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	(01)00382904428174 (17)201024(10)9085666(30)1	10/24/2020
Kit BD MAX ExK DNA 1 USA	442817	9106886	(01)00382904428174 (17)201107(10)9106886(30)1	11/7/2020
Kit BD MAX ExK DNA 1 USA	442817	9127935	(01)00382904428174 (17)201130(10)9127935(30)1	11/30/2020
Kit BD MAX ExK DNA 2 USA	442819	9114654	(01)00382904428198 (17)201107(10)9114654(30)1	11/7/2020
Kit BD MAX ExK TNA 2	442825	9106876	(01)00382904428259 (17)201107(10)9106876(30)1	11/7/2020
Kit BD MAX Enteric Parasite Panel	442960	9106889	(01)00382904429607 (17)201115(10)9106889(30)1	11/15/2020
Kit BD MAX Enteric Bacterial Panel	442963	9085672	(01)00382904429638 (17)201011(10)9085672(30)1	10/11/2020
Kit BD MAX Enteric Bacterial Panel	442963	9085673	(01)00382904429638 (17)201011(10)9085673(30)1	10/11/2020
Kit BD MAX Enteric Bacterial Panel	442963	9106961	(01)00382904429638 (17)201011(10)9106961(30)1	10/11/2020
Kit BD MAX Enteric Bacterial Panel	442963	9106962	(01)00382904429638 (17)201102(10)9106962(30)1	11/2/2020
Kit BD MAX CT/GC/TV	442970	9080876	(01)00382904429706 (17)200414(10)9080876(30)1	4/14/2020
Kit BD MAX CT/GC/TV	442970	9092733	(01)00382904429706 (17)200414(10)9092733(30)1	4/14/2020
Kit BD MAX CT/GC/TV	442970	9092734	(01)00382904429706 (17)200512(10)9092734(30)1	5/12/2020
Kit BD MAX CT/GC/TV	442970	9106875	(01)00382904429706 (17)200512(10)9106875(30)1	5/12/2020
Kit BD MAX Cdiff USA	443418	9085659	(01)00382904434182 (17)201020(10)9085659(30)1	10/20/2020
Kit BD MAX Cdiff USA	443418	9106883	(01)00382904434182 (17)201114(10)9106883(30)1	11/14/2020

Product Name	Part/Catalog Number	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
Kit BD MAX StaphSR	443419	9086668	(01)00382904434199 (17)200902(10)9086668(30)1	9/2/2020
Kit BD MAX StaphSR	443419	9092724	(01)00382904434199 (17)200902(10)9092724(30)1	9/2/2020
Kit BD MAX MRSA XT	443461	9106890	(01)00382904434618 (17)200828(10)9106890(30)1	8/28/2020
Kit BD MAX MRSA XT	443461	9106891	(01)00382904434618 (17)200909(10)9106891(30)1	9/9/2020
Kit BD MAX MRSA XT	443461	9114657	(01)00382904434618 (17)200922(10)9114657(30)1	9/22/2020
Kit BD MAX Vaginal Panel	443712	9092737	(01)00382904437121 (17)200321(10)9092737(30)1	3/21/2020
Kit BD MAX Vaginal Panel	443712	9092738	(01)00382904437121 (17)200321(10)9092738(30)1	3/21/2020
Kit BD MAX Vaginal Panel	443712	9127920	(01)00382904437121 (17)200321(10)9127920(30)1	3/21/2020
Kit EXT Enteric Bacterial Panel	443812	9114557	(01)00382904438128 (17)201107(10)9114557(30)1	11/7/2020
Kit EXT Enteric Bacterial Panel	443812	9126778	(01)00382904438128 (17)201117(10)9126778(30)1	11/17/2020
Kit BD MAX Enteric Viral Panel	443985	9085674	(01)00382904439859 (17)201101(10)9085674(30)1	11/1/2020
