

C. difficile - The Urgent Threat

C. difficile is the most commonly recognized cause of infectious diarrhea in healthcare settings and the US burden of *Clostridium difficile* infection (CDI) is close to 500,000 infections annually¹

Revogene provides healthcare systems an opportunity to minimize the overall burden of *C. difficile* through improved care and efficiency.

- · Reduce the risk of missing a true positive with the accuracy of molecular
- Fast, actionable results enable physicians to make informed decisions about patient management and treatment resulting in reduced healthcare costs associated with isolation and antibiotics.
- Revogene is a flexible, reliable molecular platform that allows health systems to provide testing closer to the patient and advance the quality of care through simplified sample processing and efficient workflows

Your lab can improve outcomes for patients suspected of having CDI.

- What steps is your facility taking to minimize the burden of C. difficile?
- How would a rapid, easy-to-use molecular platform with just 3 steps help you improve outcomes and satisfaction among patients and physicians?



revogene

C. difficile

Total Trusted Solution

- Revogene is a flexible molecular platform that can help standardize testing throughout a health system improving clinical efficiencies
- Revogene's small footprint enables networks to place instruments everywhere from the central laboratory to near-patient testing facilities allowing clinicians to make treatment decisions quickly and provide optimal patient care

Improve Efficiency, Deliver Standardization

- Improve overall lab efficiency with Revogene's simplified sample prep and 2 minutes hands-on-time
- Molecular accuracy using real-time PCR technology allows laboratories to deliver actionable results for improved decision making and appropriate management of patients suspected of having a CDI

Revogene *C. difficile* Procedure Steps

Sample to Result in 3 Steps Less than 2 minutes hands on time





Liquid/soft stool

Disposable Transfer Loop

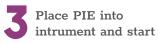






Load Sample into the PIE





Product Specifications

Intended Use

The Revogene® C. difficile assay is a simple and direct, qualitative in vitro diagnostic test to detect the toxin B (tcdB) gene of C. difficile in liquid or soft stool specimens from patients suspected of having a C. difficile infection (CDI).

Turnaround Time

< 70 minutes

Sample Type

Unformed (liquid or soft) stool specimens

Sample Storage

- Stool specimens: 25°C for up to 2 days; 2-8°C for up to 4 days
- Inoculated SBT: 25°C for up to 2 days; 2-8°C for up to 3 days

Kit Storage

24 individual pouches

Store at $2^{\circ}-25^{\circ}$ C until expiration date indicated on kit label and on each pouch

Performance*

*Compared to direct culture with fresh stool specimens.

Sensitivity 93% Specificity

Catalog Number

CPT Codes

Revogene C. difficile — 410300

87493

References

 L Clifford McDonald, Dale N Gerding, Stuart Johnson, Johan S Bakken, Karen C Carroll, Susan E Coffin, Erik R Dubberke, Kevin W Garey, Carolyn V Gould, Ciaran Kelly, Vivian Loo, Julia Shaklee Sammons, Thomas J Sandora, Mark H Wilcox; Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), Clinical Infectious Diseases, Volume 66, Issue 7, 19 March 2018, Pages el—e48, https://doi.org/10.1093/cid/cix1085

Ready to get a handle on *C. difficile* testing? Let's talk.

Contact a specialist at 1-888-763-6769. meridianbioscience.com/contact-us

