Test Definition: GAPCR

Streptococcus Group A, Molecular Detection, PCR, Throat

Overview

Useful For

Detecting group A streptococcal infections in patients with signs and symptoms of pharyngitis using a throat swab specimen

The test is **not intended for** monitoring treatment for group A *Streptococcus* infections.

Highlights

This test provides rapid detection of *Streptococcus pyogenes*/Group A *Streptococcus* in patients with pharyngitis.

Method Name

Real-Time Polymerase Chain Reaction (PCR)

NY State Available

Yes

Specimen

Specimen Type

Varies

Specimen Required

Patient Preparation: Do not collect throat swab specimens immediately after use of antiseptic mouthwash.
Specimen Type: Throat swab
Supplies: BD E-Swab (T853)
Container/Tube:
Preferred: BD Liquid Amies Elution Swab (ESwab)
Acceptable: Copan Liquid Amies Elution Swab (ESwab)
Specimen Volume: Entire collection/1 ESwab
Collection Instructions:
1. **Must be collected and transported using the ESwab collection kit.**
2. Using a tongue blade to hold the tongue down, firmly rub the swab over the tonsils, posterior pharynx, and any areas of inflammation with exudate. Ensure that areas with exudate or inflammation are swabbed.
3. Avoid the tongue, teeth, and gums as the swab is withdrawn.
4. Insert the swab back into the ESwab transport tube and break the swab at the indicated score line.
5. Label specimen according to policy.
6. Send refrigerated. **Do not freeze**.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Specimens collected in media other than ESwab collection kit	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	6 days	
	Ambient	48 hours	

Clinical & Interpretive

Clinical Information

Group A streptococci are gram-positive, beta-hemolytic disease-causing bacteria that commonly cause infections in the throat (pharyngitis or strep throat) or on skin (cellulitis and impetigo) and can cause a wide range of other infections (eg, sepsis, pneumonia, and meningitis). Pharyngitis may also be caused by other bacteria, including *Neisseria gonorrhoeae* and *Corynebacterium diphtheriae*, for which specific culture methods are required. If left untreated, mild infections can lead to more serious infections. The most severe but least common forms of invasive Group A streptococcal disease (GAS) are necrotizing fasciitis and streptococcal toxic shock syndrome. Several million cases of strep throat and impetigo occur each year with approximately 9000 to 11,500 cases of invasive GAS disease occurring in the United States, resulting in 1000 to 1800 deaths.(1) Treating an infected person with an appropriate antibiotic generally prevents the spread of the infection and reduces the risk of post-infectious complications, such as rheumatic fever and acute glomerular nephritis.(2)

Reference Values

Negative

Interpretation

Positive: *Streptococcus pyogenes* DNA is detected.
Negative: *Streptococcus pyogenes* DNA is not detected.

Cautions

Additional follow-up testing by culture is required if the Xpert Xpress Strep A test result is negative and clinical symptoms persist or if there is an outbreak of acute rheumatic fever.

As with many diagnostic tests, negative results from the Xpert Xpress Strep A test do not preclude a Strep A infection and should not be used as the sole basis for treatment or other patient management decisions. The Xpert Xpress Strep A

test does not differentiate asymptomatic carriers of Group A streptococci from those exhibiting streptococcal infection. The results from the Xpert Xpress Strep A test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

A negative test result does not exclude the possibility of infection because the test result may be affected by improper specimen collection, technical error, sample mix-up, or because the number of organisms in the sample is below the limit of detection of the test.(3)

Because the detection of *Streptococcus pyogenes* is dependent on the organism's DNA present in the sample, reliable results are dependent on proper specimen collection, handling, and storage.

The Xpert Xpress Strep A test has been validated only with Copan Liquid Amies Elution Swab (ESwab) Collection Kit (Copan 480C, Copan 480CE, or Copan 480CFA) or equivalent.

Variants or nucleotide alterations (ie, polymorphisms) in primer or probe binding regions may affect detection of new or unknown *S pyogenes* strains resulting in a false-negative result.

This test has not been evaluated for patients without signs and symptoms of pharyngitis.

This test cannot rule out pharyngitis caused by disease-causing organisms other than Group A streptococci.

The analyte target (bacterial nucleic acid) may persist in vivo, independent of pathogen viability. Detection of the analyte target does not imply that the corresponding pathogen is either infectious or is the causative agent of the clinical symptoms.(3)

Clinical Reference

1. Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Division of Bacterial Diseases. Active Bacterial Core Surveillance (ABCs) Report: group A Streptococcus, 2003. CDC. 2004. Accessed January 31, 2024. Available at www.cdc.gov/abcs/reports-findings/survreports/gas03.pdf
2. Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Division of Bacterial Diseases. Scarlet Fever: All You Need to Know. CDC. Updated May 10, 2023. Accessed January 31, 2024. Available at www.cdc.gov/groupastrep/diseases-public/scarlet-fever.html
3. Package insert: Xpert Xpress Strep A. Cepheid; 301-9326 Rev. D, 06/2019

Performance

Method Description

The GeneXpert Dx System automates and integrates sample purification, nucleic acid extraction and amplification, and detection of the target sequence using real-time polymerase chain reaction (PCR). The system requires single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized.

The Xpert Xpress Strep A test, performed on the GeneXpert Instrument Systems, is a rapid, qualitative test using real-time PCR to detect *Streptococcus pyogenes* DNA. The assay includes a sample processing control to ensure an adequate amplification process and to monitor for the presence of inhibitors in the PCR reaction. A probe check control verifies reagent rehydration, PCR tube filling, and all reaction components, including probes and dyes, are present and functional in the cartridge.(Package insert: Xpert Xpress Strep A. Cepheid; 301-9326, Rev. D, 06/2019)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 day

Specimen Retention Time
6 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
87651

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
GAPCR	Group A Streptococcus PCR, Throat	60489-2

Result ID	Test Result Name	Result LOINC® Value
GAPCR	Group A Streptococcus PCR, Throat	60489-2