Luminex

ARIES® Flu A/B & RSV+SARS-CoV-2 (CE-IVD)

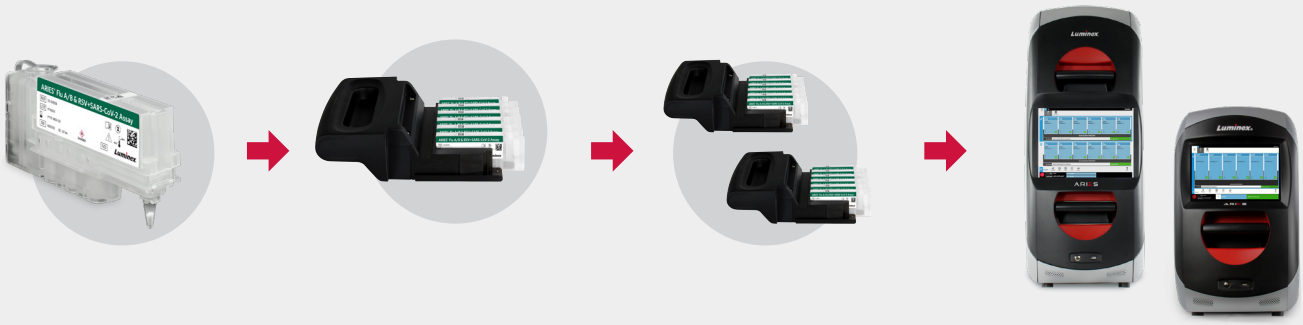
ARIES® Flu A/B & RSV+SARS-CoV-2 is a multiplex real-time sample-to answer PCR test utilized in the detection and differentiation of SARS-CoV-2, influenza A, influenza B, and RSV.

Accurate detection of respiratory viruses is important in patient care, as it guides both therapy and infection control measures.[1] Children, the elderly, and the immunocompromised remain the most vulnerable to severe disease. SARS-CoV-2 is now among the most relevant acute respiratory infection-causing pathogens. The WHO recommends countries prepare for the co-circulation of influenza and SARS-CoV-2 viruses, especially in light of their overlapping symptomology.[2] Likewise, RSV epidemics were projected to be more intense and to affect patients in a broader age range than in typical RSV seasons.[3] Thus, laboratories must adapt their testing algorithms to the reemergence and fluctuation of respiratory pathogens.

The ARIES® Flu A/B & RSV+SARS-CoV-2 Assay offers:

- **Reliable Performance**: Sensitive detection of influenza A, influenza B, RSV, and SARS-CoV-2 in a single test. The 2-gene design (N and E genes) supports broad coverage of SARS-CoV-2 variants, while the built-in sample processing control confirms result validity.
- **Scalable Throughput**: Process up to 12 samples in just over two hours (with the ARIES® System) accommodating variable, day-to-day, and seasonal testing demands.
- **Convenience**: Simply add your sample directly into the benchtop stored cassette, saving time, effort, and valuable temperature controlled storage space.

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

Performance

The clinical data summarized in the two tables below demonstrates the reliability of this multi-target assay.

Clinical Performance

The clinical performance of the ARIES® Flu A/B & RSV+SARS-CoV-2 Assay was compared to a molecular assay with confirmation of positive results by PCR followed by bidirectional sequencing (BDS) assays. For each target in the ARIES® Flu A/B & RSV+SARS-CoV-2 Assay, the PPA (positive percent agreement) and NPA (negative percent agreement) performance for combined prospective and pre-selected specimen analysis is shown below.

Pathogen	PPA	NPA
Influenza A	98.5%	99.3%
Influenza B	100%	100%
RSV	98.6%	99.7%
SARS-CoV-2	95.8%	98.4%

Limit of Detection (LoD)

Pathogen	Strain	LoD (copies/mL)
Influenza A	A/Brisbane-02-2018/ H1N1 98.5%	199
	A/Kansas/14/2017 (H3N2)	1,472
Influenza B	B/Colorado/06/2017	375
	B/Phuket/3073/2013	627
RSV	RSV/A/Long	832
	RSV B WV/14617/85	872
SARS-CoV-2	SARS-CoV-2 /Isolate: USA-WA 1/2020	648
	SARS-CoV-2/ Hong Kong	243

Testing with confidence: In silico analysis established our broad viral strain coverage prior to releasing the product to the market and is regularly confirmed through our Biosurveillance program. Influenza A and B inclusivity was assessed with sequences available from the GISAID database between January 1, 2017 and January 6, 2022. The assay oligos for influenza A, influenza A H1, influenza A H3, and influenza B are predicted to have ~100% inclusivity against the analyzed sequences.

We are continuously monitoring the GISAID database SARS-CoV-2 Variants of Concern sequences. Please go to **https://www.luminexcorp.com/covid19-testing-solutions/**, select "**Click here**" to view the results of our in silico inclusivity analysis.

Ordering

Product Name	Part Number
ARIES® Flu A/B & RSV+SARS-CoV-2 Assay† (24 tests) CE-IVD	50-10055
ARIES® System	ARIES-M12V1-IVD
ARIES® M1 System	ARIES-M6V1-IVD
SYNCT™ Software	CN-SW47

†For detection and identification of influenza A, influenza B, RSV, and SARS-CoV-2 viral nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals with clinical signs and symptoms of respiratory tract infections, including COVID-19.

REFERENCES

1. Ginocchio CC and McAdam AJ. Current Best Practices for Respiratory Virus Testing. J Clin Microbiol; 2011 Sept;49(9Supppl):S44-S48.
2. Influenza Update N° 412, 07 February 2022, based on data up to 23 January 2022. WHO (Internet). Cited May 2022. Available from: **https://www.who.int/publications/m/item/influenza-update-n-412**.
3. Zheng She, Pitzer VE, Shapiro ED, et al. Estimation of the Timing and Intensity of Reemergence of Respiratory Syncytial Virus Following the COVID-19 Pandemic in the US. JAMA Netw Open. 2021;4(12):e2141779. doi:10.1001/jamanetworkopen.2021.41779.

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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.

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