

Xpert® Xpress Strep A

Rapid, quality results. No compromise.



The Need

To accurately diagnose pharyngitis caused by Group A Streptococcus (GAS) due to increasing incidence and prevalence globally.

- Annually, **616 million people** are diagnosed with GAS pharyngitis, **more than 18.1 million people develop severe GAS** disease and more than **517,000 people die** due to severe GAS disease.¹

Reduce overuse of antibiotics for the treatment of pharyngitis.

- Based on recent literature **37% of children** presenting with pharyngitis tested positive for GAS, however **56% of visits were associated with antibiotic prescriptions**. Similarly, **18% of adults** presented with pharyngitis caused by GAS, but **72% were treated** with antibiotics.²

The Impact

- Diagnose GAS with accuracy which supports antimicrobial stewardship and may reduce the amount of patients inappropriately prescribed antibiotics.
- Gain testing efficiencies and reduce costs by eliminating culture confirmation testing³.
- Reduce the risk of GAS complications such as rheumatic fever and glomerulonephritis.
- Improve patient satisfaction with quicker time to result and appropriate prescriptions.

The Solution

- The **Xpert Xpress Strep A** test provides on-demand testing for group A strep provides on-demand testing for Group A Strep in **as soon as 18 minutes***
- Careful selection of the target gene produces quality results
- Delivering accurate and timely results optimizes fast treatment decisions

¹ The Global Burden of Group A Streptococcal Diseases. Lancet Infect Dis. 2005 Nov; 5(11):685-94.

² Fleming-Dutra KE, et al. Prevalence of Inappropriate Antibiotic Prescriptions Among US Ambulatory Care Visits, 2010-2011. JAMA. 2016 May 3;315(17):1864-73

³ Workflow studies conducted by Cepheid Solutions demonstrate that a throat culture confirmation workup costs~ \$9.13 per culture. (Average cost includes reagents, labor cost and time). Data on file.

* With Early Assay Termination (EAT) for positive results. Refer to Package Insert Xpert Xpress Strep A CE-IVD 301-6569.

[^] 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 results from the Xpert Xpress Strep A test should be interpreted in conjunction with other laboratory and clinical data available to the clinician.



Xpert® Xpress Strep A

Product Reference Sheet — CE-IVD

Test Reagent Kit	Xpert Xpress Strep A
Catalog Number	XPRSTREPA-CE-10
Technology	Real-time RT-PCR
Targets	<i>SpeB</i> gene of <i>S. pyogenes</i>
Batch or On-Demand	On-Demand
Minimum Batch Size	1
Sample Types	Specimen Collection: Throat Swab Collection Device: E-swab in liquid Amies
Sample Extraction	Automated/integrated
Precision Pipetting	Not required
TAT	As soon as 18 mins for positives* and about 24 minutes for negatives
Controls: Process	Sample Processing Control
Controls: Probe Function/Detection	Probe Check Control
Performance	Positive Predictive Value: 84.1% Negative Predictive Value: 100% Sensitivity: 100% Specificity: 94.1%
Sample Storage	15–30 °C for up to 48 hours or 2–8 °C for up to 6 days
Kit Storage	2–28 °C for up to expiration date of the kit
Commercial Controls	Refer to Xpert Xpress Strep A Package Insert or contact Cepheid Technical Support

CATALOG INFORMATION

Xpert® Xpress Strep A	10 tests	XPRSTREPA-CE-10
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COLLECTION DEVICES (NOT INCLUDED IN KIT)

CATALOG INFORMATION

Copan E-Swab in Liquid Amies	50 test kits	480CE and 480C
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CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries.

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