

## Test Menu

TOPIC	DESCRIPTION
<b>Test Name</b>	HIV-1 PrEP Monitoring
<b>Other Name (s)</b>	HIV-1 Pre-Exposure Prophylaxis (PrEP) Monitoring
<b>Analyte(s)</b>	HIV-1
<b>Test Code</b>	0580
<b>Lab location</b>	Jacksonville & Miami locations
<b>Department</b>	Retrovirology (HIV)
<b>Prior Authorization</b>	none
<b>Required Forms</b>	none
<b>Specimen Source/s</b>	Human plasma
<b>Collection Media</b>	PPT (Pearl top) or EDTA (Purple top)
<b>Supplemental Information- Special Specimen Preparation</b>	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.
<b>Minimum Volume</b>	2.5 ml plasma
<b>Storage Conditions</b>	Store centrifuged PPT or plasma frozen until shipment is prepared.
<b>Specimen Labeling</b>	Patient name, DOB, Collection date and time
<b>Packaging and Shipping Instructions and Handling</b>	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°. Please label outside of cooler with "PrEP Monitoring".
<b>Test Methodology</b>	CMIA (HIV-1/2 Ag/Ab) and TMA (HIV-1 RNA)
<b>Turnaround Time</b>	2-3 days
<b>Result Indicator</b>	Laboratory Interpretation: Positive, Negative, Inconclusive, Quantitative values expressed in RNA copies/ml blood
<b>Unsatisfactory Specimen</b>	<ol style="list-style-type: none"> <li>1) Quantity not sufficient (QNS)</li> <li>2) No ID on specimen</li> <li>3) Mismatch history/specimen</li> <li>4) Grossly hemolyzed</li> <li>5) Leaked in transit</li> <li>6) Laboratory Accident</li> <li>7) No specimen received</li> <li>8) Plasma rec'd &gt;6 days post-collection</li> <li>9) Specimen not centrifuged</li> <li>10) Wrong specimen received</li> </ol>
<b>Interferences and Limitations</b>	For use only in monitoring individuals actively enrolled with HIV PrEP
<b>Additional Information &amp; Notes</b>	See quick reference guide for more information
<b>Reference Range</b>	NA
<b>Reference Lab</b>	NA
<b>Reflex testing</b>	NA

**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

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## 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 5 ml blood in a sterile Plasma Preparation Tube (PPT), “pearl top”, BD reference #362788. The algorithm requires a minimum of 2.5 ml plasma. **Do not refrigerate whole blood.** Alternatively, one may collect 7 ml blood in EDTA (K3, 0.15% soln.), “purple top”.
- 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 at ≤-20°C (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 <6 days.
- Follow appropriate packaging and transporting guidelines. 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  
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