ThermoFisher SCIENTIFIC

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Thermo Fisher Scientific, Clinical Diagnostics, Spitalhofstraße 94, D-94032 Passau

URGENT MEDICAL DEVICE FIELD ACTION
Thermo Scientific™ QMS® Everolimus Immunoassay
- UPDATE -

Catalog Numbers
0373852
0380000

October 24, 2016

Dear Valued Customer:

On August 22, 2016 we sent you the below notice on the QMS® Everolimus Immunoassay. Since this letter was sent to you additional information has come to light regarding patient samples. Originally in the "REASON FOR FIELD ACTION" section we reported that "Current patient samples are not in question." Thermo Fisher wishes to update that statement to the following: "You may observe bias in patient samples ranging from -15.7% to +5.2% with an average bias of -5.6% when comparing your assay to the LC-MS reference method".

Additionally, Thermo Fisher is also updating the "RISK TO HEALTH" section. The update clarifies that all ranges (sub-therapeutic, therapeutic, supra-therapeutic) may be affected by as much as 16%.

These changes are incorporated into the text below.

The purpose of this letter is to advise you that Microgenics Corporation, part of Thermo Fisher Scientific, is conducting a field action for QMS® Everolimus Immunoassay. We are asking customers to discontinue use of the affected products listed in the following table, and destroy any remaining inventory of the affected lots per instructions below.

REASON FOR FIELD ACTION

The assay is intended for use in the quantitative determination of Everolimus in human whole blood. Our product review has revealed that over time the affected lots may yield over-quantitation in patient samples. This notification is to avoid the affected product reaching that time point in the future. You may observe bias in patient samples ranging from -15.7% to +5.2% with an average bias of -5.6% when comparing your assay to the LC-MS reference method

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AFFECTED PRODUCT INFORMATION

Product Name	Catalog Number	Lot Number	Expiration Date
QMS Everolimus (ROW) Immunoassay	0373852	72258007	31 July 2017
QMS Everolimus (US) Immunoassay	0380000	72258049	31 July 2017

RISK TO HEALTH

Over-recovery of whole blood assay results in all ranges (sub-therapeutic, therapeutic, supra-therapeutic) may be affected by as much as 16% (for example, a reported assay result of 2.9 ng/mL instead of the actual whole blood concentration of 2.5 ng/mL) would not be expected to significantly alter dosage adjustment by the treating clinician. Given standardized medication toxicity and close monitoring of patients for markers of efficacy, the risk of developing serious or long-range adverse health consequences due to a single reported erroneous everolimus concentration result is deemed to be negligible. Patient samples in all ranges (sub-therapeutic, therapeutic, supra-therapeutic) may be affected.

ACTIONS TO BE TAKEN BY THE CUSTOMER / USER

1. Determine if you are using or have inventory of any of the affected lots of QMS Everolimus Immunoassay.
2. Discontinue use and destroy any remaining inventory of the affected lots of QMS Everolimus Immunoassay per your local waste ordinances.
3. Retain a copy of this letter for your laboratory records.
4. If you have forwarded kits of the affected lots of QMS Everolimus Immunoassay to another laboratory, please provide a copy of this letter to them.
5. Complete the attached Medical Device Field Action Response Form and return the form within 5 days to Thermo Fisher Scientific Technical Service as instructed in the form below.
6. For product refund and to discuss alternative options for Everolimus reagent supply, please contact your local Thermo Fisher Scientific sales office or approved distributor in your region.

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR

If you are a distributor of the product, please contact your affected customer base, advise them of the situation, and provide them with a copy of this letter. You should insert your contact information, email and fax numbers in the Medical Device Field Action Response Form and request that they return the form to you. You should fill out the distributor section of the attached Medical Device Field Action Response Form and return the form within 5 days to Thermo Fisher Scientific Technical Service as instructed in the form.

TYPE OF ACTION BY THE MANUFACTURER
Microgenics Corporation is in process of implementing actions to prevent future occurrences.

We appreciate your immediate attention to this field action. 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,

Microgenics GmbH

Enclosure - Acknowledgment & Receipt Form

CDD
Clinical Diagnostics
Division

Microgenics GmbH
Spitalhofstraße 94
94032 Passau
Germany
Telefon +49 (0) 851 – 88689 – 0
Telefax +49 (0) 851 – 88689 – 10

Manager/Geschäftsführer:
Henry Johe, Dr. Ralf Schlegel,
Petrus Thomas Adrianus van der Zande

Registergericht: Passau HRB 5772
UStIdNr. DE198185408

Bankverbindung:
Deutsche Bank
Konto-Nr. 096399100
BLZ: 50070010
IBAN: DE63500700100096399100
SWIFT: DEUTDEFFXXX

www.thermoscientific.com

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MEDICAL DEVICE FIELD ACTION RESPONSE
Acknowledgment & Receipt Form
Response Required
- UPDATE -

«Ship_To_Name»
«Ship_To_Address_Line_1»
«Ship_To_Address_Line_2»
«Ship_To_City»«Ship_To_State»«Ship_To_Zip»
«Ship_To_Country»

Thermo Scientific™ QMS® Everolimus Immunoassay

Product Name	Catalog Number	Lot Number	Expiration Date
QMS Everolimus (ROW) Immunoassay	0373852	72258007	31 July 2017
QMS Everolimus (US) Immunoassay	0380000	72258049	31 July 2017

I have read and understand the attached customer letter and field action instructions: _____ (initials)

I have discontinued use of the affected lots: _____ (initials)

I understand that this applies to all inventories of the affected lots that I have received: ____ (initials)

Number of units destroyed _____

Any adverse medical events associated with the field action 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 email to cdx.de.order@thermofisher.com

Signature of Receipt by Customer: _____

Name/Title:	
Telephone:	
Email Address:	
Company	

NOTE: Distributors please use the Acknowledgement & Receipt form on reverse side.

CDD
Clinical Diagnostics Division

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BLZ: 50070010
IBAN: DE63500700100096399100
SWIFT: DEUTDEFFXXX

www.thermoscientific.com

DISTRIBUTORS:

I understand that this applies to all inventory of the affected lot that I have received _____ (initials)

I have identified and notified my customers that were shipped or may have been shipped product affected by this letter by [specify date and method of notification]:

_____

_____

_____

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

Signature of Receipt by Distributor: _____

Name/Title:	
Telephone:	
Email Address:	
Company	