Kit BD MAX Enteric Viral Panel	443985	9107980	(01)00382904439859 (17)201107(10)9107980(30)1	11/7/2020

Kits name	Part/Catalog Number.	Lot / Serial Number.	UDI (GTIN, DI + PI)	Date of Mfr	Kitting date	Exp. Date	Qty MFRd	Qty in BD Control	Qty Distributed to Field	Legal manufacturer
Kit BDMax Check-Points CPO IVD EU	278102	9114645	(01)00180002781029 (17)200719(10)9114645(30)1	4/11/2019	5/17/2019	7/19/2020	170	40	130	Check-Points
Kit BD Max Cdiff EU	442555	9127912	(01)00382904425555 (17)201114(10)9127912(30)1	5/6/2019	6/3/2019	11/14/2020	818	814	4	BD DS Quebec
Kit BD Max ExK DNA 1 USA	442817	9085666	(01)00382904428174 (17)201024(10)9085666(30)1	4/15/2019	5/9/2019	10/24/2020	100	6	94	BD DS Quebec
Kit BD Max ExK DNA 1 USA	442817	9106886	(01)00382904428174 (17)201107(10)9106886(30)1	4/29/2019	5/24/2019	11/7/2020	231	210	21	BD DS Quebec
Kit BD Max ExK DNA 1 USA	442817	9127935	(01)00382904428174 (17)201130(10)9127935(30)1	5/22/2019	6/6/2019	11/30/2020	250	250	0	BD DS Quebec
Kit BD Max ExK DNA 1 EU LUO	442818	9085668	(01)00382904428181 (17)201024(10)9085668(30)1	4/15/2019	5/15/2019	10/24/2020	729	282	447	BD DS Quebec
Kit BD Max ExK DNA 1 EU LUO	442818	9106887	(01)00382904428181 (17)201107(10)9106887(30)1	4/29/2019	5/24/2019	11/7/2020	599	599	0	BD DS Quebec
Kit BD Max ExK DNA 2 USA	442819	9114654	(01)00382904428198 (17)201107(10)9114654(30)1	4/29/2019	6/3/2019	11/7/2020	291	291	0	BD DS Quebec
Kit BD Max ExK DNA 2 EU LUO	442820	9114655	(01)00382904428204 (17)201107(10)9114655(30)1	4/29/2019	6/3/2019	11/7/2020	125	115	10	BD DS Quebec
Kit BD Max ExK TNA 2	442825	9106876	(01)00382904428259 (17)201107(10)9106876(30)1	4/29/2019	5/7/2019	11/7/2020	235	149	86	BD DS Quebec
Kit BD Max MRSA	442953	9071522	(01)00382904429539 (17)191219(10)9071522(30)1	4/15/2019	5/9/2019	12/19/2019	494	318	176	BD DS Quebec
Kit BD Max Enteric Parasite Panel EU	442960	9106889	(01)00382904429607 (17)201115(10)9106889(30)1	5/7/2019	5/31/2019	11/15/2020	824	469	355	BD DS Quebec
Kit BD Max Enteric Bacterial Panel EU	442963	9085672	(01)00382904429638 (17)201011(10)9085672(30)1	4/2/2019	5/15/2019	10/11/2020	832	387	445	BD DS Quebec
Kit BD Max Enteric Bacterial Panel EU	442963	9085673	(01)00382904429638 (17)201011(10)9085673(30)1	4/2/2019	5/15/2019	10/11/2020	788	587	201	BD DS Quebec
Kit BD Max Enteric Bacterial Panel EU	442963	9106961	(01)00382904429638 (17)201011(10)9106961(30)1	4/2/2019	5/24/2019	10/11/2020	832	742	90	BD DS Quebec
Kit BD Max Enteric Bacterial Panel EU	442963	9106962	(01)00382904429638 (17)201102(10)9106962(30)1	4/24/2019	5/24/2019	11/2/2020	828	570	258	BD DS Quebec
Kit BD Max CT/GC/TV	442970	9080876	(01)00382904429706 (17)200414(10)9080876(30)1	4/8/2019	5/16/2019	4/14/2020	817	216	601	BD DS Quebec
Kit BD Max CT/GC/TV	442970	9092733	(01)00382904429706 (17)200414(10)9092733(30)1	4/8/2019	5/21/2019	4/14/2020	822	579	243	BD DS Quebec

