Luminex

Package Insert | IVD

ARIES® GBS Assay

IVD For *In Vitro* Diagnostic Use.

For Use With the ARIES® Systems.

Rx Only

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ARIES® GBS Assay Package Insert

89-30000-00-486 Rev. C
Assay Kit Part Number: 50-10021
February 2017

CE

EC REP

WMDE
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The Netherlands

Luminex Corporation (Luminex) reserves the right to modify its products and services at any time. Notifications will be sent to end users regarding changes that impact the use, performance and /or safety and effectiveness of the device. Any modifications to the device will be made in accordance with applicable regulatory requirements. Luminex assumes no liability for any damages resulting from the off-label application or misuse of this information.

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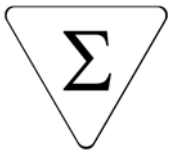
Key to Symbols

5.1.4* 	Use-by date Indicates the date after which the medical device is not to be used.	5.3.7* 	Temperature Limit Indicates the temperature limits to which the medical device can be safely exposed.
5.1.5* 	Batch Code Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.4.2* 	Do not reuse Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.1.6* 	Catalog(ue) Number Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.4.4* 	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
5.1.1* 	Manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.5.5* 	Contains Sufficient for <n> Tests Indicates the total number of IVD tests that can be performed with the IVD kit reagents.
5.4.3* 	Consult instructions for use. Indicates the need for the user to consult the instructions for use.	5.4.1* 	Biological Hazard
BC	Build Code	GHS02† 	Highly flammable liquid and vapor
5.2.8* 	Do not use if package is damaged. Indicates a medical device that should not be used if the package has been damaged or opened.	5.5.1* 	*In vitro* diagnostic medical device Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.

5.1.2* EC REP	Authorized representative in the European Community Indicates the Authorized representative in the European Community.	‡ CE	Conformite Europeenne (EU CE Marking of Conformity) Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)
§ Rx Only	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. Only). 21 CFR 809 (FDA Code of Federal Regulations)	0434B ‖ 	Caution To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

* ANSI/AAMI/ISO 15223-1:2012, Medical devices—Symbols to be used with medical devices labels, labeling, and information to be supplied—Part 1: General requirements.

† ST/SG/AC.10/30/Rev.6 Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Sixth revised edition.

‡ Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)

§ 21 CFR 809 (FDA Code of Federal Regulations)

|| ISO 7000: Fifth edition 2014-01-15, graphical symbols for use on equipment - registered symbols. (General I (QS/RM))

Standard Terms and Conditions For Use of Assay Product

By opening the packaging containing this assay product or cassette ("Product") or by using such Product in any manner, you are consenting and agreeing to be bound by the following terms and conditions. You are also agreeing that the following terms and conditions constitute a legally valid and binding contract that is enforceable against you. If you do not agree to all of the terms and conditions set forth below, you must promptly return the Product for a full refund prior to using them in any manner.

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strict compliance with the United States Food and Drug Administration and all applicable domestic and international laws and regulations, now and hereinafter enacted.

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89-30000-00-187 Rev C

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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.

Summary and Explanation of the Test

The ARIES® GBS Assay uses Luminex Corporation's real-time PCR chemistry in combination with the ARIES® Systems. The ARIES® Systems are capable of automated nucleic acid extraction and purification, real-time PCR detection of nucleic acid sequences, and data analysis. The ARIES® GBS Assay detects *Streptococcus agalactiae,* also known as Group B *Streptococcus* or GBS.

Infection with Group B *Streptococcus* (GBS) is the leading infectious cause of neonatal morbidity and mortality, causing meningitis, pneumonia, and septicemia in newborns and their mothers. Women vaginally or rectally colonized with GBS during pregnancy are at increased risk of transmitting the bacteria to their newborn infant during child birth. Vaginal GBS colonization has been reported to occur in about 12% to 27% of women worldwide (WHO 2006).

In current CDC guidelines, the use of a combination of screening at 35 to 37 weeks of gestation and intrapartum antibiotic prophylaxis have yielded significant reductions in the rate of GBS disease among newborns, but the rates of maternal GBS colonization have remained constant for over four decades (Verani, et al., 2010). Although laboratory testing with culture media, which typically requires up to three days with long incubation and sub-culture remains the gold standard, polymerase chain reaction (PCR) based nucleic acid amplification tests (NAAT) are being established to enable fast turn-around time and improved accuracy for the detection of GBS (Goodrich and Miller 2007 and Davies, et al., 2004).

Principles of the Procedure

Lim broth (Todd Hewitt broth with colistin and nalidixic acid (CNA)) enriched specimen is added to the sample chamber of an ARIES® GBS Assay cassette. The cassette is then placed into an ARIES® magazine which can hold up to six cassettes. The magazine is inserted into an ARIES® instrument. A barcode on top of the ARIES® GBS Assay cassette is automatically scanned by the ARIES® instrument, associating a preloaded ARIES® GBS Assay protocol file with the cassette. The ARIES® GBS Assay protocol file contains the necessary parameters to run the cassette, analyze data, and generate reports.

Once a run is started, the sample processing control (SPC) is automatically added to the sample chamber of the cassette to control for sample lysis, recovery of extracted nucleic acid, detection of inhibitory substances, and confirmation of PCR reagent integrity. Sample and SPC lysis, as well as isolation and purification of nucleic acids, are automated within the ARIES® Systems and the ARIES® GBS Assay cassette. Purified nucleic acids are automatically transferred to the cassette's PCR tube that contains the lyophilized GBS Master Mix for the PCR amplification step. The GBS Master Mix contains a primer pair specific to GBS, and a second primer pair specific to the SPC sequence. Total assay time, including extraction and PCR cycling, takes approximately two hours.

Materials Provided

The ARIES® GBS Assay (Part Number 50-10021) includes 24 assay cassettes.

