Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

bd.com

URGENT MEDICAL DEVICE PRODUCT ADVISORY

BD MAX™ Reagents

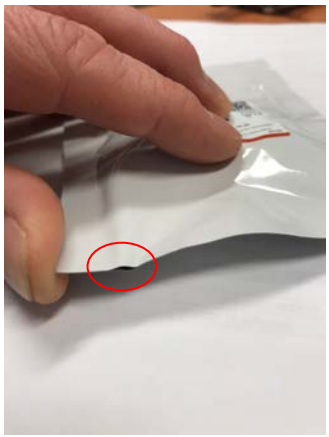
July 17, 2019

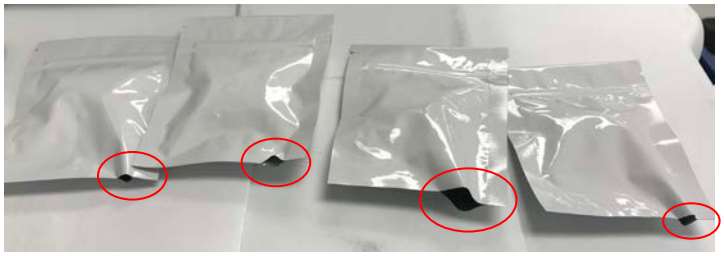
Product name / Catalog number	Lot number	UDI	Date of Manufacture	Expiration Date
See Appendix	See Appendix	See Appendix	See Appendix	See Appendix

For the Attention of: Molecular Lab Manager/Risk Manager/R&D Associate

Description of the problem and health hazard(s):

BD has discovered that approximately 1.4% of the foil bags containing master mix and extraction tubes for BD MAX™ assays listed in the Appendix may not have been sealed properly. The scope of the issue is limited to product manufactured in May – mid-June 2019. The issue was immediately rectified and all product manufactured after mid-June 2019 is not impacted. Reference Images of improperly sealed foil bags below:





The package insert enclosed with all BD MAX assays instructs customers 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. If these instructions for use are followed, there is no need for action to be taken regarding tests already administered as an unsealed pouch would be discovered prior to use.

The impact for the 1.4% of foil bags that are not properly sealed is potential increased exposure of the products to humidity. If impacted product is used, this may lead to a false negative result or a non-reportable result (UNR); however, based on the relatively low target prevalence and the low rate of affected product, even when all other mitigations are removed from consideration, the expected

decrease in sensitivity as caused by false negative results would be substantially less than 1%. Exposure to humidity would likely effect the Sample Processing Control (SPC). In the case that the target becomes falsely negative and the Sample Processing Control (SPC) does not amplify, the result generated will be a non-reportable result instead of being a false negative result. An unresolved result could cause the need to repeat the assay potentially causing a delay in reporting results and/or delay in administering 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.

Our records indicate you have been shipped one or more of the lots of product referenced in the Appendix.

Please Take the Following Action(s):

1. Thoroughly inspect all foil bags prior to use. If any of the foil bags in your inventory contain holes, dispose of the product and note the quantity in the attached Customer Response Form in order to request replacement.
2. Even if you do not have inventory of the product listed in the Appendix, complete the attached Customer Response Form and return to the BD contact noted on the form so that BD may acknowledge your receipt of this notification.
3. Share this Advisory Letter with all users of the BD MAX instrument within your facility to ensure awareness.
4. Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program.
   Web: MedWatch website at www.fda.gov/medwatch
   Phone: 1-800-FDA-1088 (1-800-332-1088)
   Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

Actions Taken by BD:

BD has identified the root cause of this situation and has implemented corrective actions to prevent recurrence in the future.

Contact Information: If you require further assistance, please contact:

BD Contact	Contact Information	Areas of Support
BD Customer/Technical Support	800-638-8663 Monday – Friday between 7:00am and 7:00pm (EST) in the United States.	For customers outside the US, contact your local BD representative or distributor.

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.

