Abbott GmbH
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DIAGNOSTICS

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued April 24, 2020

Product

Product Description	List Number	Lot Number	UDI
ARCHITECT iGentamicin Reagent Kit	1P31-25	All	All

Explanation

This letter is to inform you of a Product Correction for the ARCHITECT iGentamicin assay, and to provide instructions on the actions your laboratory must take.

Abbott identified that samples tested for ARCHITECT STAT High Sensitive Troponin-I and STAT High Sensitivity Troponin-I assays (LN 3P25 and LN 2R98) may show interaction when processed directly after the ARCHITECT iGentamicin (LN 1P31) assay and patient results might be impacted. Preliminary results from Abbott internal analysis of field data from these two assays show false elevation of patient results with a frequency of 0.002%.

At this time there are no indications that the issue impacts other assays, however, the investigation is ongoing. Further, corrective actions may be implemented and communicated upon completion of the investigation.

Until the investigation will be completed, please refer to the 'Necessary Action' section of this letter for recommendations on an interim mode of control to mitigate the above mentioned issue.

Patient Impact

The first sample processed on board directly after ARCHITECT iGentamicin assay may show incorrect results.

Necessary Actions

In order to prevent the interaction described above:	
If…	**Then…**
you can use a separate instrument	Separate the ARCHITECT iGentamicin assay from other testing by dedicating a single instrument to iGentamicin.
you cannot use a separate instrument	Separate ARCHITECT iGentamicin testing from other testing on your instrument. Refer to Maintenance Procedure in the ARCHITECT System Operations Manual Section 9, under "As needed maintenance description": For ARCHITECT i2000/i2000SR: 2130 "Flush Fluids" For ARCHITECT i1000SR: 2137 "Flush Fluids" after batch or general testing with the iGentamicin assay. To perform the procedure: Put the instrument back in Ready mode and **perform 2 flushes**, select: • System • Maintenance • As Needed o Select 2130 "Flush Fluids" (for i2000/i2000SR) OR o Select 2137 "Flush Fluids" (for i1000SR)

- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Complete and return the Customer Reply Form.
- Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4 ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (http://www.fda.gov/MedWatch/report.htm), by mail (http://www.fda.gov/MedWatch/getforms.htm), by phone (1-800-332-1088), or by fax (1-800-FDA-0178).

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.