

URGENT MEDICAL DEVICE PRODUCT ADVISORY

Date: January 2, 2018

Product Name	UDI	Catalog No.	Lot No.	Expiration Date (YYYYMMDD)	Product Package Size
BD Phoenix Gram Negative Panels containing colistin	N/A	See Attached List	All	Various	Various

For the Attention of: Microbiology Manager/Supervisor

Description of the problem and health hazard(s):

As a result of our continuous antimicrobial resistance surveillance, BD would like to make you aware of newly recognized or emerging strains that may yield an increased rate of false susceptibility in *in vitro* antimicrobial susceptibility test (AST) results to colistin. BD has conducted investigational testing with gram-negative bacterial strains from our internal collection, as well as recently-acquired clinical isolates using the BD PhoenixTM Automated Microbiology System to identify any shift in performance for colistin since the drug was initially approved for use in the BD Phoenix Gram Negative Panels. The investigation demonstrated a higher than expected rate of very major errors (resistant isolates reported as susceptible) with colistin compared to colistin in broth-microdilution (BMD) panels.

EUCAST and CLSI recently issued a joint recommendation that broth-microdilution (BMD) is the only reference method validated for antimicrobial susceptibility testing (AST) of colistin.

Antimicrobial susceptibility testing of colistin has been fraught with difficulties. A joint **EUCAST and CLSI subcommittee recently issued recommendations** confirming that broth microdilution (BMD) is so far the only valid method and that disk diffusion does not work because of the poor diffusion of the large colistin molecule. The report did not evaluate gradient tests of colistin, but reports in the literature have questioned the validity of MICs obtained with gradient tests. https://clsi.org/media/1700/clsi-news-winter-2016.pdf

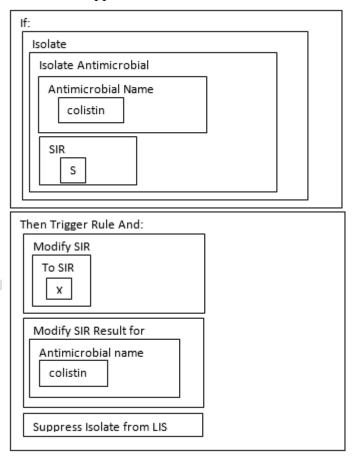
Our records indicate you may have been shipped the above-referenced product. BD is not requesting that customers discard, return or discontinue use of the product.

Please Take the Following Actions:

- 1. Share this Product Advisory with all users of the product within your facility to ensure awareness.
- 2. Perform an alternate method of testing prior to reporting <u>susceptible</u> colistin results. A <u>resistant</u> Phoenix colistin result does not require alternate testing.
- 3. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification.
- 4. Report any adverse health consequences experienced with the use of this product to BD.
- 5. Please review the additional mitigations below that can be utilized if required by your facility's procedures.

If you are an EpiCenter customer, a custom EpiCARE rule can be created to suppress 'S' for CL:

- Refer to EpiCenter help for how to create a custom EpiCARE rule
- Create a custom rule for "colistin" to Modify SIR of 'S' to 'X'
- If the isolate antimicrobial name is colistin and the SIR is S; then trigger rule and modify SIR to X for colistin and suppress isolate from LIS.



• Test the resulting EpiCARE rule as described in EpiCenter help

If you are a Phoenix 100 or M50 standalone customer:

- Refer to Configuration section of the instrument User Manual for creating Custom Interpretation Rule Set
- Enter a new S (susceptible) breakpoint of 0.25 for each colistin interpretation group listed
- The new lower S breakpoint will result in a report of "< the lowest dilution on the panel" and will show an interpretation of "X". An MIC of 1 or 2 will give an interpretation of "I". Results showing an "X" or "I" interpretation should not be reported.

Actions Taken by BD:

BD is currently evaluating additional corrective measures to address this situation.

Contact Information

If you require further assistance, please contact:

BD Contact	Contact Information	Areas of Support
BD Customer/Technical Support	000 050 0005	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.

CUSTOMER RESPONSE FORM BD Phoenix Gram Negative Panels Containing Colistin

Please assist BD by promptly returning this form to: Your Distributor

Facility:						
Please	use full, current facility name	e. 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	ne appropriate personnel within	my organization.				
Name:						
Title:						
Signature/Date:		,				