Luminex®

VERIGENE®

The VERIGENE® System | Enabling Better Care. Today.

VERIGENE® *Clostridium difficile* Nucleic Acid Test (CDF)

The VERIGENE® *Clostridium difficile* Nucleic Acid Test (CDF) is a qualitative multiplexed in vitro diagnostic test for the rapid detection of toxin A (*tcdA*), toxin B (*tcdB*), and *tcdC* gene sequences of toxigenic *Clostridium difficile* and for presumptive identification of PCR ribotype 027 strains from unformed (liquid or soft) stool specimens.

By simultaneously targeting both the toxin A and toxin B genes and differentiating the 027 strain, VERIGENE CDF delivers comprehensive results directly from a stool sample in less than 2 hours, while requiring less than 5 minutes of user hands-on time. Features include:

- Automation with a sample to result system
- An on-demand and scalable workflow
- Ease of use with only one pipetting step

The test is performed on the VERIGENE System.

> "*C. difficile* infection is a major medical and infection control problem in many health care facilities... Accurate and timely diagnosis is necessary both for appropriate clinical management of the patient and for the timely implementation of infection control and pharmacy measures."
>
> Pancholi P, Kelly C, Raczkowski M, Balada-Llasat JM.[1]

VERIGENE® CDF
Targets
Toxin A (*tcdA* gene)
Toxin B (*tcdB* gene)
PCR Ribotype 027 hypervirulent strain*

** For epidemiologic purposes only*

Performance

VERIGENE CDF Test vs. Direct Culture & PCR Ribotyping[2,3]

Toxigenic *C. difficile*	Toxigenic *C. difficile*/027*
n=1869	
Sensitivity 98.7% (154/156) (95.5%-99.8%)	**Pos Agreement** 97.5% (39/40) (86.8%-99.9%)
Specificity 87.6% (1500/1713) (85.9%-89.1%)	**Neg Agreement** 97.8% (1787/1828) (97.0%-98.4%)

** For epidemiologic purposes only*

VERIGENE CDF Test vs. Enriched Culture & PCR Ribotyping[2,3]

Toxigenic *C. difficile*	Toxigenic *C. difficile*/027*
n=1869	
Sensitivity 91.8% (247/269) (87.9%-94.8%)	**Pos Agreement** 91.4% (53/58) (81.0%-97.1%)
Specificity 92.5% (1480/1600) (91.1%-93.7%)	**Neg Agreement** 98.5% (1783/1811) (97.8%-99.0%)

Usage

The CDF test is indicated for use as an aid in the diagnosis of *C. difficile* infections. Detection of PCR ribotype 027 strains of *C. difficile* by the CDF test is solely for epidemiological purposes and is not intended to guide or monitor treatment for *C. difficile* infections. Concomitant culture is necessary only if further typing or organism recovery is required.

Ordering Information

Product Name	Part Number
VERIGENE® *Clostridium difficile* Nucleic Acid Test (CDF) Kit Includes: 20 CDF Test Cartridges 20 Extraction Trays 20 Stool Preparation Sample Kits	20-005-022
VERIGENE® *Clostridium difficile* Nucleic Acid (CDF) Amplification Reagent Kit Includes: 20 CDF Amplification Trays	20-012-022

References

1. Pancholi P, Kelly C, Raczkowski M, Balada-Llasat JM. Detection of toxigenic *Clostridium difficile*: comparison of the cell culture neutralization, Xpert *C. difficile*, Xpert *C. difficile*/Epi, and Illumigene *C. difficile* assays. J Clin Microbiol 2012;50:1331-1335.
2. Of the 1875 specimens evaluated, 6 specimens were culture positive but were not PCR-ribotyped because the isolate was either not sent or the result was inconclusive. These 6 specimens were not included in the performance characteristics above.
3. VERIGENE *Clostridium difficile* Nucleic Acid Test (CDF) Package Insert (89-30000-00-793).

Luminex®
complexity simplified.

orders@luminexcorp.com or support@luminexcorp.com

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.

www.luminexcorp.com/CDF

HEADQUARTERS
UNITED STATES
+1 512 219 8020
info@luminexcorp.com

EUROPE
+31 73 800 1900
europe@luminexcorp.com

CANADA
+1 416 593 4323
info@luminexcorp.com

CHINA
+86 21 8036 9888
infocn@luminexcorp.com

JAPAN
+81 3 5545 7440
infojp@luminexcorp.com

SS285531