Lab Dept: Microbiology

Test Name: GROUP A STREP DNA BY PCR

General Information

Lab Order Codes:	GASDN
Synonyms:	Streptococcus Group A PCR; Beta strep group A PCR; Throat, group A strep only
CPT Codes:	87651 – Streptococcus, group A, amplified probe technique
Test Includes:	Detection of group A strep by PCR using throat specimens from patients suspected of having streptococcal pharyngitis. This assay targets the *Streptococcus pyogenes* exotoxin B gene (speB). If other organisms are suspected, refer to Throat Culture, Routine.

Logistics

Test Indications:	Patients suspected of having streptococcal pharyngitis.
Lab Testing Sections:	Microbiology
Phone Number:	MIN Lab: 612-813-5866 STP Lab: 651-220-6555
Test Availability:	Daily, 24 hours
Turnaround Time:	45 minutes
Special Instructions:	Requisition must state specific type of specimen and date/time of collection.

Specimen

Specimen Type:	Throat swab

Container: ESwab

CHC#: 32447, Kit ESwab Regular Flocked

Draw Volume: 1 swab

Collection: **Throat swab**

1. Remove the swab, taking care not to touch the tip of the swab or lay it down.
2. Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline
3. Gently swab the posterior pharynx, tonsils, or other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab when collecting the specimens.
4. Remove the cap from the tube. Do not place the cap open side down or touch the inside of the cap.|
5. Insert the swab into the transport medium containing tube.
6. Break the swab shaft at the pre-scored line by bending it against the tube wall.
7. Replace the cap onto the tube and close tightly.

Transport/Storage: Transport to the Laboratory at room temperature. If a delay is anticipated, refrigerate specimen at 4°C. Specimens are stable at room temperature for 2 days and 6 days at refrigerated temperature (2 – 8°C).

Patient Preparation: None

Sample Rejection: Specimen not submitted in appropriate transport container; improperly labeled specimen: incorrect specimens. If an unacceptable specimen is received, the patient's caregiver will be notified and another specimen will be requested before the specimen is discarded.

Interpretive

Reference Range Negative Group A streptococci not detected by PCR

Limitations: This assay does not detect other beta-hemolytic streptococci including group C or group G. If suspected, order Throat Culture, Routine. Group C and G have been associated with pharyngitis and, occasionally, acute nephritis but do not cause rheumatic fever.

● Additional follow-up testing by culture is required if the Xpert Xpress Strep A test result is negative and clinical symptoms persist, or there is an outbreak of acute rheumatic fever (ARF).
● The performance of the Xpert Xpress Strep A test was evaluated using the procedures provided in the package insert only.
●Careful compliance with the instructions in the Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System package insert is necessary to avoid erroneous results.
● Because the detection of *Streptococcus pyogenes* is dependent on the organism's DNA present in the sample, reliable results are dependent on proper sample collection, handling, and storage.
● The Xpert Xpress Strep A test provides qualitative results and does not provide the quantitative value of the organism detected in the specimen.
● Mutations or nucleotide polymorphisms in primer or probe binding regions may affect detection of new or unknown *Streptococcus pyogenes* strains resulting in a false negative result.
● 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.
● 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.
● This test has not been evaluated for patients without signs and symptoms of pharyngitis.
● This test cannot rule out pharyngitis caused by other bacterial or viral pathogens besides Group A streptococci.
● Cross-reactivity with organisms not tested by the manufacturer during the verification may lead to erroneous results.
● 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 infectious, or is the causative agent of the clinical symptoms.

Methodology: Real-Time Polymerase Chain Reaction (RT-PCR)

References:

Red Book (2012):668-680: Group A Streptococcal Infections, American Academy of Pediatrics

Miller, J. Michael (1999) A Guide to Specimen Management in Clinical Microbiology, American Society for Microbiology, Washington, D.C, pg 100.

E.J. Baron and R.B. Thompson, Jr (2011) Specimen Collection, Transport, and Processing: Bacteriology in J. Versalovic, et al., (ed.), Manual of Clinical Microbiology, 11th edition, American Society for Microbiology, Washington, D.C., pg 237

Xpert Xpress Strep A Package Insert, 301-6574, Rev. B. May 2018, Sunnyvale CA: Cepheid

ESwab Package Insert, HPC030, Rev.00, Feb 2016, Murrieta, CA: Copan Diagnostics Inc.

Updates	11/11/2020: Updated ESwab information.