The assay protocol file, package insert, and *ARIES® Quick Guid*e ship separately on a USB as part of the ARIES® GBS Assay Protocol File (CN-0336-01).

TABLE 1. **ARIES® GBS Assay Contents Provided By Luminex®**

Item	Part Number	Description
ARIES® GBS Assay	50-10021	24 ARIES® GBS Assay cassettes which contain necessary reagents for sample extraction, nucleic acid purification, and amplification.
ARIES® GBS Assay Protocol File	CN-0336-01	An assay protocol file, a package insert, and an *ARIES® Quick Guide* containing instructions for use are provided on a USB.

Materials Required But Not Provided

Reagents for primary specimen collection:

- Specimens in liquid Stuart's or Amies media

Reagents for specimen enrichment:

- Lim broth (Todd Hewitt broth with colistin and nalidixic acid (CNA))

Equipment:

- -65°C to -95°C freezer
- 2°C to 8°C refrigerator
- Luminex® ARIES® Systems (either an ARIES® System or an ARIES® M1 System can be used) and accessories
  - ARIES® magazines
  - ARIES® Sample Prep Tray
  - Hand-held barcode reader
  - Optional printer
- Vortex mixer
- Appropriately sized pipettor

Plasticware and Consumables:

- Nuclease-free aerosol-barrier pipette tips

Warnings and Precautions

1. For *In Vitro* Diagnostic Use.
2. For prescription use only.
3. Handle all samples as if infectious using safe laboratory procedures such as those outlined in CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, and in the CLSI Document M29 *Protection of Laboratory Workers from Occupationally Acquired Infections*.
4. Thoroughly clean and disinfect all surfaces with 10% bleach.
5. Avoid contamination from positive controls and samples by following good laboratory practices.
6. Avoid contamination by using a new nuclease-free aerosol barrier tip to add an individual primary sample aliquot to each cassette.
7. Wear appropriate personal protective equipment (PPE), including a lab coat and disposable gloves, when performing procedures. Wash your hands thoroughly after performing the test.

8. Follow your institution's safety procedures for working with chemicals and handling biological samples.
9. Do not use cassettes, kits, or reagents beyond their expiration date.
10. The cassettes are single-use. Do not reuse cassettes.
11. Store cassettes at the temperatures recommended on the cassette label. Do not freeze.
12. Only use the extraction protocol file provided by Luminex on the USB drive.
13. Only use the procedures described in this package insert. Any deviation from the outlined procedures can result in extraction failure or cause erroneous results.
14. Only use ARIES® Systems that have been properly maintained according to the manufacturer's recommendations.
15. ARIES® cassettes contain guanidinium thiocyanate. Refer to the Safety Data Sheet (SDS) regarding safe handling practices for any spills.
16. In the event that a PCR tube falls off the cassette or a cassette leaks inside the ARIES® instrument, you should perform appropriate decontamination procedures to reduce the risk of contamination. Immediately clean all surfaces of the ARIES® magazine and the surrounding bench top with water. Wipe the surfaces with a lint-free cloth. Follow that with a fresh 10% bleach solution. Allow the bleach solution to sit for a minimum of 10 minutes. Thoroughly rinse bleached surfaces with deionized water. Dispose of all lint-free cloths in the appropriate waste container. Immediately contact Luminex Technical Support in order to retrieve the PCR tube from the ARIES® instrument. Do not throw away the cassette before you contact Technical Support. Do not attempt to retrieve the tube or put your hands inside the ARIES® instrument at any time. Do not proceed with additional testing until the PCR tube has been removed from the ARIES® instrument. Discard the cassette in accordance with the procedures defined by appropriate biohazard safety guidelines or regulations.
17. Refer to the appropriate ARIES® system operation manual for electrical and mechanical warnings.
18. Do not let the ARIES® Systems get wet or allow standing water to pool under the instruments.
19. Safety Data Sheets (SDS) are available by contacting Luminex Corporation or visiting our website at *www.luminexcorp.com*.

Reagent Storage, Handling, and Stability

ARIES® GBS Assay cassettes are shipped refrigerated. Store at room temperature (15°C to 30°C) after receipt.

Always check the expiration date on the kit box and cassettes.

Specimen Handling and Storage

Specimen Collection

Vaginal-rectal swab specimens should be obtained by appropriately trained individuals.

Specimen Transport

When transporting biological specimens, ensure that all applicable regulations for the transport of etiologic agents are met.

Transport specimens at an ambient temperature or refrigerated at 2°C to 8°C. On receipt into the lab, keep refrigerated at 2°C to 8°C.

Specimen Storage

Enriched Specimens

Specimens must be put into Lim broth for enrichment within 24 hours of receipt into the laboratory. Specimens must be enriched in *Streptococcus agalactiae* (GBS) selective media (Todd Hewitt broth supplemented with colistin (10 µg/ml)) and nalidixic acid (15 µg/ml) (Lim broth) at 37°C under aerobic

conditions for 18 to 24 hours. Enriched specimens can be stored at 18°C to 25°C for up to 24 hours or at 2°C to 8°C for up to 7 days. The enriched specimens or any left-over enriched specimen can be stored at -70°C or colder for up to three months.

Assay Procedure

Adding Assay Files to the ARIES® Systems

The ARIES® GBS Assay protocol file is provided on the USB flash drive. The assay protocol file only needs to be imported to the ARIES® Systems once. To import the assay protocol file, complete the following:

1. Insert the USB flash drive into one of the five USB connectors (one in the front and four in the back).
2. Select  in the upper left-hand corner of the screen and navigate to **Assay Management**.
3. Select 

from the Page Action bar. The **Import File** dialog box displays.
4. Choose the **Location** and **File Name** of the assay file. Select **OK**.

Entering Orders

Sample barcodes are scanned to associate them with an order. An assay cassette is also then scanned to specify the assay and associate the cassette with a specific sample. Refer to "*Running an Assay*" on page 9 for more information.

