

Overview

Useful For

Aiding in the diagnosis of adenovirus infections

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Varies

Necessary Information

Specimen source is required.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Body fluid

Sources: Pleural, peritoneal, ascites, pericardial, or amniotic

Container/Tube: Sterile container

Specimen Volume: 0.5 mL

Collection Instructions: Do not centrifuge.

Specimen Type: Respiratory

Sources: Bronchial washing, bronchoalveolar lavage, nasopharyngeal aspirate or washing, sputum, or tracheal aspirate

Container/Tube: Sterile container

Specimen Volume: 1 mL

Specimen Type: Spinal fluid

Container/Tube: Sterile vial

Specimen Volume: 0.5 mL

Collection Instructions: Do not centrifuge.

Specimen Type: Stool

Supplies: Stool Collection Kit, Random (T635)

Container/Tube: Sterile container

Specimen Volume: 1 g

Specimen Type: Swab

Supplies:

-M4-RT (T605)

-Bartels FlexTrans VTM-3 mL (T892)

-Jiangsu VTM-3 mL (T891)

Sources: Nasal, throat, respiratory, genital, or ocular

Container/Tube: Multimicrobe media (M4-RT) and Eswabs

Specimen Volume: Entire specimen

Collection Instructions: Place swab back into a multimicrobe media (M4-RT, M4, or M5).

Specimen Type: Tissue

Supplies:

-M4-RT (T605)

-Bartels FlexTrans VTM-3 mL (T892)

-Jiangsu VTM-3 mL (T891)

Container/Tube: Sterile container containing 1 mL to 2 mL of sterile saline or multimicrobe medium (M4-RT, M4, or M5)

Specimen Volume: Entire collection

Collection Instructions: Collect fresh tissue specimen.

Specimen Type: Urine

Container/Tube: Sterile container

Specimen Volume: 1 mL

Collection Instructions: Collect a random urine specimen.

Forms

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

Reject Due To

Other Calcium alginate-tipped swab Wood swab Transport swab containing gel

Specimen Minimum Volume

Body Fluid, Respiratory Specimen, Spinal Fluid, or Urine: 0.3 mL

Stool: 0.5 g

Swab or Tissue: NA

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	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 57 adenovirus serotypes that have been grouped into 6 separate subgenera.

Culture is the gold standard for the diagnosis for adenovirus infection. However, it can take up to 3 weeks to achieve culture results (Mayo Clinic's shell vial culture provides more rapid results, reported at 2 and 5 days). Serological tests have faster turnaround times, but can be less sensitive compared to culture. PCR offers a rapid, specific, and sensitive means of diagnosis by detecting adenovirus DNA.

Reference Values

Negative

Interpretation

A positive result indicates the presence of adenovirus DNA in the clinical sample.

A negative result does not rule out the presence of adenovirus 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 support the use of this assay for clinical testing.

Accuracy/Diagnostic Sensitivity and Specificity:

A study of 715 clinical specimens compared shell vial culture and this PCR assay. Included in the study were 286 swab specimens (nasal, throat, rectal, skin), 49 eye specimens, 221 respiratory specimens (bronchial washings, sputa, bronchioalveolar lavage, tracheal secretions), 55 fresh tissue specimens, 72 stools, and 27 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 assay. Comparison of cell culture with LC PCR yielded the following: total specimens positive by LC PCR was 60 (stool=9; respiratory=4; tissue=4; swabs=24; eye specimens=14; and urine=4) and total specimens by culture were 52 (stool=8; respiratory=3; tissue=3; swabs=23; eye specimens=13; and urine=2). Of the 60 total positive specimens, PCR produced a 13.5% increased rate of detection of adenovirus compared with culture. This assay detected all 57 serotypes of adenovirus tested.

Supplemental Data (Spiking Studies):

To supplement the above data, 30 negative specimens of various types (CSF, 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 (nonspiked) specimens. One hundred percent of the spiked specimens were positive and 100% of the nonspiked specimens were negative.

Analytical Sensitivity/Limit of Detection (LoD):

The LoD of this assay is 10 targets per 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%.

Reportable Range:

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

Clinical Reference

1. Buckwalter SP, Teo R, Espy MJ, et al: Real-time qualitative PCR for 57 human adenovirus types from multiple specimen sources. *J Clin Microbiol* 2011;50(3):766-771 doi:10.1128/jcm.05629-11
2. 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;79:12635-12642
3. 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;43:3049-3053

4. Jothikumar N, Cromeans TL, Hill VR, et al: Quantitative real-time PCR assays for the detection of human adenoviruses and identification of serotypes 40 and 41. Appl Environ Microbiol 2005;71:3131-3136

5. Robinson C, Echavarria M: Adenovirus. In Manual of Clinical Microbiology. Edited by PR Murray, EJ Baron, JH Jorgensen, et al: Ninth edition. Washington, DC, ASM Press, 2007, pp 1589-1600

6. Thavagnanam S, Christie SN, Doherty GM, et al: Respiratory viral infection in lower airways of asymptomatic children. Acta Paediatr Mar;99(3):394-398

7. Kaneko H, Maruko I, Iida T, et al: The possibility of human adenovirus detection in the conjunctiva in asymptomatic cases during a nosocomial infection. Cornea Jun 2008;27(5):527-530

Performance

Method Description

Respiratory, swab, stool, tissue, and urine samples were 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 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

Specimen Retention Time

1 week

Performing Laboratory Location

Rochester

Fees & Codes

Test Classification

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

CPT Code Information

87798