Luminex®

ARIES® SARS-CoV-2 Assay (EUA-IVD)

For Use Under Emergency Use Authorization (EUA)

The ARIES® SARS-CoV-2 Assay is a qualitative, multiplex, real-time PCR-based *in vitro* diagnostic test intended for the detection of SARS-CoV-2 nucleic acid in nasopharyngeal swab (NPS) specimens from individuals suspected of having COVID-19.

Features and Benefits:

- **Precise Results:** A moderate-complexity, sample-to-answer test that enables targeted SARS-CoV-2 detection
- **Fast Turnaround Time:** Minimal hands-on time and an automated workflow delivers results in about 2 hours
- **Robust Detection:** Exonuclease-sensitive probes for the ORF1ab and N viral genes provide exceptional specificity

Performance

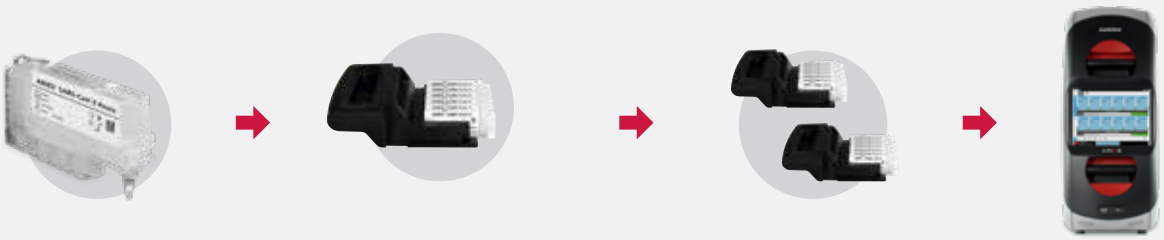
The performance of the ARIES® SARS-CoV-2 Assay was evaluated using blind and randomized clinical specimens. The results are summarized in the table below.

Table 1. Clinical Performance of the ARIES® SARS-CoV-2 Assay

Target RNA Concentration	Number of Samples Tested	SARS-CoV-2-ORF1ab		SARS-CoV-2-N		Overall SARS-CoV-2 Result	% Positivity
		Mean C_t Value	% Agreement (# Pos/Neg/Total)	Mean C_t Value	% Agreement (# Pos/Neg /Total)		
SARS-CoV-2 2X LoD	20	30.4	100% 20/20	33.1	95% 19/20[a]	Positive	100%
SARS-CoV-2 3X LoD	5	29.18	100% 5/5	31.8	100% 5/5	Positive	100%
SARS-CoV-2 5X LoD	5	28.9	100% 5/5	31.4	100% 5/5	Positive	100%
NCM (Negative)	30	N/A	100% 30/30	N/A	100% 30/30	Negative	0%

a. A single replicate was negative for the N gene, but the ORF1ab gene target was detected, so the specimen was still assigned a positive result.

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

Usage

The ARIES® SARS-CoV-2 Assay detects SARS-CoV-2 viral RNA from nasopharyngeal swab (NPS) samples. SARS-CoV-2 RNA is generally detectable in NPS specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ARIES® SARS-CoV-2 Assay is intended for use on ARIES® Systems by trained clinical laboratory personnel who are specifically instructed and trained in *in vitro* diagnostic procedures.

Ordering Information

Product Name	Part Number
ARIES® SARS-CoV-2 Assay* Protocol File	50-10047 Provided Separately+
ARIES® Two Module System (IVD)	ARIES-M12V1-IVD
ARIES® M1 System (IVD)	ARIES-M6V1-IVD
SYNCT™ Software	CN-SW47

* IVD – Emergency Use Authorization.
+ Contact your Molecular Business Manager, or contact support@luminexcorp.com.

Luminex®
complexity simplified.

orders@luminexcorp.com or support@luminexcorp.com

EUA - In Vitro Diagnostic Use Under Emergency Use Authorization. This test has not been FDA cleared or approved. This test has been authorized by the FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. §360bb-3(b)(1), unless the authorization is terminated or revoked sooner.

ARIES® SARS-CoV-2 Assay has been funded with $642,450 of Federal funds, approximately 36% of the expected overall cost of development, from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research Innovation and Ventures under Contract No. 75A50120C00043. Luminex financed the remaining $1,118,663 of the program, constituting 64% of the total program costs.

luminexcorp.com

HEADQUARTERS
UNITED STATES
+1.512.219.8020
info@luminexcorp.com

EUROPE
+31.73.800.1900
europe@luminexcorp.com

CANADA
+1.416.593.4323
info@luminexcorp.com

CHINA
+86.21.8036.9888
infocn@luminexcorp.com

JAPAN
+81.3.5545.7440
infojp@luminexcorp.com