The Sample ID is required on all orders and is the link between sample and cassette. The Accession ID and Requisition Number can also perform this role and associate the cassette to the sample, but they are optional unless otherwise chosen to be required. You can set requirement and visibility options in the Sample Options dialog box located on the Order Management > Settings page.

Enabling the Automatic Print and Export Results Options

The Auto Print and Auto Export options are settings that need to be enabled prior to starting the run on the ARIES® instrument. Results can also be printed and exported manually after a run. Refer to "*Manually Printing Reports*" on page 10 for more information.

To enable the Auto Print feature, complete the following:

1. Select  in the upper left-hand corner of the screen and navigate to **Results > Settings**.
2. Toggle the **Generate Reports After Run** button to **Yes.**
3. For the **Sample Reports to Printer** option, select **Default** or **All**.

To export results automatically after a run, complete the following:

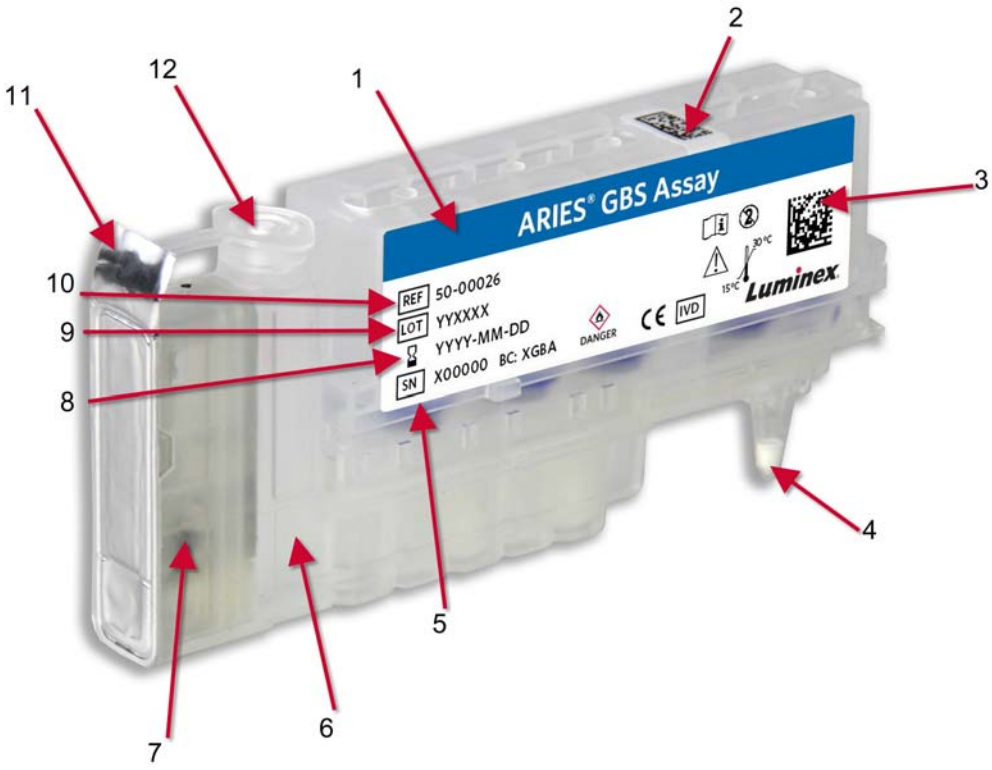
1. Select  in the upper left-hand corner of the screen and navigate to **Results > Settings**.
2. Toggle the **Summary Report as CSV** button to **Yes.**
3. Enter the **CSV Output Location** by selecting the folder icon in the upper right-hand corner of the **CSV Output location** box. The **Select Folder** dialog box opens.
   a. Choose the **Location** for the export.
   b. Select **OK**.

To automatically export LIS results as either HL7 or CSV, complete the following:

1. Select ☰ in the upper left-hand corner of the screen and navigate to **Administration > LIS Settings.**
2. Toggle the **Enable Export to LIS** button to **Yes**.
3. Toggle the **Auto Export to LIS** button to **Yes.**
4. Enter the **LIS Export Location** by selecting the folder icon in the upper right-hand corner of the **LIS Export Location** box. The **Select Folder** dialog box opens.
   a. Choose the **Location** for the export.
   b. Select **OK**.

CAUTION: Validation of LIS compatibility must be performed by the user.

FIGURE 1. **ARIES® Cassette**



1. Assay type	7. Side cassette
2. Cassette barcode (top)	8. Cassette expiration date
3. Cassette barcode (side)	9. Cassette lot number
4. PCR tube	10. Cassette part number
5. Cassette serial number	11. Back seal
6. Sample chamber	12. Cassette cap

Entering Orders on the ARIES® Systems

When entering orders, the Sample ID and Assay are required for an order to be valid.

NOTE: The order should be created prior to placing the cassette in the magazine. If you scan the cassette while the cassette is in the magazine, it is possible to scan the incorrect cassette barcode.

1. Select  in the upper left-hand corner of the screen and navigate to **Order Management > Sample Orders**.
2. Select  from the Page Action bar. The **New Order** dialog box displays.
3. Remove the assay cassette from its packaging and visually inspect the cassette for any damage.

   CAUTION: If the cassette(s) appears damaged in any way or if you see any leaks, DO NOT USE THE CASSETTE. Immediately contact Luminex Technical Support to report the damage.
4. Close the cassette cap to seal the cassette sample chamber.
5. Pick up and scan the barcode on the top (or side) of the cassette with the hand-held barcode reader or enter the required cassette information manually. A touch screen keyboard or a drop-down menu displays.

   NOTE: If the keyboard does not automatically appear, toggle the keyboard icon to **Yes**. The keyboard will appear when you click in a field.

