

HIV-1 RNA, Qualitative, Real-Time PCR

CPT Code: 87535

Order Code: 16185

ABN Requirement: No

Specimen:

Preferred: EDTA plasma

Alternative: Serum

Volume: 1.6 mL

Minimum Volume: 0.8 mL

Container:

Preferred: EDTA (Lavender Top) tube

Alternative: Red Top Tube (No gel barrier) or Serum Separator Tube (SST, gel barrier)

Collection Instructions: Label transport tube with specimen type. Specimen must be labeled with patient identifiers and submitted only for HIV testing.

Collection:

EDTA Plasma:

1. Gently invert tube 8 to 10 times immediately after draw.
2. Centrifuge for 10 minutes.
EDTA plasma must be separated from cells within 2 hours of collection.
3. Pre-squeeze transfer pipet bulb and draw off approximately 2/3 of the upper plasma layer. **Note:** *This ensures that the buffy coat and red cells remain undisturbed.*
4. Aliquot plasma into labeled transport tube as "EDTA plasma" and cap tightly.

Discard original tube.

Red Top Serum:

1. Gently invert tube 5 times immediately after draw.
2. Allow blood to clot for 30-60 minutes.
3. Centrifuge for 10 minutes.
4. Aliquot serum into labeled transport tube as “Red Top Serum” and cap tightly.

Discard original tube.

SST Serum:

1. Gently invert tube 5 times immediately after draw.
2. Allow blood to clot 30 minutes.
3. Centrifuge for 10 minutes.

Transport:

EDTA plasma and Red Top serum: Store sample frozen at -20°C after collection and ship the same day per packaging instructions provided with the Cleveland HeartLab shipping box. Ship sample on dry ice.

SST serum: Store sample refrigerated at 2°C to 8°C after collection and ship the same day per packaging instructions provided with the Cleveland HeartLab shipping box. SST tube cannot be shipped frozen.

Stability:

Ambient (15-25°C): 72 hours

Refrigerated (2-8°C): 5 days

Frozen (-20°C): 42 days

Causes for Rejection: Specimens other than EDTA plasma or serum; improper labeling; samples not stored properly; samples older than stability limits; frozen SST tube

Methodology: Real-Time Polymerase Chain Reaction

Turn Around Time: 2 to 6 days

Reference Range:

HIV Testing Pathway Algorithm:

https://www.questdiagnostics.com/hcp/intguide/InfectDis/HIV/TS_HIV4thGenScreen_Figure.pdf

Clinical Significance:

HIV-1 Qualitative is an in vitro nucleic acid amplification test for the qualitative detection of human immunodeficiency virus type 1 (HIV-1) RNA in human serum and plasma by PCR. The test is intended to be used as an aid in diagnosis of HIV-1 infection. Detection of HIV-1 nucleic acid is indicative of HIV-1 infection, respectively. The presence of HIV-1 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 or HIV-2 is indicative of acute or primary HIV-1 infection. The HIV-1 Qualitative PCR may also be used as an additional test to confirm the presence of HIV-1 infection in an individual with specimens reactive for HIV-1 antibodies or antigens. The assay may also be used as an aid in the diagnosis of infection with HIV-1 in pediatric subjects and pregnant women. This assay is not intended to be used for monitoring patient status, or for screening donors of blood, plasma, or human cells, tissues, and cellular and tissue-based products (HCT/Ps) for HIV.

The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.