

Luminex

ARIES

ARIES[®] HSV 1&2 Assay



The ARIES[®] HSV 1&2 Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and typing of herpes simplex virus (HSV-1 and 2) DNA in cutaneous or mucocutaneous lesion specimens from symptomatic patients or in cerebrospinal fluid (CSF) from patients suspected of HSV infections of the central nervous system (CNS). The ARIES[®] HSV 1&2 Assay offers:

- **High Sensitivity** — Aid in the diagnosis of more patients and reduce time to treatment
- **Comprehensive Coverage** — Test broad sources of lesions (nasal, ocular, oral, skin, genital/anogenital lesions) and CSF
- **Flexibility** — Run as many as 12 tests per batch, supporting STAT testing and low- to medium-volume batch testing
- **Fast Time to Results** — Get answers in less than two hours with minimal hands-on time to support rapid treatment decisions
- **Full Integration** — Automate all aspects of testing, from sample extraction through analysis, to enable easy implementation across multiple shifts
- **Error-reducing Safeguards** — Internal barcode scanning matches samples to cassettes and may reduce data input errors

Performance — Cutaneous and Mucocutaneous

The reference/comparative method used to evaluate the clinical performance of the ARIES® HSV 1&2 Assay was ELVIS® HSV-ID and D3 Typing Test System.

Summary of HSV-1 and 2 Results for Cutaneous Lesions

ARIES® HSV 1&2 Assay	REFERENCE METHOD	
HSV-1		95% CI
Sensitivity	91.1% (51/56)	80.4%-97.0%
Specificity	94.2% (274/291)	90.8%-96.6%
HSV-2		
Sensitivity	95.0% (96/101)	88.8%-98.4%
Specificity	88.8% (308/347)	85.0%-91.9%

Summary of HSV-1 and 2 Results for Mucocutaneous Lesions

ARIES® HSV 1&2 Assay	REFERENCE METHOD	
HSV-1		95% CI
Sensitivity	97.0% (262/270)	94.2%-98.7%
Specificity	95.4% (878/920)	93.9%-96.7%
HSV-2		
Sensitivity	98.5% (250/263)	96.2%-99.6%
Specificity	93.2% (1109/1190)	91.6%-94.6%



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

Clinical Performance—CSF

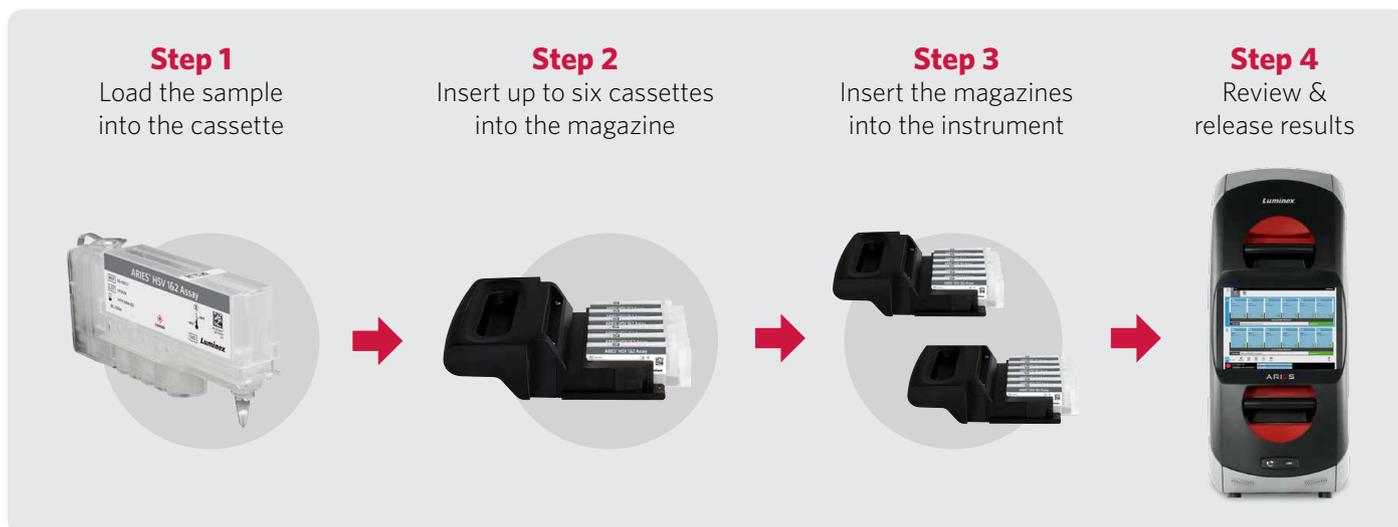
The following table represents post-discordant analysis, where contrived positive and natural specimens tested by both the ARIES[®] System and the nucleic acid testing (NAT) reference method were positive.

ARIES [®] HSV 1&2 Assay	REFERENCE METHOD	
HSV-1		95% CI
PPA	100% (33/33)	89.6%-100%
NPA	100% (155/155)	97.6%-100%
HSV-2		
PPA	100% (38/38)	90.8%-100%
NPA	99.3% (141/142)	96.1%-99.9%

Usage

The test is indicated for use with symptomatic individuals to aid in the diagnosis of HSV infections. The assay is not intended to be used for prenatal screening. The ARIES[®] HSV 1&2 Assay is indicated for use on ARIES[®] Systems.

Workflow



The operator simply adds specimen to the sample chamber, puts the cassette in the magazine, loads the magazine into an ARIES[®] System, and the run will start automatically.

Ordering Information*

Product Name	Part Number
ARIES® HSV 1&2 Assay	50-10031 (24 tests)
ARIES® HSV 1&2 Assay Protocol File Kit	CN-0371-01 (one time order only)
ARIES® Two Module System Includes: Instrument System Operation Manual Two Magazines Quick Guide Two Sample Prep Trays Power Cord Handheld Barcode Scanner and Stand	ARIES-M12V1-IVD
ARIES® M1 System Includes: Instrument System Operation Manual One Magazine Quick Guide Two Sample Prep Trays Power Cord Handheld Barcode Scanner and Stand	ARIES-M6V1-IVD
SYNCT™ Software	CN-SW47-01

*Products are CE Marked for IVD use.

Luminex®
complexity simplified.

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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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