   NOTE: If manually entering the **Cassette Lot Expiration**, select the calendar icon and choose the date using the calendar. The date is shown in the YYMMDD format.

   a. If applicable, to add a control, choose **Control** in the **Sample Type** drop-down menu.
   b. In the **Control** field, click the magnifying glass to select a control from the **Controls** dialog box.
   c. Select the type of control in the **Control Type** drop-down menu.

   NOTE: You can define the controls on the **Assay Management > Controls** page. Refer to the appropriate ARIES® system operation manual for more information on controls.
6. Pick up and scan the Sample ID on the sample tube or enter the required information manually.
7. Scan the **Data Matrix** barcode on the screen next to **Save**, or manually select **Save**.

Adding Samples to the Cassettes

1. Place the enriched specimen tube in the Sample Prep Tray.

   NOTE: If the tube does not fit in the tray, it can be placed in a separate tube rack or held by hand.

2. Pull the tab to remove the foil seal from the cassette.

   CAUTION: Use caution when pulling the back seal off the cassettes. The foil is sharp and may cause injury.

3. Place the cassette in the Sample Prep Tray next to the sample.

4. Vortex the Lim broth enriched specimen for 5 to 10 seconds to homogenize the mixture.
5. Open the cassette cap to access the cassette sample chamber.
6. Using an appropriately sized pipettor and aerosol barrier pipette tip, aspirate 200 µL of the enriched specimen from the sample tube.

   CAUTION: Ensure that the correct amounts of sample are used.

   CAUTION: Use care to avoid contamination of the pipettor during transfer of the sample from the sample tube to the cassette.

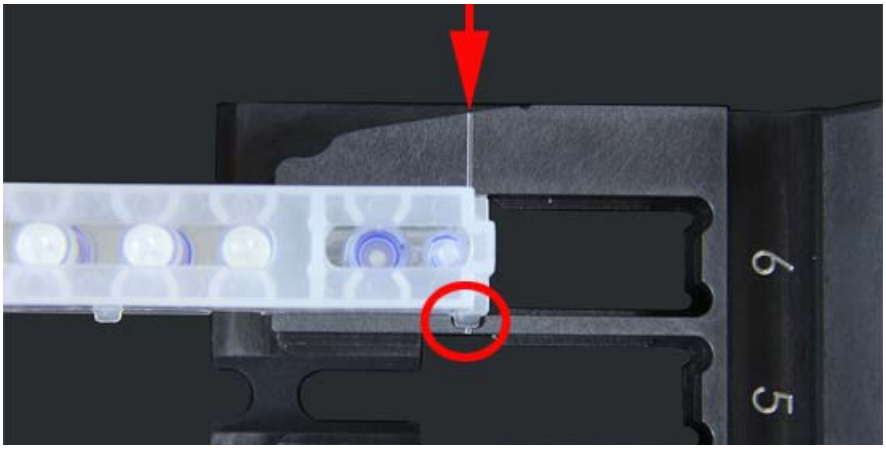
7. Place the sample in the cassette sample chamber by inserting the pipette tip near the bottom of the chamber before expelling the sample.

8. Close the cassette cap to seal the cassette sample chamber.

   CAUTION: Do not vortex or shake the cassette.

   WARNING: Failure to ensure that the cassette cap is fully closed may cause a delay or failure in results and expose you to biohazards.

9. Place the cassette into the magazine by lining the cassette up with the first notch (a tab on the cassette fits into the notch).



NOTE: The PCR tube must face toward the numbers on the magazine.

10. Gently insert the cassette into the magazine.
11. Gently slide the cassette all the way back toward the numbers. Repate for all other cassettes.

WARNING: Do not use your index finger to push the cassette into the magazine. You may indirectly dispense the reagent. Luminex recommends using the palm of your hand, or holding the cassette and sliding the cassette into proper position.

Running an Assay

1. Select  in the upper left-hand corner of the screen and navigate to **Run > Run**.
2. Insert the magazine into the ARIES® instrument. The ARIES® instrument automatically scans the barcode printed on the top of the ARIES® GBS Assay cassettes, identifies associated orders and the proper assay protocol files before starting the run.

   NOTE: Ensure that the **Auto run upon Magazine Insertion** is toggled to **Yes** in the **Run Options** dialog box, located on the **Run Settings** page. The instrument automatically scans the cassettes once the magazine is inserted and starts the run.

3. If there are any errors, the ARIES® instrument displays the specific error (for example, cassettes that cannot be run together, cassette IDs that have not been read, or assay files not loaded on to the ARIES® instrument). These errors must be corrected in order for the run to begin.
   a. If there are no errors, and the auto run option is selected, the color indicator of the cassette turns purple, the magazine state indicator indicates PLEASE DO NOT REMOVE THE MAGAZINE and an orange lock icon displays on the left-hand side of the magazine state indicator. The Run Status bar, located at the bottom of the Run page, displays an orange progress bar next to the estimated time to completion, colored purple. If you do not have the Auto Run feature enabled, you can start the run manually by selecting 

from the Page Action bar.

   NOTE: If you are using an ARIES® System with two modules, highlight the module you want before selecting **Start Run**.

Monitoring the Run

From the Run page, select 

on the Page Action bar to display the status of the magazine(s), the estimated time to completion, and the customizable name of the ARIES® instrument. This status screen is intended to be visible from across the room, allowing you to monitor your runs while you are working on other projects.

TIP: On the Run > Settings page, you can customize whether the estimated completion time or estimated time remaining displays.

Reviewing, Printing, and Exporting Run Results

When the ARIES® GBS Assay run finishes successfully, the cassettes are colored green on the Run page. See *Table 2,* on page 10 for other color indicators. Refer to the appropriate ARIES® system operation manual for more color definitions.

TABLE 2. **Color Indicators**

Color	Reason
Red	Cassettes contain errors, were not scanned successfully, require additional information, or the run failed or was aborted. Contact Luminex Technical Support for assistance.
Yellow	Information was manually entered on the Run page or the cassette is expired.
Green	Run finished successfully, the cassettes were scanned with no errors.
Blue	Magazine is inserted and a cassette is detected for this slot.
Purple	Module is currently running: the magazine slot is in use.
White	Empty module, no magazine is inserted or no cassette is detected.

