ThermoFisher SCIENTIFIC

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:

URGENT FIELD SAFETY NOTICE

Thermo Scientific™ QMS™ Calibrator and Associated Teicoplanin Reagent

Catalog Numbers
0374652
0374645

June 18, 2018

CUSTOMER INFORMATION
XXXXXX
XXXXXX

XXXXXXX

Dear Lab Manager,

The purpose of this letter is to advise you that Microgenics Corporation, part of Thermo Fisher Scientific, is conducting a field correction for the QMS™ Calibrator and associated Teicoplanin Reagent. The QMS Calibrator and associated Teicoplanin Reagent is intended for the quantitative determination of Teicoplanin in human serum or plasma on automated clinical chemistry analyzers.

REASON FOR FIELD CORRECTION:
To date four (4) complaints have been logged on calibrator catalog number 0374652, lot number 73032439. This lot showed a shift in UK NEQAS (proficiency survey) samples and in control recovery across the assay range on multiple analyzer platforms. Performance of calibrator lot 73032439 indicates degradation by ~25% across the assay range and may show significant shifts in assay recovery.

QMS Teicoplanin Calibrator lot number 73032439 should be handled in accordance with the “actions to be taken” section below. In addition to the above complaints, the total precision on QMS Teicoplanin Reagent lots above concentrations of 50 µg/mL shows CV recoveries upwards of 15%. The claim for QMS Teicoplanin Reagent future lots is being revised to reflect dilution step that would update the Assay Range from 3-100 µg/mL to 3-50 µg/mL.

PRODUCT INFORMATION:
Our records indicate that you have purchased one or more of the products listed in Table 1. Catalog number 0374652, lot number 73032439 is being recalled. Catalog number 0374645, included in Table 1, is included in the recall due to the assay range change to 3-50 µg/mL when a dilution step is added as part of a revised Instructions For Use (IFU). For catalog number 0374645 only the IFU is impacted. The reagent currently functions to label claim between Assay Range from 3-50 µg/mL.

Table 1

Product Name	Catalog Number	Lot Number
QMS™ Teicoplanin Calibrator	0374652	73032439
QMS™ Teicoplanin Reagent	0374645	All current and future lots under this Catalog Number are affected. An IFU update is required.

RISK TO HEALTH:

Therapeutic teicoplanin drug concentrations are 5 to 50 µg/mL. Therapeutic drug monitoring and analysis of serum teicoplanin concentration alone is not sufficient for optimization of drug therapy, nor is it a replacement for frequent clinical assessment to evaluate for evidence of therapeutic efficacy or failure. Drug concentration results are always assessed in conjunction with the patient's full clinical picture by treating physicians during optimization of drug therapy. Other indicators of efficacy, including clinical assessment parameters and other diagnostic monitoring tests are used to verify appropriate therapeutic response to the prescribed antibiotic dose.

ACTIONS TO BE TAKEN BY THE CUSTOMER / USER:

Actions for QMS Teicoplanin Calibrator (Catalog Number 0374652, Lot Number 73032439)

1. Determine if you are using or have inventory of the affected lot of QMS Teicoplanin Calibrator.
2. Discontinue use and destroy any remaining inventory of the affected lots of QMS Teicoplanin Calibrator per your local waste ordinances.
3. Retain a copy of this letter for your laboratory records.
4. Requirement for review of previously reported test results when used with QMS Teicoplanin Calibrator (Catalog Number 0374652, Lot Number 73032439) should be determined by the appropriate technical expert.
5. If you have forwarded the affected lot, 73032439, of QMS Teicoplanin Reagent to another laboratory, please provide a copy of this letter to them.
6. Complete the attached Field Safety Notice Response Form, and return the form **within 5 days of the date of this letter** to Thermo Fisher Scientific Technical Service by:
    - FAX: +49 (0)3302883-242
    - E-mail: cdx.de.order@thermofisher.com

Actions for QMS Teicoplanin Reagent (Catalog Number 0374645, Current Lot and Future Lots)

7. Determine if you are using or have inventory of QMS™ Teicoplanin Reagent Catalog Number 0374645
8. Take note of the corrected Assay Range below:
    - Updated Assay Range: 3-50 µg/mL
9. For all samples (including quality controls) that recover a value above 50 µg/mL, follow the dilution protocol below:
    - Prepare a 1:1 dilution consisting of 1part sample to 1 part calibrator A.
    - Invert the diluted sample gently at least 5 times.
    - Run diluted sample on analyzer per approved laboratory protocols.
    - Multiply the diluted sample result by a factor of 2 to obtain the result.

    **Note: The calibrators used to calibrate the reagent should be used as-is; do NOT dilute the calibrators.*
10. Requirement for review of reported test results when used with QMS Teicoplanin Reagent Catalog Number 0374645 should be determined by the appropriate technical expert.
11. If you have forwarded QMS Teicoplanin Reagent Set, Catalog Number 0374645, to another laboratory, please provide a copy of this letter to them.
12. Complete the attached Field Safety Notice Response Form, and return the form **within 5 days of the date of this letter** to Thermo Fisher Scientific Technical Service by:
    - FAX: +49 (0)3302883-242
    - E-mail: cdx.de.order@thermofisher.com

For questions or additional instructions please contact your local Thermo Fisher Scientific sales office or approved distributor in your region.

Any regulatory questions you may have should be addressed to the European Authorized Representative for the Manufacturer, Microgenics Corporation:

B·R·A·H·M·S GmbH

Dr. Bernhard Ciommer,
Medical Device Safety Officer,
Director RA&QA Compliance
Neuendorfstrasse 25
16761 Hennigsdorf
Germany

Telephone: +49 3302 883 752
FAX: +49 3302 883 640
e-mail: EU-vigilance@thermofisher.com

Please be advised that the relevant National Competent Authorities have been advised of this safety notice.

We appreciate your immediate attention to this field correction. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction. If you have any questions, please contact your local Thermo Fisher Scientific sales office or approved distributor in your region.

Sincerely,

ppa. Dr. Bernhard Ciommer
Medical Device Safety Officer

FIELD SAFETY NOTICE RESPONSE FORM
Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION
XXXXXX
XXXXXX

XXXXXXX

Thermo Scientific™ QMS™ Calibrator and Associated Teicoplanin Reagent

Catalog Number
0374645
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I have read and understand the attached customer letter and field correction instructions: _____ (initials)

I have read and understand the assay range is: **3-50 µg/mL and the dilution protocol for values that recover above 50 µg/mL:** _____ (initials)

I understand that this assay range correction applies to all inventory of the affected reagent lots that I have received: ____ (initials)

I have discontinued use of the affected calibrator lot 73032439: _____ (initials)

Any adverse events associated with the field correction product? _____ Yes _____ No
If yes, please explain:

_____

_____
Use additional sheet(s) if necessary.

RETURN RESPONSE (please provide additional information, if applicable):

PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING TECHNICAL SERVICE FAX NUMBER +49 (0)3302883-242 or e-mail cdx.de.order@thermofisher.com

Signature of Receipt by Customer: _____

Name/Title:	
Telephone:	
Email Address:	

Clinical Diagnostics
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