

MEDICAL DEVICE FIELD NOTIFICATION
Thermo Scientific™ MAS™ chemTRAK H

Catalog Number: CHA-3

March 5, 2019

CUSTOMER INFORMATION

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Dear Lab Manager,

The purpose of this letter is to advise you that Microgenics Corporation, part of Thermo Fisher Scientific, is conducting a field notification for the Thermo Scientific™ MAS™ chemTRAK H product. MAS chemTRAK H is intended for use as a consistent test sample for monitoring assay conditions in many clinical laboratory determinations.

REASON FOR FIELD CORRECTION:

The on-market lot of MAS chemTRAK H, Level 3 Part Number: **CHA-3** / Lot Number: **CHA19073** / EXP: **2019-07-31** is showing variability in the carbon dioxide (CO₂) levels resulting in some vials experiencing high carbon dioxide (CO₂) values.

PRODUCT INFORMATION:

Our records indicate that you have purchased the product lot listed in Table 1.

Table 1

Product Name	Catalog Number	Lot Number
MAS chemTRAK H Assayed, Level 3	CHA-3	CHA19073

RISK TO HEALTH:

The product issue, as described, is not anticipated to lead to reporting of erroneous clinical chemistry test results during device use as intended (i.e., as an assayed control for monitoring quantitative assay conditions in clinical laboratory determinations of any of the listed analytes). The conclusion that vial-to-vial variability of Level 3 Control is not anticipated to cause immediate or long-range adverse patient health effects is supported by the following:

- Quantitative assay(s) and calibrators used by clinical chemistry laboratories to assay patient serum specimens for CO₂, are not impacted by the described product issue; analytical results generated with quantitative assay use are expected to be accurate and reliable.
- Assayed MAS ChemTRAK H Control has manufacturer-assigned values in product labeling for the listed constituents. However, these analyte values and associated ranges are provided as guidelines to the end user; the clinical laboratory establishes its own ranges based on its own test systems and criteria.
- Out-of-range recovery of Level 3 control for CO₂ during use with quantitative assays for analyte determination will be readily recognized by the clinical chemistry laboratory technician. Quality Control (QC) results must meet laboratory criteria for acceptability before patient test results are reported. If control values shift out of range and do not meet criteria for acceptability of the analytical run, the “out of control” run will be rejected by the technician. This will prompt immediate corrective action before patient results are released.

- Rejection of an “out of control” run may cause a limited delay in reporting of patient CO₂ results. However, a limited delay in reporting of these clinical chemistry results is not expected to affect timely patient assessment/diagnosis or alter clinical management for such patients.

ACTIONS TO BE TAKEN:

Actions for MAS chemTRAK H (Catalog Number CHA-3 / LN CHA19073 / EXP: 2019-07-31)

1. Determine if you are using or have inventory of the affected lots of MAS chemTRAK H Level 3 as listed in Table 1.
2. Retain a copy of this letter for your laboratory records.
3. Do not use this lot for analysis of CO₂. Use of this lot for other analysis detailed in the Instructions for Use may be used following established Laboratory practices and Instructions for Use provided with the product. This product does not need to be returned.
4. Please complete the Acknowledgment & Receipt Form attached to this Notification within 5 days of the date of this letter to Thermo Fisher Scientific as instructed in the form to:
 - +49 (0) 3302 883-819 or
 - E-mail: eu-vigilance@thermofisher.com.
5. Contact Customer Service for replacement product as needed.
6. If needed, call Technical Services for replacement. The following replacement MAS chemTRAK, Level 3 lots are available.

MAS chemTRAK, Level 3 LN: **CHA20023A / EXP: 2020-02-29**

MAS chemTRAK, Level 3 LN: **CHA20113A / EXP: 2020-11-30**

If you need to request any of the above lots, please request this using normal channels.

If you have any additional questions regarding this field notification, contact Thermo Fisher Scientific Technical Service by:

- **FAX: 888-527-8001 (USA only) or +1-510-979-5420 (outside USA)**
- **PHONE: 1-800-232-3342 (USA only) or 510-969-5000 (outside the USA) then press option 2, then option 2**
- **E-mail: mas.controls@thermofisher.com**

We appreciate your immediate attention to this field notification. We apologize for any inconvenience this may have caused and appreciate your understanding.

Sincerely,



David Schultenover, CQE, CPGP
Sr. Director, Regulatory, Quality and Compliance
Clinical Diagnostics – Niche Products
Thermo Fisher Scientific

Enclosure - Acknowledgment & Receipt Form

**MEDICAL DEVICE FIELD Notification RESPONSE
Acknowledgment & Receipt Form
Response Required**

CUSTOMER INFORMATION

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Thermo Scientific™ MAST™ chemTRAK H Level 3

Catalog Number	Lot Number
CHA-3	CHA19073

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

I have read and I understand that I should not use this lot for analysis of CO₂. _____ (initials)

PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING SERVICE FAX NUMBER +49 (0) 3302 883-819, or e-mail: eu-vigilance@thermofisher.com

Signature of Receipt: _____

Name/Title:	
Telephone:	
Email Address:	