The **Run** page includes visual indicators such as a status bar, an estimated time to completion indicator, and a **Run Complete** notification once the run has completed.

Automatically Printing and Exporting Results

NOTE: To ensure that the LIS Reporting (Auto Print) feature is enabled, check that **Sample Reports to Printer** is set to **All** or **Default** in the **Export Settings** dialog box located on the **Results > Settings** page.

When the run finishes successfully, the result reports are automatically printed at the default printer and exported in .CSV and .PDF format to the designated location. Refer to "*Enabling the Automatic Print and Export Results Options*" on page 4.

Manually Printing Reports

To manually select a report to print, complete the following:

1. Select  in the upper left-hand corner of the screen and navigate to **Results**. Regardless of the type of report you want to view, select only one result. Otherwise, the **Create Report** icon grays out.
2. Select **Create Report** from the Page Action bar. Choose the type of report you want to view from the drop-down menu. There are three options: **Run Report**, **Detailed Report**, and **Summary Report**.

   NOTE: Selecting a single result gives you the option to generate a **Run Report**, **Summary Report**, or a **Detailed Report**. You cannot select more than one result and run a **Summary Report** or a **Detailed Report** -- the **Create Report** icon grays out. When generating a **Run Report**, you can select multiple results from the same run and still use the **Create Report** icon. With **Run Report**, the **Create Report** icon is disabled only when results from multiple runs are selected. Once the report opens, choose to export 

or print the result 

.

   - The Run Report displays the run results for all samples in the run and any comments or logs associated with that run.
   - The Summary Report displays the run result for one individual sample and any comments or logs associated with that sample.
   - The Detailed Report displays all cassette information for one individual sample, the Amplification and Melt Graphs, and any comments or logs associated with that sample. Access to run this report is restricted to users with administrative rights.

Manually Exporting Results

To manually export results, complete the following:

1. Select the result(s) to export on the **Results** page and select 

from the Page Action bar.
2. Choose the **Location** and the **File Name** for the export in the **Export File** dialog box and select **OK**.

NOTE: You can only export to a USB drive or a mapped network drive.

Interpretation of Sample Results

The ARIES® software determines results for the sample and the sample processing control (SPC) for each sample based on the amplification cycle (Ct) value and the melting temperature (T_m) value provided in the assay protocol file. All assay outcomes are listed in *Table 3,* on page 11.

TABLE 3. **Interpretation of Sample Results**

Example	SPC		GBS		Call
	Ct Value	T_m Value	Ct Value	T_m value	
1	N/A	+	+	+	GBS Positive
2	+	+	>	+	GBS Negative
3	>	+	>	+	Invalid
4	-	+	>	+	Invalid
5	N/A	+	-	+	Invalid
6	+	+	N/A	-	GBS Negative
7	>	+	N/A	-	Invalid
8	-	+	N/A	-	Invalid
9	N/A	-	N/A	N/A	Invalid

Legend			
+	Indicates that a valid Ct value is present.	-	Indicates that a valid Ct value is not present.
>	Indicates that the Ct value obtained is above the Ct cutoff.	N/A	Not applicable. All possible outcomes will result in the same call.

Invalid Results

In case of an “Invalid” result, re-test the sample with a new assay cassette. If the problem is unresolved, contact Luminex Technical Support.

Quality Control

Quality control procedures intended to monitor the ARIES® Systems and assay performance are outlined in *Table 4,* on page 12.

TABLE 4. **Controls to Monitor Quality**

Control Type	Use
Sample Processing Control	Verifies proper sample lysis and nucleic acid extraction, and proper reagent, cassette, ARIES® instrument, and assay protocol performance.

Each ARIES® GBS Assay cassette contains a Sample Processing Control, which is processed with the sample and analyzed during the amplification reaction.

External controls may be used in accordance with local, state, federal accrediting organizations, as applicable. A reference GBS strain or well characterized GBS clinical isolates may be used as positive controls. Uninoculated Lim broth may be used as a negative control.

Limitations

1. The detection of bacterial nucleic acids depends on proper sample collection, handling, transportation, storage, and preparation (including extraction). Failure to observe proper procedures in any one of these steps listed in this package insert can lead to an incorrect result.
2. This assay has been validated with Lim broth medium only. Performance of the assay has not been validated with other GBS selective broth enrichment media.
3. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women. Use remaining enriched Lim broth to obtain culture isolates. Laboratories must validate their own culturing procedures.
4. Patients who have used systemic or topical (vaginal) antibiotic treatment in the week prior as well as patients diagnosed with placenta previa should not be tested with this assay.
5. There is a risk of false negative results due to improperly collected, transported, or handled swab samples.
6. There is a risk of false negative results due to the presence of sequence variants in the targets of the assay, procedural errors, amplification inhibitors in samples, or inadequate numbers of organism(s) for amplification.
7. There is a risk of false positive results due to potential cross-contamination by target organism(s), their nucleic acid or amplified product, or from non-specific signals in the assay.
8. A positive result does not necessarily indicate the presence of viable organisms.
9. Results from the ARIES® GBS Assay should be used as an adjunct to clinical observations and other information available to the physician.
10. The test is not intended to differentiate carriers of Group B *Streptococcus* from those with streptococcal disease. Test results may be affected by concurrent antimicrobial therapy as GBS DNA may continue to be detected.
11. For use only on the ARIES® System or ARIES® M1 System.

Disposal

Dispose of hazardous or biologically contaminated materials according to the practices of your institution.

