DiaSource

Clostridium difficile GDH + Toxin A and B Combo Rapid Test

Overview Clostridium difficile

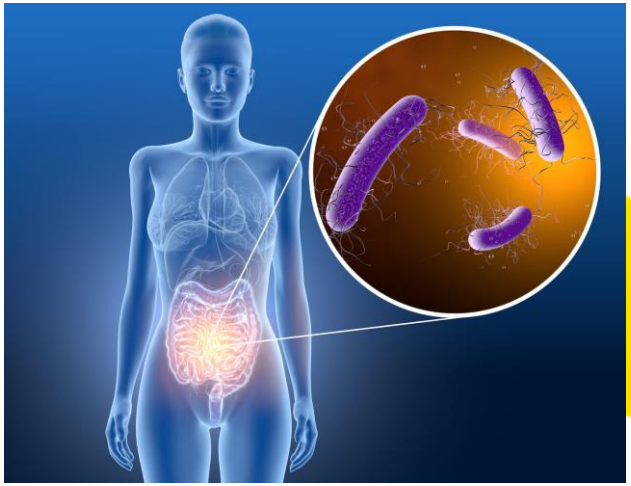
Clostridium difficile (C. difficile) is a Gram-positive, spore-forming anaerobic bacterium that is a leading cause of healthcare-associated infections, particularly antibiotic-associated diarrhea and colitis.
C. difficile are bacteria which can be present as part of the ‘normal’ bacteria in the large bowel of up to 5% of healthy adults.

It is transmitted primarily via the fecal-oral route, through ingestion of spores that can persist on surfaces, hands, or medical equipment for long periods due to their resistance to standard disinfectants.

GDH is the abbreviation for ‘Glutamate Dehydrogenase antigen’. This antigen is a substance which can be found in liquid stool (diarrhoea).

Once in the gut, especially after disruption of the normal intestinal microbiota by antibiotics, C. difficile can proliferate and produce two potent toxins: **Toxin A (an enterotoxin) and Toxin B (a cytotoxin).**

These toxins damage the intestinal epithelial cells, leading to inflammation, diarrhea, and in severe cases, pseudomembranous colitis.
Toxin B is now recognized as the more critical factor in disease severity, although both toxins play significant roles in pathogenesis.



European Centre for Disease Prevention and Control (ECDC) and World Health Organization (WHO)

Epidemiology Clostridium difficile

C. difficile infection (CDI) is a growing global public health concern.

In Europe, it is estimated that over 124,000 cases of CDI occur annually in acute care hospitals, with approximately 3,700 deaths directly attributable to CDI, according to the ECDC (2023).

Worldwide, CDI contributes to millions of cases and thousands of deaths annually, placing a heavy burden on healthcare systems.
The spread of hypervirulent strains, such as ribotype 027, has been linked to more severe outbreaks.
While historically confined to hospitals and long-term care facilities, CDI is increasingly reported in community settings as well, sometimes in younger individuals with no prior antibiotic exposure.

Common symptoms include watery diarrhea (≥3 loose stools in 24 hours), abdominal pain or cramping, low-grade fever, nausea, and loss of appetite.

In more serious cases, patients can develop pseudomembranous colitis, toxic megacolon, bowel perforation, or sepsis, which may require intensive care or surgical intervention.

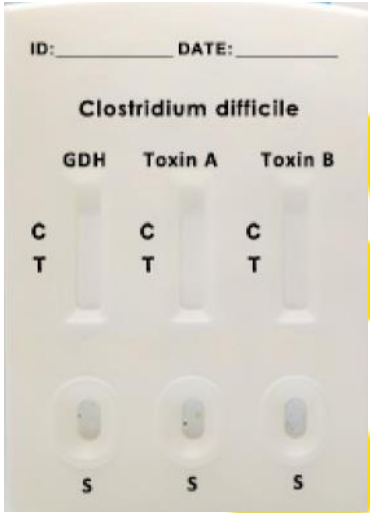
Why use combo rapid test for Clostridium difficile ?

The reason for using a combo rapid test for Clostridium difficile and its Toxins A & B is to enable fast and accurate identification of both the presence of the bacteria and its disease-causing toxins, helping clinicians confirm active infection rather than mere colonization.
Early and accurate diagnosis is critical to initiating appropriate treatment, reducing the risk of severe complications such as pseudomembranous colitis, and limiting nosocomial transmission.

Dual Detection: This combo test detects both C. difficile antigen (such as GDH) and the specific toxins A and B, offering a more complete diagnostic picture in one test—helping distinguish between colonization and active infection.

Quick Diagnosis: Results are available within minutes, facilitating timely clinical decisions in both inpatient and outpatient settings.

Point-of-Care Testing: Designed for use at the bedside, in emergency rooms, or outpatient facilities—no need for laboratory culture or ELISA platforms, which are time-consuming and resource-intensive.



Why use combo rapid test for Clostridium difficile ?

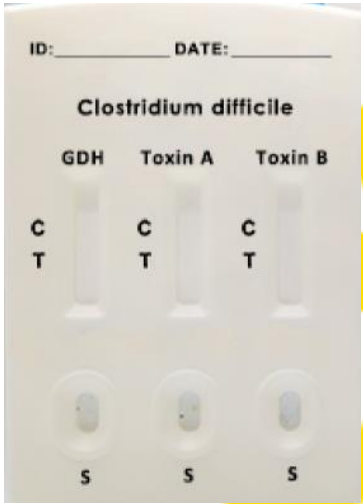
Non-invasive: Uses a stool sample, which is routinely collected for gastrointestinal diagnostics—no need for blood draws or invasive procedures.

High Specificity and Clinical Relevance: By detecting both the organism and its toxins, this test increases diagnostic accuracy and helps avoid over-treatment or under-treatment.

Differentiating Causes of Diarrhea: C. difficile infection can mimic other causes of antibiotic-associated or hospital-acquired diarrhea. This test helps clinicians confidently identify C. difficile as the source, ensuring appropriate isolation and therapy.

Cost-Effective: Reduces reliance on multiple tests or confirmatory procedures, saving time, resources, and laboratory costs—especially important in high-throughput hospital environments.

Infection Control Impact: Rapid identification supports early implementation of infection control measures to prevent healthcare-associated outbreaks and protect vulnerable patients.



Clostridium difficile GDH + Toxin A and B combo

Article code	#RAPAD635	#RAPAG602
Reading	**Visual** reading	**Visual** reading
Detection type	Qualitative detection of Clostridium difficile GDH, Toxin A and Toxin B antigens	Qualitative detection of Clostridium difficile GDH
Regulatory status	CE-IVD	CE-IVD
Specimen type	Feces	Feces
Reading time	10 minutes	10 minutes
Number of Tests per kit	10 tests	10 tests
Storage temperature	2-30°C	2-30°C
Shipping temperature	Ambient temperature	Ambient temperature
Sensitivity	95.1%(GDH) / 94.3%(Toxin A) / 91.8%(Toxin B)	95.1%
Specificity	95.5%(GDH) / 97.2%(Toxin A) / 96.6%(Toxin B)	95.5%

Clostridium difficile GDH + Toxin A and B combo