Luminex®

ARIES® SARS-CoV-2 (CE-IVD) Assay

The ARIES® SARS-CoV-2 Assay is a real-time RT-PCR-based in vitro diagnostic test that qualitatively detects SARS-CoV-2 nucleic acid from nasopharyngeal swab (NPS) samples in UTM™, Liquid Amies (ESwab™), or equivalent.

The ARIES® SARS-CoV-2 CE-IVD Assay offers:

- **Fully Integrated Testing:** Automate all aspects of testing, from sample preparation through analysis, in a self-contained cassette.
- **Flexible Throughput:** In two hours, process from 1 to 12 tests per batch; both STAT testing and medium volume sample batching are supported.
- **A Versatile Portfolio:** With a growing portfolio of cassette-ready assays and the tools to create laboratory developed tests (LDTs)*, ARIES® Systems deliver reliable detection for a wide range of testing needs.
- **Reliable Performance:** In addition to sensitive detection of SARS-CoV-2 through the ORF1ab and N gene targets, a sample processing control included in the cassette confirms result validity.

Performance

A limit of detection (LoD) study was performed to evaluate the analytical sensitivity of the ARIES® SARS-CoV-2 Assay using one strain of the SARS-CoV-2, isolate USA-WA1/2020.

The confirmed ARIES SARS-CoV-2 Assay LoD concentration is 3.00 x 10^3 GCE/mL.

Combined Clinical Performance of the ARIES® SARS-CoV-2 Assay for the SARS-CoV-2 Target

Reference Method Result	Number of Samples Tested	Positive	Negative	% Agreement with Reference Method	
Positive	89*	85	4†	PPA	95.5%
Negative	85	0	85	NPA	100.0%
Total	174				

**Includes 30 contrived ESwab™ specimens.*

†Three of the four false negative (FN) specimens were confirmed negative and one was positive for SARS-CoV-2 by PCR followed by bidirectional sequencing.

Workflow

Step 1
Load the sample into the cassette.

Step 2
Insert up to six cassettes into the magazine.

Step 3
Insert one or both magazines into the instrument.

Step 4
Review & release results.

Due to its optimized PCR protocol, the ARIES® SARS-CoV-2 Assay cannot be run in the same magazine as other ARIES® CE-IVD assays.

Ordering Information

Product Name	Part Number
ARIES® SARS-CoV-2 Assay (24 Tests)	50-10051
ARIES® Two Module System	ARIES-M12V1-IVD
ARIES® M1 System	ARIES-M6V1-IVD
SYNCT™ Software	CN-SW47

Products are CE Marked for IVD use.

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.

*Luminex does not endorse the use of any LDT for diagnostic use.

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

SS308164