

URGENT – MEDICAL DEVICE CORRECTION

Thermo Scientific™ QMS® Tacrolimus Calibrator

Catalog Number: 10015573; Lot Number 74085025, 74175462, 74267412, 73925326, 73767734 & 73712031

June 8, 2022

Dear Valued Customer,

Our records indicate that you have previously purchased Thermo Scientific™ QMS® Tacrolimus Calibrator, catalog number 10015573, lot numbers 74267412, 74175462, 74085025, 73925326, 73767734 and 73712031.

The purpose of this Medical Device Correction is to advise you that Microgenics Corporation, part of Thermo Fisher Scientific, is conducting a medical device correction for these six (6) lots of Thermo Scientific™ QMS® Tacrolimus Calibrator. The QMS® Tacrolimus Calibrator set is intended for use in calibration of the QMS® Tacrolimus Immunoassay.

Thermo Scientific™ QMS® Tacrolimus Immunoassay is intended for the quantitative determination of tacrolimus in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of kidney, liver, and heart transplant patients receiving tacrolimus therapy. This in vitro diagnostic device is intended for clinical laboratory use only.

REASON FOR MEDICAL DEVICE CORRECTION:

Through internal investigation into complaints for elevated results observed with the QMS® Tacrolimus Immunoassay, Thermo Fisher has identified Thermo Scientific™ QMS® Tacrolimus Calibrator, catalog number 10015573, lot numbers 74267412, 74175462, 74085025, 73925326, 73767734 and 73712031. Lots 74267412, 74175462 are recovering between 85 – 93% of their target values (as shown in the table below), resulting in over-quantitation in patient result values. While complaints associated with a change in patient management have been received, based on internal studies, the average level of bias observed for patients’ samples is approximately 8% compared to correctly assigned lots of calibrators. MORE Diagnostics Rap/Tac/CsA Controls are recommended in the QMS® Tacrolimus Immunoassay instructions for use for the purposes of assay quality control, however as these QC materials are value assigned using the QMS Tacrolimus Calibrators, this bias would not have been identified by out-of-range control results for laboratories using this QC material (or other commercially available third party controls that have been similarly value assigned using impacted calibrator lots). Root cause investigation findings indicate that the shift is associated with a change to the anchor calibrator testing process that resulted in bias being introduced to the anchor calibrator values (Refer to the table below for the calibrator recovery values versus the target). These calibrators were then used to produce the calibrator lots listed above.

QMS Tacrolimus Calibrator Catalog Number 10015573				
QMS Tacrolimus Calibrator Kit Lot Number / expiration date	74267412 / Exp. 2022-05-12		74175462 / Exp. 2022-03-10	
	Target Value (ng/mL)	Cascadion LC/MS Recovery (ng/mL)	Target Value (ng/mL)	Cascadion LC/MS Recovery (ng/mL)
Calibrator Level				
QMS Tacrolimus Calibrator Level 1	0	0	0	0
QMS Tacrolimus Calibrator Level 2	2	1.8	2	1.7
QMS Tacrolimus Calibrator Level 3	5	4.5	5	4.3
QMS Tacrolimus Calibrator Level 4	10	9.2	10	8.6
QMS Tacrolimus Calibrator Level 5	20	18.6	20	17.4
QMS Tacrolimus Calibrator Level 6	30	27.3	30	26.3

Table 1 Only lots 74267412 and 74175462 were available for this study; data is not available for the lots 74085025, 73925326, 73767734 and 73712031. All lots are included in the recall.

This Medical Device Correction is being taken to recall Thermo Scientific™ QMS® Tacrolimus Calibrator, catalog number 10015573, lot numbers 74267412, 74175462, 74085025, 73925326, 73767734 and 73712031.

RISK TO HEALTH: Therapeutic drug monitoring of Tacrolimus dose is necessary for safe use of the drug to minimize side effects and provide adequate immunosuppression to avoid organ rejection episodes. Over-quantification of the patient results could result in physician erroneously lowering the drug dose.

ACTIONS TO BE TAKEN BY THE CUSTOMER:

- Determine if you have used or have remaining inventory of QMS® Tacrolimus Calibrator catalog number 10015573, lot 74267412, 74175462, 74085025, 73925326, 73767734, or 73712031. As QMS® Tacrolimus Calibrator catalog number 10015573, lot numbers 74267412, 74175462, 74085025, 73925326, 73767734 and 73712031 have all expired.
- If this has not already occurred following the expiration of the lots listed above, transition to new lot(s) where corrections have been made. Lot 74395275 and Lot 74459127 have had the testing correction applied and are currently available in stock.
- Dispose of any remaining inventory of the impacted lots in accordance with local, regional, national regulations.
- Inform all physician/clinicians who received affected lots of the potential of over-quantitation in patient result values.
- Pass this notification on to all who need to be aware within your organization or to any organization where the potentially affected calibrator lots have been transferred.
- Discuss the need for re-analysis of test results with the Clinical Lab Director and treating physician/healthcare provider.
- Retain a copy of this letter for your laboratory records.
- Call Technical Service if assistance is needed for lot replacement (free of charge).
- Please complete the Acknowledgment & Receipt Form attached to this Notification within 5 days of the date of this letter to Thermo Fisher Scientific Technical Service as instructed in the form to:
 - U.S. FAX: 888-527-8801;
 - OUS FAX: +1-510-979-5420 (outside USA); or
 - E-mail: TechService.mgc@thermofisher.com.
- If you have any additional questions regarding this Medical Device Correction, contact Thermo Fisher Scientific Technical Support by:
 - **FAX: 888-527-8001 (USA only) or +1-510-979-5420 (outside USA)**
 - **PHONE: (+1)-800-232-3342 then press option 2, then option 2, or contact your local country representative.**
 - **E-mail: TechService.mgc@thermofisher.com**

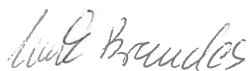
Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This Medical Device Correction has been communicated to the appropriate Regulatory Agency.

We appreciate your immediate attention to this Medical Device Correction and apologize for any inconvenience this may have caused. Thermo Fisher Scientific is committed to supplying innovative, high quality products for your use and are taking necessary actions to prevent recurrence of this issue. If you have any questions, please contact Technical Service at +1-800-232-3342, option 2, then option 2, or via email at TechService.mgc@thermofisher.com.

Sincerely,



Mark Brandes
Sr. Manager, Quality
Clinical Diagnostics – Niche Products
Thermo Fisher Scientific

Enclosure – Acknowledgment & Receipt Form

**MEDICAL DEVICE CORRECTION RESPONSE
Acknowledgment & Receipt Form
Response Required**

CUSTOMER INFORMATION

Thermo Scientific™ QMS Tacrolimus Immunoassay Calibrator

Catalog Number	Product Name	Lot Number
10015573	Thermo Scientific™ QMS® Tacrolimus Calibrator	74267412, 74175462, 74085025, 73925326, 73767734, 73712031

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

Any adverse medical events associated with the product listed in this Medical Device Correction? Yes ___ No ___
If yes, please explain:

I have read and I understand that I should not use these lot to verify the performance of the QMS Tacrolimus Immunoassay Kit: _____(initials)

PLEASE RETURN COMPLETED RESPONSE FORMS with your name, telephone, email, company name and address TO THE FOLLOWING TECHNICAL SERVICE FAX NUMBER 888-527-8801 (USA toll free), +1-510-979-5420 (outside USA), or e-mail: TechService.mgc@thermofisher.com

Signature of Receipt: _____

Name/Title:	
Telephone:	
Email Address:	
Company Name	
Shipping Address	Street Address:
	City, State, Zip Code: