EntericBio

REVOLUTIONISING

MOLECULAR ENTERIC TESTING

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INTRODUCTION



In 2009, Serosep pioneered the development of the EntericBio® system, placing the company at the forefront of the molecular diagnostics market in the field of gastrointestinal health. Since then, the EntericBio® system has become the market leader in GI realtime PCR testing in the UK and Ireland, providing medium/high throughput labs with a rapid, reliable and easy to use solution for their enteric pathogen testing needs.

The EntericBio® system is unique as it is capable of detecting target DNA and RNA direct from stool specimens, circumventing the requirement for commercial nucleic acid extraction purification and minimising hands on time for laboratory personnel. Designed to identify a wide range of pathogens responsible for gastrointestinal infections, EntericBio harnesses the power of advanced molecular techniques enabling healthcare professionals to quickly pinpoint the exact pathogen(s) causing symptoms and allowing for swift and targeted treatment strategies.

With its user-friendly interface, automation capabilities, and comprehensive pathogen panels, the EntericBio® system streamlines the diagnostic process, providing results that are not only reliable but also actionable. By facilitating early and accurate detection, this innovative system contributes to more effective patient care, reduced healthcare costs, and a better understanding of the epidemiology of gastrointestinal infections.



THE BENEFITS

The EntericBio® PCR based test from Serosep is faster, more accurate and more comprehensive compared to traditional stool culture methods, which can take days to yield results and involve several labour-intensive steps. EntericBio® provides results within 3 hours, detects multiple pathogens simultaneously, and greatly reduces the risk of false negatives. It also simplifies the workflow, lowering the hands-on time and expertise required while also enhancing lab safety by minimising exposure to infectious agents.

EntericBio offers several benefits:

- No DNA/RNA extraction
- No manual pipetting
- Rapid results within 3 hours
- Ready to use lyophilised PCR reagents
- Automated results analysis
- 1-48 tests processed per run
- High throughput with consecutive runs
- Clinical waste reduction

THE

PROCESS

REVOLUTIONISING

MOLECULAR ENTERIC TESTING

The EntericBio® molecular system is rapid, reliable and easy to use, providing results within 3 hours direct from stool sample. The process is complete in four easy steps (see diagram below).

The system can process up to 48 tests per run with up to 240 tests in under 8 hours with no DNA/RNA extraction, automated setup and ready to use lyophilised PCR reagents.

1



Add Samples

Add sample to stool preparation solution (SPS)

2



Heat Treat

Process SPS on EntericBio® heatstation

3



Automated Set-up

Transfer to EntericBio® Workstation for automated PCR set-up

4



Amplify & Detect

Transfer to realtime PCR Instrument for automated results analysis using EntericBio® fastfinder software

