Luminex

ARIES®

HSV 1&2 Assay

Welcome to the New Way to Work

ARIES® HSV 1&2 Assay Offers

- **High Sensitivity:** Aid in the diagnosis of more patients and reduce time to treatment.
- **High Accuracy:** Confidence in results, gives patients and clinicians peace of mind, and helps ensure correct treatment. Integrated sample processing control ensures the assay run is successful from extraction through amplification.
- **Fast Time to Results:** Answers in as little as 2 hours will allow physicians to counsel and treat sooner to decrease transmission.
- **Fully Integrated:** Automate all aspects of testing, from sample preparation through analysis.
- **Reduce User Error:** Internal barcode scanning matches samples to cassettes, enabling Position Independent Results no matter where each cassette is placed. Reduce data input errors with electronic ordering through bidirectional laboratory information system (LIS) connectivity.

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

Performance

The performance of the ARIES® HSV 1&2 Assay was assessed at three (3) geographically diverse clinical sites in the United States.

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 Results for Cutaneous Lesions (N=347)

ARIES® HSV 1&2 Assay	REFERENCE METHOD		
	POSITIVE	NEGATIVE	TOTAL
Positive	51	17[1]	68
Negative	5[2]	274	279
Total	56	291	347
		95% CI	
Sensitivity	91.1% (51/56)	80.4%-97.0%	
Specificity	94.2% (274/291)	90.8%-96.6%	

[1]Thirteen (13) HSV 1 ARIES® positive speciments that were negative by the refererence method were positive by bi-directional sequencing analysis using analytically validated primers that targeted genomic regionsdistinct from the ARIES® HSV 1&2 Assay. The remaining four (4) false positive specimens were negative for both HSV 1 and HSV 2 by bi-directional sequencing.

[2]All five (5) HSV 1 ARIES® negative specimens that were positive by the reference method were negative by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from the ARIES® HSV 1&2 Assay. One of these specimens was positive for HSV 2 by both ARIES® and sequencing.

Summary of HSV 1 Results for Mucocutaneous Lesions (N=1190)

ARIES® HSV 1&2 Assay	REFERENCE METHOD		
	POSITIVE	NEGATIVE	TOTAL
Positive	262	42[1]	304
Negative	8[2]	878	886
Total	270	920	1190
		95% CI	
Sensitivity	97.0% (262/270)	94.2%-98.7%	
Specificity	95.4% (878/920)	93.9%-96.7%	

[1]Nineteen (19) HSV 1 ARIES® positive specimens that were negative by the reference method were positive by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from the ARIES® HSV 1&2 Assay. Twenty (20) false positive specimens were negative for both HSV-1 and HSV-2 by bi-directional sequencing. The remaining three (3) specimens were unavailable (QNS) for sequence analysis.

[2]Seven (7) HSV 1 ARIES® negative specimens that were positive by the reference method were negative by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from the ARIES® HSV 1&2 Assay. One (1) of these specimens was positive for HSV 2 by both ARIES® and sequencing. One (1) false negative specimen was positive for HSV-1 by bi-directional sequencing.

Summary of HSV 2 Results for Cutaneous Lesions (N=448)

ARIES® HSV 1&2 Assay	REFERENCE METHOD		
	POSITIVE	NEGATIVE	TOTAL
Positive	96	39[1]	135
Negative	5[2]	308	313
Total	101	347	448
		95% CI	
Sensitivity	95.0% (96/101)	88.8%-98.4%	
Specificity	88.8% (308/347)	85.0%-91.9%	

[1]Thirty-five (35) HSV 2 ARIES® positive specimens that were negative by the reference method were positive by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from the ARIES® HSV 1&2 Assay. The remaining four (4) false positive specimens were negative for both HSV-1 and HSV-2 by bi-directional sequencing.

[2]All five (5) HSV 2 ARIES® negative specimens that were positive by the reference method were cofirmed as negative by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from ARIES® HSV 1&2. Two (2) of these specimens was positive for HSV 1 by both ARIES® and sequencing.

