Technical Briefing

TECHLAB®

Diagnosis of gastrointestinal bacteria

The need for accurate detection of gastrointestinal bacteria

Gastrointestinal diseases can cause great discomfort and distress to a patient.

Rapid and accurate diagnosis of gastrointestinal disease is central to a patient receiving appropriate treatment and symptomatic relief in a timely manner and is necessary to inform public health actions.

TECHLAB® offer a range of high-quality diagnostic kits for detection of bacteria commonly associated with gastrointestinal disturbance.

Helicobacter pylori

Approximately half the global population is infected with *H. pylori*. Most have no symptoms, and do not require treatment. However, a minority of these people develop gastritis, and a small fraction develop gastric ulcers or gastric cancer.

The standard procedure to diagnose *H. pylori* involves endoscopy with biopsy. Current guidelines still recommend this for patients with alarm symptoms such as GI bleeding or sudden weight loss, or for patients >55 years. However, younger patients who do not have alarm symptoms may benefit from non-invasive tests, such as a faecal antigen test. These tests can also verify that *H. pylori* infection has been eradicated after treatment.

Foodborne illness

Foodborne illness occurs when disease-causing pathogens contaminate food. Two common bacterial foodborne pathogens are *Campylobacter* species and Shiga toxin-producing *Escherichia coli* (STEC). A common cause of bacterial food poisoning is *Clostridium perfringens* enterotoxin.

Campylobacter species

Campylobacter species the most commonly reported cause of bacterial gastroenteritis in the UK. There are four species commonly associated with human disease: *C. jejuni*, *C. coli*, *C. lari*, and *C. upsaliensis.*

In approximately 1 of 1,000 cases, *Campylobacter* species are closely linked to the subsequent development of Guillian-Barre Syndrome, an acute auto-immune paralysis. *C. jejuni* infection has also been associated with reactive arthritis in both children and adults.

Shiga toxin-producing *Escherichia coli* (STEC)

Shiga toxin-producing *Escherichia coli* (STEC) cause foodborne and waterborne diarrhoeal disease that can progress to haemorrhagic colitis and haemolytic uremic syndrome (HUS).

STEC derive their name from their ability to produce toxins (Stx1 & Stx2) similar in structure and function to the Shiga toxin produced by *Shigella dysenteriae*. Similar to STEC are VTEC (verotoxigenic *Escherichia coli*, which produce a Shiga-like toxin). STEC and VTEC are both types of enterohaemorrhagic *E. coli.*

STEC strain O157:H7 has historically been the focus of attention in the UK, where it was first isolated from undercooked hamburgers. STEC infections caused by non-O157 strains have become more prevalent in recent years.

Since certain treatments and medications can increase the risk of HUS, prompt detection of STEC is necessary to prevent outbreaks and secondary transmission.

Clostridium perfringens

C. perfringens is a common source of food poisoning in the UK.

C. perfringens, a spore-forming bacterium, is found naturally in the environment and forms part of the normal gut flora in humans and animals.

Spores of *C. perfringens* can survive cooking and, during certain sub-optimal food preparation conditions (slow cooling and unrefrigerated storage), the spores germinate to form vegetative (growing) cells. Disease is caused by the production of an enterotoxin.

Symptoms are usually self-limiting and recovery is swift (within 24 h). Vulnerable populations, such as the elderly, may be more seriously affected.

Product	Format	Product Code	Time to result
H. PYLORI QUIK CHEK™	Rapid EIA	30925	< 30 min
H. PYLORI CHEK™	96-well plate	T5051	2 hours
CAMPYLOBACTER QUIK CHEK™	Rapid EIA	T31025	< 30 min
CAMPYLOBACTER CHEK™	96-well plate	T31096	2 hours
SHIGA TOXIN QUIK CHEK™	Rapid EIA	T30625	< 30 min
SHIGA TOXIN CHEK™	96-well plate	T30696	2 hours
CLOSTRIDIUM PERFRINGENS ENTEROTOXIN TEST	96-well plate	T5006	<3 hours

