



Technical Briefing: TECHLAB®

Diagnosis of *Clostridioides difficile*

The need for accurate detection of *Clostridioides difficile*

Clostridioides difficile is the major cause of nosocomial diarrhoea and pseudomembranous colitis.

C. difficile is a spore-forming bacterium and infection usually occurs when the normal gut microflora is altered or killed by antibiotics allowing the germination of spores into vegetative cells. Once *C. difficile* growth begins, toxins A and B may be produced, causing diarrhoea and colitis.

The glutamate dehydrogenase (GDH) of *C. difficile* is a good antigen marker for the organism in faeces because it is produced in high amounts by all strains, toxigenic or non-toxigenic.

Not all strains of *C. difficile* produce toxins (non-toxigenic), therefore current UK guidelines advise that organisations adhere to a two-stage testing approach which consists of a test to screen for glutamate dehydrogenase (using EIA, NAAT, or PCR), followed by a sensitive toxin test.

C. difficile disease results from production of two main toxins; toxin A, an enterotoxin, and toxin B, a cytotoxin. Toxigenic strains of *C. difficile* produce both toxins or only toxin B.

Rapid, accurate diagnosis of diarrhoea caused by *C. difficile* is central to a patient receiving appropriate treatment in a timely manner and is necessary to inform infection prevention interventions.

Product	Format	Product Code	Detects	Time to result
<i>C. DIFF QUIK CHEK COMPLETE</i> ®	Rapid EIA	T30525C	GDH Toxins A&B	30 min
<i>C. DIFF CHEK</i> ™-60	96-well plate	TL5025	GDH	1hr
<i>C. DIFFICILE TOX A/B IT</i> ™	96-well plate	T5015	Toxins A&B	1hr
<i>C. DIFFICILE QUIK CHEK</i> ®	Rapid EIA	30390	GDH	30 min
<i>TOX A/B QUIK CHEK</i> ®	Rapid EIA	30394	Toxins A&B	30 min
<i>C. difficile Toxin/Antitoxin Kit</i>	Tissue Culture	T5000	Toxin B	18 hrs

GDH: glutamate dehydrogenase

Description and Key Benefits

The TECHLAB® range of kits largely comprise two formats:

CHEK™	QUIK CHEK™
96-well plate-based enzyme immunoassay (EIA)	Single test membrane EIA technology in a cassette
<ul style="list-style-type: none"> ▪ ELISA-based, 96-well plate format ▪ Suitable for screening large numbers of samples ▪ Results within 2 hours ▪ Simple procedure ▪ Automatable ▪ Highly standardised 	<ul style="list-style-type: none"> ▪ Direct faecal specimen testing in a rapid assay format ▪ Individual device ▪ Membrane bound EIA technology ▪ Suitable for smaller numbers of samples or for 'out-of-workflow' testing ▪ Results within 30 minutes ▪ Easy to interpret ▪ No equipment needed ▪ Highly specific and sensitive