Summary of HSV 2 Results for Mucocutaneous Lesions (N=1453)

ARIES® HSV 1&2 Assay	REFERENCE METHOD		
	POSITIVE	NEGATIVE	TOTAL
Positive	259	81[1]	340
Negative	4[2]	1109	1113
Total	263	1190	1453
		95% CI	
Sensitivity	98.5% (250/263)	96.2%-99.6%	
Specificity	93.2% (1109/1190)	91.6%-94.6%	

[1]Fifty-eight (58) HSV 2 ARIES® positive specimens that were negative by the reference method were positive by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from the ARIES® HSV 1&2 Assay. Twenty-one (21) false positive specimens were negative for both HSV-1 and HSV-2 by bi-directional sequencing. The remaining two (2) specimens were unavailable (QNS) for sequence analysis.

[2]All four (4) HSV 2 ARIES® negative specimens that were positive by the reference method were negative by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from ARIES® HSV 1&2 Assay. Three (3) of these specimens were positive for HSV 1 by both ARIES® and sequencing.

Intended Use

The ARIES® HSV 1&2 Assay is a real-time polymerase chain reaction (PCR) based test for the simultaneous detection and differentiation of Herpes Simplex Virus Type 1 (HSV 1) and Type 2 (HSV 2) DNA in cutaneous or mucocutaneous specimens from symptomatic patients. The test is indicated for use as an aid in diagnosis of HSV infection in symptomatic patients. The ARIES® HSV 1&2 Assay is indicated for use on ARIES® Systems.

WARNING: The ARIES® HSV 1&2 Assay is not FDA cleared for use with cerebrospinal fluid (CSF). The assay is not intended to be used for prenatal screening.

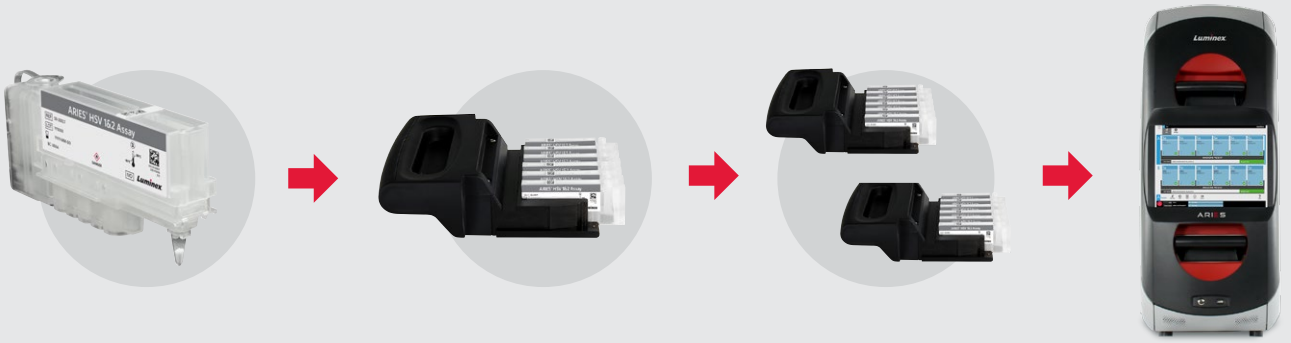
Workflow

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



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

Ordering Information

Product Name	Part Number
ARIES® HSV 1&2 Assay	50-10017 (24 tests)
ARIES® HSV 1&2 Assay Protocol File Kit	CN-0337-01 (one time order only)
ARIES® Two Module System IVD 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 IVD Includes: Instrument System Operation Manual One Magazine Quick Guide Two Sample Prep Trays Power Cord Handheld Barcode Scanner and Stand	ARIES-M6V1-IVD

Luminex®

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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. Validation of the LIS compatibility must be performed by the end user. ARIES Systems are class 1(I) laser products.

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