MAYO CLINIC LABORATORIES

Test Definition: LCADP

Adenovirus, Molecular Detection, PCR, Plasma

Overview

Useful For
Aiding in diagnosing adenovirus infections using plasma specimens

Method Name
Real-Time Polymerase Chain Reaction (PCR)/DNA Probe Hybridization

NY State Available
Yes

Specimen

Specimen Type
Plasma EDTA

Specimen Required
Collection Container/Tube: Lavender top (EDTA)
Submission Container/Tube: Screw-capped, sterile container
Specimen Volume: 1 mL
Collection Instructions: Centrifuge and aliquot plasma into a sterile, plastic vial.

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume
0.3 mL

Reject Due To

Gross hemolysis	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma EDTA	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical & Interpretive

Clinical Information

Human adenoviruses cause a variety of diseases, including pneumonia, cystitis, conjunctivitis, diarrhea, hepatitis, myocarditis, and encephalitis. In humans, adenoviruses have been recovered from almost every organ system. Infections can occur at any time of the year and in all age groups. Currently, there are over 50 adenovirus serotypes that have been grouped into 6 separate subgenera.

Although adenovirus can be recovered in cell culture, it can take up to 3 weeks for the virus to be identified by culture methods (Mayo's shell vial culture provides more rapid results, reported at 2 and 5 days). Polymerase chain reaction assays offer a rapid, specific, and sensitive means of diagnosis by detecting adenovirus DNA.

Reference Values

Negative

Interpretation

A positive result indicates the presence of adenovirus nucleic acid in the clinical specimen.

A negative result does not rule out the presence of adenoviruses because viral DNA may be present at levels below the detection limits of this assay.

Cautions

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 "Negative" for this assay, adenovirus DNA may be detected from asymptomatic individuals in certain settings. This assay should only be used to test patients with clinical history and symptoms consistent with adenovirus disease, and is not used to screen healthy patients.

Supportive Data

The following data support the use of this assay for clinical testing.

Accuracy/Diagnostic Sensitivity and Specificity:
A study of 791 clinical specimens compared shell vial culture and this polymerase chain reaction (PCR) assay. Included in the study were 288 swab specimens (nasal, throat, rectal, skin), 125 eye specimens, 221 respiratory specimens (bronchial washings, sputa, bronchioalveolar lavage, tracheal secretions), 56 fresh tissue specimens, 72 stools, 5 urines, and 24 body fluids/other specimens. Specimens were inoculated into culture tubes and examined for cytopathic effects over a period of 14 days, and subsequently assayed with this LightCycler (LC) assay. Comparison of cell culture with LC PCR yielded the following: total specimens positive by LC PCR was 83 (stool=7; respiratory=8; tissue=3; swabs=29; eye specimens=30; miscellaneous= 1 and urine=4) and total specimens positive by culture were 76 (stool=6; respiratory=7; tissue=3; respiratory swabs=28; eye specimens=29; and urine=2, miscellaneous = 1). Of the 83 total positive specimens, PCR detected approximately 10% more adenovirus infections compared with culture. This assay detected all 57 serotypes of adenovirus tested.

Supplemental Data (Spiking Studies):
To supplement the above data, 30 negative samples of various types (cerebrospinal fluid, ocular, respiratory, stool, urine, and plasma) were spiked with adenovirus positive control plasmid at the limit of detection (approximately 10 targets/microliter). The 30 spiked specimens were run in a blinded manner with 30 negative (non-spiked) specimens. One hundred percent of the spiked specimens were positive, and 100% of the non-spiked specimens were negative.

Analytical Sensitivity/Limit of Detection:
The lower limit of detection of this assay is 10 targets/microliter in specimen matrix.

Analytical Specificity:
No PCR signal was obtained from extracts of 150 bacterial, viral, parasitic, and fungal isolates that could cause similar disease or could be found as normal flora in sites normally tested for this organism.

Precision:
Interassay precision was 100% and intra-assay precision was 100%.

Reference Range:
The reference range for this assay is "Negative."

Reportable Range:
This is a qualitative assay and results are reported as negative or positive for targeted adenovirus DNA.

Clinical Reference

1. Florescu DF, Schaenman JM: Adenovirus in solid organ transplant recipients: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13527
2. Buckwalter SP, Teo R, Espy MJ, Sloan LM, Smith TF, Pritt BS: Real-time qualitative PCR for 57 human adenovirus types from multiple specimen sources. J Clin Microbiol. 2012 Mar;50(3):766-771. doi:10.1128/jcm.05629-11
3. Ebner K, Pinsker W, Lion T: Comparative sequence analysis of the hexon gene in the entire spectrum of human adenovirus serotypes: phylogenetic, taxonomic, and clinical implications. J Virol. 2005 Oct;79(20):12635-12642
4. Ebner K, Suda M, Watzinger F, Lion T: Molecular detection and quantitative analysis of the entire spectrum of human adenoviruses by a two-reaction real-time PCR assay. J Clin Microbiol. 2005 Jul;43(7):3049-3053
5. Jothikumar N, Cromeans TL, Hill VR, Lu X, Sobsey MD, Erdman DD: Quantitative real-time PCR assays for the detection of human adenoviruses and identification of serotypes 40 and 41. Appl Environ Microbiol. 2005 Jun;71(6):3131-3136
6. Robinson C, Echavarria M: Adenovirus. In: Murray PR, Baron EJ, Jorgensen JH, eds. Manual of Clinical Microbiology. ASM Press; 2007:1589-1600
7. Kaneko H, Maruko I, Iida T, et al: The possibility of human adenovirus detection from the conjunctiva in asymptomatic cases during a nosocomial infection. Cornea 2008 Jun;27(5):527-530

Performance

Method Description

Respiratory, swabs, stools, tissues, plasma, and urine samples are processed according to specimen source. Viral nucleic acid is extracted by the MagNA Pure automated instrument (Roche Applied Science). Primers and fluorescence resonance energy transfer (FRET) probes target a relatively conserved 185 base-pair region of the adenovirus penton gene. The LightCycler instrument (Roche Applied Science) amplifies and monitors the development of target nucleic acid sequences after the annealing step during polymerase chain reaction (PCR) cycling. This automated PCR system rapidly detects amplicon development through stringent air-controlled temperature cycling in capillary cuvettes. The detection of amplified products is based on the FRET principle. For FRET product detection, a hybridization probe with a donor

fluorophore, fluorescein, on the 3'-end is excited by an external light source and emits light that is absorbed by a second hybridization probe with an acceptor fluorophore, LC-Red 640, at the 5'-end. The acceptor fluorophore then emits a light of a different wavelength that can be measured with a signal that is proportional to the amount of specific PCR product.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday, Wednesday, Friday

Report Available
2 to 5 days

Specimen Retention Time
1 week

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
87798

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
LCADP	Adenovirus PCR, P	21055-9

Result ID	Test Result Name	Result LOINC® Value
56088	Adenovirus PCR, P	21055-9