

## Alere Inc

Waltham, Mass  
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## BioFire Diagnostics LLC

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## GenMark Diagnostics Inc

Carlsbad, Calif  
(760) 448-4300  
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1. What is the brand name of your company's molecular diagnostic instrument?	Alere i Strep A	FilmArray: FilmArray Torch, FilmArray 2.0, FilmArray EZ	ePlex
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CLIA waiver, 2015; FDA 510(k), 2015.	FDA 510(k), 2011.	CE mark, 2016; FDA 510(k), 2017.
3. What is the intended use or primary function of the product?	Point-of-care diagnosis of <i>Streptococcus A</i> .	Diagnostic testing.	Intended to perform in vitro diagnostic multiplex nucleic acid tests for the simultaneous qualitative detection and identification of pathogens by processing single-use cartridges developed and manufactured by GenMark Diagnostics.
4. What type of specimen/sample does the product employ?	Throat swab.	Cerebrospinal fluid, nasopharyngeal swab, positive blood culture, stool in Cary Blair medium.	Nasopharyngeal swab.
5. What types of diseases, conditions, or analytes does the system detect?	Strep A.	Blood culture identification; meningitis/encephalitis; gastrointestinal and respiratory infections.	Viral and bacterial nucleic acids associated with respiratory infection; additional panels in development.
6. What platform technologies does the product employ?	Isothermal nucleic acid amplification molecular technology.	Polymerase chain reaction.	Electrowetting, eSensor detection, microarrays, polymerase chain reaction.
7. Under ideal conditions, what is the time to first result; how are the test results made available?	First results in 8 minutes or less; test results are made available via large display screen.	FilmArray requires 2 minutes of hands-on time; results are available in about 1 hour. Respiratory Panel 2 (RP2) results are available in 45 minutes.	Approximately 1.5 hours.
8. What are the product's maximum capacity and throughput under ideal conditions?	The Alere i can store 999 patient test results and 99 quality control test results; memory allows search and retrieval; archiving and exporting are available via USB.	One sample per pouch running unit. The FilmArray platforms offer scalability from one pouch running unit to 12 pouch running units. Run time is 45 to 60 minutes.	Flexible and scalable solution analyzes up to 24 tests per run.
9. Briefly describe any automation or connectivity features or options.	The Alere i platform features visual guides and unidirectional connectivity to the user's network.	Integrated sample preparation, amplification, detection, and analysis; software automatically analyzes the result for each target.	Random access sample-to-answer solution with fully integrated nucleic acid extraction, amplification, and detection; single-use, self-contained cartridge requires no user-added reagents; bidirectional laboratory information system (LIS) interface with result release controls.
10. What types of technical support are available?	Technical support is available online through the Alere website.	24/7 phone technical support; email technical support.	Onsite training, updates, and repair services; 24/7 continuous multilingual telephone and email support; remote support and monitoring.
11. What capabilities, features, or accessories distinguish this product from others on the market?	Delivers molecular results that detect Strep A in 8 minutes or less; CLIA waived; uses isothermal nucleic acid amplification technology, which does not require lengthy or complex thermocycling or DNA purification; delivers polymerase chain reaction-caliber results in a broad range of settings; kit features a compact footprint, intuitive touchscreen, visual guides, and unidirectional connectivity to the user's network.	Designed to be the new standard for syndromic infectious disease molecular diagnostics; integrated sample preparation, amplification, detection, and analysis; delivers accurate results in 45 to 60 minutes.	Streamlines the diagnostic workflow from physician order entry to release of the final report with accurate, actionable test results; intuitive user experience; true sample-to-answer workflow; random, continuous access; data reporting; quality control tracking; modular, scalable design; bidirectional LIS interface.

## Hamilton Robotics

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## Luminex Corp

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## Roche Diagnostics

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VeriSeq NIPT Microlab Star	Aries	Cobas Liat polymerase chain reaction (PCR) system
For in vitro diagnostic use; not FDA cleared; Illumina assay kit is CE marked.	CE mark, 2015; FDA 510(k), 2015.	FDA 510(k), 2014.
Noninvasive prenatal testing (NIPT).	The in vitro diagnostic (IVD) platform performs nucleic acid-based tests in clinical laboratories.	In vitro diagnostic test for detection of influenza A/B virus, respiratory syncytial virus (RSV), and Strep A bacteria.
Maternal whole blood.	Variable depending upon the assay.	Throat swab and 1 mL of Liquid Amies medium for Strep A; nasopharyngeal swab and 3 mL of universal transport media for influenza A/B, and influenza A/B and RSV.
Fetal chromosome abnormalities.	IVD tests are available for <i>Bordetella</i> , <i>C. difficile</i> , Group B <i>Streptococcus</i> , herpes simplex virus 1 and 2, influenza A and B virus, and respiratory syncytial virus.	Influenza A/B, RSV, and Strep A.
Polymerase chain reaction (PCR)-free whole-genome sequencing.	Polymerase chain reaction.	Real-time (RT) PCR.
Up to 96 samples from sample accession to report in approximately 1 day.	Requires minimal upfront sample processing of approximately 5 minutes and less than 2 hours from sample in to result out.	20 minutes for influenza A/B, and influenza A/B and RSV; 15 minutes for Strep A.
48-96 samples per batch, eight individual channels.	Has six channels, and can run up to six samples per module. There are two modules in each instrument for a total of 12 samples per run.	Over 20,000 results can be stored; one assay/test can be run at a time.
The automated next-generation sequencing system is preconfigured and qualified to work with Illumina's NIPT reagents, consumables, and analysis software during plasma isolation, library prep, quantification, and sample pooling.	Aries is fully integrated, and performs nucleic acid extraction, amplification, and analysis on the same instrument.	Roche's Cobas IT 1000 can be used as a data management system; Cobas Liat can connect directly to a laboratory information system via HL7 interface and through other third-party data management systems that offer a driver for the Cobas Liat.
Installation, training, post-installation.	Complete maintenance and field service support is available.	Toll-free customer support number; onsite implementation support as needed; web-based self-serve support.
VeriSeq NIPT Microlab Star is configured and optimized for Illumina's VeriSeq NIPT workflow, and uses a single tube of maternal whole blood drawn as early as 10 weeks gestation; the PCR-free protocol decreases risks of error associated with amplification procedures, reduces time required for sample preparation, and simplifies the workflow.	Sample-to-answer system designed to deliver laboratory performance, increase laboratory efficiency, and fit seamlessly into today's Lean laboratory environment; uses internal barcode scanning and other advanced features to minimize operator errors; two independent magazine modules each support from one to six cassettes, allowing for both stat and batch testing.	The only RT-PCR system CLIA-waived for testing influenza A/B, influenza A/B and RSV, and Strep A in 20 minutes or less; no confirmation of negative results is required; approximately 1 minute of hands-on time and the ability to walk away while test runs.

## UPCOMING TECH GUIDES

Each month, *CLP* invites IVD manufacturers and clinical laboratory suppliers to complete a standardized topic-specific questionnaire highlighting their products.

Below is a preview of topics that will appear in future print issues of *CLP*.

### October

Hematology analyzers

### November-December

Lab and patient safety products

### January/February

Lab and point-of-care glucose monitors

### March

Laboratory software and information technologies

### April/May

Microbiology systems and tools

### June

Anatomic and digital pathology instruments and tools  
Urinalysis assays and instruments

To be considered for inclusion, contact associate editor Elaine Sanchez Wilson at [ewilson@medqor.com](mailto:ewilson@medqor.com).

