PRODUCT LAUNCH

PROFLOW™

C.difficile Toxin A/B LATERAL FLOW KIT

Rapid, Simple, Inexpensive.

The latest offering from Pro-Lab Diagnostics to aid laboratory diagnosis of *Clostridium difficile.*

PRO-LAB DIAGNOSTICS

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Pro-Lab Diagnostics is pleased to introduce...

A new lateral flow test for the detection of C.difficile Toxin A/B direct from stool samples using a simple test procedure and providing results in 15 minutes!

Clostridium difficile has gained notoriety as a "hospital super-bug" at the fore of public awareness. *Clostridium difficile* is a Gram-positive, anaerobic, spore-forming bacilli that causes severe diarrhoea and other intestinal disease and is a major nosocomial pathogen resulting in high rates of morbidity and mortality. It is the most serious cause of antibiotic associated diarrhoea (AAD) and has been associated with a range of symptoms. This has led to strict monitoring and controls on infection rates for hospital trusts, which in turn has added importance to the need for accurate diagnosis of infection and effectiveness of infection control measures.

Proflow™ *C. difficile* Toxin A/B lateral flow test is designed for the detection of *C. difficile* toxins in the faeces of patients with diarrhoea. The test therefore is a valuable tool in the diagnosis of *C. difficile* infection.

Simple, rapid and cost effective.

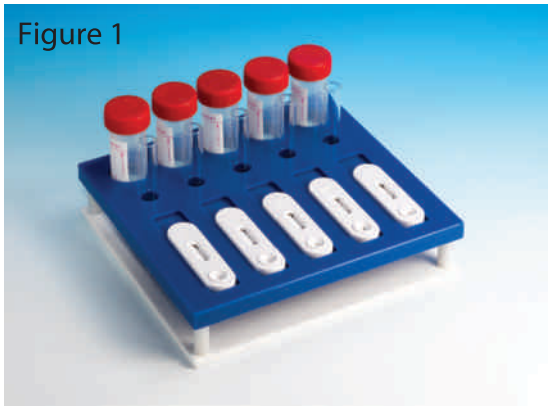
Figure 1

PRINCIPLE OF THE TEST

The Proflow™ *C. difficile* Toxin A/B was designed as a rapid lateral flow immunoassay to detect the presence of Toxin A and Toxin B antigen in fresh, frozen and media stored human stool specimens.

The Proflow™ *C.difficile* Toxin A/B rapid test consists of anti-Toxin A and anti-Toxin B antibodies coated onto the test line region of the nitrocellulose zone of the test strip and anti-species specific antibodies coated onto the control line region.

Anti-Toxin A and anti-Toxin B antibodies are also conjugated to red latex particles and dried onto inert glass fibre that is inserted into the test strip below the nitrocellulose zone.

Toxin A and Toxin B present in the sample combine with the antibody/red latex to form a complex. As this complex migrates up the nitrocellulose strip it binds to the antibodies in the test region forming a visible pink/red band. Excess conjugate forms a second pink/red band in the control region of the device. The control line should always appear as a visible pink/red band in the control region of the device to indicate that the test device is functioning correctly.

ASSAY PROTOCOL

1. Ensure the *C. difficile* Toxin A/B Dilution Buffer is at room temperature (15-30°C). Mix gently before use.
2. Ensure all stool specimens are at room temperature (15-30°C). Mix samples thoroughly.
3. Remove the required number of devices from their individual foil pouches and lay on a clean, flat surface, or on a ProFlow™ Station (fig 1)
4. Label each device with appropriate patient information.
5. Label test tubes and place in a rack.
6. Add 750uL *C. difficile* Toxin A/B Dilution Buffer to each tube.
7. Sample addition
   - If the sample is liquid, use a disposable transfer pipette to transfer 50uL of sample to the sample diluent tube. Holding the pipette vertically, add the entire contents of the pipette into the test tube.
   - If sample is solid, add a small amount of stool (approximately 3mm in diameter) into the test tube.
   - For samples stored in Cary Blair or C&S transport media, add 100uL of sample to the sample dilution tube.
8. Use the same transfer pipette to mix the sample with the diluent.
9. Transfer 150uL of diluted sample to the device sample port. Holding the pipette vertically over the device sample port; carefully add the buffered-sample drop-wise. Time the assay from this point.
10. Read assay results immediately at the end of the 15 minute incubation. Do not read results after 15 minutes as they may be inaccurate.