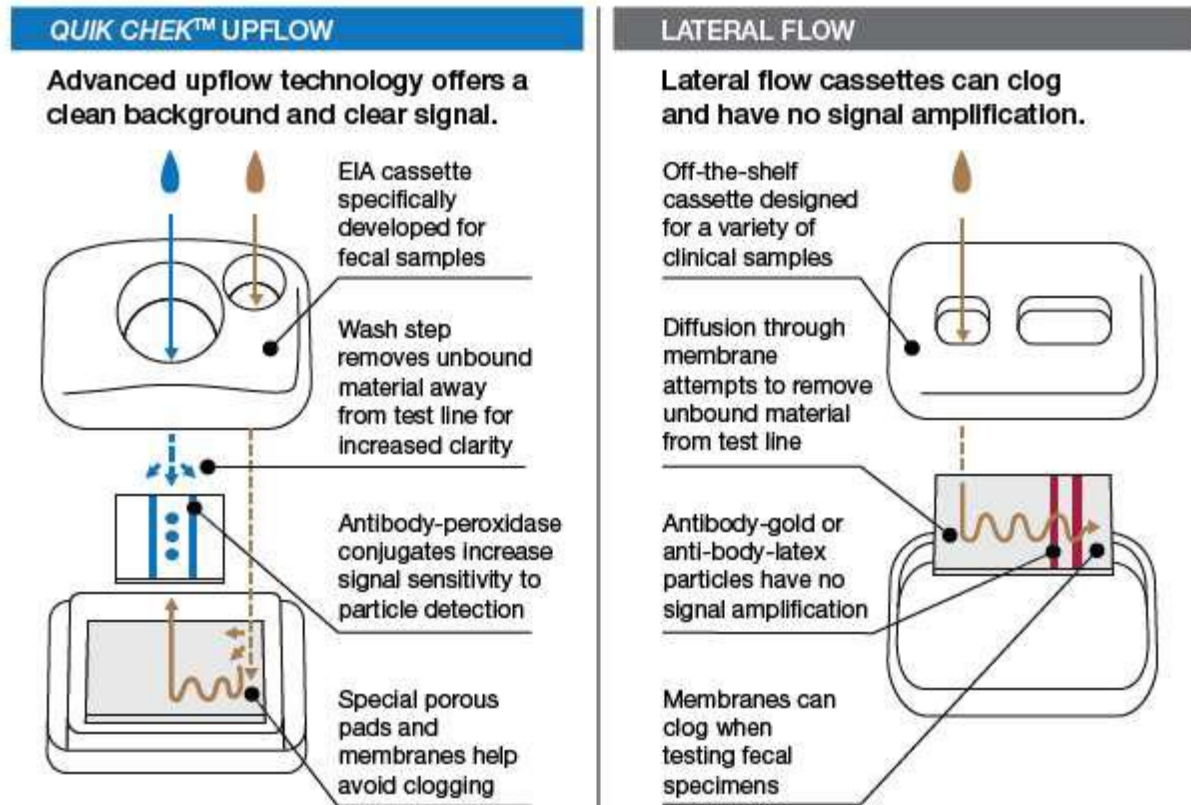


C. DIFF CHEK™ - 60



C. DIFF QUIK CHEK COMPLETE®

How TECHLAB® QUIK CHEK™ kits differ from lateral flow assays



QUIK CHEK™ kits

- Membrane enzyme immunoassay (EIA)
- Additional steps (wash/conjugate steps):
 - The wash step makes it easier to see the results
 - The conjugate step serves to amplify particle detection
- Superior sensitivity
- Results within 30 minutes

Watch this video on YouTube to find out more: <https://www.youtube.com/watch?v=Hhywc7HJ-7g>



Product information

C. DIFF QUIK CHEK COMPLETE® (Product code: T30525C (25 tests) or T30550C (50 tests))

The *C. DIFF QUIK CHEK COMPLETE*® test is a rapid membrane enzyme immunoassay for the simultaneous detection of *Clostridioides difficile* glutamate dehydrogenase (GDH) antigen and toxins A and B in a single reaction well.

- Individual test
- Direct faecal specimen testing in a rapid assay format
- Membrane EIA technology
- Screens for the presence of *C. difficile*
- Simultaneous detection of *C. difficile* GDH and toxins A and B
- Results in 30 minutes
- Easy to interpret
- No equipment needed
- Highly specific and sensitive

C. DIFF CHEK™-60 (Product code: TL5025)

A qualitative enzyme immunoassay for the detection of glutamate dehydrogenase (GDH) produced in high amounts by both toxigenic and non-toxigenic strains of *Clostridioides difficile*.

A positive result in the test, which is highly specific for the glutamate dehydrogenase of *C. difficile*, confirms the presence of this organism in a faecal specimen; a negative result indicates the absence of the organism.

A positive result should be followed by a toxin-specific test to confirm the presence of toxigenic *C. difficile*.

- Easy to complete
- High sensitivity (>99%)
- Results in around 60 minutes

C. DIFFICILE TOX A/B II™ (Product code: T5015)

The *C. DIFFICILE TOX A/B II*™ is a qualitative second-generation rapid ELISA for the detection of *Clostridioides difficile* toxins A and B in faecal specimens.

