

FIELD SAFETY NOTICE - URGENT

Thermo Scientific™ QMS® Tacrolimus Calibrator
Catalog Number: 10015573; Lot Number 74085025, 74175462 & 74267412

January 13, 2022

Dear Valued Customer,

Our records indicate that you have previously purchased Thermo Scientific™ QMS® Tacrolimus Calibrator, catalog number 10015573, lot number 74085025 (expired), 74175462 or 74267412.

The purpose of this field safety notice is to advise you that Microgenics Corporation, part of Thermo Fisher Scientific, is conducting a field safety corrective action for these 3 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 FIELD SAFETY CORRECTIVE ACTION:

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 74175462, 74267412, and 74085025 (expired) are recovering between 82 – 94% of their target values, resulting in over-quantitation in patient result values. Root cause investigation is in process, however interim 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; note - although lot # 74085025 has already expired, calibrator values for this lot are additionally included for customer reference). These calibrators were then used to produce the calibrator lots listed below.

QMS Tacrolimus Calibrator Catalog Number 10015573						
QMS Tacrolimus Calibrator Kit Lot Number / expiration date	74267412 / Exp. 2022-05-12		74175462 / Exp. 2022-03-10		74085025 / Exp. 2021-12-04	
Calibrator Level	Target Value (ng/mL)	Cascadion LC/MS Recovery (ng/mL)	Target Value (ng/mL)	Cascadion LC/MS Recovery (ng/mL)	Target Value (ng/mL)	Cascadion LC/MS Recovery (ng/mL)
QMS Tacrolimus Calibrator Level 1	0	0	0	0	0	0
QMS Tacrolimus Calibrator Level 2	2	1.8	2	1.7	2	1.7
QMS Tacrolimus Calibrator Level 3	5	4.5	5	4.3	5	4.1
QMS Tacrolimus Calibrator Level 4	10	9.2	10	8.6	10	8.2
QMS Tacrolimus Calibrator Level 5	20	18.6	20	17.4	20	17.6
QMS Tacrolimus Calibrator Level 6	30	27.3	30	26.3	30	25.3

This field safety corrective action is being taken to recall Thermo Scientific™ QMS® Tacrolimus Calibrator, catalog number 10015573, lot numbers 74175462 and 74267412. This field safety notice additionally communicates that this issue extends to lot 74085025, however no action is being taken on this lot as it has already expired.

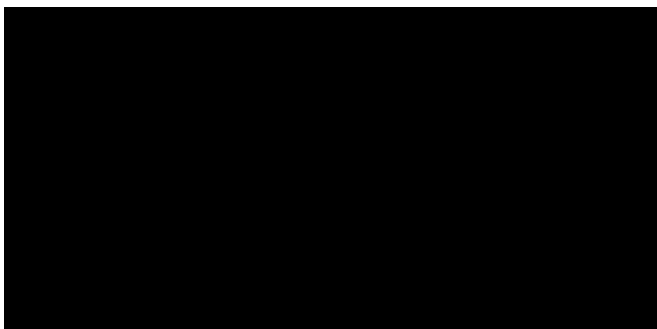
RISK TO HEALTH: The probability for this product to cause serious adverse health consequences has been evaluated and is considered remote.

ACTIONS TO BE TAKEN BY THE CUSTOMER:

- Determine if you are using or have inventory of QMS® Tacrolimus Calibrator catalog number 10015573, lot 74175462 or lot 74267412.
- Call Technical Service, if assistance is needed for lot replacement (free of charge).
- Discontinue use of affected in-date lots, and 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 to replace any of your remaining inventory of lots 74175462 or 74267412.
- Dispose of the effected lots in accordance with local, regional, national regulations.
- Contact your health care professional, as appropriate, for further action.
- Retain a copy of this letter for your laboratory records.
- This notice needs to be passed on to all who need to be aware within your organization or to any organization where the potentially affected calibrator lots have been transferred.
- 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 field notification, 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**

This field correction notice has been communicated to the appropriate Regulatory Agency.

We appreciate your immediate attention to this field safety notice 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.



**FIELD SAFETY NOTICE 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	74085025 74175462 74267412

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 field notification? 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: