

ARIES[®]

ARIES[®] Systems | Welcome to the New Way to Work

ARIES[®] GBS Assay



ARIES[®] GBS Assay Offers:

- **High Sensitivity:** Aid in the diagnosis of more patients, using PCR to improve patient outcomes.
- **High Accuracy:** Confidence in results gives patients and clinicians peace of mind, and helps ensure correct treatment. Integrated sample processing control ensures the assay run is successful from extraction through amplification.
- **Ease of Use:** A simple to use, sample to answer assay for antepartum detection of GBS colonization, that is accessible to all sizes of laboratories.
- **Fully Integrated:** Automate all aspects of testing, from sample preparation through analysis.
- **Reduce User Error:** Internal barcode scanning matches samples to cassettes, enabling Position Independent Results no matter where each cassette is placed. Additionally, reduce data input errors with electronic ordering through bidirectional laboratory information system (LIS) connectivity.

Performance

The performance of the ARIES[®] GBS Assay was assessed at three (3) geographically diverse clinical sites in the United States.

Refer to Package Insert for additional details: Luminex Corporation | ARIES[®] GBS Assay (IVD) Kit Package Insert.

Summary of ARIES[®] GBS Assay Performance Compared with Reference Culture

ARIES [®] GBS Assay	Reference Method		Total
	Positive	Negative	
Positive	124	48*	172
Negative	5†	510	515
Total	129	558	687‡
			95% Confidence Interval
Sensitivity	96.1%	91.3% – 98.3%	
Specificity	91.4%	88.8% – 93.5%	

* Forty-five (45) ARIES[®] GBS positive specimens that were negative by the reference method were positive by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from the ARIES[®] GBS Assay.

† Two (2) ARIES[®] GBS negative specimens that were positive by the reference method were negative by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from the ARIES[®] GBS Assay.

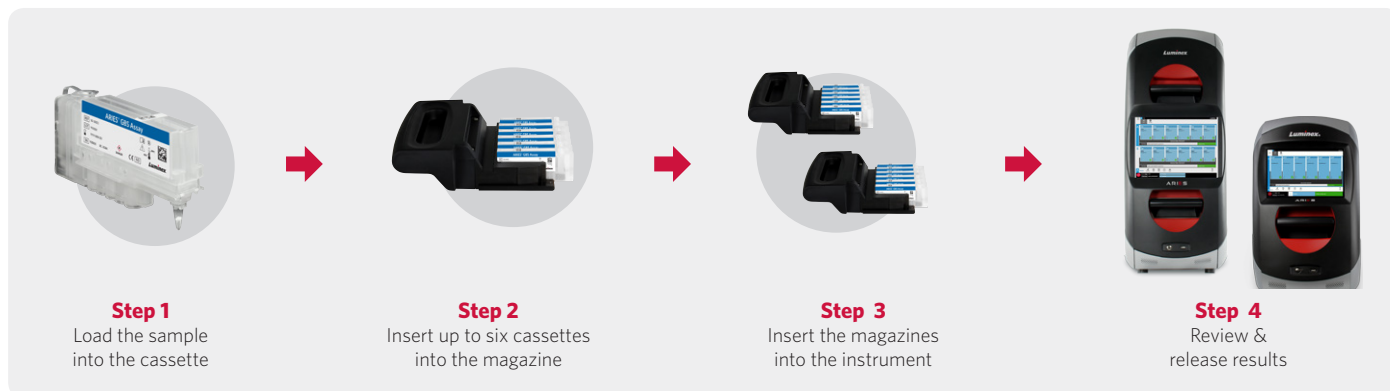
‡ One (1) specimen (01027) generated an invalid result by the ARIES[®] GBS Assay after allowable re-run. This specimen was negative by the reference method and was excluded from the device performance calculations.

Intended Use

The ARIES® GBS Assay, performed on ARIES® Systems, is a real-time polymerase chain reaction (RT-PCR) based qualitative *in vitro* diagnostic test. The ARIES® GBS Assay is designed to detect Group B *Streptococcus* (GBS) nucleic acid from 18-24 hour Lim broth enrichments of vaginal-rectal swab specimens obtained from pregnant women. The ARIES® GBS Assay is intended for use as a method for detection of GBS colonization in antepartum women. It is not intended to diagnose or monitor treatment of a GBS infection.

The ARIES® GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

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.

Ordering Information*

Product Name	Part Number
ARIES® GBS Assay	50-10021 (24 tests)
ARIES® GBS Assay Protocol File	CN-0336-01 (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, FDA Cleared for IVD use, and Health Canada Licensed.

Luminex®
complexity simplified.

orders@luminexcorp.com or support@luminexcorp.com

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. Validation of the LIS compatibility must be performed by the end user. ARIES® Systems are class 1(I) laser products.

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