Kit BD Max CT/GC/TV	442970	9092734	(01)00382904429706 (17)200512(10)9092734(30)1	5/6/2019	5/29/2019	5/12/2020	822	796	26	BD DS Quebec
Kit BD Max CT/GC/TV	442970	9106875	(01)00382904429706 (17)200512(10)9106875(30)1	5/6/2019	5/29/2019	5/12/2020	384	341	43	BD DS Quebec
Kit BD Max Cdiff USA	443418	9085659	(01)00382904434182 (17)201020(10)9085659(30)1	4/11/2019	5/17/2019	10/20/2020	803	520	283	BD DS Quebec
Kit BD Max Cdiff USA	443418	9106883	(01)00382904434182 (17)201114(10)9106883(30)1	5/6/2019	6/3/2019	11/14/2020	803	803	0	BD DS Quebec
Kit BD Max StaphSR	443419	9086668	(01)00382904434199 (17)200902(10)9086668(30)1	4/17/2019	5/30/2019	9/2/2020	832	633	199	BD DS Quebec
Kit BD Max StaphSR	443419	9092724	(01)00382904434199 (17)200902(10)9092724(30)1	4/17/2019	5/28/2019	9/2/2020	822	814	8	BD DS Quebec
Kit BD Max MRSA XT	443461	9106890	(01)00382904434618 (17)200828(10)9106890(30)1	4/12/2019	5/21/2019	8/28/2020	824	773	51	BD DS Quebec
Kit BD Max MRSA XT	443461	9106891	(01)00382904434618 (17)200909(10)9106891(30)1	4/24/2019	5/22/2019	9/9/2020	830	820	10	BD DS Quebec
Kit BD Max MRSA XT	443461	9114657	(01)00382904434618 (17)200922(10)9114657(30)1	5/7/2019	6/4/2019	9/22/2020	820	820	0	BD DS Quebec
Kit BD Max GC RT PCR Assay	443486	9092736	(01)00382904434861 (17)200425(10)9092736(30)1	4/19/2019	5/29/2019	4/25/2020	416	399	17	BD DS Quebec
Kit BD Max Vaginal Panel	443712	9092737	(01)00382904437121 (17)200321(10)9092737(30)1	4/12/2019	5/15/2019	3/21/2020	832	314	518	BD DS Quebec
Kit BD Max Vaginal Panel	443712	9092738	(01)00382904437121 (17)200321(10)9092738(30)1	4/12/2019	5/17/2019	3/21/2020	408	286	122	BD DS Quebec
Kit BD Max Vaginal Panel	443712	9127920	(01)00382904437121 (17)200321(10)9127920(30)1	4/12/2019	5/17/2019	3/21/2020	416	390	26	BD DS Quebec
Kit BD Max Enteric Viral Panel RUO	443715	9114647	(01)00382904437152 (17)201107(10)9114647(30)1	4/29/2019	5/29/2019	11/7/2020	40	13	27	BD DS Baltimore
Kit EXT Enteric Bacterial Panel	443812	9114557	(01)00382904438128 (17)201107(10)9114557(30)1	4/29/2019	5/10/2019	11/7/2020	810	175	635	BD DS Quebec
Kit EXT Enteric Bacterial Panel	443812	9126778	(01)00382904438128 (17)201117(10)9126778(30)1	5/9/2019	5/21/2019	11/17/2020	827	815	12	BD DS Quebec
Kit EXT Enteric Bacterial Panel	443812	9129979	(01)00382904438128 (17)201122(10)9129979(30)1	5/14/2019	5/28/2019	11/22/2020	816	748	68	BD DS Quebec
Kit BD Max Enteric Viral Panel EU	443985	9085674	(01)00382904439859 (17)201101(10)9085674(30)1	4/23/2019	5/8/2019	11/1/2020	399	94	305	BD DS Baltimore
Kit BD Max Enteric Viral Panel EU	443985	9107980	(01)00382904439859 (17)201107(10)9107980(30)1	4/29/2019	5/29/2019	11/7/2020	347	183	164	BD DS Baltimore
Total							22036	16361	5675	