

## CoproStrip *C. difficile* Positive Control Set

**REF: 41220-10**



### INTENDED USE

Savyon's CoproStrip *C. difficile* Positive Control Set (Cat#41220-10) is an external quality control set for the CoproStrip *C. difficile* GDH + Toxin A + Toxin test (Cat# 41220). The test is intended for the simultaneous qualitative detection of *Clostridium difficile* Glutamate Dehydrogenase (GDH), Toxin A and Toxin B in human faeces that aids in the diagnosis of *C. difficile* infection.

### PRINCIPLE

The CoproStrip *C. difficile* Positive Control Set is composed of 3 bottles; each contains antigen extract solution for testing in respect to the test strip:

1. PC GDH (Cat#41220-21)
2. PC Toxin A (Cat#41220-22)
3. PC Toxin B (Cat#41220-23)

### PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- Only use with Savyon CoproStrip *C. difficile* GDH + Toxin A + Toxin test (Cat# 41220).
- The set of bottles should remain closed until use.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The bottles should be discarded in a proper biohazard container after testing.

### STORAGE AND STABILITY

Store the CoproStrip *C. difficile* Positive Control Set solution bottles at refrigerated temperature (2- 8°C). The CoproStrip *C. difficile* Positive Control Set is stable through the expiration date printed on the box label. Do not freeze.

### MATERIALS PROVIDED

Savyon's CoproStrip *C. difficile* Positive Control set contains:

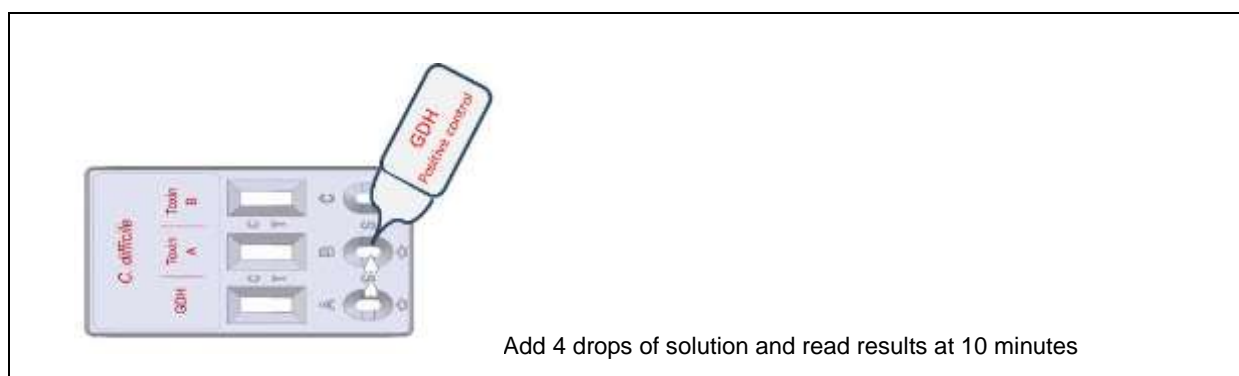
1. 4 ml solution of *C. difficile* GDH antigen
2. 4 ml solution of *C. difficile* Toxin A antigen
3. 4 ml solution of *C. difficile* Toxin B antigen

### PROCEDURE

**Allow the positive control set bottles to reach to room temperature (15-30°C) prior to testing. Do not open the test pouch until ready to perform the assay.**

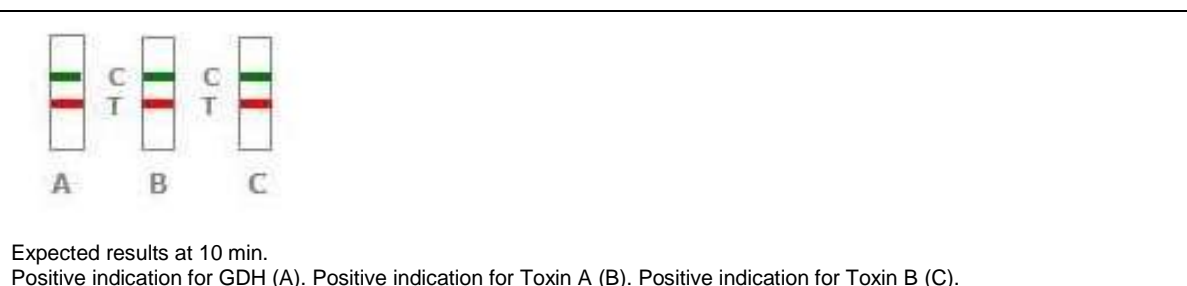
Remove the CoproStrip *C. difficile* GDH + Toxin A + Toxin test device (Cat# 41220) from the pouch and place it on the worktable. Shake the tested Positive control bottles for several seconds prior to testing. Add the CoproStrip *C. difficile* Positive Control solution (**exactly 4 drops**) into the testing hole carefully (see illustration 1) in respect to the tested strip (e.g., GDH antigen solution into the GDH strip hole and etc...). Ensure the normal flow of the liquids along the test. Read results at 10 minutes (see illustration 2).

### Illustration 1



## INTERPRETATION OF RESULTS

### Illustration 2



**GDH POSITIVE CONTROL:** See Figure A in illustration 2.

Two lines appear on the test strip. A **red** test line marked in the illustration with the letter T in the test zone and a **green** control line (marked in the illustration with the letter C in the control zone).

**Toxin A POSITIVE CONTROL:** See Figure B in illustration 2.

Two lines appear on the test strip. A **red** test line marked in the illustration with the letter T in the test zone and a **green** control line (marked in the illustration with the letter C in the control zone).









**Toxin B POSITIVE CONTROL:** See Figure C in illustration 2.

Two lines appear on the test strip. A **red** test line marked in the illustration with the letter T in the test zone and a **green** control line (marked in the illustration with the letter C in the control zone).

**INVALID:** A total absence of the green control line regardless the appearance or not of the red test line in each strip.

**Note:** Incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control positive failure or variations. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

The intensity of the red /green lines can vary between different runs of the same test strip.

Symbols for IVD components and Reagents			
	Manufacturer		For <i>in vitro</i> diagnostic use only
	Authorized representative		Consult instructions for use
	Catalogue Code		Temperature limitation
	Lot Number		Use by

CE

EU REP

**European Authorized Representative:**

**MedNet EC-REP GmbH**

Borkstrasse 10,

48163 Muenster, Germany



**Savyon® Diagnostics Ltd.**

3 Habosem St. Ashdod 7761003

ISRAEL

Tel.: +972.8.8562920

Fax: +972.8.8523176

E-mail: [support@savyondiagnostics.com](mailto:support@savyondiagnostics.com)