

ARIES[®]

ARIES[®] Systems

ARIES[®] Norovirus Assay



The ARIES[®] Norovirus Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the identification and differentiation of norovirus genogroup I (GI) and genogroup II (GII) RNA.

- **Ease of Use:** A simple, fully closed sample to answer system that can be easily operated with minimal risk of contamination
- **High Performance:** Report results with a high degree of confidence
- **Fully Integrated:** Automate all aspects of testing, from sample preparation through analysis, to enable easy implementation on weekends and night shifts
- **Flexible:** Ability to run both IVD and laboratory developed assays on the same system simultaneously, when using a Universal Assay Protocol
- **Scalable:** On-demand testing of up to 12 samples per run for rapid, actionable results

Performance

Performance of the ARIES[®] Norovirus Assay was established by testing raw (fresh or frozen) stool samples retrospectively collected from six geographically diverse sites in the United States and Europe.

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

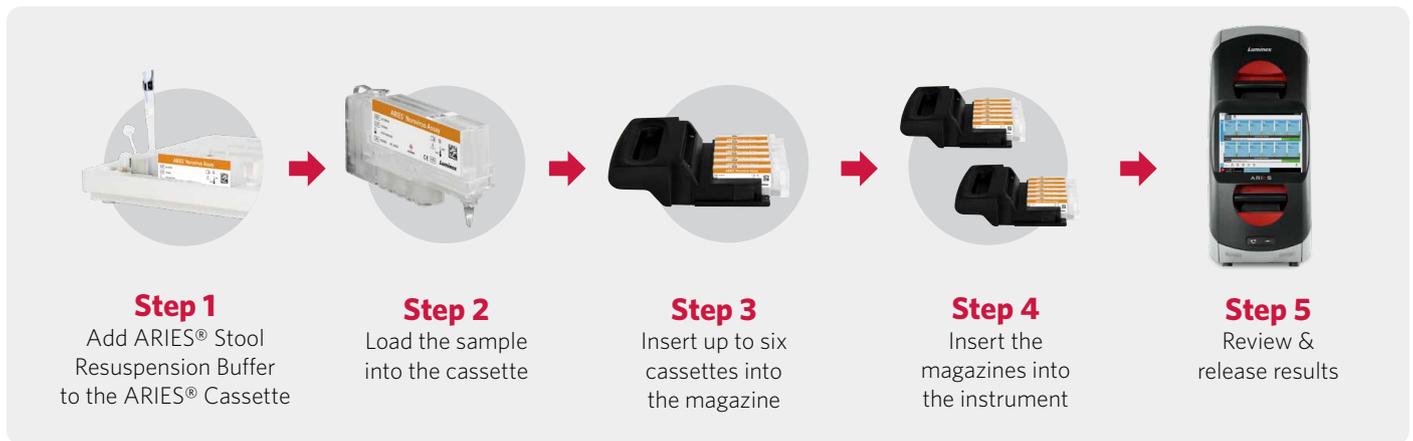
Table 1: Summary of Norovirus GI Results After Discordant Analysis (N=200)

ARIES [®] Norovirus Assay	NAAT Reference Method and Bidirectional Sequencing		
	Norovirus GI Positive	Norovirus GI Negative	Total
Norovirus GI Positive	14	1	15
Norovirus GI Negative	0	185	185
Total	14	186	200
95% CI			
PPA	100%	78.5% - 100%	
NPA	99.5%	97.0% - 99.9%	

Table 2: Summary of Norovirus GII Results After Discordant Analysis (N=200)

ARIES [®] Norovirus Assay	NAAT Reference Method and Bidirectional Sequencing		
	Norovirus GII Positive	Norovirus GII Negative	Total
Norovirus GII Positive	84	1	85
Norovirus GII Negative	0	115	115
Total	84	116	200
95% CI			
PPA	100%	95.6% - 100%	
NPA	99.1%	95.3% - 99.8%	

Workflow



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 ARIES® Norovirus Assay is intended to aid in the diagnosis of norovirus infections when used in conjunction with clinical evaluation, laboratory findings, and epidemiological information. The assay also aids in the detection and identification of norovirus infections in the context of outbreaks. The assay is tested from raw or unpreserved, unformed stool specimens collected from individuals with symptoms of acute gastroenteritis. The ARIES® Norovirus Assay is indicated for use with ARIES® Systems.

Ordering Information*

Product Name	Part Number
ARIES® Norovirus Assay Kit <i>Note: This includes ARIES® Norovirus Assay Cassettes and ARIES® Norovirus Assay Loops</i>	50-10042 (24 tests)
ARIES® Norovirus Assay Protocol File	CN-0338-01 (one time order only)
ARIES® Stool Resuspension Buffer** <i>Note: The ARIES® Stool Resuspension Buffer must be ordered separately</i>	30-00103
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 for IVD Use

** General Purpose Reagent (GPR)

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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