >6 days post-collection 9) Specimen not centrifuged 10) Wrong specimen received 11) Expired collection device was used for specimen collection
Interferences and Limitations	For use only in monitoring individuals actively enrolled with HIV PrEP
Additional Information & Notes	See quick reference guide for more information
Reference Range	N/A
Reference Lab	N/A
Reflex testing	N/A

Mission:

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



Ron DeSantis
Governor

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State Surgeon General

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

BUREAU OF PUBLIC HEALTH LABORATORIES JACKSONVILLE, FLORIDA

Quick Reference Guide To HIV-1 Pre-Exposure Prophylaxis (PrEP) Monitoring

The Department of Health, Bureau of Public Health Laboratories offers HIV-1 PrEP monitoring at the Jacksonville and Miami PHLs. This service is limited to HIV seronegative persons actively enrolled in an oral or long-acting injectable PrEP care regimen.

- No preliminary restrictions such as fasting are required for a satisfactory plasma specimen.
- Collect 5mL of blood in a sterile Plasma Preparation Tube (PPT), “pearl top”, BD reference #362788. The algorithm requires a minimum of 2.5mL of plasma. **Do not refrigerate whole blood.** Alternatively, one may collect 7mL of blood in EDTA (K3, 0.15% soln.), “purple top”.
- 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.**
- Centrifuge (10-15 minutes at 1000 x g) the PPT or purple top **within 8 hours of collection.** PPT is now ready to freeze until shipment is prepared (decanting plasma is not required). Purple tops will require decanting of plasma from cells, into a **sterile screw-top plastic tube**.
- Immediately place PPT or plasma in -20°C freezer. Send plasma(s) on approx. 2-3 kg dry ice (if available), do not allow dry ice to contact specimens. However, if dry ice is not available, specimens may be sent on 3-4 frozen refrigerant packs in a Styrofoam cooler. Please label the cooler on the outside with **“PrEP Monitoring”**. Do not allow specimens to thaw before shipping. PPT and plasma specimens are acceptable upon receipt at laboratory if frozen or maintained at 2-8°C for <6 days.
- Follow appropriate packaging and transporting guidelines. Send these specimens as “UN 3373 Biological Substance Category B”. Do not transport dry ice in an airtight container.
- Ship plasma(s) priority overnight to the public health laboratory **Monday thru Friday only**. If the work week includes a holiday, please call the laboratory for collection and shipping instructions.
- The HIV-1 PrEP monitoring service may be electronically ordered through HMS, order #0580.

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 06/20/24