Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6081

DIAGNOSTICS

Urgent Field Safety Notice
Product Recall

Immediate Action Required

To Chairman Medical Board and the relevant Head of Departments

Date Issued August 28, 2018

Product

Product	List Number (LN)	Lot Number	Expiration Date	UDI*
ARCHITECT ICT Module	09D28-03	180326	26DEC2018	(01)00380740019327(17)181226 (10)180326(21)180326301 through (01)00380740019327(17)181226 (10)180326(21)180326399

*Note Regarding UDI: Only last 3 digits of UDI are incrementing to reflect the specific serial numbers of module, in this case from serial number 301 to 399.

Explanation

The purpose of this letter is to inform you of a product recall for the ARCHITECT ICT Module, List Number 09D28-03, Lot Number 180326, and to provide instructions on what actions your laboratory must take.

Abbott has received customer complaints regarding higher than expected serum or plasma Chloride results when using ARCHITECT ICT Module, LN 09D28-03, Lot Number 180326. Based on an analysis of QC data from existing customers, the results generated using this lot number may be up to 6.2% higher than expected. The customer QC data do not indicate an issue with urine Chloride results.

As this issue only impacts the Chloride electrode element of the ICT module, Potassium and Sodium results are not impacted.

Patient Impact

There is the potential to generate falsely elevated serum or plasma Chloride results when using ARCHITECT ICT Module, LN 09D28-03, Lot Number 180326.

There is also the potential to delay the reporting of Chloride ICT results due to the time required for the user to attempt troubleshooting of the issue with falsely elevated serum Chloride Quality Control (QC) results.

Necessary Actions	Immediately discontinue the use of ARCHITECT ICT Module, LN 09D28-03, Lot Number 180326. **Destroy any remaining inventory** of the impacted lot number according to your laboratory procedures. Please review this letter with your Medical Director and follow your laboratory protocol regarding the need for reviewing previously reported patient results. Please complete and return the attached Customer Reply Form. Your local Abbott Representative can help provide you with credit or replacement product. Retain this letter for your laboratory records.
Contact Information	We sincerely regret any inconvenience this may have caused your laboratory. 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 1-877-4ABBOTT (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).