

Thermo Fisher Scientific

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Date: October 21st, 2015

To: Laboratory Director, Laboratory Manager and Laboratory Personnel

Subject: AcroMetrix® HBV Low control recovery on Abbott m2000

Catalog Number: 965001

Lot Number: 434214, 515204 and 520219

Dear Valued Customer,

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

Please be advised that AcroMetrix HBV Low control, lots 434214, 515204 and 520219, may give no results due to IC (internal control) failure when run on the Abbott m2000. As such, AcroMetrix HBV Low, lots 434214, 515204 and 520219, should not be run on the Abbott m2000. The IC failure only applies to the AcroMetrix HBV Low 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 Clinical Diagnostics | Thermo Fisher Scientific

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.