

ARIES[®]

ARIES[®] Systems

ARIES[®] HSV 1&2 Assay



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. ARIES[®] HSV 1&2 Assay Offers:

- **High Sensitivity** — Aid in the diagnosis of more patients and reduce time to treatment
- **Comprehensive Lesion Source Coverage** — Test nasal, ocular, oral and skin lesions in addition to genital/anogenital lesions
- **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 simple implementation across multiple shifts
- **Error-reducing Safeguards** — Internal barcode scanning matches samples to cassettes and may reduce data input errors

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		TOTAL
	POSITIVE	NEGATIVE	
Positive	51	17 ¹	68
Negative	5 ²	274	279
Total	56	291	347
			95% Confidence Interval
Sensitivity	91.1% (51/56)	80.4%-97.0%	
Specificity	94.2% (274/291)	90.8%-96.6%	

¹Thirteen (13) 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. The remaining four (4) false positive specimens were negative for both HSV 1 and HSV 2 by bi-directional sequencing.

²All 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=1,190)

ARIES® HSV 1&2 Assay	REFERENCE METHOD		TOTAL
	POSITIVE	NEGATIVE	
Positive	262	42 ¹	304
Negative	8 ²	878	886
Total	270	920	1,190
			95% Confidence Interval
Sensitivity	97.0% (262/270)	94.2%-98.7%	
Specificity	95.4% (878/920)	93.9%-96.7%	

¹Nineteen (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 bidirectional sequencing. The remaining three (3) specimens were unavailable (QNS) for sequence analysis.

²Seven (7) HSV 1 ARIES® negative specimens that were positive by the reference method were negative by bidirectional 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 bidirectional sequencing.

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

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

¹Thirty-five (35) HSV 2 ARIES® positive specimens that were negative by the reference method were positive by bidirectional 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 bidirectional sequencing.

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

Summary of HSV 2 Results for Mucocutaneous Lesions (N=1,453)

ARIES® HSV 1&2 Assay	REFERENCE METHOD		TOTAL
	POSITIVE	NEGATIVE	
Positive	259	81 ¹	340
Negative	4 ²	1,109	1,113
Total	263	1,190	1,453
			95% Confidence Interval
Sensitivity	98.5% (250/263)	96.2%-99.6%	
Specificity	93.2% (1109/1190)	91.6%-94.6%	

¹Fifty-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.

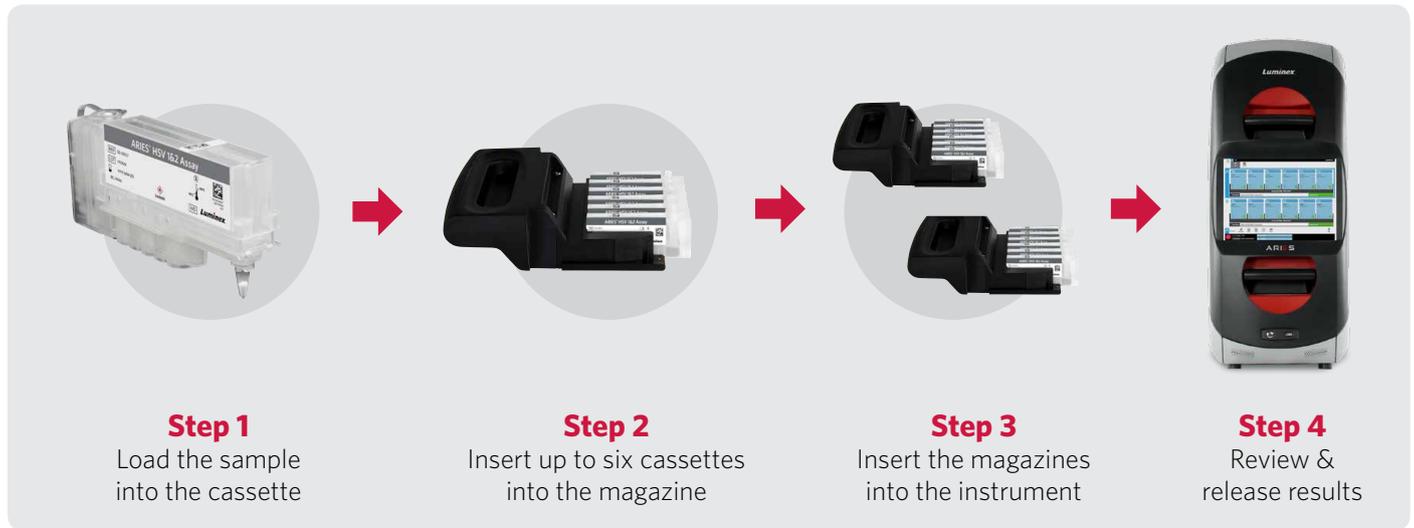
²All four (4) HSV 2 ARIES® negative specimens that were positive by the reference method were negative by bi-directional sequencing analysis using analytically validated primers that targeted genomic regions distinct from ARIES® HSV 1&2 Assay. Three (3) of these specimens were positive for HSV 1 by both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

Usage

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



The operator simply adds the 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
SYNCT™ Software	CN-SW47-01

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