Performance Characteristics

Clinical Performance

The performance of the ARIES® GBS Assay was evaluated prospectively from May 2016 to August 2016, at three geographically distinct clinical sites within the United States, using an ARIES® System. Specimens for the clinical study consisted of excess leftover de-identified Lim broth cultures from pregnant women at 35 to 37 weeks of gestation, whose standard-of-care screening called for the collection of vaginal-rectal swab specimens for GBS testing, ordered by a physician. The vaginal-rectal swab specimens were enriched by being placed into Lim broth for 18 to 24 hours at 35°C to 37°C. After enrichment, an aliquot of the Lim broth was used for standard-of-care testing, and the leftover Lim broth was used for reference culture testing and for ARIES® GBS Assay testing. Reference culture testing was performed in accordance with published CDC guidelines, whereby enriched Lim broth aliquots were subcultured to 5% sheep blood agar plates and incubated for 18 to 24 hours at 35°C to 37°C with 5% CO_2. Plates with no GBS colonies at 24 hours, were incubated for an additional 24 hours before being called negative. Suspected GBS colonies (both hemolytic and non-hemolytic) were tested with catalase reagent and Gram stained. Catalase-negative, Gram-positive cocci were then confirmed to be Group B *Streptococcus* by latex agglutination. A total of 726 specimens were collected at the three sites. Thirty-eight (38) of the 726 specimens were excluded because they did not meet the pre-determined inclusion and exclusion criteria. A total of 688 specimens meeting the predetermined inclusion and exclusion criteria were prospectively tested for Group B *Streptococcus* by both the reference culture and the ARIES® GBS Assay. Fourteen (14) of the 726 specimens were invalid, and of the 14 invalids, 13 specimens resolved upon re-run, and 1 specimen remained invalid. For the 687 eligible specimens, the ARIES® GBS Assay sensitivity was 96.1% (124/129) with a lower bound 95% confidence interval of 91.2% and specificity was 91.4% (510/558) with a lower bound 95% confidence interval of 88.8%.

TABLE 5. **ARIES® GBS Assay Performance Compared with Reference Culture**

ARIES® GBS Assay	Reference Method		
	Positive	Negative	Total
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.

Expected Results

Approximately 10% to 30% of pregnant women are colonized with GBS in the vagina or rectum. Clinical performance of the ARIES® GBS Assay with Lim enrichment broth was established in specimens from antepartum women between 35 and 37 weeks gestation collected at three geographically-distinct clinical sites within the United States. During clinical evaluation of the assay, 18.8% (129/688) based on culture and 25.0% (172/688) of women were reported as positive for GBS by the ARIES® GBS Assay.

Analytical Performance

Limit of Detection

A Limit of Detection (LoD) study was performed at Luminex Corporation to evaluate the analytical sensitivity of the ARIES® GBS Assay using common GBS serotypes (Ia, Ib, II, III, V, and one non-hemolytic serotype). Preliminary LoD concentrations were determined using serial dilutions of each quantified GBS serotype in Lim broth. These preliminary LoD concentrations were confirmed by testing 20 replicates of each strain. All GBS serotype concentrations were verified by colony counting (CFU/mL). The LoD for each GBS serotype was determined as the lowest concentration that had a positivity rate of ≥95%. The final LoD concentrations for the common GBS serotypes are shown in *Table 6,* on page 14.

TABLE 6. **ARIES® GBS Assay Limit of Detection Results**

Serotype	GBS Strain	Concentration (CFU/mL)	Positivity	95% Confidence Interval
I a	ATCC® BAA -1138	5,900	95.0% (19/20)	75.1% - 99.9%
I b	CDC# 2008232729	1,650	100.0% (20/20)	83.2% - 100.0%
II	ATCC® BAA -1175	14,433	100.0% (20/20)	83.2% - 100.0%
III	ATCC® BAA -1176	6,733	100.0% (20/20)	83.2% - 100.0%
V	CDC# 2008232731	4,933	100.0% (20/20)	83.2% - 100.0%
Non Hemolytic	ATCC® BAA -13813	817	95.0% (19/20)	75.1% - 99.9%

Interfering Substances

The potential inhibitory effect of substances expected to be found in vaginal-rectal swab specimens was evaluated for the ARIES® GBS Assay by testing three replicates each of GBS serotype Ib and serotype III at concentrations near the assay LoD as well as negative Lim broth spiked with the potentially highest concentration of each substance. The results of the study as indicated in *Table 7,* on page 14 demonstrate that the substances tested at the concentrations listed do not interfere with the assay. All GBS positive results, for both serotypes tested, were 100% positive and all GBS negative results were 100% negative.

TABLE 7. **Interfering Substance Information**

Interfering Substance		Test Concentration
1	Human Genomic DNA	1.2×10^6 copies/mL
2	Human Whole Blood (EDTA)	2.0% (v/v)
3	Human Whole Blood (Sodium Citrate)	2.0% (v/v)
4	Human Serum	2.0% (v/v)
5	Human Urine Sample	2.0% (v/v)

	Interfering Substance	Test Concentration
6	Mucus	0.05% (w/v)
7	Human Fecal Sample	0.47% (w/v)
8	Human Amniotic Fluid	2.0% (v/v)
9	AquaGel® Lubricating Gel	0.59% (w/v)
10	Human Meconium Sample	0.88%(w/v)
11	Monistat® Cream	0.29% (w/v)
12	Yeast Gard® (Douche)	1.89% (v/v)
13	Vagisil® Cream	0.35% (w/v)
14	Pepto Bismol®	1.00% (v/v)
15	Kaopectate®	1.33% (v/v)
16	Metamucil® Fiber Supplement	0.08% (w/v)
17	Exlax® (Chocolate Pieces)	0.60% (w/v)
18	Phillips® Milk of Magnesia	1.78% (v/v)
19	Dulcolax® Suppositories	0.25% (w/v)
20	Preparation H® Cream	0.25% (w/v)
21	K-Y® Jelly Personal Lubricant	1.22% (w/v)
22	Vagisil® Powder	0.31% (w/v)
23	Norforms® Suppositories	0.30% (w/v)
24	FDS® Deodorant Spray	0.53% (w/v)
25	Gold Bond® Powder	0.40% (w/v)
26	Neutrogena® Body Oil	1.41% (v/v)
27	Vaginal Contraceptive Foam	0.59% (w/v)
28	Fleet® Enema	1.93% (v/v)

Carry-Over and Cross Contamination

Carry-over and cross contamination for the ARIES® GBS Assay were evaluated by testing 30 high GBS positive samples in series alternating with 30 GBS negative (Lim broth) samples. The high positive samples were run adjacent to negative samples across 10 consecutive runs using one ARIES® instrument. No carry-over or cross contamination was observed, and the overall percent agreement was 100% for positive and negative samples.

