Luminex

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.

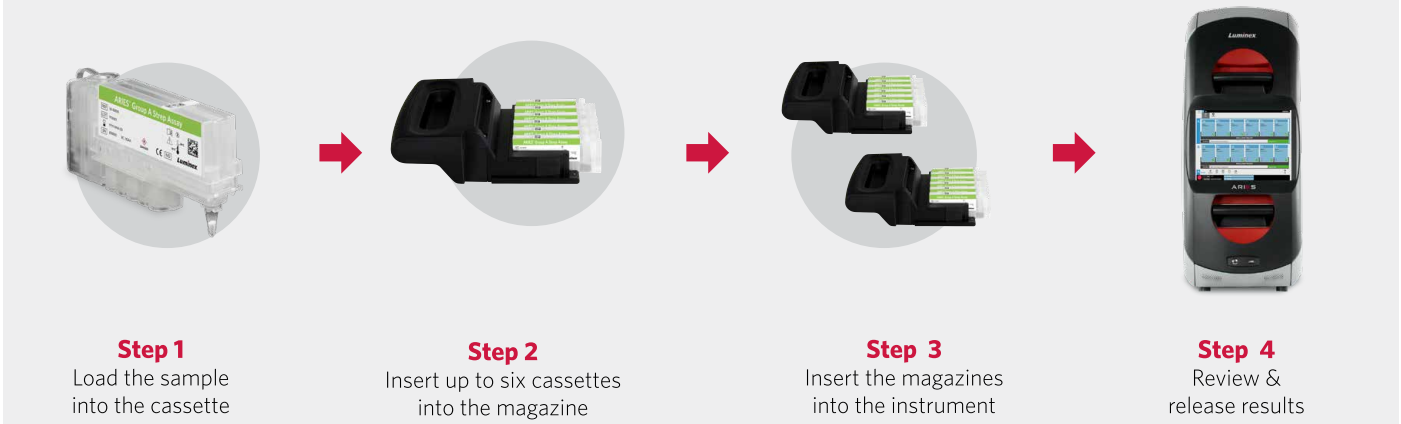
ARIES® Group A Strep Assay	Bacterial Culture		
	Positive	Negative	Total
Positive	156	10[2]	166
Negative	4[1]	448	452
Total	160	458	618[3]
		95% CI	
Sensitivity	97.5%	93.7% - 99.0%	
Specificity	97.8%	96.0% - 98.8%	
PPV	94.0%	89.3% - 96.7%	
NPV	99.1%	97.7% - 99.7%	

[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



Step 1
Load the sample into the cassette

Step 2
Insert up to six cassettes into the magazine

Step 3
Insert the magazines into the instrument

Step 4
Review & release results

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 Quick Guide Two Sample Prep Trays Power Cord Handheld Barcode Scanner and Stand	ARIES-M12V1-IVD
ARIES® M1 System Includes: Instrument System Operation Manual One Magazine Quick Guide Two Sample Prep Trays Power Cord Handheld Barcode Scanner and Stand	ARIES-M6V1-IVD
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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