



February 11th, 2019

URGENT: FIELD SAFETY NOTICE – BDDS-19-1405

BD MAX™ Enteric Bacterial Panel
 Catalog Number (REF): 442963
 Type of action: Device destruction of Lot Numbers: 8194784 and 8199682 only when used in conjunction with the BD MAX™ Extended Enteric Bacterial Panel catalog number (REF) 443812.

Attention: Laboratory Managers and Risk Managers

This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD is conducting a Field Safety Corrective Action for two lot numbers (listed in table 1 below) of the BD MAX™ Enteric Bacterial Panel (catalog number 442963) but only if they are being used in conjunction with the BD MAX™ Extended Enteric Bacterial Panel (catalog number 443812). According to our distribution records, your organisation may have received the impacted products.

Product Name & Catalog Number (REF)	Lot number	Expiration Date
BD MAX™ Enteric Bacterial Panel 442963	8194784	2020-02-22
	8199682	2020-02-22

Table 1: Affected Lot Numbers

Description of the Problem

Through internal testing, BD has observed a shift in certain PCR metrics for BD MAX™ Extended Enteric Bacterial Panel (ExEBP) master mixes when used with sample buffer tubes from the BD MAX™ Enteric Bacterial Panel (EBP) lot numbers listed above. The result of this shift may cause false negative results for Enterotoxigenic *Escherichia coli* and *Plesiomonas shigelloides*, targets of the ExEBP assay.

If you are only using the EBP assay, there is **no impact** for these targets with the lots listed above. The product removal is only targeted at Users who are running these lots of EBP in combination with the ExEBP assay.

Although prevalence rates are considered to be low, if no other cause of enteric infection is determined you may choose to confirm any negative result for Enterotoxigenic *Escherichia coli* (ETEC) and *Plesiomonas shigelloides* obtained using the ExEBP assay by using an alternate method or repeating the ExEBP assay using sample buffer tubes from a lot of EBP not listed above. Note that treatment for these infections is mainly supportive and antibiotics are not commonly used except in severe cases.



Advice on action to be taken:

1. If you are running the ExEBP assay using the lot numbers of EBP listed in Table 1, immediately stop use of and quarantine the unused EBP product.
2. Discard or destroy the quarantined product.
3. Share this notification with all users of the BD MAX™ instrument within your facility to ensure awareness.
4. If you have further distributed the impacted product lot numbers of EBP, please identify those users and notify them at once of this field safety notice.
5. Complete the customer response form on page 3 indicating:
 - a. that you do not have any of the affected product listed in the table above
OR
 - b. that you are running the EBP assay alone (*do not destroy the product*)
OR
 - c. that you have units of the affected product and are using with the ExEBP assay (*please destroy the product*).
6. Return the completed customer response form to alastair.thornley@bd.com for replacement products as soon as possible or no later than the March 15th, 2019.

BD will provide replacement products for all kits of the EBP assay appropriately destroyed upon receipt of the completed customer response form.

If you have additional questions, please contact your local BD Diagnostic Systems Representative or Alastair Thornley (Product Manager UK & Ireland) on 07557945460 or e-mail alastair.thornley@bd.com.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours Sincerely,





Customer Response Form – BDDS-19-1405

BD MAX™ Enteric Bacterial Panel

Catalog Number (REF): 442963

Lot Numbers: 8194784 and 8199682 only when used in conjunction with the BD MAX™ Extended Enteric Bacterial Panel catalog number (REF) 443812.

Please read in conjunction with Field Safety Notice BDDS-19-1405 and return completed form by email to alastair.thornley@bd.com by 15th March 2019.

- I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Tick the appropriate box below

We do not have any of the affected product as listed in table 1 above in our possession

OR

We have units of the affected product from table 1 above in our possession and we are solely running the BD MAX™ Enteric Bacterial Panel and will not destroy the product

OR

We have units of the affected product in our possession and are using with BD MAX™ Extended Enteric Bacterial Panel (catalog code 443812), therefore we will destroy the product and complete the quantities in the table below

Product Catalog (REF) Number	Lot Number	Quantity of units on hand and destroyed
442963	8194784	
442963	8199682	

Account/Organisation Name	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Signature:	Date:

This form must be returned to BD before this action can be considered closed for your account.