MICROGEN
BIOPRODUCTS

PathFlow™

CLOSTRIDIUM DIFFICILE GDH AND TOXIN A/B

The PathFlow™ *C. difficile* GDH and Tox A/B Combi Cassette is a rapid chromatographic immunoassay for the qualitative detection of *Clostridium difficile* Glutamate Dehydrogenase (GDH), Toxin A and Toxin B in the human faecal specimen.

What is the Test?

- The PathFlow™ *C. difficile* GDH & Tox A/B Combi Cassette simultaneously detects three distinct antigens in faecal specimens for *C. difficile*; GDH, Toxin A and Toxin B.

What is the Disease?

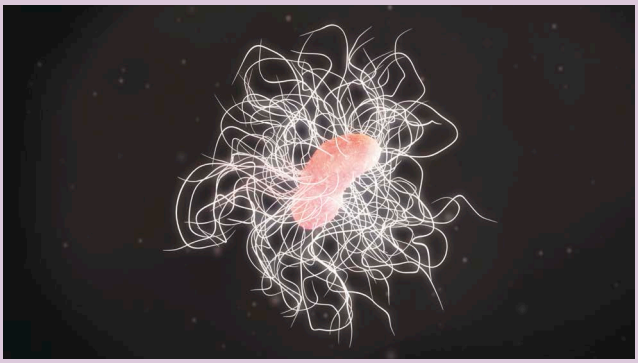
- *Clostridium difficile* is an opportunistic anaerobic bacterium that can grow in the intestine once normal flora has been altered by antibiotics.
- Toxigenic strains of *C. difficile* can cause infection (*Clostridium difficile* infection – CDI) through the production of two toxins; Toxin A (tissue-damaging enterotoxin) and/or Toxin B (cytotoxin).

Symptoms

- CDI can present as a spectrum of symptoms; ranging from asymptomatic carriage or mild diarrhoea, to potentially life-threatening pseudomembranous colitis.

Mortality/Morbidity – Clinical Implications

- The organism is spread via oral-faecal route, acquired from infected individuals both directly and indirectly.



- Due to its contagious abilities *C. difficile* poses a real threat to healthcare environments (large concentration of at-risk individuals – immunocompromised/undertaking antibiotic treatment), so rapid detection is paramount to prevent spread.

Why use PathFlow™

- The PathFlow™ *C. difficile* GDH and Tox A/B Combi Cassette allows for the rapid and accurate detection of *C. difficile,* with test results available after 10 minutes.
- The ability to conduct simultaneous GDH/Tox A&B testing coupled with rapid provision of results allows for *Clostridium difficile* infections to be managed more effectively.

- **Complete system, no additional reagents required and provides concurrent detection.**
- **Simple and easy to use.**
- **Rapid result offered. Available after 10 minutes or within 10-20 minutes.**
- **Can be used for both solid and liquid specimens.**
- **In-built procedural control.**
- **Ability to rapidly identify *C. difficile* is key for patient care.**

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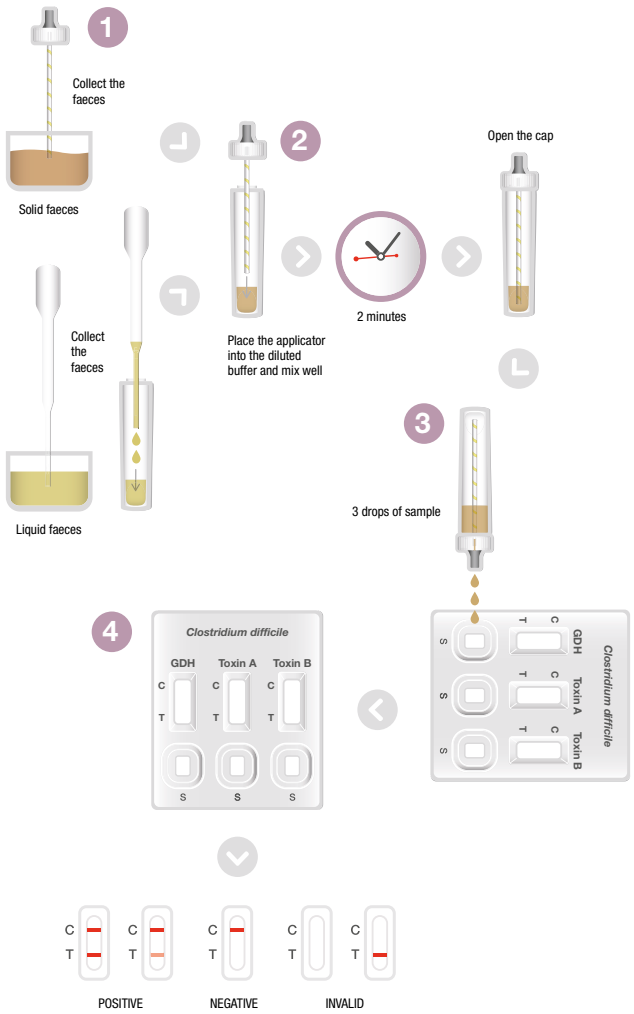
Procedure



Step 1. Collect the faecal specimen; the assay will produce optimum results if performed 6 hours within collection.
Step 2. Solid Specimens – Unscrew the cap of the specimen collection tube and collect approximately 50mg of faeces. Liquid Specimens – Hold the dropper vertically, aspirate faecal specimens and then transfer 2 drops of liquid specimen (approximately 80µl) into specimen collection tube. Tighten cap on collection tube, then mix vigorously and leave for 2 minutes. Bring the pouch up to room temperature, remove test cassette from the foil pouch and use it ASAP.
Step 3. Hold the specimen collection tube upright and unscrew the cap. Invert the tube and transfer 3 full drops of specimen to each well on the testing cassette.
Step 4. Read the result after 10 minutes, do not read after 20 minutes.

Performance – Tested vs. another leading commercial rapid test

GDH
Sensitivity – 98.7%
Specificity – 98.3%
Accuracy – 98.5%
Tox A&B
Sensitivity – 98.2%
Specificity – 98.6%
Accuracy – 98.5%

Ordering Information

Code – M588CE
Description – PathFlow™ *C. difficile* GDH and Tox A/B Combi
Size – 25 Test Kits
Storage – 2°C-30°C

Distributed by:

MICROGEN BIOPRODUCTS

PathFlow™ - *Leading The Way to a Better Diagnosis*

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