

ARIES®

ARIES® Systems

ARIES® Group A Strep Assay



The ARIES® Group A Strep Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection of *Streptococcus pyogenes* (Group A β -hemolytic *Streptococcus*) in throat swab specimens from patients with signs and symptoms of pharyngitis.

The ARIES® Group A Strep Assay offers an easy to use, automated system that delivers higher sensitivity and specificity than existing rapid tests, and a faster turnaround than culture methods.

- **Specific:** Identify patients with *Streptococcus pyogenes* infection to aid in the diagnosis of pharyngitis
- **Flexible and Efficient:** Run from 1 to 12 tests per batch, supporting both STAT testing and low to medium volume sample batching
- **Fully Integrated:** Automate all aspects of testing, from sample preparation through analysis
- **Fast Time to Results:** Answers in less than 2 hours enable timely treatment decisions
- **Error-reducing Safeguards:** Internal barcode scanning matches samples to cassettes and may reduce data input errors

Performance

ARIES® Group A Strep Assay Performance Compared to Bacterial Culture followed by Identification with MALDI-TOF MS

Refer to Package Insert for additional details: Luminex Corporation | ARIES® Group A Strep Assay (IVD) Kit Package Insert.

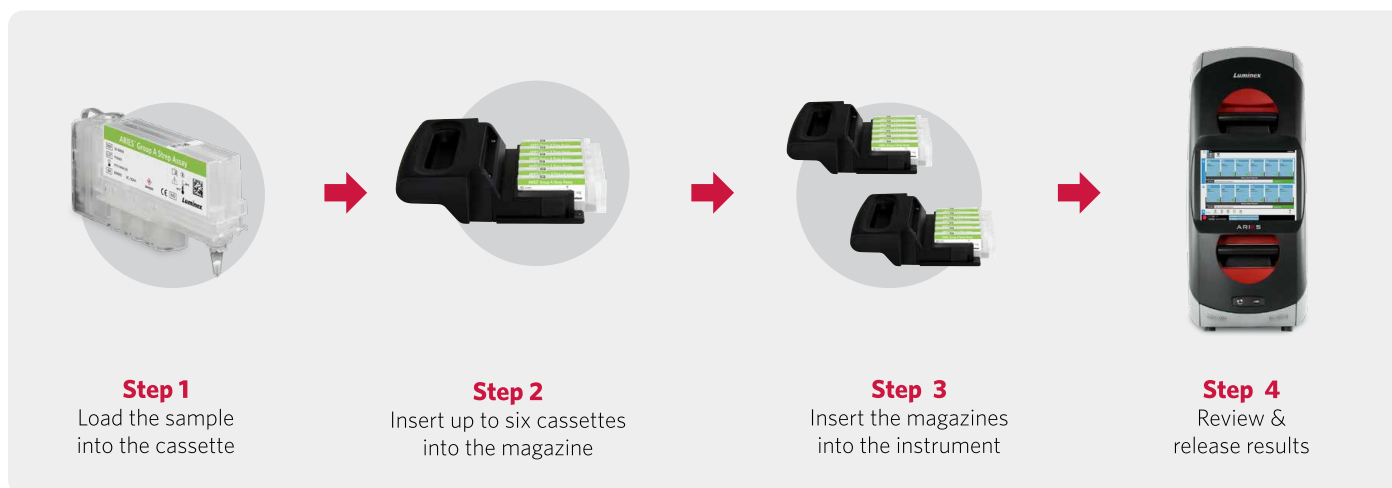
ARIES® Group A Strep Assay	Bacterial Culture		
	Positive	Negative	Total
Positive	156	10 ²	166
Negative	4 ¹	448	452
Total	160	458	618 ³
95% CI			
Sensitivity	97.5%	93.7% - 99.0%	
Specificity	97.8%	96.0% - 98.8%	
PPV	94.0%	89.3% - 96.7%	
NPV	99.1%	97.7% - 99.7%	

¹ Two (2) of the ARIES® Group A Strep Assay negative specimens that were positive by bacterial culture followed by identification with MALDI-TOF MS (i.e., False Negative) were Group A Strep negative by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from the ARIES® Group A Strep Assay.

² Seven (7) of the ARIES® Group A Strep Assay positive specimens that were negative by bacterial culture followed by identification with MALDI-TOF MS (i.e., False Positive) were positive by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from the ARIES® Group A Strep Assay.

³ Five (5) specimens generated inconclusive results by comparator culture method (MALDI-TOF MS log(score) <2.00). All five specimens were excluded from the device performance calculations.

Workflow



The operator simply adds specimen to the sample chamber, puts the cassette in the magazine, loads the magazine into the ARIES® System, and the run will start automatically.

Usage and Targets

The ARIES® Group A Strep Assay can be used as an aid in the diagnosis of Group A Streptococcal pharyngitis. The assay is not intended to monitor treatment for Group A *Streptococcus* infections.

The ARIES® Group A Strep Assay is indicated for use with ARIES® Systems.

Ordering Information*

Product Name		Part Number
ARIES® Group A Strep Assay		50-10041 (24 tests)
ARIES® Group A Strep Assay Protocol File Kit		CN-0385-01 (one time order only)
ARIES® Two Module System Includes: Instrument System Operation Manual Two Magazines		ARIES-M12V1-IVD Quick Guide Two Sample Prep Trays Power Cord Handheld Barcode Scanner and Stand
ARIES® M1 System Includes: Instrument System Operation Manual One Magazine		ARIES-M6V1-IVD Quick Guide Two Sample Prep Trays Power Cord Handheld Barcode Scanner and Stand
SYNCT™ Software		CN-SW47

* Products are CE Marked and FDA Cleared for IVD Use.

Luminex®
complexity simplified.

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For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions. Please contact Luminex at support@luminexcorp.com to obtain the appropriate product information for your country of residence. ARIES® Systems are class 1(I) laser products. Validation of the LIS compatibility must be performed by the end user.

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