Luminex®

VERIGENE®

System

Enabling Better Care. Today.

The VERIGENE® System enables clinicians to rapidly identify and treat the bacteria and viruses responsible for some of the most complex, costly, and deadly infectious diseases.

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

The VERIGENE® System is a simple to use, highly accurate multiplex *in vitro* diagnostic platform that rapidly detects infectious pathogens and drug resistance markers, enabling clinicians to deliver timely and targeted therapy for some of the most complex, costly, and deadly infectious diseases.

Through delivery of this time-critical information, VERIGENE is powering faster patient treatment decisions in top healthcare centers, leading to reduced length of stay, improved patient outcomes, lower costs, optimized antibiotic therapy and reduced spread of antibiotic resistance.[1-5]

- **Instrumentation:** VERIGENE Reader and Processor *SP*
- **Automation:** Sample to Result
- **Workflow:** On-Demand and Scalable
- **Regulatory Status:** FDA Cleared*/CE-IVD
- **CLIA Complexity:** Moderate*
- **Assay Controls:** On-Board
- **Hands-On Time:** <5 Minutes (One Pipetting Step)
- **Run Time:** 2 – 2.5 Hours

* When used with specific FDA Cleared VERIGENE tests

Sample to Result Workflow

Step 1

Load Test Cartridge, test consumables, and sample into Processor *SP*

Step 2

Automated sample preparation and test processing in Processor *SP*

Step 3

Place slide from Test Cartridge in VERIGENE® Reader for results

VERIGENE® Instrumentation

VERIGENE System instrumentation consists of a VERIGENE Reader and one or multiple VERIGENE Processor *SP*s.

The VERIGENE Processor *SP* is a modular, easy to use benchtop analyzer that combines automated nucleic acid extraction, purification, amplification (if required), and hybridization in each module. These advanced capabilities allow users to run VERIGENE assays on-demand in response to testing needs, without the need for batch processing, specially trained personnel, or specialized facilities.

The VERIGENE Reader manages sample information, reads results from processed cartridges, and allows for results printing, internal data storage, and laboratory information system (LIS) connectivity without the use of an external PC.

VERIGENE's scalability and ease of use make it a valuable system for use in both hospital-based and reference laboratories, regardless of size and testing demands.

NanoGrid Technology

The VERIGENE System utilizes advanced automation and proprietary chemistry to enable rapid direct detection of nucleic acids and high-sensitivity protein detection on the same platform. Nanosphere's unique gold nanoparticle probe technology is the driving force behind all VERIGENE tests, providing a versatile and extremely reliable foundation for the VERIGENE System's growing menu of infectious disease tests.

VERIGENE® Infectious Disease Test Menu	FDA Cleared	CE-IVD
Bloodstream Infections		
VERIGENE® Gram-Positive Blood Culture Test Identification and antibiotic resistance determination for a broad panel of gram-positive bacteria directly from positive blood culture bottles	✓	✓
VERIGENE® Gram-Negative Blood Culture Test Identification and antibiotic resistance determination for a broad panel of gram-negative bacteria directly from positive blood culture bottles	✓	✓
Respiratory Tract Infections		
VERIGENE® Respiratory Pathogens *Flex* Test Identification of a broad panel of viruses and bacteria commonly responsible for respiratory infections from nasopharyngeal swabs (NPS)	✓	✓
Gastrointestinal Tract Infections		
VERIGENE® *C. difficile* Test Identification of toxin-producing *C. difficile* and differentiation of the hypervirulent strain from unformed (liquid or soft) stool specimens	✓	✓
VERIGENE® Enteric Pathogens Test Identification of a broad panel of common pathogenic enteric bacteria, viruses and genetic virulence markers from stool sample liquid or soft stool preserved in Cary-Blair medium	✓	✓

References

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2. Buchan BW, Ginocchio CC, Manii R, et. al. Multiplex identification of gram-positive bacteria and resistance determinants directly from positive blood culture broths: Evaluation of an automated microarray-based nucleic acid test. PLoS Medicine 2013;10(7): e1001478.
3. Wojewoda CM, Sercia L, Navas M, et. al. Evaluation of the VERIGENE gram-positive blood culture nucleic acid test for rapid detection of bacteria and resistance determinants. J Clin Microbiol 2013;51(4): 1188-92.
4. Alby K, Daniels LM, Weber DJ, Miller MB. Development of a treatment algorithm for streptococci and enterococci from positive blood cultures identified with the VERIGENE Gram-Positive Blood Culture Assay. J Clin Microbiol 2013;51(11): 3869-71.
5. Mancini N, Infurnari L, Ghidoli N, et. al. Potential impact of a microarray-based nucleic acid assay for rapid detection of gram-negative bacteria and resistance markers in positive blood cultures. J Clin Microbiol 2014;52(4). 1242-5.

Luminex®
complexity simplified.

For ordering, please contact: customerorders@nanosphere.us

For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions. Please contact us at **info@nanosphere.us** or **1-888-837-4436** to obtain the appropriate product information for your country of residence.

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