No manual pipetting

Ready to use
Lyophilised PCR reagents

Easy to use

THE PROCESS

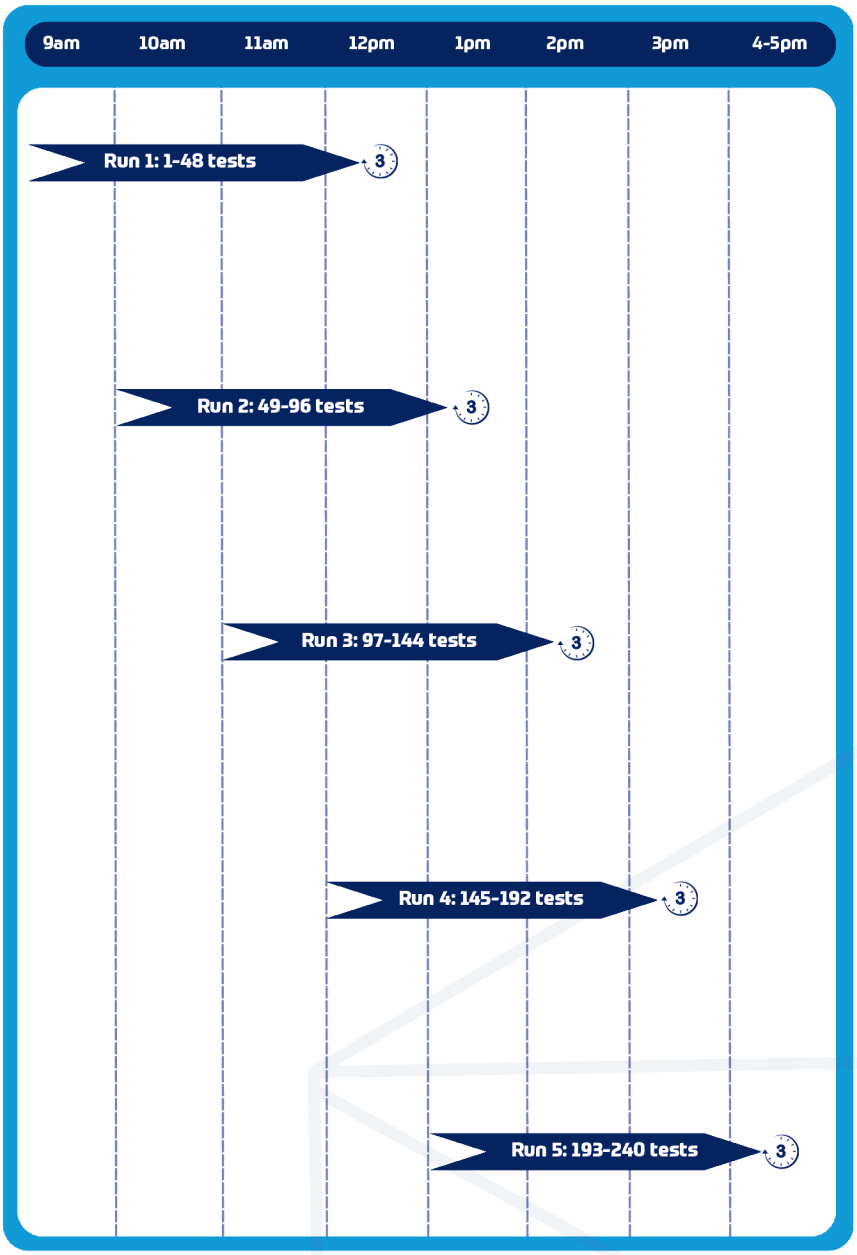
SCAN WATCH HERE

WORKFLOW

EntericBio

WORKFLOW 1 SYSTEM*

Run 1 (Test 001-048)	Time
1. Add Sample	30 mins
2. Heat Treatment	30 mins
3. PCR Setup on workstation	40 mins
4. Amplification & Detection (RT-PCR)	50 mins
Run 2 (Test 049-096)	**Time**
1. Add Sample	30 mins
2. Heat Treatment	30 mins
3. PCR Setup on workstation	40 mins
4. Amplification & Detection (RT-PCR)	50 mins
Run 3 (Test 097-144)	**Time**
1. Add Sample	30 mins
2. Heat Treatment	30 mins
3. PCR Setup on workstation	40 mins
4. Amplification & Detection (RT-PCR)	50 mins
Run 4 (Test 145-192)	**Time**
1. Add Sample	30 mins
2. Heat Treatment	30 mins
3. PCR Setup on workstation	40 mins
4. Amplification & Detection (RT-PCR)	50 mins
Run 5 (Test 193-240)	**Time**
1. Add Sample	30 mins
2. Heat Treatment	30 mins
3. PCR Setup on workstation	40 mins
4. Amplification & Detection (RT-PCR)	50 mins



* Workflow for the EntericBio Dx Panel processes 32 tests

- 1-48 tests processed per run (including +/- controls)
- Ready to use lyophilised PCR reagents
- Less than 30 mins hands on time
- Direct from stool sample
- Time to result: under 3 hours
- High throughput up to 240 tests in an 8 hour working day

