Xpert® Xpress Strep A

Rapid, Quality Results. No Compromise.



The Need

Accurately diagnose pharyngitis caused by Group A Streptococcus (GAS)

- Annually, **616 million people** have 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

- **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 Solution

Cepheid's on-demand Group A Strep test:

- Produces results in **as soon as 18 minutes**
- Delivers careful selection of the target gene
- Eliminates need to perform culture confirmation of negative results
- Expedites treatment decisions

The Impact

- Support antimicrobial stewardship with accurate diagnosis of GAS and reduce the amount of patients inappropriately prescribed antibiotics.
- Gain testing efficiencies and reduce costs by eliminating culture confirmation testing.[^3]
- Reduce the risk of GAS complications such as rheumatic fever and glomerulonephritis.
- Potential to improve patient satisfaction with quick time to result and appropriate prescriptions.

1 Sims Sanyahumbi A, Colquhoun S, Wyber R, et al. Global Disease Burden of Group A Streptococcus. 2016 Feb 10. In: Ferretti JJ, Stevens DL, Fischetti VA, editors. Streptococcus pyogenes : Basic Biology to Clinical Manifestations [Internet]. Oklahoma City (OK): University of Oklahoma Health Sciences Center; 2016-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK333415/

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.

* For positive samples only; otherwise, the test runtime is approximately 24 minutes.

^ 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).

Xpert® Xpress Strep A

Product Reference Sheet — IVD

Point of Care (POC)

Test Reagent Kit	Xpert **Xpress** Strep A
Catalog Number	XPRSTREPA-10
Technology	Real-time RT-PCR
Targets	*Streptococcus pyogenes* DNA
Batch or On-Demand	On-demand
Minimum Batch Size	1
Sample Type	**Specimen:** Throat swab **Collection Device:** E-swab in liquid Amies 480CFA*
Sample Extraction	Automated/integrated
Precision Pipetting	Not required
TAT	As early as 18 mins for positives^ and about 24 minutes for negatives
Controls: Process	Sample Processing Control
Controls: Probe Function/Detection	Probe Check Control

Performance	**Moderate**	**Point-of-Care**
Sensitivity	100%	99.4%
Specificity	94.1%	94.1%
Positive Predictive Value	84.1%	85.3%
Negative Predictive Value	100%	99.8%

Sample Stability	15–30 °C for up to 48 hours or 2–8 °C for up to 6 days
Kit Storage	2–28 °C
Commercial Controls	Refer to Package Insert or Contact Cepheid Technical Support

COLLECTION KITS

Copan ESwab in liquid Amies	480CFA

* Refer to IFU Xpert **Xpress** Strep A.

^ With Early Assay Termination (EAT) for positive results. Refer to the most current instructions for use Xpert **Xpress** Strep A.

IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries.

CORPORATE HEADQUARTERS
904 Caribbean Drive
Sunnyvale, CA 94089 USA
TOLL FREE **+1.888.336.2743**
PHONE **+1.408.541.4191**
FAX **+1.408.541.4192**

EUROPEAN HEADQUARTERS
Vira Solelh
81470 Maurens-Scopont France
PHONE **+33.563.82.53.00**
FAX **+33.563.82.53.01**
EMAIL **cepheid@cepheideurope.fr**

www.**Cepheid**.com

© 2024–2025 Cepheid. 10111-03

danaher