FIELD SAFETY NOTICE

Product Name:	EntericBio realtime Gastro Panel 1
Product code:	**EBGPIA**
Date:	17.06.14
FSN Reference:	**2014/01**

BACKGROUND

The Serosep EntericBio realtime Gastro Panel I test system detects Salmonella, Shigella, Campylobacter, SLT 1 and SLT 2 using realtime PCR.

We wish to inform you of additional updates to the product limitations which we have identified through evaluation studies. These limitations are described in the 'Limitations of Method' section of the current revision of the User Manual.

DESCRIPTION

- The stx2 genotype stx2f is not detected with EntericBio realtime Gastro Panel 1 assay. This information has been added to the User Manual. Reported detection of the Stx2f genotype in clinical samples from humans is rare*.
  *Gannon, V.P., C. Teerling, S.A. Masri, C.L. Gyles. 1990. Molecular cloning and nucleotide sequence of another variant of the Escherichia coli Shiga-like toxin II family. JGen Microbiol 136:1125–1135.

  The following update has been added to the Limitations of Method:

  "The stx2 genotype stx2f is not detected with EntericBio realtime Gastro Panel I assay"

- In cases of dual infection, Salmonella and Shigella may be co-amplified in the same well. Due to differences in the limit of detection of these two targets, amplification competition may occur where Shigella is present in very high numbers in the same sample.
  The User Manual already stated that a positive result for Salmonella and/or Shigella should be confirmed by routine culture methods as per local/national guidelines. However for further clarification we have added the following update to the Limitations of Method:

  "*Culture confirmation of Shigella (IpaH) PCR positive samples should also include Salmonella culture due to the possibility of PCR competition between the IpaH and Salmonella target*"

- In the Limitations of Method we have clarified the following limitation (new text in bold):

  "*Tests of clearance or status of asymptomatic carriage of Salmonella should include testing from a routine 24hr enrichment broth with the EntericBio assay and/or routine enriched culture.* ***This should also be considered where testing is requested on non-liquid stool samples submitted as part of a clinical follow up on patients with a recent clinical history of foreign travel associated gastroenteritis***"

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ACTION AND RECOMMENDATIONS

1. Review the 'Limitations of Method' information provided in the User Manual - EBRT 17 Revision No. 11.

2. Ensure that this notice is communicated to the appropriate personnel within your Laboratory.

3. Remove previous versions of the User Manual from the point of use, ensuring that users have access to the current revision.

Please retain this Field Safety Notice as required by your Quality Management System.

Please acknowledge receipt of this Field Safety Notice by completing the attached acknowledgement form and returning it to Serosep Technical support.

Should you have any questions or concerns regarding the information provided with this Field Safety Notice, please contact Serosep Technical Support by email technicalsupport@entericbio.com or telephone +00353 (0)61 358190.

Yours sincerely,

Tom Russell
Quality Manager

Attachment 1: Field Safety Notice Acknowledgement Form
Attachment 2: EntericBio realtime Gastro Panel I User Manual - EBRT 17 Revision No. 11.

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Field Safety Notice

Acknowledgement Form

FSN Number: **2014/01**

Subject: Update to 'Limitations of Method' for EntericBio realtime Gastro Panel I

Please acknowledge receipt of this Field Safety Notice by completing this form and returning it to technicalsupport@entericbio.com or fax +00353 (0)61 358191.

I acknowledge receipt of this Field Safety Notice

Laboratory _____

Name (please print) _____

Position _____

Signature _____

Date _____