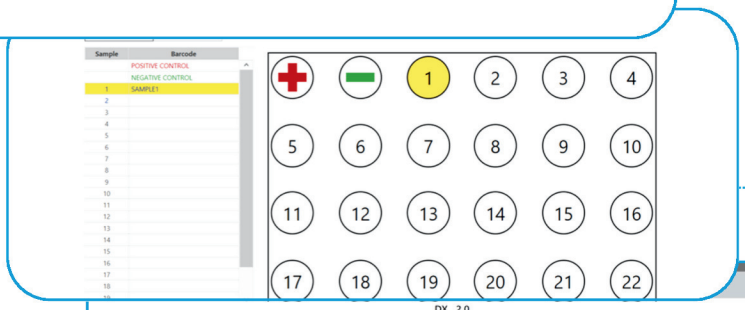
THE TECHNOLOGY

SAMPLE TRACKING SOFTWARE

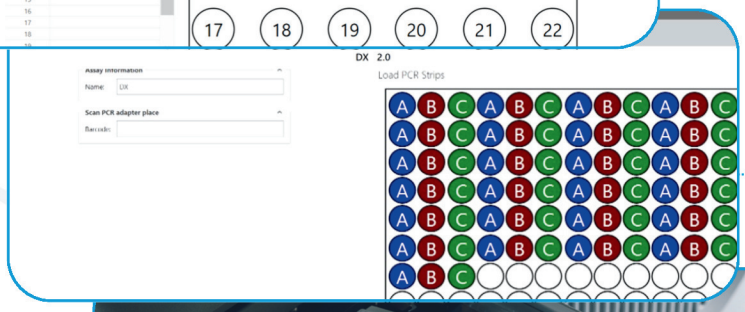
The EntericBio® Sample tracking software enables tracking of samples throughout the EntericBio process, starting with the initial specimen transfer into the SPS until entry into the RT PCR Cycler.



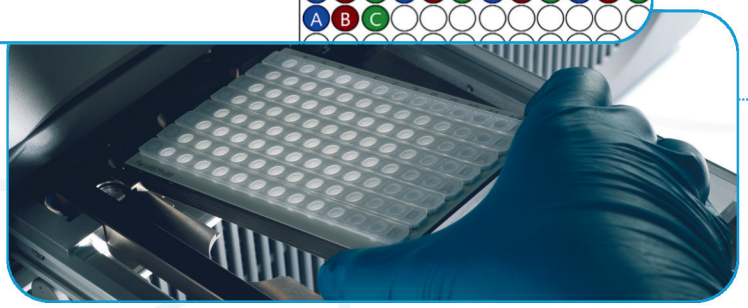
Assay name and Sample Rack barcode defined for use in creation of worklist



Scanning of sample barcodes whilst loading samples into Sample Racks – software displays a visual representation of where each sample should be loaded after barcode scanning



Loading of PCR strips - software displays visual of representation of number of strips required and where they should be loaded



Transfer PCR plate on to RT PCR cycler

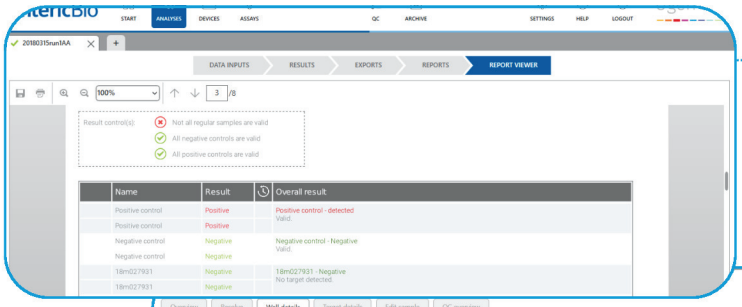
BENEFITS

- Streamlining work flow
- Minimising potential risk/errors in the process
- Ability to track sample numbers
- Easy to use

