

Thermo Fisher Scientific

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Date: October 21st, 2015

To: Laboratory Director, Laboratory Manager and Laboratory Personnel

Subject: AcroMetrix® HBV Mid control recovery on Abbott m2000

Catalog Number: 965002

Lot Number: 434902 and 515202

Dear Valued Customer,

The following information pertains only to customers with the Abbott m2000 instrument.

Please be advised that AcroMetrix HBV Mid control, lots 434902 and 515202, may give no results due to IC (internal control) failure when run on the Abbott m2000. As such, AcroMetrix HBV Mid, lots 434902 and 515202, should not be run on the Abbott m2000. The IC failure only applies to the AcroMetrix HBV Mid lots listed above. Measures are being taken to ensure that all future lots will not have the same issue.

We do not have an alternative product available for use with the Abbott m2000.

For technical assistance within the USA, please contact our Technical Service group at 1-800-232-3342, option 2, option 2 or by email: mas.controls@thermofisher.com. For all other countries, please contact your local Thermo Fisher Scientific sales office or authorized distributor partner.

We apologize for any inconvenience this may cause and thank you for your continued support of the AcroMetrix quality control products.

Sincerely,

Belinda Lee

Product Manager - Quality Control Products and LabLink xL

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ACTIONS TO BE TAKEN BY THE DISTRIBUTOR:

If you are a distributor of the product, please contact your customers and advise them of the change, and provide them with a copy of this letter.