Description and Key Benefits

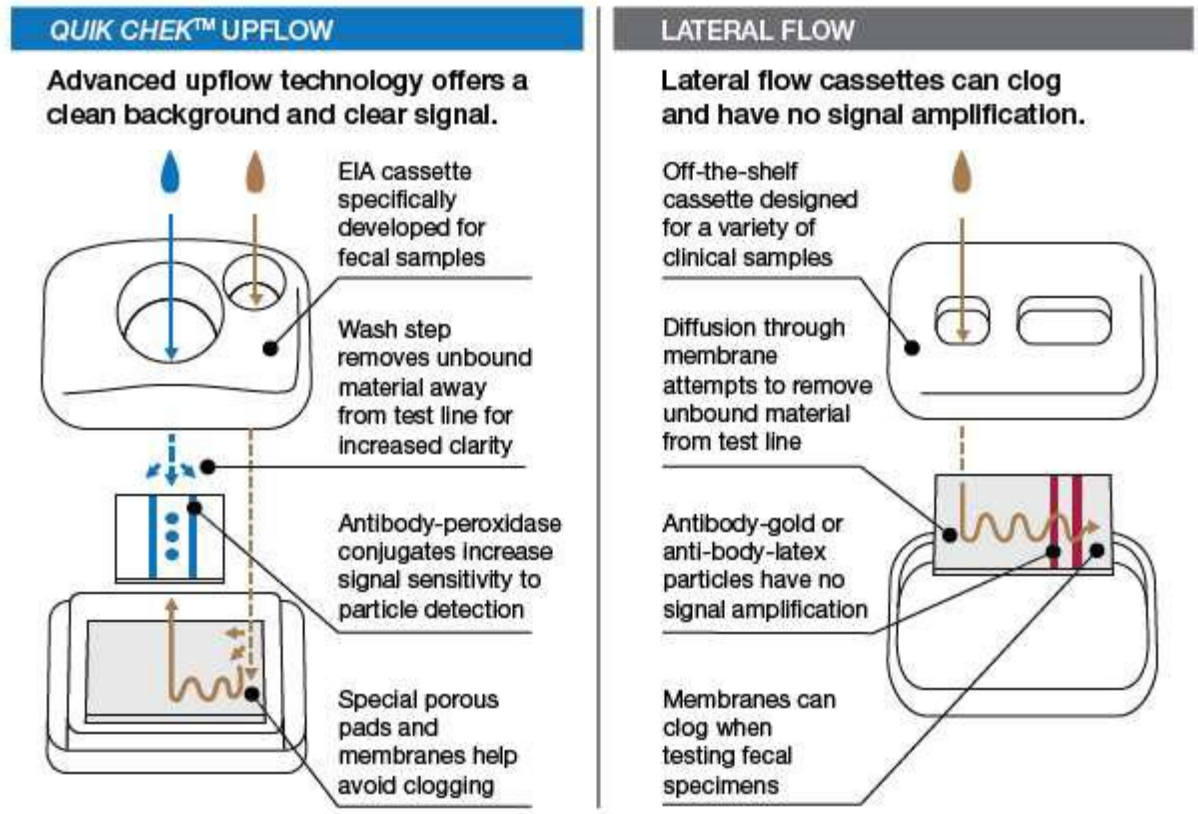
The TECHLAB® range of kits largely comprise two formats:

CHEK™	QUIK CHEK™
96-well plate-based enzyme immunoassay (EIA)	Single test membrane EIA technology in a cassette
▪ ELISA-based, 96-well plate format ▪ Suitable for screening large numbers of samples ▪ Results within 2 hours ▪ Simple procedure ▪ Automatable ▪ Highly standardised	▪ 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

CAMPYLOBACTER CHEK™

CAMPYLOBACTER QUIK CHEK™

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

H. PYLORI CHEK™ (Product code: T5051)

The *H. PYLORI CHEK*™ test is an enzyme immunoassay for the qualitative detection of *Helicobacter pylori* specific antigen in human faecal specimens. A highly specific alternative to endoscopy-based diagnosis.

- ELISA format
- Ideal screening tool
- Non-invasive alternative to endoscopy
- Utilizes highly specific antibodies to *H. pylori* antigen
- Specimens may be fresh, frozen, or in transport media
- Results in around 60 minutes

H. PYLORI QUIK CHEK™ (Product code: 30925)

The *H. PYLORI QUIK CHEK*™ test is a rapid membrane enzyme immunoassay for the qualitative detection of *Helicobacter pylori* specific antigen in human faecal specimens.

- Individual test
- Direct faecal specimen testing in a rapid assay format
- Highly sensitive membrane EIA technology
- Non-invasive alternative to endoscopy
- Utilizes highly specific antibodies to H. *pylori* antigen
- Specimens may be fresh, frozen, or in transport media
- Results in <30 minutes
- Easy to interpret
- No equipment needed

CAMPYLOBACTER CHEK™ (Product code: T31096)

The *CAMPYLOBACTER CHEK*™ test is an enzyme immunoassay for the qualitative detection of a *Campylobacter*-specific antigen in human faecal specimens.

It is designed to detect *C. jejuni, C. coli, C. lari,* and *C. upsaliensis* from patients with signs and symptoms of gastroenteritis.

The test is intended for use with preserved faecal specimens in transport media and unpreserved faecal specimens.

