30 Tuas Avenue 2
Singapore 639461
Registration No. 201114149N

bd.com

URGENT MEDICAL DEVICE PRODUCT ADVISORY

28th January 2019

Catalog Number	Lot Number	Expiration Date
246009- Phoenix Ast-S Indicator	8103973	2/28/2019
	-	-
	-	-
246006- Bag Phoenix Ap Ast Indicator	8150670	6/30/2019

For the Attention of: Microbiology Manager/Supervisor

cc: Chairman Medical Board and relevant Head of Departments

Description of the problem and health hazard(s):

BD has recently confirmed that BD Phoenix™ panels that have been inoculated using certain lots of BD Phoenix AST Indicator solution are demonstrating an increased occurrence of test aborts within 45 minutes after the panel is placed into the Phoenix instrument. Customers experiencing test aborts receive the following instrument Special Message report: *An insufficient amount of indicator was detected in the panel. The AST portion of the panel has been terminated and the isolate should be retested.*

Laboratories that monitor instrument generated messages will recognize in a timely manner any abort messages that may occur. This will allow for prompt response and set up a new panel limiting any risk to a patient from a delay in results.

Our records indicate you may have been shipped the above-referenced lots of product. Corrective actions have been implemented and new lots are now available to replace your affected inventory.

Please Take the Following Action(s):

1. Complete the attached Customer Response Form and return to the BD contact noted on the form whether you have any of the impacted material so that BD may acknowledge your receipt of this notification.
2. **Discard any remaining inventory of the affected lots upon receipt of replacement. BD will process replacement of any discarded inventory upon receipt of the Customer Response Form.**

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3. Share this Advisory Letter with all users of the BD Phoenix instrument within your facility to ensure awareness.
4. Report any adverse health consequences experienced with the use of this product to BD.
5. There are other identifiers/ lots affected globally. Please reach out to us if any clarification needed.

Actions Taken by BD:

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

BD will replace your remaining affected inventory upon receipt of the Customer Response Form.

For all other inquiries please contact your local BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

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]

Regulatory Affairs & Compliance Executive
Becton Dickinson & Company
3A International Business Park
#12-10/18 ICON@IBP,
609935, Singapore

Distributor Response Form
Medical Device Correction Notice

Phoenix™ AST Indicator Product Advisory

Facility: _____

Please use full, current facility name. Do not use initials.

Street Address: _____

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

Contact Person: _____

Telephone No.:_____**Email Address**: _____

Fax No.: _____

☐ I have read and understood the attached notice.

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

☐ We have affected product(s) in inventory.

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

Product Name	Catalog No.	Lot No.	No. of Units
Phoenix™ AST-s Indicator	246009		
Phoenix™ AP AST Indicator Bag	246006		

Name:	
Title:	
Signature/Date:	