Analytical Reactivity (*Inclusivity*)

The analytical reactivity (inclusivity) of the ARIES® GBS Assay was evaluated against twelve (12) *Streptococcus agalactiae* isolates spanning 12 serotypes (Ia, Ib, Ic, II, III, IV, V, VI, VII, VIII, IX, and a non-hemolytic strain), which differed from those tested as part of the LoD study. Each isolate was diluted in negative Lim broth to a concentration near the LoD and tested in triplicate. All GBS strains were identified as positive by the ARIES® GBS Assay. The study results are shown in *Table 8,* on page 16.

TABLE 8. **ARIES® GBS Assay Analytical Reactivity (Inclusivity) Results**

Serotype	GBS Strain	Positivity
Serotype I a	CDC#2008232728	100% (3/3)
Serotype I b	ATCC BAA-1174	100% (3/3)
Serotype I c	ATCC 27591	100% (3/3)
Serotype II	CDC#2008232738	100% (3/3)
Serotype III	CDC#2008232582	100% (3/3)
Serotype IV	CDC#2011201884	100% (3/3)
Serotype V	ATCC BAA 611	100% (3/3)
Serotype VI	CDC#2010228816	100% (3/3)
Serotype VII	CDC#4832-06	100% (3/3)
Serotype VIII	CDC#5030-08	100% (3/3)
Serotype IX	CDC#7509-07	100% (3/3)
Non-Hemolytic	CDC#2009207634	100% (3/3)

Analytical Specificity

Cross Reactivity

Cross reactivity for the ARIES® GBS Assay was assessed with 113 microorganisms that represent various non-GBS groups of streptococci, including isolates phylogenetically related to *S.agalactiae*, along with other bacteria, parasites and viruses normally found in vaginal and anal flora as well as organisms that cause vaginal or digestive tract infections. Bacterial and fungal organisms were tested at ≥ 10^6 CFU/mL or highest available concentration and viruses were tested at ≥ 10^5 $TCID_{50}$/mL or highest available concentration. These potential cross reactive organisms were spiked into negative matrix (Lim broth) and tested in triplicate (n=3) on the ARIES® instrument. The results for all replicates were negative, demonstrating that the organisms listed in *Table 9,* on page 16 do not cross react with the ARIES® GBS Assay.

Microbial Interference

Microbial interference for the ARIES® GBS Assay was assessed with 113 organisms that represent various non-GBS groups of streptococci including isolates phylogenetically related to *S.agalactiae* and other bacteria, parasites and viruses normally found in vaginal and anal flora as well as organisms that cause vaginal or digestive tract infections. Bacterial and fungal organisms were tested at ≥ 10^6 CFU/mL or highest available concentration and viruses were tested at ≥ 10^5 $TCID_{50}$/mL or highest available concentration. The potential interfering organisms were spiked into Lim broth containing GBS near LoD concentration and tested in triplicate (n=3) on the ARIES® instrument. GBS was correctly detected in all replicates, demonstrating that none of the organisms listed in *Table 9,* on page 16 interfered with the ARIES® GBS Assay at the GBS concentration tested.

TABLE 9. **Organism Information**

Organisms Tested		
Achromobacter xerosis	*Haemophilus ducreyi*	*Pseudomonas fluorescens*
Acinetobacter calcoaceticus	*Haemophilus influenza*	*Rahnella aquatilis*
Acinetobacter lwoffi	*Helicobacter pylori*	*Rhizobium radiobacter*

Organisms Tested		
Aerococcus viridans	Hepatitis B virus (HBV)	*Rhodospirillum rubrum*
Aeromonas hydrophila	Hepatitis C virus (HCV)	*Ruminococcus productus*
Alcaligenes faecalis	Herpes Simplex Virus, type I (HSV1)	*Saccharomyces cerevisiae*
Arcanobacterium pyogenes	Herpes Simplex Virus, type II (HSV2)	*Salmonella enterica*[4]
Bacillus cereus	Human immunodeficiency virus (HIV-1)	*Salmonella typhimurium*
Bacillus subtilis	Human Papilloma Virus 16 (HPV 16)	*Serratia marcescens*
Bacteroides fragilis	Human Papilloma Virus 18 (HPV 18)	*Shigella flexneri*
Bifidobacterium adolescentis	*Kingella denitrificans*	*Shigella sonnei*
Bifidobacterium breve	*Kingella kingae*	*Staphylococcus aureus*
Brevibacterium linens	*Klebsiella oxytoca*	*Staphylococcus epidermidis*
Campylobacter jejuni	*Klebsiella pneumonia*	*Staphylococcus saprophyticus*
Candida albicans	*Lactobacillus acidophilus*	*Streptococcus anginosus*
Candida dubliniensis	*Lactobacillus brevis*	*Streptococcus bovis*
Candida glabrata	*Lactobacillus casei*	*Streptococcus canis*
Candida parapsilosis	*Lactobacillus delbrueckii lactis*	*Streptococcus dysgalactiae*
Candida tropicalis	*Lactobacillus jensenii*	*Streptococcus mitis*
Chlamydia trachomatis	*Listeria monocytogenes*	*Streptococcus mutans*
Chromobacterium violaceum	*Micrococcus luteus*	*Streptococcus oralis*
Citrobacter freundii	*Mobiluncus mulieris*	*Streptococcus parasanguinis*
Clostridium difficile	*Moraxella lacunata*	*Streptococcus pneumoniae*
Clostridium sporogenes	*Moraxella osloensis*	*Streptococcus pseudoporcinus*
Corynebacterium spp.[2]	*Morganella morganii*	*Streptococcus pyogenes*
Corynebacterium urealyticum	*Mycobacterium gordonae*	*Streptococcus salivarius*
Corynebacterium xerosis	*Mycobacterium smegmatis*	*Streptococcus sanguinis*
Cryptococcus neoformans	*Mycoplasma genitalium*	*Streptococcus suis*
Cytomegalovirus (CMV)	*Neisseria gonorrhoeae*	*Streptococcus uberis*
Elizabethkingia meningoseptica[1]	*Peptococcus sp.*	*Streptomyces griseus*
Enterobacter aerogenes	*Peptostreptococcus anaerobius*	*Treponema pallidum*
Enterobacter cloacae	*Plesiomonas shigelloides*[3]	*Trichomonas vaginalis*
Enterococcus durans	*Porphyromonas asaccharolytica*	*Ureaplasma urealyticum*
Enterococcus faecalis	*Prevotella melaninogenica*	*Veillonella parvula*