PERFRORMANCE CHARACTERISTICS

A ring trial of leading UK hospitals was performed to assess the performance of the Proflow™ Toxin A/B kit compared to their current CDI testing algorithm, (including GDH lateral flow, GDH EIA, Toxin EIA, NAAT).

		Expected	
		Toxin+	**Toxin-**
Proflow™ Toxin A/B	**Toxin+**	**31**	**0**
	Toxin-	**0**	**85**

Sensitivity = 100%
Sensitivity = 100%
PPV = 100%
NPV = 100%

The performance of Proflow™ Toxin A/B kit was compared to a commercially available EIA test on 282 retrospective stool samples at a clinical laboratory and an in-house site.

		***C. difficile* Toxin A/B EIA**	
		Toxin+	**Toxin-**
Proflow™ Toxin A/B	**Toxin+**	**112**	**1**
	Toxin-	**15**	**154**

Sensitivity: 88% (112/127) 95%CI 81 – 93%
Specificity: 99% (153/154) 95%CI 96 – 100%

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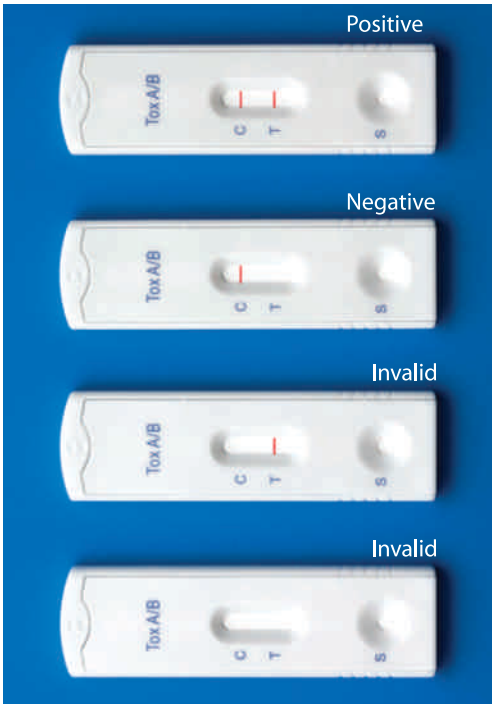
INTERPRETATION OF RESULTS



A coloured line in the test line (T) indicates a positive result.

Any visible test line is considered a positive result.

No coloured line in the test line (T) indicates a negative result.

To serve as a procedural control, a coloured line will always appear in the control line (C).

If this line is not present the test is considered invalid.

ORDERING INFORMATION

PL.3001	**Proflow™ GDH Test Kit**	**x20 tests**
PL.3002	**Proflow™ *C.difficile* Toxin A/B Test Kit**	**x20 tests**
PL.C1781	**Proflow™ Station (blue)**	**x1 unit**

ALSO AVAILABLE

PL.2002	**Prolisa™ GDH EIA Kit**	**x96 tests**
PL.PA500	**Portrait™ Analyser (inc. Laptop)**	**x1 unit**
PL.GBCDIFF.10	***C.difficile* Assay Test Cartridge**	**x10 Cartridges**
PL.GBCDIFF.30	***C.difficile* Assay Test Cartridge**	**x30 Cartridges**
PL.ACC-1	**Sample Preparation Tray**	**x1 unit**
PL.ACC-2	**Cartridge Carrier**	**x1 unit**

Pro-Lab Diagnostics. 3 Bassendale Road, Bromborough. UK.
Tel 0151 353 1613 Fax 0151 353 1614 Email uksupport@pro-lab.com

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