

GenomEra[®] *C. difficile* Assay Kit

Enabling 1-step algorithm to reliably
detect toxigenic *C. difficile*





Why choose our test?

The GenomEra® *C. difficile* Assay Kit offers a rapid and simple high-performance molecular assay as an aid in diagnosing *Clostridioides difficile* infection from liquid or unformed stool samples in less than one hour.

Key benefits of the test

- Fast results: four results in 50 minutes
- Short hands-on time: less than 5 min for 4 samples
- Easy to use system with pre-loaded and sealed GenomEra® Test Chips
- Provides a solution for 1-step algorithm to simplify *C.difficile* testing

Toxin producing *C. difficile* is a gram-positive, anaerobic, spore-forming bacterium. It is the most severe cause of antibiotic-associated diarrhea and the most common cause of pseudomembranous colitis. The GenomEra *C. difficile* Assay Kit enables reliable detection of the *tcdB* gene, which is considered as the major virulence factor of toxigenic *C. difficile*.

Key facts

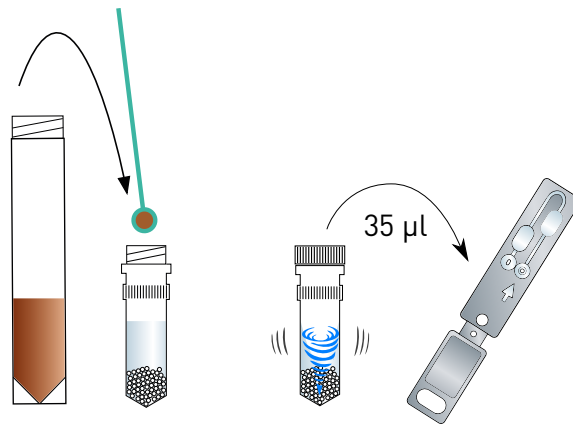
- A rapid molecular test for detecting the toxin B gene (*tcdB*) of *Clostridioides difficile* bacteria from stool samples in less than one hour
- Simple, cost-effective, and reliable test for improved patient outcomes
- High-performance results with automated result interpretation
- Can be run at the same time with other tests that utilise the end-point PCR (50 min)

Assay principle

The GenomEra *C. difficile* Assay Kit is a rapid and easy-to-use end-point PCR test for the qualitative detection of *C. difficile* tcdB gene, ensuring comprehensive coverage of the virulent *C. difficile* strains.

The test is performed directly from liquid or unformed stool specimens with very short and easy sample preparation and no need for DNA extraction. Molecular detection allows a significantly faster outcome compared to conventional methods, yielding automated test results on the GenomEra® Software in just 50 minutes.

Test procedure



Picture 1. Dip a 1 µL loop to liquid stool sample or a 10 µL loop to FecalSwab stool suspension using a single-use loop. Shake the sample into the GenomEra Z-tube. Rub the loop against the beads/tube walls. Shake the tube for 5 min at full speed. Pipette 35 µL of the prepared sample per Test Chip.

Clinical performance

The clinical performance of the GenomEra *C. difficile* Assay Kit was evaluated on 322 unpreserved stool samples (65 fresh, 257 frozen) at three study centers—two in Finland and one in the Netherlands. The reference methods used in the evaluation were toxigenic culture and toxin A & B enzyme immunoassay.

Sample size	Sensitivity (% , n)	Specificity (% , n)	PPV (%)	NPA, %
n = 322	99.0 (97/98)	99.1 (222/224)	98.0	99.6

Table 1. GenomEra® *C. difficile* Assay Kit proved highly sensitive and specific in clinical use. PPV, positive predictive value; NPV, negative predictive value.



Ordering information

To place an order, please contact your local distributor at uniogen.com/distributors/

Product name	Product code
GenomEra <i>C. difficile</i> Assay Kit, 20 tests	CDX-40-01-20
GenomEra <i>C. difficile</i> Assay Kit, 40 tests	CDX-40-01-40
GenomEra <i>C. difficile</i> Assay Kit with loops, 40 tests	CDX-40-02-40
GenomEra CDX System	CDX-10-020

Manufacturer

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Distributor



GenomEra® products carry the Finnish Key Flag Symbol, a valued and trusted symbol of Finnish origin.

The test is CE marked in accordance with the IVD directive. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability. GenomEra is a registered trademark of Uniogen Oy.

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