

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 Phoenix™ 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 susceptible colistin results. A resistant 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.

The image shows a screenshot of the EpiCARE rule configuration interface. It is divided into two main sections: 'If:' and 'Then Trigger Rule And:'.

The 'If:' section contains a nested box labeled 'Isolate'. Inside this box is another box labeled 'Isolate Antimicrobial'. Within 'Isolate Antimicrobial', there is a box for 'Antimicrobial Name' with the value 'colistin' entered, and a box for 'SIR' with the value 'S' entered.

The 'Then Trigger Rule And:' section contains three boxes:
1. 'Modify SIR' box, which includes a 'To SIR' sub-box with the value 'X' entered.
2. 'Modify SIR Result for' box, which includes an 'Antimicrobial name' sub-box with the value 'colistin' entered.
3. A box labeled 'Suppress Isolate from LIS'.

- Test the resulting EpiCARE rule as described in EpiCenter help

If you are a Phoenix100 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 | 800-638-8663 Monday – Friday between 8:30am and 5:00pm (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.

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. 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.

| | |
|-----------------|--|
| Name: | |
| Title: | |
| Signature/Date: | |