

## 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

No

## 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 Avoid the tongue, teeth, and gums as the swab is withdrawn.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        | Ambient                  | 48 hours |                   |
|               | Refrigerated (preferred) | 6 days   |                   |

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**

- 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](http://www.cdc.gov/abcs/reports-findings/survreports/gas03.pdf)
- 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](http://www.cdc.gov/groupastrep/diseases-public/scarlet-fever.html)
- 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 amplification, and detection of the target sequence in simple or complex samples using real-time polymerase chain reaction (PCR) and reverse transcriptase PCR assays. The system requires the use of 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 eliminated.

The Xpert Xpress Strep A test, performed on the GeneXpert Instrument Systems, is a rapid, qualitative in vitro diagnostic test for the detection of *Streptococcus pyogenes* (Group A beta-hemolytic *Streptococcus*, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis. The Xpert Xpress Strep A test utilizes an automated real-time PCR to detect *S pyogenes* DNA. (Package insert: Xpert Xpress Strep A. Cepheid; 301-6574, Rev D, 06/2019)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 day

Specimen Retention Time

7 days

Performing Laboratory Location

Jacksonville

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             |