Luminex

ARIES®

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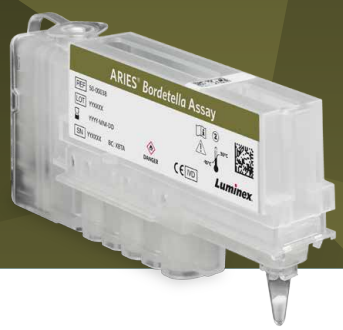
ARIES® *Bordetella* Assay



The ARIES® *Bordetella* Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and identification of *Bordetella pertussis* and *Bordetella parapertussis* nucleic acid in nasopharyngeal swab (NPS) specimens obtained from individuals suspected of having a respiratory tract infection attributable to *B. pertussis* or *B. parapertussis*. Features include:

- **Specific:** Aids in diagnosis and surveillance reporting by identifying patients with *B. pertussis* infection
- **Flexible and Efficient:** Run 1 to 12 tests per batch, utilizing both STAT testing and low to medium sample batching
- **Fully Integrated**: Automate all aspects of testing, from sample preparation through analysis
- **Fast Time to Results:** Answers in less than 2 hours with minimal hands-on time results
- **Error-Reducing Safeguards:** Internal barcode scanning matches samples to cassettes and may reduce data input errors

Performance

The performance of the moderate complexity ARIES® *Bordetella* Assay was assessed at five (5) geographically diverse clinical sites in the United States.

Refer to Package Insert for additional details: Luminex Corporation | ARIES® Bordetella Assay (IVD) Kit Package Insert.

Table 1: ARIES® *Bordetella* Assay Performance for *B. pertussis*

Specimen Description	PPA		95% CI	NPA		95% CI
Prospective	30/32*	93.8%	79.2% - 99.2%	1009/1020	98.9%	98.1% - 99.5%
Pre-selected	37/37	100%	90.5% - 100%	77/77	100%	95.3% - 100%
Total	67/69	97.1%	89.9% - 99.6%	1086/1097	99.0%	98.2% - 99.5%

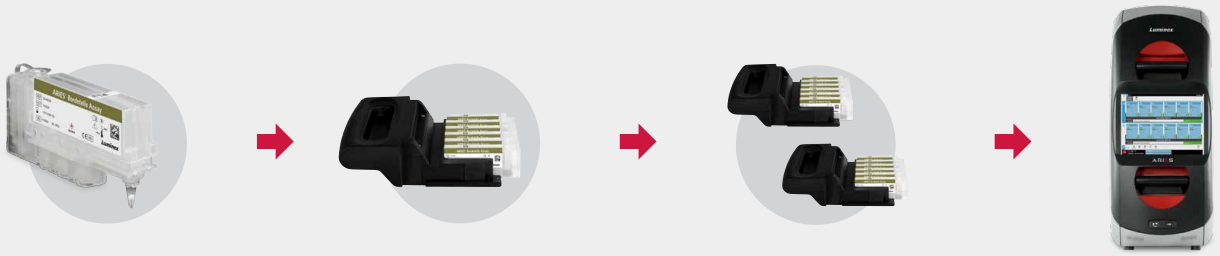
**Two (2) prospective specimens generated false negative results by ARIES® Bordetella Assay when compared to the composite comparator method (02-179 and 06-267).*

Table 2: ARIES® *Bordetella* Assay Performance for *B. parapertussis*

Specimen Description	PPA		95% CI	NPA		95% CI
Prospective	2/2	100%	15.8% - 100%	1048/1050	99.8%	99.3% - 100%
Pre-selected	20/20	100%	83.2% - 100%	93/94*	98.9%	94.2% - 100%
Contrived	50/50	100%	92.9% - 100%	50/50	100%	92.9% - 100%
Total	72/72	100%	95.0% - 100%	1191/1194	99.7%	99.3% - 99.9%

**One (1) pre-selected specimen generated a false positive result by ARIES® Bordetella Assay when compared to the composite comparator method (01-122).*

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.

Usage and Targets

The direct detection and identification of *B. pertussis* and *B. parapertussis* nucleic acids from symptomatic patients aids in the diagnosis of *B. pertussis* and *B. parapertussis* respiratory infection in conjunction with other clinical findings and epidemiological information. Negative results for the ARIES® *Bordetella* Assay do not preclude *B. pertussis* or *B. parapertussis* infection and positive results do not rule out co-infections with other respiratory pathogens. The ARIES® *Bordetella* Assay targets the *B. pertussis* toxin promoter and the *B. parapertussis* IS1001 insertion element in the bacterial genomes. The ARIES® *Bordetella* Assay is indicated for use with ARIES® Systems.

Ordering Information*

Product Name	Part Number
ARIES® *Bordetella* Assay	50-10037 (24 tests)
ARIES® *Bordetella* Assay Protocol File	CN-0388-01 (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

*Products are CE Marked and FDA Cleared 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. Validation of the LIS compatibility must be performed by the end user. ARIES® Systems are class 1(I) laser products.

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