MAYO CLINIC LABORATORIES

Test Definition: ADVQU

Adenovirus DNA Detection and Quantification, Plasma

Overview

Useful For

Aiding in the diagnosis of disseminated adenovirus infections in at-risk individuals

Measuring adenoviral load in plasma to monitor disease progression and antiviral response in individuals with disseminated infection

Highlights

This assay detects and quantifies the adenoviral (ADV) DNA present in the plasma of at-risk individuals, such as organ or hematopoietic stem cell transplant recipients, for developing disseminated ADV infection. The assay is calibrated to the First World Health Organization International Standard for human ADV for nucleic acid amplification techniques (NIBSC code: 16/234; adenovirus species C, type 2), and results are reported in IU/mL.

Method Name

Real-Time (Quantitative) Polymerase Chain Reaction (rt-qPCR)

NY State Available

Yes

Specimen

Specimen Type

Plasma EDTA

Ordering Guidance

Request this test only in at-risk individuals, such as organ or hematopoietic stem cell transplant recipients, suspected of developing disseminated adenoviral infection.

Shipping Instructions

1. Ship specimen frozen on dry ice only.
2. If shipment will be delayed for more than 24 hours, freeze plasma at -20 to -80 degrees C (up to 30 days) until transport and ship 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: 1.5 mL (plasma)
Collection Instructions:

1. Centrifuge blood collection tube per manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot plasma into plastic vial.

Specimen Minimum Volume
0.8 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	Reject
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma EDTA	Frozen (preferred)	30 days	
	Refrigerated	6 days	

Clinical & Interpretive

Clinical Information
Human adenoviruses (ADV) are ubiquitous, nonenveloped, double-stranded DNA viruses capable of infecting humans. ADV are classified into 7 species (A through G), and over 100 types based on serological and genetic analysis.(1) While infections can be asymptomatic, a variety of clinical presentations can occur following infection, in part due to differences in cell tropism across ADV types.(2) The most common clinical presentations include respiratory, gastrointestinal, and ocular infections.

Adenovirus infections are commonly acquired in early childhood, but infections and outbreaks have been reported in adult populations as well.(3) In immunocompetent individuals, infections are typically self-limiting and do not require medical intervention. However, there is a higher risk of more severe infection, including disseminated disease, in immunocompromised patients such as solid organ and hematopoietic stem cell transplant recipients.

In individuals at risk for severe disease, the most common diagnostic method is detection of the ADV DNA with various molecular assays, which have been developed to detect and quantify various ADV species and types associated with human disease.(2) Additionally, plasma specimens are used for diagnostic screening in high-risk transplant patients as a marker of dissemination. However, presence of ADV in non-blood specimens is not a definitive marker of disease, as it can be shed in urine, saliva, tears, or stool of asymptomatic patients.(3,4) Therefore, serial quantitative measurement of ADV viral load in plasma of high-risk patients is recommended to guide clinical management strategies, but there is no consensus on a definitive ADV viral load thresholds to guide therapeutic intervention.(3,4) Currently, the primary use of quantitative plasma ADV DNA assays is to monitor the trend of viral load over time as a surrogate for disease progression.

Reference Values

Undetected

Interpretation

The quantification range of this assay is 30 to 10,000,000 IU/mL (1.48 log to 7.00 log IU/mL), with a limit of detection (at 95% detection rate) at 30 IU/mL.

An "Undetected" result indicates that ADV DNA is not detected in the plasma specimen (see Cautions). In at-risk individuals, follow-up serial weekly testing is recommended.

A result of "<30 IU/mL" indicates that the ADV DNA level present in the plasma specimen is below 30 IU/mL (1.48 log IU/mL), and the assay cannot accurately quantify the ADV DNA present below this level.

A quantitative value (reported in IU/mL and log IU/mL) indicates the ADV DNA level (ie, viral load) present in the plasma specimen.

A result of ">10,000,000 IU/mL" indicates that the ADV DNA level present in the plasma specimen is above 10,000,000 IU/mL (7.00 log IU/mL), and this assay cannot accurately quantify the ADV DNA present above this level.

