meridian BIOSCIENCE

3471 River Hills Drive
Cincinnati, Ohio 45244
513.271.3700
meridianbioscience.com

URGENT MEDICAL DEVICE CORRECTION

February 14, 2022

Dear Meridian Bioscience Europe,

This is to inform you of a voluntary, firm-initiated, product field correction involving:

Product Name:	Revogene®
Catalog Number(s):	610210 / 130840**
UDI:	00840733102318
Serial Number(s):	All
Meridian Reference Number:	1524213-01/28/22-001C

**Catalog number 610210 is a Meridian-branded Revogene. Catalog number 130840 is a GenePOC-branded Revogene. Both Meridian-branded and GenePOC-branded Revogene instruments are under the scope of this field action.

Reason for the Voluntary Recall:
Meridian Bioscience Inc. has determined that the photomultiplier tube, a key component in the Revogene instrument's optics system, may have compromised functionality in some instruments. When this failure occurs, the photomultiplier tube exhibits a significant drop in the raw fluorescence signal at all positions of the microfluidic cartridge (PIE) simultaneously. As a result, **the user is likely to observe an increase in false-positive or indeterminate results.**

We are aware of 42 instances of compromised photomultiplier tubes and 42 complaints associated with the problem. This is approximately 9% of units in the field.

The failure is independent of the assay being run; specifically, it may occur with any cleared Revogene assay run on an impacted instrument. This includes the Revogene Carba C (Catalog #410500), the Revogene Group A Strep (Catalog #410400), the Revogene *C. difficile* (Catalog #410300), the Revogene Group B Strep LB (Catalog #410200) or the Revogene Group B Strep DS (Catalog #410100) assay. There have been no observed trends with the presence of this failure and a particular assay test run execution.

Meridian has opened an investigation into the root cause of this compromised functionality. At this time, the investigation remains ongoing.

Risk to Health:
In the event of a false positive result, the incorrect assumption would be made as to the cause of patient symptoms and the incorrect treatment may be prescribed. The impact of the prescription of incorrect treatment varies by assay.

To date, we are not aware of any adverse events, such as patient injury or death, associated with the use of an instrument containing a compromised photomultiplier tube.

How to Recognize a Potentially Compromised Photomultiplier Tube:
Use of an instrument that may contain a compromised photomultiplier tube may result in an increase in the observance of false-positive or indeterminate results.

The following scenarios may indicate a potentially compromised photomultiplier tube:

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- The occurrence of any of the following error codes:

Error Code (Refers to the first three (3) characters of the displayed code)	Description
057-XXX	Excitation result value is under a defined threshold for channel 1 (LED 1).
058-XXX	Excitation result value is under a defined threshold for channel 2 (LED 2).
059-XXX	Excitation result value is under a defined threshold for channel 3 (LED 3).

- Positive results obtained with external negative control material
- Full runs of positive results
- Full runs of indeterminate (IND) results
- In the case where two or more assays are included on the same run, full runs with a combination of positive or indeterminate results (one result type per assay)

In order to aid in the recognition of a potentially compromised photomultiplier tube, Meridian recommends incorporating testing with an external negative control that has been validated by the individual facility with each patient test run.

REQUIRED CUSTOMER ACTIONS:

- **Identify those who may have received the affected product and notify them of this issue. It is recommended to advise the user that they should incorporate testing with an external negative control that has been validated by the individual facility with each patient test run.** This will aid in the identification of a potentially compromised photomultiplier tube. A copy of the attached customer or distributor letter may be provided.

- **If a customer reports an issue that could potentially be caused by a compromised photomultiplier tube (see *How to Recognize Potentially Compromised Photomultiplier Tube* above) OR a positive result is obtained with the external negative control material, please contact Meridian Bioscience Technical Service immediately and advise the customer to cease using the instrument until a representative can complete an evaluation .** If a compromised photomultiplier tube is confirmed by Meridian Bioscience, a replacement instrument will be provided:
  - Telephone: (800) 343-3858 or 1-(513) 271-3700
  - Fax: (513) 272-5432
  - Email: MBI-TechService@meridianbioscience.com

- **Meridian Bioscience Inc. has developed a software solution aimed at identifying photomultiplier tubes that are at risk for failure.**
  - The Meridian Bioscience Technical Service Team will contact you to coordinate the shipment of upgraded instruments upon software availability (see *Actions to be Taken by Meridian).*

- **Complete and return the Confirmation of Notification Form included with this letter.** Any Confirmation of Notification forms completed by the affected customers / distributors are to be forwarded to Meridian Bioscience Inc. Technical Service personnel.

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Actions to be Taken by Meridian:
Meridian Bioscience Inc. has developed a software solution aimed at identifying the photomultiplier tubes that are at risk for failure. The software solution will cause the instrument to present a software flag labeled "Detection Error" and will generate an indeterminate result when an at-risk photomultiplier tube is identified. The instrument then will be prevented from use in further testing.

When the software solution is available, instruments containing the revised software version will be provided to the impacted facilities.

Contact Information:
If you have any questions, please call Meridian Bioscience Technical Service at 1-800-343-3858, or email at MBI-TechService@meridianbioscience.com.

Supply of safe, effective, and reliable product is our highest priority. We apologize for any inconvenience or concern this action may cause and we thank you for your continued support of Meridian Bioscience.

Sincerely,

Megan Berling
Regulatory Affairs, Manager, Risk Management & Post-Market Activities

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Confirmation of Notification – Meridian Bioscience Europe

PRODUCT FIELD CORRECTION NOTICE

Revogene®
Catalog Number: 610210
Serial Number: All
Meridian Reference Number: 1524213-01/28/22-001C

Impacted customers and/or distributors have been notified of this field action.
☐ Yes ☐ No

I have read and understood this notification. I will keep this notification on file.
☐ Yes ☐ No

Contact Name _____ Date _____

Signature _____ Phone Number _____

Institution Name _____ Email _____

Address _____

For more information, please contact **Meridian Bioscience Technical Services at 1-800-343-3858 (North America).**

Please return this Response Form to:

Ryan Spradling, Technical Service Supervisor
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