

1 October 2025

**URGENT- FIELD SAFETY NOTICE
(FSCA 01-25-M)
ACTION REQUIRED**

Thermo Fisher Scientific MAS® Omni•CARDIO™ Liquid Assayed Integrated Cardiac Control

Dear Valued Customer,

The purpose of this letter is to advise you that Microgenics Corporation, part of Thermo Fisher Scientific Inc., is conducting a Field Safety Corrective Action for the in-vitro diagnostic products listed below (Table 1). Our records indicate that you have purchased units of the affected product. Please read the following information carefully.

Table 1: List of Products

Product Description	Catalog Number	Lot Number	Expiration Date (YYYY-MM-DD)	UDI
MAS® Omni•CARDIO™ Liquid Assayed Integrated Cardiac Control	OCRD-UL	OCRD2704U	2027-04-30	00884883011946
	OCRD-L	OCRD2704L		00884883011953
	OCRD-101	OCRD27041		00884883011960
	OCRD-202	OCRD27042		00884883011977
	OCRD-303	OCRD27043		00884883011984
	OCRD-SP	OCRD2704S		00884883011991
	OCRD-MP	OCRD2704M		00884883012004

Intended Purpose

Thermo Fisher Scientific MAS® Omni•CARDIO™ Liquid Assayed Integrated Cardiac Control is intended for use in the clinical laboratory as an assayed control serum for monitoring assay conditions related to cardiac and associated critical marker determinations.

REASON FOR FIELD ACTION AND DESCRIPTION OF THE ISSUE

Microgenics Corporation is recalling the product MAS® Omni•CARDIO™ Liquid Assayed Integrated Cardiac Control because we have received complaints from customers reporting vial-to-vial variability when using the control with high sensitivity Troponin I assays. No other analytes are reported to be showing variability between vials. This observed issue applies to customers who purchased the product listed in Table 1 and are using the product with high sensitivity Troponin I assays. This issue could result in a delay in reporting patient results.

RISK TO HEALTH / IMPACT ON PATIENT RESULTS

Health hazard assessment performed by a medical officer determined that if there is a delay in reporting of patient results, there is a remote probability of a serious adverse event in the overall population using the device. In the population at greatest risk, there are no serious adverse health consequences expected from the delay in reporting results. There is no risk of incorrect results being reported.

ACTIONS BEING TAKEN BY THE MANUFACTURER

Microgenics Corporation is investigating the root cause of the vial-to-vial variability reported when using high sensitivity Troponin I assays and will take necessary actions to prevent a recurrence of this issue.

ACTIONS TO BE TAKEN BY A USER

1. If you are a user of the High sensitivity Troponin I Assay, determine if you have inventory of the affected lots of MAS® Omni•CARDIO™ Control, as listed in Table 1. As stated in the instructions for use, instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges.
2. You may continue to use controls that meet your laboratory's performance requirements.
3. If the variability of the material exceeds your laboratory's specification, dispose of the material in accordance with local, regional, and national regulations. After disposing of the material, contact TechService.mgc@thermofisher.com for a credit.
4. Customers using the affected product with standard/ regular Troponin I assays, can continue to use the product as long as it meets their laboratory's specification and continue monitoring performance of Troponin I in MAS® Omni•CARDIO™ control.
5. This Field Safety Notice needs to be passed to anyone within your organization or any organization where the potentially affected lots have been transferred.
6. Retain a copy of this letter for your laboratory records.
7. Please complete the notice response form attached to this notification within 10 days of the date of this letter and return to Thermo Fisher as instructed in the form to E-mail: MGC-FSCA@thermofisher.com

If you have any additional questions regarding this notice, contact Thermo Fisher Scientific Technical Support at toll free 1-800-232-3342 (USA and Canada only) or 510-979-5000 (International), Option 2, then option 3 or by email: Techservice.mgc@thermofisher.com

ACTIONS TO BE TAKEN BY A DISTRIBUTOR

1. Please notify your customers of this Field Safety Notice using this notice and request they return a response to your contact information.
2. For your convenience we are providing a customer response form template as a word document. Please place this letter on to your own letterhead and collect responses from your customers on that customer response form. Please note, customers should provide their response directly to your contact information.
3. Please inform users of the High sensitivity Troponin I Assay to determine if you have inventory of the affected lots of MAS® Omni•CARDIO™ Control, as listed in Table 1. As stated in the instructions for use, instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges.
4. They may continue to use controls that meet their laboratory's performance requirements.
5. If the variability of the material exceeds their laboratory's specification, dispose of the material in accordance with local, regional, and national regulations. After disposing of the material, contact TechService.mgc@thermofisher.com for a credit.
6. Customers using the affected product with standard/ regular Troponin I assays, can continue to use the product as long as it meets their laboratory's specification and continue monitoring performance of Troponin I in MAS® Omni•CARDIO™ Control.
7. Please maintain records of all field safety notice response forms. If necessary, such as a request from a Regulatory Agency, we will request copies of these records to be provided to us.
8. Please complete the Field Safety Notice response form attached to this notice within 10 days of the date of this letter and return to Thermo Fisher as instructed in the form to E-mail: MGC- FSCA@thermofisher.com

If you have any additional questions regarding this Field Safety Notice, contact Thermo Fisher Scientific Technical Support at toll free 1-800-232-3342 (USA and Canada only) or 510-979-5000 (International), Option 2, then option 3 or by email: Techservice.mgc@thermofisher.com

We appreciate your immediate attention to this Field Safety notice. Please distribute this information immediately to any staff that may be impacted by this issue. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

Sincerely,

Colleen Watson

Electronically signed by:
Colleen Watson
Reason: Approver of the
GxP document
Date: Oct 1, 2025
15:17:52 PDT

Colleen Watson, MS, DRSc

Senior Director Regulatory Affairs
Clinical Diagnostics Division
Site Quality Head NDx, Fremont, CA

URGENT- FIELD SAFETY NOTICE RESPONSE FORM (Distributors Only)
(FSCA 01-25-M)

Thermo Fisher Scientific MAS® Omni•CARDIO™ Liquid Assayed Integrated Cardiac Control

- ☐ I confirm I have read, understood, and have taken action according to the attached field safety notification instructions.
- ☐ I am a distributor of the affected product with the High sensitivity Troponin I Assays and I understand that this field safety notice applies to the medical device listed in Table below.

Product Description	Catalog Number	Lot Number	Expiration Date (YYYY-MM-DD)	UDI
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	OCRD-SP	OCRD2704S		00884883011991
	OCRD-MP	OCRD2704M		00884883012004

Do you have any knowledge of adverse medical events associated with the products listed in this Field Safety Notification?

☐ Yes ☐ No

If yes, please explain and contact MGC-FSCA@thermofisher.com

PLEASE RETURN COMPLETED AND SIGNED FORM TO EMAIL WITHIN 10 DAYS UPON RECEIPT to MGC-FSCA@thermofisher.com

Name/Title:	
Date:	
Company/Institute:	
Phone:	
Email:	
Signature:	

It is important that your organization takes action as detailed in this letter and also replies without delay by using this response form. Your reply is evidence, which Thermo Fisher Scientific and Regulatory Authorities need to monitor the progress.