Test Definition: LCADP
Adenovirus PCR, P

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: Spin down promptly.

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

<table>
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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Plasma EDTA</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
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Clinical and 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 51 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's shell vial culture provides more rapid results, reported at 2 and 5 days. While 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 nucleic acid.

A negative result does not rule out the presence of adenoviruses because organisms 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 PCR assay. Included in the study were 288 swab specimens (nasal, throat, rectal, skin), 125 eye specimens, 221 respiratory specimens (bronchial washings, sputa, bronchoalveolar lavage, tracheal secretions), 56 fresh tissue specimens, 72 stools, and 29 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 76 (stool=6; respiratory=7; tissue=3; swabs=28; eye specimens=29; urine=2; miscellaneous = 1) and total specimens by culture were 52 (stool= 8; respiratory=3; tissue=3; swabs=23; eye specimens=13; urine=2). Of the 76 total positive specimens, PCR produced a 13.5% increased rate of detection of adenovirus compared with culture. Analytical sensitivity was assessed by testing dilutions (in triplicate) of the plasmid control down to a level corresponding to 1 target/microliter. The limit of reproducible detection was determined to be 10 targets/microliter. Additionally, the sensitivity of plasma was known to be > or =90% at the concentration of 10 targets/microliter. This assay detected all 51 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. 100% of the spiked specimens were positive and 100% of the nonspiked specimens were negative.

**Analytical Sensitivity/Limit of Detection (LoD):**
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


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 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) and Time(s) Test Performed**
Monday, Wednesday, Friday; 6 a.m.

**Analytic Time**
Monday through Thursday: 2 days Friday, Saturday: 3 days

**Maximum Laboratory Time**
5 days

**Specimen Retention Time**
1 week

**Performing Laboratory Location**
Rochester

**Fees and 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 Regional Manager. 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. This test has not been cleared or approved by the U.S. Food and Drug Administration.

**CPT Code Information**
87798

**LOINC® Information**

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<td>Adenovirus PCR, P</td>
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