Luminex

Kit Package Insert | IVD

ARIES® Extraction Kit

IVD For *In Vitro* Diagnostic Use.

For use with the ARIES System.

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ARIES® Extraction Kit Package Insert

IVD

89-30000-00-549 Rev. B

Kit Part Number: 50-10028

07/2023

EC REP

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CE

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Key to Symbols

	Use By YYYY-MM-DD		Do not reuse / Use only once / Single use
	Batch Code		Temperature Limitation
	Catalog(ue) Number		Conformité Européenne (EU CE Marking of Conformity)
	Manufacturer		Caution. Consult accompanying documents. There are specific warnings and precautions associated with the device
	Consult instructions for use		Contains Sufficient for <n> Tests
BC	Build Code		Do not use if package is damaged
	In Vitro Diagnostic Medical Device		Biological Hazard
	Highly flammable liquid and vapor		Authorized Representative in the European Community

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Table of Contents

Intended Use

The ARIES® Extraction Kit is intended to extract nucleic acid from human biological specimens and universal transport media (UTM). The ARIES Extraction Cassette contains a Sample Processing Control (SPC). The ARIES Extraction Kit has not been validated for use with any specific analytical test method.

The ARIES Extraction Kit is indicated for use on the ARIES System.

Principles of the Procedure

The sample is added to the sample chamber of an ARIES® Extraction Cassette and processed using the ARIES System. The ARIES System automates nucleic acid extraction and concentration. No operator intervention is necessary once the ARIES Extraction Cassette is loaded into the ARIES System. The ARIES Extraction Cassette contains a combination of lysis and extraction reagents designed to rupture cells, extract nucleic acid, and remove inhibitors. After nucleic acids have been released from cells during lysis, they are bound by magnetic nucleic acid capture particles. The magnetic particles are conveyed via a series of turnstiles while being washed and finally eluted in ARIES elution buffer. The eluted nucleic acid is ready for PCR and can be used for applications on the ARIES System or another PCR amplification/ detection system.

Materials Provided

The ARIES® Extraction Kit (Part Number 50-10028) contains the following components:

Item	Part Number	Description
ARIES® Extraction Cassettes	50-10026	24 ARIES® extraction cassettes which contain the necessary reagents for sample extraction.
ARIES® Extraction Protocol File	CN-0361-01	Contains an ARIES® extraction protocol file (89-00010-00-397), package insert (89-30000-00-549) and an *ARIES® System Quick Guide* (89-00002-00-508) are provided on a USB.
ARIES® PCR Tubes	CN-0359-01	Includes 25 ARIES® PCR tubes.

Materials Required But Not Provided

Equipment:

- -70°C to -80°C freezer
- 2°C to 8°C refrigerator
- Luminex® ARIES® System and accessories
    - ARIES System magazines
    - Sample Prep Tray
    - Hand-held barcode reader
- Vortex mixer
- Appropriately sized pipettor

Plasticware and Consumables:

- Nuclease-free aerosol-barrier pipette tips

For whole blood samples:

- Proteinase K

For stool samples:

- ARIES® Stool Resuspension Buffer (30-00103) included in the ARIES Stool Resuspension Kit (30-00094)

Warnings and Precautions

1. For *In Vitro* Diagnostic Use.
2. 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*.
3. Thoroughly clean and disinfect all surfaces with 10% bleach.
4. Avoid contamination from positive controls and samples by following good laboratory practices.
5. Avoid contamination by using a new nuclease-free aerosol barrier tip to add an individual primary sample aliquot to each cassette.
6. Wear appropriate personal protective equipment (PPE), including a lab coat and disposable gloves, when performing procedures. Wash hands thoroughly after performing the test.
7. Follow your institution's safety procedures for working with chemicals and handling biological samples.
8. Do not use cassettes or reagents beyond their expiration date.
9. The cassettes are single-use. Do not reuse cassettes.
10. Store cassettes at the temperatures recommended on the cassette label. Do not freeze.
11. Only use the extraction protocol file provided by Luminex on the USB drive.
12. Only use the procedure described in this package insert. Any deviation from the outlined procedures can result in extraction failure or cause erroneous results.
13. Only use an ARIES® System that has been properly maintained according to the manufacturer's recommendations.
14. ARIES cassettes contain guanidinium thiocyanate. Refer to the SDS regarding safe handling practices for any spills.
15. In the event that a PCR tube falls off the cassette or a cassette leaks inside the ARIES System, appropriate decontamination procedures should be performed 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 System. 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 System at any time. Do not proceed with additional testing until the PCR tube has been removed from the ARIES System. Discard the cassette in accordance with the procedures defined by appropriate biohazard safety guidelines or regulations.
16. Refer to the *ARIES System Operation Manual* (89-00002-00-425) for electrical warnings.
17. Do not let the ARIES System get wet or allow standing water to pool under the system.
18. Safety Data Sheets (SDS) are available by contacting Luminex Corporation.

Reagent Storage, Handling, and Stability

ARIES® Extraction Kit 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 handling and storage should be performed according good laboratory practices and established techniques.

