

VERIGENE®

Enabling Better Care—Today.



VERIGENE® System

The VERIGENE® System offers automated, cost-effective multiplex capabilities that rapidly and accurately detect infectious pathogens and drug resistance markers, without relying on time-consuming culture methods.

Through delivery of this time-critical information, the VERIGENE System enables faster patient treatment decisions, leading to reduced length of stay, improved patient outcomes, lower costs, optimized antibiotic therapy, and a reduced spread of antibiotic resistance.¹⁻⁴

Multiplex Infectious Disease Testing in an Automated, On-Demand Format

- Tests are performed with a sample-to-answer workflow and can be run on-demand with a scalable throughput.
- Assays for the VERIGENE® System feature <5 minutes of hands-on time and deliver results in approximately 2 hours.
- All tests are IVD Cleared and CE-IVD.

Instrumentation

The VERIGENE® System consists of a VERIGENE Reader and one or multiple VERIGENE Processor SPs. The VERIGENE System's scalability and ease of use make it a valuable platform for both hospital-based and reference laboratories, regardless of size and testing demands.

The VERIGENE® Processor SP combines automated nucleic acid extraction, purification, amplification, and hybridization in each module. Users can run VERIGENE assays ondemand—without the need for batch processing, specially trained personnel, or specialized facilities.

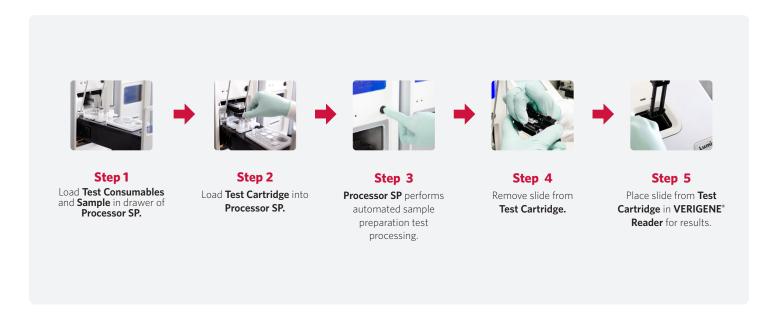


VERIGENE® Processor SP VERIGENE® Reader The VERIGENE* Reader manages sample information, reads results, and allows for result printing, internal

data storage, and LIS connectivity—without the use of an external PC.

Workflow

The workflow for the VERIGENE® System takes less than five minutes of hands-on time, and delivers results in approximately two hours.



Test Cartridges

Each VERIGENE® Test Cartridge is designed for multiplex analysis of one patient sample using nanogrid technology, which provides a versatile and extremely reliable foundation for the VERIGENE System's menu of infectious disease tests. The VERIGENE Test Cartridge is a single-use, self-contained test unit comprised of two components:

- Reagent Pack A microfluidic cassette that contains all the hybridization reagents needed for a single test.
- **2. Substrate Holder** Contains a glass slide that serves as a solid support for the microarray used to capture targeted nucleic acids.



Syndromic Testing

Using a syndromic approach enables you to test for a broad range of pathogens in a single sample. The simultaneous identification of pathogens and antimicrobial resistance markers helps accelerate treatment decisions, which leads to improved patient outcomes.

Bloodstream Infections

VERIGENE® Gram-Positive Blood Culture Test (BC-GP)

The VERIGENE BC-GP Test can aid in the diagnosis of 15 bacterial bloodstream infections and the identification of 3 resistance markers, but is not intended to be used to monitor the status of infection.



VERIGENE® Gram-Negative Blood Culture Test (BC-GN)

The VERIGENE BC-GN can aid in the diagnosis of 14 bacterial bloodstream infections and the identification of 6 resistance markers, but is not intended to be used to monitor the status of infection.



Gastrointestinal Tract Infections

VERIGENE® Enteric Pathogens Test (EP)

The VERIGENE EP Test can detect 9 of the most common bacterial and viral targets from liquid or soft stool preserved in Cary-Blair media.



Flex® Testing

Flex* Testing enables labs to test for a broad menu of infectious disease targets in a single cartridge **while paying only for selected results**. Coupled with the ability to reveal additional results on-demand when necessary, Flex Testing gives labs and clinicians the freedom to provide patient-specific testing based on symptoms, history, and clinical guidelines.

Respiratory Tract Infections

VERIGENE® Respiratory Pathogens *Flex* Test (RP *Flex*)

The VERIGENE RP Flex Test (RP Flex) is a multiplex, qualitative test that detects 16 viral and bacterial nucleic acids in nasopharyngeal swab (NPS) samples.





Ordering Information

Product Name	Part Number
Assays	
VERIGENE® Respiratory Pathogens Flex Test Kit	20-005-024
VERIGENE® Respiratory Pathogens Flex Amplification Reagent Kit	20-012-024
VERIGENE® Gram-Positive Blood Culture (Nucleic Acid Test Kit)	20-005-018
VERIGENE® Gram-Positive Blood Culture Test Utility Reagent Kit	20-012-018
VERIGENE® Gram-Negative Blood Culture Nucleic Acid Test Kit	20-005-021
VERIGENE® Gram-Negative Nucleic Acid Utility Reagent Kit	20-012-021
VERIGENE® Enteric Pathogens Nucleic Acid Test Kit	20-005-023
VERIGENE® Enteric Pathogens Nucleic Acid Test Amplification Kit	20-012-023
System	
VERIGENE® Processor SP	10-0000-07
VERIGENE® Reader	10-0000-02

REFERENCES

- 1. Beckman M, Washam M, DeBurger B, et al. Reliability of the Verigene system for the identification for Gram-positive Bacteria and detection of antimicrobial resistance markers from children with bacteremia. Diagn Microbiol Infect Dis. 2019;93(3):191-195. doi:10.1016/j.diagmicrobio.2018.10.005.
- 2. Binnicker MJ. Multiplex molecular panels for diagnosis of gastrointestinal infection: performance, result interpretation, and cost-effectiveness in positive blood cultures. J Clin Microbiol. 2015. 53:3723–3728. doi:10.1128/JCM.02103-15.
- 3. Walker T, Dumadag S, Lee C, et al. 2016. Clinical impact of laboratory implementation of Verigene BC-GN microarray-based assay for detection of Gram-negative bacteria in positive blood cultures. J Clin Microbiol 54:1789–1796. doi:10.1128/JCM.00376-16.
- **4.** Felsenstein S, Bender J, Sposto R, et al. Impact of a Rapid Blood Culture Assay for Gram-Positive Identification and Detection of Resistance Markers in a Pediatric Hospital. Arch Pathol Lab Med. 2016;140(3):267-275. doi:10.5858/arpa.2015-0119-OA.



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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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