The *C. DIFFICILE TOX A/B II*™ is an alternative to tissue culture assay for detecting *C. difficile* toxin in faecal specimens.

- ELISA format
- Simultaneously detects both toxin A and toxin B
- Utilizes highly specific antibodies
- High correlation with tissue culture but much faster
- Results in 60 minutes
- Easy to complete



C. DIFFICILE QUIK CHEK® (Product code: 30390)

The *C. DIFF QUIK CHEK®* test is a rapid membrane enzyme immunoassay for use as a screening test to detect *Clostridioides difficile* antigen, glutamate dehydrogenase (GDH), in faecal specimens from persons suspected of having *C. difficile* disease.

A positive result should be followed by a toxin-specific test to confirm the presence of toxigenic *C. difficile*.

- Individual test
- Direct faecal specimen testing in a rapid assay format
- Membrane EIA technology
- Detection of *C. difficile* GDH antigen
- Results in 30 minutes
- Easy to interpret
- No equipment needed
- Highly specific and sensitive

TOX A/B QUIK CHEK® (Product code: 30394)

The *TOX A/B QUIK CHEK®* test is a qualitative rapid membrane enzyme immunoassay that uses antibodies specific for toxins A and B of *C. difficile*.

- Individual test
- Direct faecal specimen testing in a rapid assay format
- Membrane EIA technology
- Simultaneous detection of *C. difficile* toxins A and B in faecal specimens
- Results in 30 minutes
- Easy to interpret
- No equipment needed
- Highly specific and sensitive

C. difficile Toxin/Antitoxin Kit (Product code: T5000)

A toxin/antitoxin kit for the detection of *Clostridioides difficile* toxin in faecal specimens.

The *C. DIFFICILE TOXIN/ANTITOXIN KIT* uses a tissue culture format to detect the presence of cytotoxic activity (cell rounding) in faecal specimens and confirms the identification of *C. difficile* toxin by using specific antitoxin.

Reagents in the kit include toxin control and specific antitoxin.

- Highly sensitive
- Lyophilized reagents
- Minimizes repeated testing of specimens containing high toxin levels



Supporting evidence

TECHLAB® *C. DIFF CHEK*™-60 and *C. DIFFICILE TOX A/B II*™ assays were included in the seminal work by [Planche et al., 2013: Differences in outcome according to *Clostridium difficile* testing method: a prospective multicentre diagnostic validation study of *C. difficile* infection.](#)

Listed below is a selection of peer-reviewed published work about the clinical performance of the TECHLAB® kits for diagnosis of the presence of *C. difficile* (GDH +/- Toxin A/B) in stool samples (hyperlinked to abstract or freely available version):

- [Simultaneous Detection of *Clostridioides difficile* Glutamate Dehydrogenase and Toxin A/B: Comparison of the *C. DIFF QUIK CHEK COMPLETE* and RIDASCREEN Assays \(Yoo et al., 2019\)](#)
- [The Evaluation of the Performance of *C. DIFF QUIK CHEK Complete* and Toxin A + B \(*Clostridium difficile*\) DUO Diagnostic Tests Compared with Toxigenic Culture in the Diagnosis of *Clostridium difficile* Infection \(Yazisiz et al., 2020\)](#)

Ordering

Product Code	Item Name	Item Units
T30525C	<i>C. DIFF QUIK CHEK COMPLETE</i> ®	1 box of 25
T30550C	<i>C. DIFF QUIK CHEK COMPLETE</i> ®	1 box of 50
TL5025	<i>C. DIFF CHEK</i> ™-60	1 box of 96
T5015	<i>C. DIFFICILE TOX A/B II</i> ™	1 box of 96
30390	<i>C. DIFFICILE QUIK CHEK</i> ®	1 box of 25
30394	<i>TOX A/B QUIK CHEK</i> ®	1 box of 25
T5000	<i>C. difficile</i> Toxin/Antitoxin Kit	1 box of 96

For all order enquiries, please email enquires@unahealth.co.uk