- ELISA format
- Ideal screening tool
- Detects four common human *Campylobacter* species
- Detects *Campylobacter*-specific antigen
- Utilizes preserved or unpreserved faecal specimens
- Provides results in <60 minutes

- Highly sensitive and specific

CAMPYLOBACTER QUIK CHEK™ (Product code: T31025)

The *CAMPYLOBACTER QUIK CHEK*™ test is a rapid membrane enzyme-linked immunosorbent assay for the qualitative detection of a *Campylobacter*-specific antigen in human faecal specimens.

It is designed to detect *C. jejuni*, *C. coli, C. lari,* and *C. upsaliensis* from patients with signs and symptoms of gastroenteritis in a single test device.

The test is intended for use with preserved faecal specimens in transport media and unpreserved faecal specimens.

- Individual test
- Direct faecal specimen testing in a rapid assay format
- Highly sensitive membrane EIA technology
- Detects four common human Campylobacter species
- Detects *Campylobacter*-specific antigen
- Direct faecal specimen testing in a rapid assay format
- Utilizes preserved or unpreserved faecal specimens
- Results in <30 minutes
- Easy to interpret
- No equipment needed

SHIGA TOXIN CHEK™ (Product code: T30696)

The *SHIGA TOXIN CHEK*™ test is an enzyme immunoassay for the simultaneous qualitative detection of Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2) in a single test.

The test is intended for use with human faecal samples from patients with gastrointestinal symptoms to aid in the diagnosis of disease caused by Shiga toxin producing *Escherichia coli* (STEC). It may be used directly with human faecal specimens, or broth or plate cultures derived from faecal specimens.

- One step ELISA detection
- High correlation with Vero Cell cytotoxicity assay
- Differentiation of Stx1 and Stx2 toxins
- Specific monoclonal detection of Stx1 and Stx2
- Easily adapted to automated systems

SHIGA TOXIN QUIK CHEK™ (Product code: T30625)

The *SHIGA TOXIN QUIK CHEK*™ test is a rapid membrane enzyme immunoassay for the simultaneous qualitative detection and differentiation of Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2) in a single test device.

It is intended for use with human faecal samples from patients with gastrointestinal symptoms to aid in the diagnosis of disease caused by Shiga toxin producing *Escherichia coli* (STEC). It may be used with faecal specimens, or broth or plate cultures derived from faecal specimens.

- Direct faecal specimen testing in a rapid assay format
- Individual test
- Highly sensitive membrane EIA technology
- Differentiation of Stx1 and Stx2 toxins
- Specific monoclonal detection of Stx1 and Stx2
- Strong correlation with Vero cell cytotoxicity assay
- Results in <30 minutes
- Easy to interpret
- No equipment needed

Clostridium perfringens Enterotoxin Test (Product code: T5006)

The *C. PERFRINGENS ENTEROTOXIN TEST* is a rapid ELISA for the detection of *Clostridium perfringens* enterotoxin in faecal specimens. The test is an alternative to tissue culture assay for detecting the enterotoxin in faecal specimens.

- ELISA format
- Specifically detects *C. perfringens* enterotoxin
- Utilizes highly specific antibodies
- Easy to complete
- Faster than tissue culture

Supporting evidence

Listed below is a selection of contemporary peer-reviewed published work about the clinical performance of the TECHLAB® kits for diagnosis of the presence of gastrointestinal bacteria in stool samples (hyperlinked to freely available version):

- Evaluation of CAMPYLOBACTER QUIK CHEK™ rapid membrane enzyme immunoassay to detect *Campylobacter* spp. antigen in stool samples (Franco *et al.*, 2021)
- Evaluation of Two New Membrane-Based and Microtiter Plate Enzyme-Linked Immunosorbent Assays for Detection of *Campylobacter jejuni* in Stools of Bangladeshi Children (Schnee *et al.*, 2018)
- Clinical performance of the H. PYLORI QUIK CHEK™ and H. PYLORI CHEK™ assays, novel stool antigen tests for diagnosis of *Helicobacter pylori* (Halland *et al.*, 2021)
- A Rapid Immunoassay for Detection of Shiga Toxin-Producing *Escherichia coli* Directly from Human Fecal Samples and Its Performance in Detection of Toxin Subtypes (Boone *et al.*, 2016)

Ordering

Product Code	Item Name	Item Units
30925	*H. PYLORI QUIK CHEK*™	1 box of 25
T5051	*H. PYLORI CHEK*™	1 box of 96
T31025	*CAMPYLOBACTER QUIK CHEK*™	1 box of 25
T31096	*CAMPYLOBACTER CHEK*™	1 box of 96
T30625	*SHIGA TOXIN QUIK CHEK*™	1 box of 25
T30696	*SHIGA TOXIN CHEK*™	1 box of 96
T5006	*CLOSTRIDIUM PERFRINGENS ENTEROTOXIN TEST*	1 box of 96

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