

22 July 2019

URGENT: FIELD SAFETY NOTICE – BDDS-19-1579

BD MAX™ Reagents

(Various REF / LOT Number Combinations per Attachment 1)

Type of Action: Advisory

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

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

Dear valued Customer,

BD is issuing an advisory Field Safety Notice for the specific REF/LOT Number combinations of the **BD MAX™ Reagents** listed in Attachment 1 and according to our distribution records your organisation may have received the impacted devices. The list of impacted devices was distributed between May 28th, 2019 and July 1st, 2019.

Description of the Problem

BD has discovered that the foil bags containing extraction tubes for **BD MAX™ Reagent products** listed in Attachment 1 may not have been sealed properly. The following images illustrate the defect and the location on the foil bags.



The Instructions for Use enclosed with all BD MAX™ tests advises Users to inspect the foil bags prior to use to ensure integrity of the seal and to not use reagents if the protective pouches are open or broken upon arrival. This Field Safety Notice is being issued to remind Users of the contents of the Instructions for Use.



BD estimates that the defect affects approximately 1.4% of the foil bags containing extraction tubes for **BD MAX™ Reagent** products listed in the Attachment 1. The impact for the ~1.4% of foil bags that are not properly sealed is potential increased exposure of the products to humidity, which if used, may lead to false negative results or a small subset of the 1.4% of tests depending on unresolved result reporting rate (similar to a Sample Processing Control (SPC) failure which is included in every BD Max test), organism prevalence, and other factors. This could cause the need to repeat the assay potentially causing a result delay and/or delay in treatment. A false negative result could potentially lead to a patient not being treated in a timely manner, leading to disease progression and in the case of transmittable diseases, transmission to other individuals.

There have been no reported complaints to BD for the defect from customers. We confirm that the appropriate regulatory agencies have been informed of these actions.

Actions for customers to take:

1. Thoroughly inspect all foil bags containing extraction tubes for the **BD MAX™ Reagent products** listed in Attachment 1. If any of the foil bags in your inventory contain holes, dispose of the product per your normal process.
2. If you have further distributed the device/s, please identify those users and notify them at once of this Field Safety Notice.
3. Continue to follow the Instructions for Use for all lots of **BD MAX™ Reagent products** and inspect the product prior to use.
4. Complete the customer response form on page 4 indicating:
 - the quantities destroyed **OR**
 - that your organisation does not have any impacted units left in inventory
5. Return the completed customer response form to BDUKFieldAction@bd.com for alternative replacement devices **as soon as possible or no later than August 31st, 2019.**

Upon receipt of the completed customer response form, a BD representative will contact you to discuss potential alternative solutions to replace the recalled product.

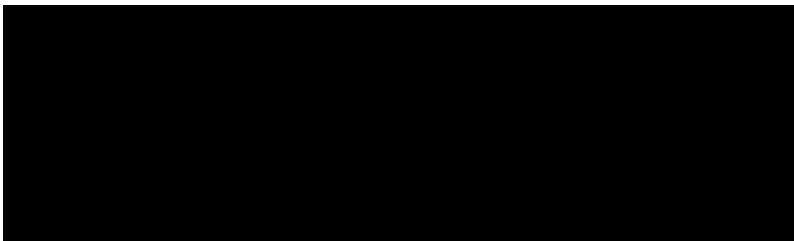


Contact Reference Person

If you have any questions about the device, please contact your local BD representative or the local BD office or e-mail BDUKFieldAction@bd.com.

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

Sincerely,



Attachment 1: List of affected BD MAX™ Reagent products



Customer Response Form - BDDS-19-1579
BD MAX™ Reagents
 (Various REF / LOT Number Combinations per Attachment 1)

Fill out and return this form to BD at e-mail BDUKFieldAction@bd.com by **August 31st, 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 Attachment 1 in our possession

OR

We have affected product(s) as listed in Attachment 1 in our inventory and have completed an inspection of all foil bags. **We do not require any replacement products.**

OR

We have affected product(s) as listed in Attachment 1 in our inventory and have completed an inspection of all foil bags. **We have destroyed the following units.**

REF	LOT Number	Quantity Destroyed
278102	9114645	
442818	9085668	
442960	9106889	
442963	9085672	
442963	9085673	
443812	9114557	
443985	9107980	

Trust Name:	
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.



Attachment 1 – List of Affected BD Max™ Reagents

REF	Product Description	LOT Number
278102	Kit BD Max™ Check-Points CPO	9114645
442818	Kit BD Max™ ExK DNA 1 Lab Use Only	9085668
442960	Kit BD Max™ Enteric Parasite Panel	9106889
442963	Kit BD Max™ Enteric Bacterial Panel	9085672
442963	Kit BD Max™ Enteric Bacterial Panel	9085673
443812	Kit BD Max™ EXT Enteric Bacterial Panel	9114557
443985	Kit BD Max™ Enteric Viral Panel	9107980