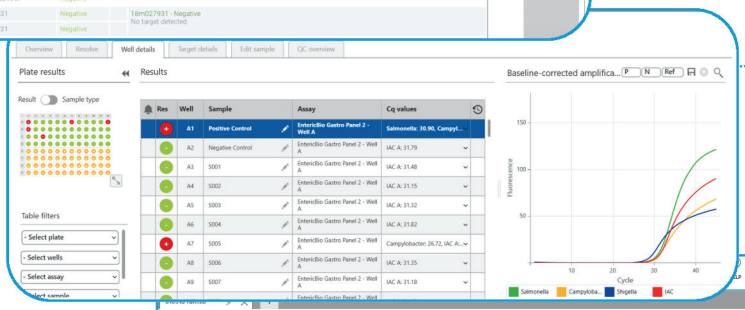
THE TECHNOLOGY

FASTFINDER ANALYSIS SOFTWARE

The FastFinder software from UgenTec enables our customers worldwide to standardise and automate the analysis of EntericBio® results for the first time. Our customer-driven philosophy is to provide innovative products and best-in-class real-time support to our users so that their service is never compromised. Modernising & automating the analysis software is a further step in enhancing our EntericBio® customers user experience.



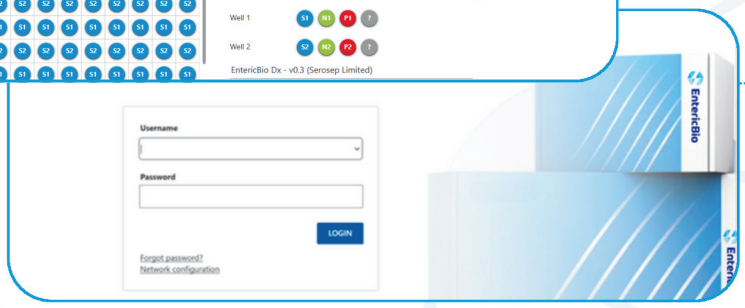
User Friendly Reports



Results Automatically Analysed



Fully Pre-Programmed Assays



Hosted Solution

BENEFITS

- Automated analysis and results interpretation
- Automated audit trail
- Automated LIMS transfer

FLEXIBLE

MODULAR MENU



A unified platform

EntericBio® presents a revolutionary approach to gastrointestinal pathogen detection with its unified platform boasting a flexible modular menu. This innovative system streamlines testing processes, enabling healthcare professionals to efficiently detect and identify a wide array of pathogens, including bacteria, parasites, viruses, and CPE (carbapenemase-producing Enterobacteriaceae), all within a single workflow.

By consolidating multiple testing procedures into one cohesive system, EntericBio® not only enhances laboratory efficiency but also ensures comprehensive and accurate results for up to 48 tests in less than 3 hours, empowering clinicians to make informed decisions promptly.

With its adaptable design and comprehensive pathogen coverage, EntericBio® sets a new standard in gastrointestinal diagnostics, revolutionising patient care and public health outcomes.

Assays include:

- Dx Panel
- GP2 Panel
- Viral Panel
- CPE Panel
- Clostridioides difficile Panel



ENTERICBIO

PANEL OVERVIEW

Dx

Bacteria
- Salmonella
- STEC
- Shigella
- Campylobacter
- Yersinia
- Vibrio

Parasite
- Cryptosporidium
- Giardia
- Entamoeba histolytica

GP2

Bacteria
- Campylobacter
- Salmonella
- Shigella
- STEC

Parasite
- Cryptosporidium
- Giardia

Viral

Viral
- Adenovirus
- Astrovirus
- Norovirus GI
- Norovirus GII
- Rotavirus
- Sapovirus

CPE

CPE
- OXA - 48
- KPC
- NDM
- VIM
- IMP
- GES

Clostridioides difficile

Bacteria
- Toxin B (tcdB)

CE IVD

- No DNA/RNA Extraction
- Automated set up
- Rapid results within 3 hours
- High throughput

COMPLETE PANEL LIST

EntericBio	Combined		Bacteria	Viral			CPE
	Dx	GP2	C.Diff	VP1	VP2	VP3	CPE
Salmonella	✓	✓					
Shigella spp. / EIEC*	✓	✓					
Campylobacter	✓	✓					
STEC* (stx 1/2)	✓	✓					
Yersinia	✓						
Vibrio	✓						
Cryptosporidium	✓	✓					
Giardia	✓	✓					
Entamoeba histolytica	✓						
C.difficile			✓				
Adenovirus				✓		✓	
Rotavirus				✓		✓	
Sapovirus				✓		✓	
Astrovirus					✓	✓	
Norovirus GI					✓	✓	
Norovirus GII					✓	✓	
OXA 48							✓
KPC							✓
NDM							✓
VIM							✓
IMP							✓
GES							✓

