Luminex

ARIES®

ARIES® Systems

ARIES® *C. difficile* Assay

The ARIES® *C. difficile* Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection of toxigenic *Clostridium difficile* nucleic acid.

- **Ease of Use:** A simple, fully closed sample to answer system that can be easily operated with minimal risk of contamination
- **Comprehensive:** Detects both toxin A and toxin B, which increases confidence in results by reducing the chance of a false negative from strains that only produce toxin A
- **Fully Integrated:** Automate all aspects of testing, from sample extraction through analysis, to enable easy implementation across multiple shifts
- **Flexible:** Ability to run both IVD and LDT assays on the same system simultaneously, when using a Universal Assay Protocol
- **Error-reducing Safeguards:** Internal barcode scanning and bidirectional LIS connectivity both increase efficiency and reduce data input errors

Performance

Performance of the ARIES® *C. difficile* Assay was evaluated at four geographically distinct sites using leftover, de-identified, unpreserved, unformed stool specimens.

Refer to Package Insert for additional details: Luminex Corporation | ARIES® C. difficile Assay (IVD) Kit Package Insert.

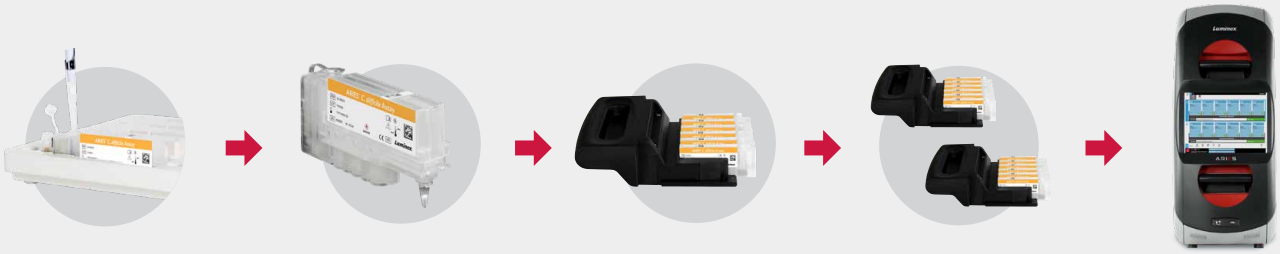
Table 1: ARIES® *C. difficile* Assay Performance Compared to Direct Toxigenic Culture

ARIES® *C. difficile* Assay	Direct Toxigenic Culture		
	Positive	Negative	Total
Positive	103	65	168
Negative	2	809	811
Total	105	874	979
		95% CI	
PPA	98.1%	93.3% - 99.5%	
NPA	92.6%	90.6% - 94.1%	

Table 2: ARIES® *C. difficile* Assay Performance Compared to Direct and Enriched Toxigenic Culture

ARIES® *C. difficile* Assay	Direct and Enriched Toxigenic Culture		
	Positive	Negative	Total
Positive	133	35	168
Negative	14	797	811
Total	147	832	979
		95% CI	
Sensitivity	90.5%	84.6% - 94.2%	
Specificity	95.8%	94.2% - 97.0%	

Workflow



Step 1
Prepare the sample using the provided stool resuspension kit

Step 2
Load the sample into the cassette

Step 3
Insert up to six cassettes into the magazine

Step 4
Insert the magazines into the instrument

Step 5
Review & release results

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

Usage and Targets

The test targets the *C. difficile* toxin A gene (*tcdA*) and toxin B gene (*tcdB*) and is intended to aid in the diagnosis of *C. difficile* infection (CDI). The assay is tested from unpreserved, unformed (liquid or soft) stool specimens obtained from patients suspected of having CDI. The ARIES® *C. difficile* Assay is indicated for use with ARIES® Systems.

Ordering Information*

Product Name	Part Number
ARIES® *C. difficile* Assay Complete Kit Includes: ARIES® Stool Resuspension Kit (30-00095) 24 *C. difficile* Test Cassettes *These two components ship separately. Does not include assay protocol file (CN-0334-01).*	50-10023 (24 tests)
ARIES® *C. difficile* Assay Protocol File	CN-0334-01 (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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