Organisms Tested		
Enterococcus faecium	*Propionibacterium acnes*	*Vibrio parahaemolyticus*
Escherichia coli	*Proteus mirabilis*	*Weissella paramesenteroides*
Flavobacterium spp.	*Proteus vulgaris*	*Yersinia enterocolitica*
Gardnerella vaginalis	*Pseudomonas aeruginosa*	

[1] Formerly *Chryseobacterium meningosepticum*

[2] Formerly *Corynebacterium genitalium*

[3] Formerly *Plesiomonas* spp.

[4] Formerly *Salmonella choleraesuis*

Reproducibility

Reproducibility of the ARIES® GBS Assay was evaluated by testing one lot of ARIES® GBS Assay Cassettes on two ARIES® Systems by two operators at each of three clinical laboratory sites on five non-consecutive days. A blinded and randomized reproducibility panel was prepared and sent to these sites by an independent operator that consisted of a GBS high positive, GBS low positive, GBS high negative, and a GBS negative sample. Each panel member was tested in triplicate by each operator each day of testing. The reproducibility panels were created by an independent operator and blinded to the testing sites. The results of the reproducibility study are in *Table 10,* on page 18 and *Table 11,* on page 18.

TABLE 10. **ARIES® GBS Assay Site to Site Reproducibility Results***

	Site 1		Site 2		Site 3	
	Agreement with expected results		Agreement with expected results		Agreement with expected results	
GBS High Positive	30/30	100.0%	30/30	100.0%	30/30	100.0%
GBS Low Positive	26/30	86.7%	29/30	96.7%	26/30	86.7%
GBS High Negative	18/30	60.0%	11/30	36.7%	17/30	56.7%
GBS Negative	30/30	100.0%	30/30	100.0%	30/30	100.0%

*The expected result for GBS High Positive target was 100% GBS Positive, GBS Low Positive was approximately 95% GBS Positive, GBS High Negative was 20% to 80% GBS Positive, and GBS Negative was 100% GBS Negative.An overall invalid rate of 0.82% (3/363) was observed in the target replicates.

TABLE 11. **Reproducibility Panel Total Results***

	Agreement with expected results		95% C.I.	
			Lower limit	Upper limit
GBS High Positive	90/90	100.0%	96.0%	100.0%
GBS Low Positive	81/90	90.0%	81.9%	95.3%
GBS High Negative	46/90	51.1%	40.3%	61.8%
GBS Negative	90/90	100.0%	96.0%	100.0%

*The expected result for GBS High Positive target was 100% GBS Positive, GBS Low Positive was approximately 95% GBS Positive, GBS High Negative was 20% to 80% GBS Positive, and GBS Negative was 100% GBS Negative.

Precision

Within laboratory precision/repeatability for the ARIES® GBS Assay was evaluated by testing GBS samples at various concentration levels across multiple days using multiple operators, multiple ARIES® GBS Assay cassette lots, and multiple ARIES® Systems. Study samples were prepared that consisted of GBS culture spiked into Lim broth at four concentration levels – high positive, low positive, high negative/ low positive, and a negative sample. These samples were blinded with respect to expected GBS concentration and tested in duplicate by two operators twice daily, across three ARIES® GBS Assay cassette lots and three ARIES® instruments for 12 non-consecutive days for a total of 96 results for each GBS concentration tested. The placement of the samples was randomized daily. The results of the study shown in *Table 12,* on page 19 demonstrate that results obtained with the ARIES® GBS Assay between multiple operators using multiple assay lots on multiple instruments within a laboratory run across multiple days are repeatable across a range of GBS concentration levels.

TABLE 12. **ARIES® GBS Assay Within Laboratory Precision/Reproducibility Results**[*, †]

Target Type	Agreement with Expected results	95% Confidence Interval
GBS High Positive	100.0% (96/96)	96.2% - 100.0%
GBS Low Positive	95.8% (92/96)	89.7% - 98.9%
GBS High Negative	78.1% (75/96)	68.5% - 85.9%
GBS Negative	100.0% (96/96)	96.2% - 100.0%

[*]Expected result for GBS High Positive target was 100% GBS Positive, GBS Low Positive was ≥ 90% GBS Positive, and GBS negative was 100% GBS Negative. The high negative/low positive sample (C20 to C80 concentration) was expected to be negative approximately 20% to 80% of the time (i.e., positive approximately 20% to 80% of the time).

[†]An overall invalid rate of 3.3% (13/397) was observed.

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