An "Inconclusive" result indicates that the presence or absence of ADV DNA in the plasma specimen could not be determined with certainty after repeat testing in the laboratory, possibly due to polymerase chain reaction inhibition or presence of interfering substance. Submission of a new specimen for testing is recommended if clinically indicated.

Cautions

Adenovirus (ADV) DNA test results should be used as an aid in diagnosis and should not be considered diagnostic in themselves.

Although the reference range is generally considered to be "Undetected" for this assay, adenovirus DNA may be detected from asymptomatic individuals in certain settings. This assay should only be used to test at-risk patients with clinical history and symptoms consistent with disseminated adenovirus disease and is not used to screen otherwise healthy individuals.

Only EDTA-plasma specimens are acceptable for testing with this assay. Visibly lipemic plasma specimens are not acceptable, as ADV DNA may be undetectable or under-quantified due to possible complete or partial polymerase chain reaction inhibition.

Due to differences in design and analytical performance for different assays detecting and quantifying ADV DNA in human plasma specimens, serial testing for ADV load in plasma of a given patient over time should be performed using the same molecular assay.

Clinical Reference

1. Lion T. Adenovirus infections in immunocompetent and immunocompromised patients. Clin Microbiol Rev. 2014;27(3):441-462. doi:10.1128/cmr.00116-13
2. Hiwarkar P, Kosulin K, Cesaro S, et al. Management of adenovirus infection in patients after haematopoietic stem cell

transplantation: state-of-the-art and real-life current approach. Rev Med Virol. 2018;28(3):e1980. doi:10.1002/rmv.1980
3. Florescu DF, Schaenman JM. AST Infectious Diseases Community of Practice. Adenovirus in solid organ transplant recipients: guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13527. doi:10.1111/ctr.13527
4. Shirley JD, Yao JD. Laboratory diagnosis of adenoviral infections in transplant recipients. Clin Microbiol News. 2023;45(22):189-199. doi:10.1016/j.clinmicnews.2024.01.003

Performance

Method Description

This laboratory-developed, real-time, polymerase chain reaction (PCR) assay uses the DSQ Alert HT Adenovirus RUO Detection Reagent (ELITechGroup Molecular Diagnostics, LLC), which contains the primer and probe set that amplifies and detects a 53-base pair (bp) sequence (77-bp long when including the 5' flap on the PCR primers) within the adenoviral hexon protein-encoding gene. This reagent contains an MGB-TaqMan hydrolysis probe labeled with FAM fluorophore (emission wavelength of 521 nm) for real-time detection of the amplified adenoviral sequences generated from the assay. The above reagent is used with the commercially available cobas omni Utility Channel Reagent Kit (Roche Molecular Systems, Inc.) on the automated cobas 5800 System (Roche Molecular Systems, Inc.). The cobas omni UC Reagent kit contains deoxynucleotide triphosphates, thermostable DNA polymerase, and primers and probes for the internal control (IC), which is an armored RNA sequence of the MS2 bacteriophage. The cobas 5800 assay-specific Utility Channel Analysis Package program analyzes the amplified target fluorescence signal to determine positivity and ADV DNA concentrations in individual PCR. The assay is calibrated to the First World Health Organization International Standard for human adenovirus for nucleic acid amplification techniques (NIBSC code: 16/234; adenovirus species C, type 2), and results are reported in IU/mL.(Package insert: cobas omni Utility Channel Reagent Kit for use on the cobas 5800/6800/8800 Systems. Roche Molecular Systems, Inc.; Doc. Rev. 3.0; 11/2022)

PDF Report

No

Day(s) Performed

Tuesday, Friday

Report Available

1 to 4 days

Specimen Retention Time

30 days

Performing Laboratory Location

Rochester

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

87799

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
ADVQU	Adenovirus DNA Detect/Quant, P	In Process

Result ID	Test Result Name	Result LOINC® Value
622150	Adenovirus DNA Detect/Quant, P	In Process