



Becton Dickinson Benelux NV

Customer Service

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BNP Paribas Fortis

BE40 0017 6316 5663

B.T.W. BE 0400.292.967 T.V.A.

RPR Gent (Afdeling Dendermonde)

bd.com

URGENT FIELD SAFETY NOTICE

Date: January 15, 2018

Product Name	Product Catalog No.	Lot No.	Expiration Date (YYYYMMDD)
BD Phoenix Gram Negative Panels containing colistin	See Attached List	See Attached List	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*



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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 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.**



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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
BD Customer/Technical Support	Please contact your local BD representative

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,

A handwritten signature in blue ink, appearing to read 'Laury Michels', with a stylized flourish at the end.

Laury Michels
Regulatory Affairs Specialist
BD Life Sciences



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Affected Product List:

PCN	Lotnumber
448103	7010882
448103	7046944
448103	7116977
448103	7143986
448103	7194505
448620	7073565
448620	7129781
448746	6355623
448746	7005754
448746	7010860
448746	7059546
448746	7073558
448746	7080746
448746	7116965
448746	7137704
448746	7157720
448746	7199792
448746	7234639
448746	7249753
448746	7276989
448746	7312987
448764	7010551
448764	7018960
448764	7039708
448764	7122541
448764	7122955
448764	7202645
448764	7206579
448764	7285889
448781	6355645
448781	7005890

PCN	Lotnumber
448781	7017960
448781	7018937
448781	7025975
448781	7025987
448781	7031760
448781	7039809
448781	7045787
448781	7054927
448781	7094660
448781	7096643
448781	7116772
448781	7129825
448781	7137632
448781	7151841
448781	7164707
448781	7186618
448781	7186699
448781	7192503
448781	7206564
448781	7206632
448781	7206921
448781	7226525
448781	7227527
448781	7234561
448781	7262751
448781	7269871
448781	7269909
448781	7276923
448781	7285866
448781	7285870
448781	7291949

PCN	Lotnumber
448790	7010895
448790	7018958
448790	7039587
448790	7054505
448790	7080729
448790	7087857
448790	7116989
448790	7122552
448790	7157708
448790	7206608
448790	7241658
448790	7255762
448790	7262794
448792	6355613
448792	7005947
448792	7080958
448792	7122568
448792	7255864
448792	7305643
448794	7025966
448794	7054631
448794	7054949
448794	7059737
448794	7059816
448794	7066540
448794	7066543
448794	7073963
448794	7073985
448794	7080717
448794	7080727
448794	7087802



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PCN	Lotnumber
448794	7087806
448794	7129771
448794	7157732
448794	7206651
448794	7206929
448794	7227502
448794	7234580
448794	7241920
448794	7249714
448794	7276921
448794	7276926
448874	6355604
448874	7005708
448874	7010553
448874	7025984
448874	7039511
448874	7045813
448874	7073997
448874	7080973
448874	7087867
448874	7094703
448874	7116808
448874	7129629
448874	7151818
448874	7157928
448874	7164913
448874	7199627
448874	7202630
448874	7227558
448874	7234638

PCN	Lotnumber
448874	7241924
448874	7291519
448874	7305560
448875	7005985
448875	7039525
448875	7087843
448875	7122521
448875	7255712
448875	7269685
448875	7291962
448877	6355633
448877	7025973
448877	7046916
448877	7059786
448877	7094701
448877	7157713
448877	7269659
448877	7312544
448878	7054501
448878	7094681
448878	7129820
448878	7157734
448878	7241626
448878	7324539
449001	7018957
449001	7023834
449001	7025514
449001	7025572
449001	7025981
449001	7031775

PCN	Lotnumber
449001	7031795
449001	7039792
449001	7045825
449001	7059746
449001	7059797
449001	7073571
449001	7080974
449001	7087803
449001	7087810
449001	7094600
449001	7094968
449001	7116992
449001	7122523
449001	7122561
449001	7129778
449001	7137655
449001	7143890
449001	7164694
449001	7186638
449001	7199624
449001	7199670
449001	7206570
449001	7227978
449001	7234566
449001	7249724
449001	7249776
449001	7255531
449001	7285924
449025	7220623
449026	7209501



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**CUSTOMER RESPONSE FORM
BD Phoenix Gram Negative Panels Containing Colistin**

Please assist BD by promptly returning this form to:

Name:

Email:

Fax No.:

Facility: _____

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

Street Address: _____

City: _____ **Zip:** _____ **Country:** _____

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.

Name:	
Title:	
Signature/Date:	