*EIEC: Enteroinvasive E. Coli | *STEC: Shiga toxin-producing E. Coli

ENTERICBIO

EQUIPMENT

EntericBio Heatstation



For heat treatment of innoculated EntericBio SPS tubes with the sample

Dimensions

- Width: 20cm (7.87 in)
- Height: 10cm (3.94 in)
- Length: 37cm (14.56 in)
- Weight: 4.1kg (9 lb)

EntericBio Workstation



For automation of the EntericBio Reaction set-up

Dimensions

- Width: 65cm (25.6 in)
- Depth: 48cm (18.9 in)
- Height: 63cm (24.8 in)
- Weight: 45kg (99.2 lb)

Fastfinder Analysis software with the ROCHE LC480 II®



For the amplification and detection of target organisms using EntericBio proprietary analysis software

Dimensions

- Width: 57.4cm (22.6 in)
- Depth: 58.8cm (23.15 in)
- Height: 49.7cm (19.6 in)
- Weight: 55kg (121.25 lb)

ANCILLARY

EQUIPMENT

Eppendorf® Centrifuge



Centrifugation of EntericBio reaction wells

Dimensions

- Width: 335mm
- Height: 250mm
- Depth: 415mm
- Weight: 29kg (64 lb)

Eppendorf® Mixmate



Mixmate is used to hold vessels and plates when mixing samples

Dimensions

- Width: 170mm
- Height: 130mm
- Depth: 230mm
- Weight: 4.15kg (9 lb)

EntericBio SUSTAINABILITY

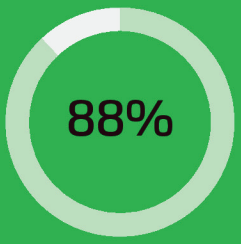


PROCESS EFFICIENCY [1]

In comparison to traditional culture and Microscopy methods, the overall lead time has been reduced by 46 hours and 13 minutes, with an overall process efficiency of 94%. As a result, the system process has become more streamlined and effective, with fewer wasteful steps.

"Significant savings in costs associated with labour, autoclaving, transport of waste, landfill & associated licensing" [2]

CLINICAL WASTE REDUCTION [2,3]



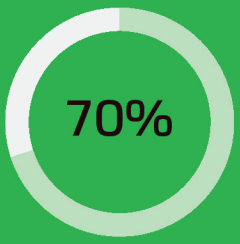
Significant reductions in clinical waste produced by the laboratory as agar plates and selenite broths are no longer required.

RECYCLABLE PACKAGING



All SPS Boxes and Entericbio Kit boxes are 100% recyclable and 100% biodegradable.

RECYCLED PACKAGING



All SPS Boxes and Entericbio Kit boxes are made from 70% recycled material.

FSC

REDUCTION IN CONSUMABLE STORAGE [1]

EntericBio offers an 85% reduction in consumable storage compared to conventional microbiology methods.



1. "Reduced Turnaround Time and Improved Process Efficiency Using the EntericBio Gastro Panel 2", M. Watson, k. Desai, R. Anderson, N. Ratnaraja; ASM Microbe, 2017
2. "Implementation of a rapid real-time multiplex polymerase chain reaction (PCR) for the detection of bacterial enteric pathogens directly from stool samples, in a large London teaching hospital setting", C. Ozongwu, P Ramnarain, R. Smith, G.L. Vanstone; ECCMID 2013
3. "Comparison of the EntericBio Multiplex PCR System with Routine Culture for Detection of Bacterial Enteric Pathogens", James O'Leary, Daniel Corcoran, and Brigid Lucey; Journal of Clincal Microbiology, Nov. 2009, p. 3449–3453

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