Test Definition: HV2QU

HIV-2 RNA Detection and Quantification, Real-Time qRT-PCR, Plasma

Overview

Useful For

Confirmatory detection of human immunodeficiency virus type 2 (HIV-2) RNA in clinical plasma specimens for the diagnosis of acute or established HIV-2 infection

Quantifying plasma HIV-2 RNA levels (viral load) in individuals living with HIV-2:
-Before initiating antiretroviral therapy to obtain baseline viral load
-For monitoring HIV-2 disease progression with or without antiretroviral therapy

Testing Algorithm

The following algorithms are available:
-HIV Prenatal Testing Algorithm, Including Follow-up of Reactive Rapid Serologic Test Results
-HIV Testing Algorithm (Fourth Generation Screening Assay), Including Follow-up of Reactive Rapid Serologic Test Results

Special Instructions

- HIV Testing Algorithm (Fourth-Generation Screening Assay), Including Follow-up of Reactive Rapid Serologic Test Results
- HIV Prenatal Testing Algorithm, Including Follow-up of Reactive Rapid Serologic Test Results

Method Name

Reverse Transcription Real-time Polymerase Chain Reaction (RT-qPCR)

NY State Available

Yes

Specimen

Specimen Type

Plasma EDTA

Ordering Guidance

This test is indicated for either 1) confirmatory qualitative detection of HIV-2 RNA in individuals with indeterminate or positive HIV-2-specific antibody but negative HIV-1-specific antibody test results; or 2) baseline or serial monitoring of HIV-2 viral load in those with confirmed HIV-2 infection with or without antiretroviral therapy.

Shipping Instructions

Ship specimen frozen on dry ice. If shipment will be delayed for more than 24 hours, freeze specimen at -20 to -80 degrees C (up to 35 days) before shipment and then transport on dry ice.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Lavender top (EDTA)
Submission Container/Tube: Plastic vial
Specimen Volume: 2.1 mL Plasma
Collection Instructions: Centrifuge and aliquot plasma into a plastic vial.

Specimen Minimum Volume

Plasma: 1.1 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma EDTA	Frozen (preferred)	60 days	ALIQUOT TUBE
	Refrigerated	6 days	ALIQUOT TUBE

Clinical & Interpretive

Clinical Information

Human immunodeficiency virus type 2 (HIV-2) is a lentivirus, a retrovirus in the same genus (*Lentiviridae*) as HIV-1. It was first isolated in 1986 in West Africa, where it is currently endemic. Most of these cases in the United States have been found in the northeastern United States, and the majority had a West African origin or connection.

Compared to HIV-1 infection, HIV-2 infection is associated with slower rate of progression, low viral load (which may not be reliably measured with current methods), slower rates of decline in CD4 cell count, and lower rates of transmission (sexually or vertically). Up to 95% of HIV-2-infected individuals are long-term non-progressors, and individuals with undetectable HIV-2 viral load have similar survival rates as that of the uninfected population. However, HIV-2 does cause immunosuppression as well as AIDS with the same signs, symptoms, and opportunistic infections seen in HIV-1. Due to the rarity of HIV-2, there are scant data from controlled trials to inform management decisions.

Reference Values

Undetected

Interpretation

The quantification range of this assay is 50 to 3,160,000 IU/mL (1.70 log to 6.50 log IU/mL), with a limit of detection (based on a 95% detection rate) of 18 IU/mL.

An "Undetected" result indicates that HIV-2 RNA is not detected in the plasma specimen (see Cautions). The limit of detection for this assay is 18 IU/mL.

A result of "<50 IU/mL" indicates that the HIV-2 RNA level present in the plasma specimen is below 50 IU/mL (1.70 log IU/mL), and the assay cannot accurately quantify the HIV-2 RNA present below this level.

A quantitative value (reported in IU/mL and log10 IU/mL) indicates the HIV-2 RNA level (i.e., viral load) present in the plasma specimen.

A result of ">3,160,000 IU/mL" indicates that the HIV-2 RNA level present in the plasma specimen is above 3,160,000 IU/mL (6.50 log IU/mL), and this assay cannot accurately quantify the HIV-2 RNA present above this level.

An "Indeterminate" result suggests the presence of an atypical HIV-2 target sequence. Since the HIV-2 RNA sequence is atypical, repeat testing is unlikely to change this result and therefore is not recommended.

An "Equivocal" result indicates that the presence or absence of HIV-2 RNA in the plasma specimen could not be determined with certainty due to atypical real-time reverse transcriptase-polymerase chain reaction (RT-qPCR) probe reactivity. Submission of a new specimen for testing is recommended.

An "Inconclusive" result indicates that the presence or absence of HIV-2 RNA in the plasma specimen could not be determined with certainty after repeat testing in the laboratory, possibly due to RT-qPCR inhibition. Submission of a new specimen for testing is recommended.

Cautions

This assay is optimized for the detection and quantification of HIV-2 groups A, B, and A/B, but due to unexpected mismatches between the polymerase chain reaction primers and unusual or rare HIV-2 target sequences, some plasma specimens may yield "Undetected" or under-quantified results despite the presence of HIV-2 RNA. Results should be interpreted with caution, considering the patient's risk factors for HIV-2 infection, the analytical sensitivity of the assay, and possible source of the infecting HIV-2 strain. Follow-up HIV-2 RNA testing is recommended for patients with initially "Undetected" HIV-2 RNA test results but at high risk for or suspected to have HIV-2 infection.

Due to potential differences in assay performance, serial monitoring of HIV-2 viral load in a given patient should be performed with the same quantitative molecular assay.

Clinical Reference

1. New York State Department of Health AIDS Institute Clinical Guidelines Program. Diagnosis and management of HIV-2 in adults. June 20, 2023. Available at https://www.hivguidelines.org/wp-content/uploads/2023/01/NYSDOH-AI-Diagnosis-and-Management-of-HIV-2-in-Adults_9-10-2025_HG.pdf
2. U.S. Department of Health and Human Services. HIV-2 infection. December 6, 2023. Available at https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/special-populations-hiv-2-infection
3. Spach DH, Budak JZ. National HIV Curriculum: HIV-2 infection. February 3, 2025. Available at

https://www.hiv.uw.edu/go/key-populations/hiv-2/core-concept/all#citations

Performance

Method Description

This assay utilizes real-time polymerase chain reaction (PCR) technology for the qualitative and quantitative detection of human immunodeficiency virus type 2 (HIV-2) RNA in human plasma. Testing involves 3 major processes with the ELITe InGenius integrated system: automated extraction and purification of viral RNA; reverse transcription of viral target RNA sequence to generate complementary DNA (cDNA); and PCR amplification and real-time detection of fluorescent dye-labeled oligonucleotide (Pleiades) probes that allow the specific and simultaneous detection and quantitation of the target sequence as well as an internal MS2 internal control. The assay is calibrated to the Second World Health Organization International Standard for HIV-2 RNA, NIBSC 16/296.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Varies (once per week)

Report Available

1 to 14 days

Specimen Retention Time

60 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87539

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HV2QU	HIV-2 RNA Detect / Quant, P	69354-9

Result ID	Test Result Name	Result LOINC® Value
623478	HIV-2 RNA Detect / Quant, P	69354-9