Microgenics Corporation
46500 Kato Road
Fremont, CA 94538
Main: (510) 979-5000
E-mail: techservice.mgc@thermofisher.com
www.thermoscientific.com

>Company<
>Department<
>Contact<
>Street<
>Zip Code Town<
>COUNTRY<

Date: 16/May/2017

Urgent: Field Safety Notice FSCA 01-17-M

Product:	Various Microgenics Application Sheets (refer to attached list)
FSCA-ID:	FSCA 01-17-M
Topic:	Incomplete Instructions for Use for Microgenics Application Sheets

Dear Customer,

Microgenics Corporation ("Manufacturer"), part of Thermo Fisher Scientific, is sending this Field Safety Notice ("FSN") to inform you of an issue related to assay application sheets ("Application Sheets") that may have been distributed to you by our affiliate, Microgenics GmbH ("Microgenics") in regard to certain assays manufactured by Microgenics Corporation ("Assays"). Please carefully read the following information.

Details on affected device:

Product:	Various Microgenics Application Sheets (Refer to the attachment)
Application Reference:	Please refer to attachment

Description of the problem:
During an internal assessment we found that Application Sheets provided by Microgenics for expanded use of some Assays are inadequate. Specifically, the appropriate validation data for the expanded use of these Assays, as indicated in the Instructions for Use when not used on Manufacturer approved analyzers, is inadequate. In addition Microgenics did not clearly state in these Application Sheets that the parameters provided are only to be used as starting points and that each Assay setting needs to be validated individually by the user.

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The objective of this FSN is to inform you that the information given on the specific Application Sheets provided by Microgenics (see attachment) for use with non-Microgenics approved analyzers are inadequate and action must be taken. Note: The Assays associated with this FSN perform as indicated in the Assay's Instructions for Use.

Risk to health:
Assays not validated for use with other platforms could potentially lead to erroneously low or erroneously high test results. Risk is mitigated by the fact that good laboratory practice and user instructions provided in the Assays' Instructions for Use suggests the use of control specimens to ensure proper assay performance. Additionally, the Instructions for Use further indicate that Assays provide only a preliminary analytical test result and that clinical consideration and professional judgment should be applied to any test result.

ACTIONS TO BE TAKEN BY CUSTOMERS / USERS:

1. Please check immediately if you are using any of the affected Application Sheets on the platforms as listed in the attachment.
2. Immediately discontinue use of the affected Application Sheets being used on your specific instrument platforms. Review your internal assay validations to determine if your current instrument settings using these Assays require additional action within your clinical laboratory setting. Consult a qualified healthcare professional as appropriate.
3. Contact your local Sales Representative or local Customer Service for assistance and to check if additional action is required.
4. Retain a copy of this letter for your laboratory records.
5. Complete the attached VIGILANCE RESPONSE FORM and return the form within 5 days to Microgenics' Technical Service as instructed in the form below.

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR

1. Please check if you have circulated any Application Sheets listed in the attachment.
2. 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 number in the VIGILANCE RESPONSE FORM and request that they return the form to you.
3. Please fill out the distributor section of the attached VIGILANCE RESPONSE FORM and return the form within 5 days to Microgenics' Technical Service as instructed in the form.

TYPE OF ACTION BY THE MANUFACTURER

Going forward, please contact your Sales Representative or Application Specialist for copies of current Application Sheets for all Instrument Platforms. Your Sales Representative or Application Specialist will have the most up to date information regarding validated Application Sheets.

Please forward this notice to those who need to be aware within your organization or to any organization where the potentially affected Application Sheets have been transferred.

Please verify your receipt of this notification by completing the attached vigilance response form and return it to us by fax +49 (0)3302883-242 or email to cdx.de.order@thermofisher.com **within five days** upon receipt.

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Any technical questions you may have should be addressed to our Customer Service at 00800 6070 8090.

Any regulatory questions you may have should be addressed to:

David Schultenover, CQE, CPGP
Sr. Director Regulatory, Quality and Compliance

Microgenics Corporation
46500 Kato Road | Fremont, CA 94538
Office: (510) 771-5169 | Mobile (510)203-5413
dave.schultenover@thermofisher.com │ thermofisher.com

Please be advised that the relevant National Competent Authorities have been advised of this safety notice.

The European Authorized Representative for the Manufacturer, Microgenics Corporation, is:

BRAHMS GmbH
Neuendorfstrasse 25
16761 Hennigsdorf
Germany

Telephone: +49 3302 883 752
Telefax: +49 3302 883 640
e-mail: EU-vigilance@thermofisher.com

We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

Sincerely

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Attachment

Microgenics Corporation
46500 Kato Road
Fremont, CA 94538

>Company<
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>Zip Code Town<
>COUNTRY<

VIGILANCE RESPONSE FORM – CUSTOMER - FSCA 01-17-M

Please tick as appropriate:

☐ I confirm that I have received the information on

Product:	**Specific listed Microgenics Application Sheets (See Attached list)**

☐ I understand the advice on actions to be taken as mentioned in this Field Safety Notice.

We currently have ☐ assay applications we have ceased using.

We currently have ☐ assay applications we will continue using as we have generated the needed supporting data. (Please list these below)

Signature and date:

PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING FAX NUMBER: +49 (0)3302883-242 or email to cdx.de.order@thermofisher.com within 5 days

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VIGILANCE RESPONSE FORM – DISTRIBUTOR - FSCA 01-17-M

DISTRIBUTORS:

I have identified and notified my customers that received or may have received Assay Applications affected by this letter by [specify date and method of notification]:

_____

_____

_____

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

Signature of Receipt by Distributor: _____

Name/Title:	
Telephone:	
Email Address:	