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.*

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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.




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