Luminex®

ARIES®

Flu A/B & RSV Assay

Welcome to the New Way to Work

The ARIES® Flu A/B & RSV Assay is a rapid, accurate method for the detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) from nasopharyngeal swab (NPS) specimens using the ARIES® System. Key features include:

- **Comprehensive and Flexible:** The inclusion of multiple pathogens with broad strain coverage provides a single test for pediatric, immunocompromised, and adult populations. The ability to mask particular pathogens also provides flexibility to meet each physician's order.
- **Excellent Clinical Performance:** High clinical performance reduces the need for confirmatory testing that may be associated with rapid antigen tests, thereby providing results you can trust. An integrated sample processing control ensures the assay run is successful from extraction through amplification.
- **Fast Time to Results:** Answers in less than 2 hours with minimal hands-on time allows for rapid diagnosis and early initiation of treatment, and may lead to more positive patient outcomes.
- **Reduce User Error:** Internal barcode scanning matches samples to cassettes, enabling Position Independent Results no matter where each cassette is placed. Data input errors are also reduced with electronic ordering through bidirectional LIS connectivity.

Performance

All 2,479 eligible prospective clinical specimens were analyzed by comparing the ARIES® Flu A/B & RSV Assay with the xTAG® Respiratory Viral Panel (RVP) assay (FDA-cleared under k112781), as shown below:

Target	PPA		95% CI	NPA		95% CI	"No Call" by Reference
Influenza A	299/312	95.8%	93.0% - 97.8%	2131/2165	98.4%	97.8% - 98.9%	2
Influenza B	45/48	93.8%	82.8% - 98.7%	2417/2431	99.4%	99.0% - 99.7%	0
RSV	270/278	97.1%	94.4% - 98.7%	2165/2201	98.4%	97.7% - 98.9%	0

Refer to Package Insert for additional details: Luminex Corporation | ARIES® Flu A/B & RSV Assay (IVD) Kit Package Insert.

Intended Use

The ARIES® Flu A/B & RSV Assay is a polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) nucleic acid in nasopharyngeal swabs (NPS) specimens from patients with signs and symptoms of respiratory tract infection in conjunction with clinical and laboratory findings.

Negative results do not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial culture, immunofluorescence, x-ray findings) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory viral infection.

Performance characteristics for influenza A were established when influenza A/H3N2 and A/H1N1 were the predominant influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

The ARIES® Flu A/B & RSV Assay is indicated for use with the ARIES® System.

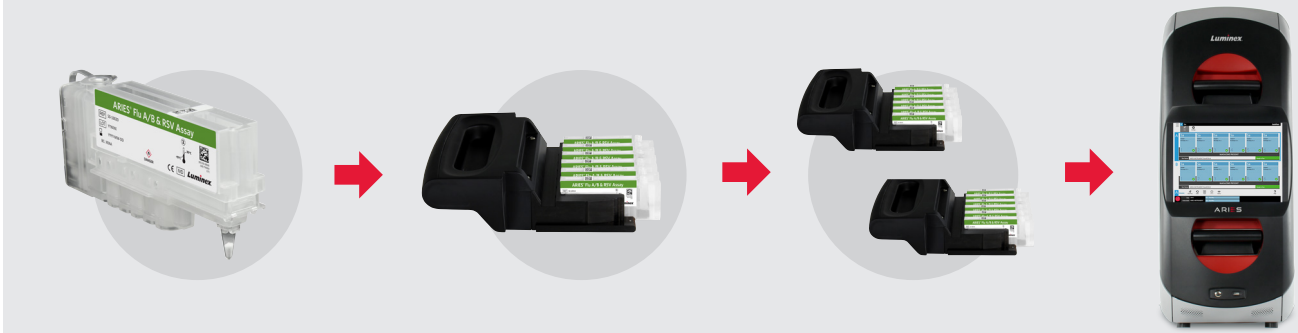
Workflow

Step 1
Load the sample into the cassette

Step 2
Insert up to six cassettes into the magazine

Step 3
Insert the magazines into the instrument

Step 4
Review & release results



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*

Description	Part Number
ARIES® Flu A/B & RSV Assay Kit	50-10020 (24 tests)
ARIES® Flu A/B & RSV Assay Protocol Kit	CN-0335-01 (one time order only)
ARIES® Two Module System IVD Includes: Instrument System Operation Manual Two Magazines Quick Guide Two Sample Prep Trays Power Cord Handheld Barcode Scanner	ARIES-M12V1-IVD

*Products are CE-Marked for IVD use.

The ARIES® System is crafted to increase laboratory efficiency, ensure result accuracy, and fit seamlessly into today's lean laboratory.

Luminex®

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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. The ARIES® System is a class 1(I) laser product. Validation of the LIS compatibility must be performed by the end user.

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