Extraction Procedure

Adding Extraction Files to the ARIES® System

The ARIES® extraction protocol file is provided on the USB flash drive. The extraction protocol file only needs to be imported to the ARIES System once. To import the extraction 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 touch 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 protocol file. Select **OK**.

Entering Orders

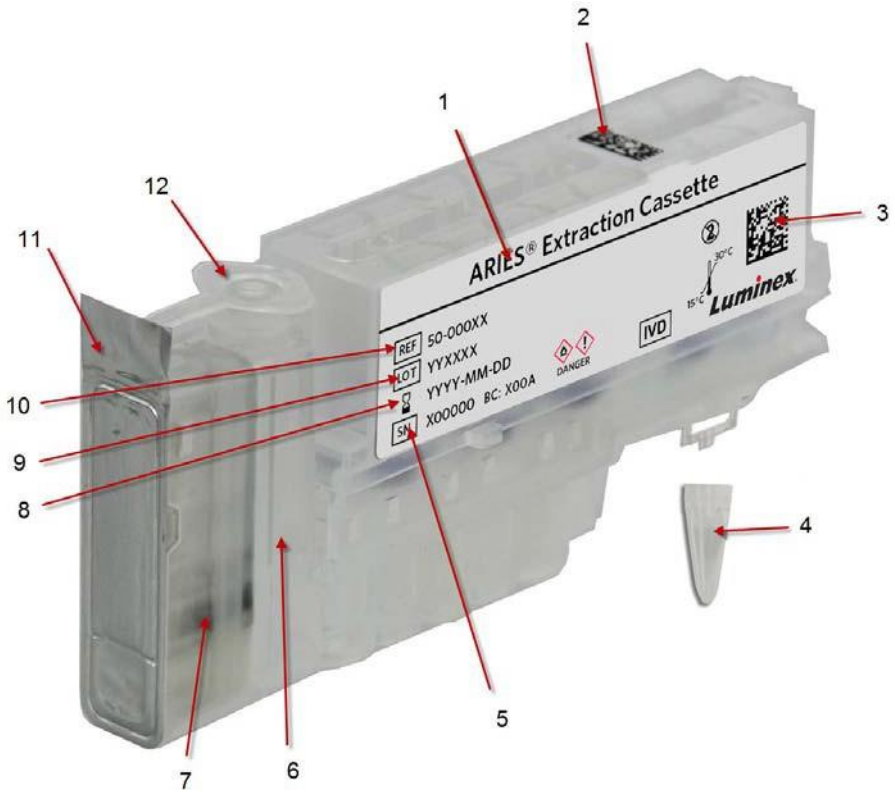
Orders are created by scanning an extraction cassette and sample barcode, and selecting the extraction protocol file.

The Sample ID is required on all orders and is the link between sample and cassette. The Accession ID and/or 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 **Settings** page under **Order Management**.

Enabling the Automatic Run Option

The ARIES® System can start runs automatically or manually. To ensure that the ARIES System will begin a run automatically, check that **Auto run upon Magazine Insertion** is toggled to **Yes** in the **Run Options** dialog box located on the **Run** > **Settings** page. For information on how to start runs manually, refer to the *ARIES System Operation Manual* (89-00002-00-425).

FIGURE 1. **ARIES® Extraction Cassette**



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

Adding PCR Tubes to the Cassettes

1. Remove the extraction 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. Do not throw away the cassette before contacting Technical Support.

2. Close the cassette cap to seal the cassette sample chamber.
3. Remove a PCR tube from its packaging and visually inspect the tube for any damage.
4. Place the empty PCR tube into the ARIES® Sample Prep Tray. Gently push the cassette onto the PCR tube. An audible click indicates the tube is securely fitted.

Entering Orders on the ARIES® System

When entering orders, both a Sample ID and a protocol file must be specified for the order to be accepted.

1. Select  in the upper left-hand corner of the touch screen and navigate to  **Order Management** > **Sample Orders**.

2. Select 

from the Page Action bar. The **New Order** dialog box displays.
3. Scan the barcode on the top (or side) of the cassette with the hand-held barcode reader. The required cassette information can also be entered manually by selecting any field on the **New Order** dialog box. A touch screen keyboard or a drop-down menu displays.

   NOTE: If the keyboard does not automatically appear, click the  keyboard toggle to "Yes". The keyboard now appears when you click in a field.

4. Select the **Assay** field's magnifying glass  . Choose the extraction protocol file from the **Assays** pop-up list.
5. Select the **Sample ID** field. Scan the sample barcode with the hand-held barcode reader to populate the **Sample ID** field. The required sample information can also be entered manually by selecting any field on the **New Order** dialog box. A touch screen keyboard or a drop-down menu displays.
6. Scan the Data Matrix barcode on the screen next to **Save** with the hand-held barcode reader. You can also manually select **Save.**
7. Select **Close**.

Adding Samples to the Cassettes

1. Place the sample tube in the Sample Prep Tray.
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 sample 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, add the required volume of sample. Refer to Table 1, "*Recommended Volumes by Sample Type*".