Sincerely,

[redacted]

Gail Griffiths
Sr. Director, Corporate Regulatory Compliance

[redacted]

Dr. Charles Cooper, M.D.
WW VP Medical Affairs

CUSTOMER RESPONSE FORM
BD MAX Assay Reagents

Please assist BD by promptly returning this form to:
BD Regulatory Compliance
Email: BDRC2@bd.com
Fax No.: 312-949-0227

Facility: _____
Please use full, current facility name. Do not use initials.

Ship to Street Address: _____

City:_____ **State**: _____ **Zip**: _____

Contact Person: _____

Telephone No.: _____**Fax No.**: _____

Email Address: _____

☐ I have read and understood the attached notice.

☐ I have shared this notice with the appropriate personnel within my organization.

☐ We do NOT have any affected product(s) in inventory.

☐ We have affected product(s) in inventory and have completed an inspection of all foil bags. We do not require any replacement products.

☐ We have affected product(s) in inventory and have completed an inspection of all foil bags. We request the following replacement(s).

Product Name	Catalog No.	Lot No.	No. of Units

Name:	
Title:	
Signature/Date:	

FOR BDDS USE ONLY		
BILL TO ACC'T NO. **9000000446**	ORDER REASON **517**	DELIVERY P.O. NO.
SHIP TO ACC'T NO.	JUSTIFICATION CODE	INVOICE P.O. NO.

APPENDIX - Affected Product List

Product Name	Part/Catalog Number	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
Kit BD MAX ExK DNA 1 USA	442817	9085666	[redacted]	10/24/2020
Kit BD MAX ExK DNA 1 USA	442817	9106886	[redacted]	11/7/2020
Kit BD MAX ExK DNA 1 USA	442817	9127935	[redacted]	11/30/2020
Kit BD MAX ExK DNA 2 USA	442819	9114654	[redacted]	11/7/2020
Kit BD MAX ExK TNA 2	442825	9106876	[redacted]	11/7/2020
Kit BD MAX Enteric Parasite Panel	442960	9106889	[redacted]	11/15/2020
Kit BD MAX Enteric Bacterial Panel	442963	9085672	[redacted]	10/11/2020
Kit BD MAX Enteric Bacterial Panel	442963	9085673	[redacted]	10/11/2020
Kit BD MAX Enteric Bacterial Panel	442963	9106961	[redacted]	10/11/2020
Kit BD MAX Enteric Bacterial Panel	442963	9106962	[redacted]	11/2/2020
Kit BD MAX CT/GC/TV	442970	9080876	[redacted]	4/14/2020
Kit BD MAX CT/GC/TV	442970	9092733	[redacted]	4/14/2020
Kit BD MAX CT/GC/TV	442970	9092734	[redacted]	5/12/2020
Kit BD MAX CT/GC/TV	442970	9106875	[redacted]	5/12/2020
Kit BD MAX Cdiff USA	443418	9085659	[redacted]	10/20/2020
Kit BD MAX Cdiff USA	443418	9106883	[redacted]	11/14/2020

Product Name	Part/Catalog Number	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
Kit BD MAX StaphSR	443419	9086668	[redacted]	9/2/2020
Kit BD MAX StaphSR	443419	9092724		9/2/2020
Kit BD MAX MRSA XT	443461	9106890		8/28/2020
Kit BD MAX MRSA XT	443461	9106891		9/9/2020
Kit BD MAX MRSA XT	443461	9114657		9/22/2020
Kit BD MAX Vaginal Panel	443712	9092737		3/21/2020
Kit BD MAX Vaginal Panel	443712	9092738		3/21/2020
Kit BD MAX Vaginal Panel	443712	9127920		3/21/2020
Kit EXT Enteric Bacterial Panel	443812	9114557		11/7/2020
Kit EXT Enteric Bacterial Panel	443812	9126778		11/17/2020
Kit BD MAX Enteric Viral Panel	443985	9085674		11/1/2020
Kit BD MAX Enteric Viral Panel	443985	9107980		11/7/2020