CAUTION: The following procedures are examples only. Users should develop and validate application-specific procedures.

TABLE 1. **Recommended Volumes by Sample Type**

Universal transport media (UTM)	Pipette 200 µL of sample into chamber.
Cerebrospinal fluid (CSF)	Pipette 200 µL of sample into chamber.
Bronchoalveolar lavage (BAL)	Pipette 200 µL of sample into chamber.
Plasma and urine	Pipette 200 µL of sample into chamber.
Whole blood	Pipette 100 µL of Proteinase K into chamber. Add 50 µL of whole blood into chamber and incubate.
Stool	Add stool sample and 400 µL of ARIES® Stool Resuspension Buffer into chamber.

CAUTION: Ensure that appropriate 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.

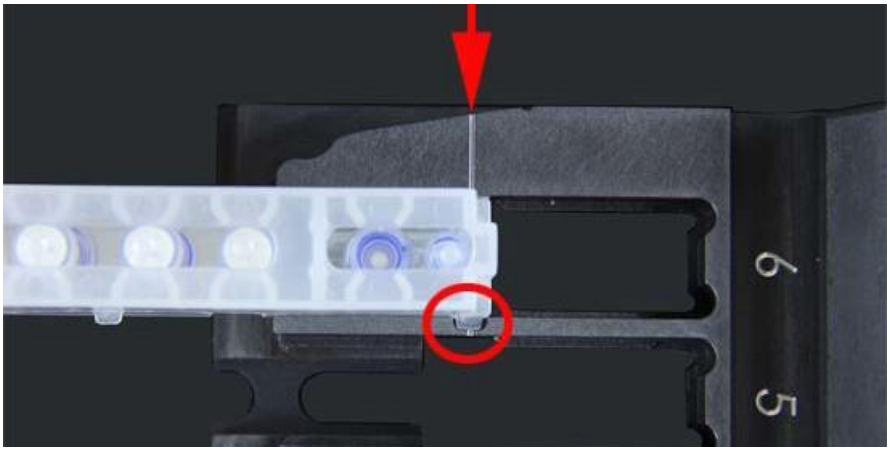
7. Place the sample in the cassette sample chamber by inserting the pipette tip near the bottom of the chamber before expelling the sample.

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

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

WARNING: Do not vortex or shake the cassette.

9. Place the cassette into the magazine by lining the cassette up with the first notch (there is a tab on the cassette that 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 toward the numbers. Repeat 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 it into proper position.

12. Insert the magazine into the ARIES System. For information on monitoring the run's status, refer to *"Monitoring the Run"* on page 8.

NOTE: To ensure that the ARIES System will begin the run automatically, check that **Auto run upon Magazine Insertion** is toggled to **Yes** in the **Run Options** dialog box located on the **Run** > **Settings** page. For more information, refer to the section *"Enabling the Automatic Run Option"* on page 3. For information on how to start runs manually, refer to the *ARIES System Operation Manual* (89-00002-00-425).

13. When the run is complete, remove the magazine from the ARIES® system. Remove the cassette from the magazine.

14. Holding the cassette in one hand, gently remove the PCR tube by pulling it towards you with your other hand.

15. Use or store the eluate.

Monitoring the Run

From the **Run** page, select  on the Page Action bar to display the status of the magazine(s), their estimated time to completion, and the customizable name of the ARIES® System. 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 the Run

When the ARIES® Extraction Kit run finishes successfully, the cassettes are colored green on the **Run** page. See Table 2, "*Color Indicators*" for other color indicators. Refer to the *ARIES System Operation Manual* (89-00002-00-425) for more color definitions.

TABLE 2. **Color Indicators**

Color	Reason
Red	Cassettes require additional information, were not scanned successfully or contain errors such as an invalid result. The run failed or was aborted. Contact Technical Support for further assistance
Yellow	Information was manually entered on the **Run** page
Green	Run finished successfully, 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 inserted or no cassette 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.

Printing Run Reports

1. To print a report, choose  **Results** from the  **System Navigation** menu.
2. Select the result(s). When generating a **Run Report**, you can select single or multiple results from the same run and use the **Create Report** icon. With **Run Report**, the **Create Report** icon is disabled only when results from multiple runs are selected.
3. Select 

from the Page Action bar. Choose **Run Report** from the drop-down menu. Once the report opens, you can choose to export 

or print the result 

.

Sample Processing Control

A sample processing control is available to monitor the ARIES® System. Each ARIES Extraction Cassette contains a sample processing control, which is processed with the sample. This consists of RNA and DNA viral particles. The RNA component of the sample processing control is a non-infectious intact Murine Hepatitis Virus (MHV) strain A59. The DNA component of the sample processing control is a lambda phage containing a specific 5 kb segment of the Murine Hepatitis Virus (MHV) genome. User-designed primers and probes may be used if targeted toward the MHV strain A59 genome. The sample processing control may be used to verify sample lysis and nucleic acid extraction when using the ARIES Extraction Cassette.

Limitations

Successful extraction of 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 can lead to an incorrect result.

Disposal

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

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