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

DIAGNOSTICS

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

To Chairman Medical Board and relevant Head of Departments.

Date Issued January 03, 2019

Product

Product Name	List Number	Lot Number	Expiration Date	UDI Number
ARCHITECT Magnesium	7D70-21	36338UN17	6-Jan-19	[redacted]
		79865UN17	9-Mar-19	[redacted]
		12921UN17	3-May-19	[redacted]
		43618UN17	9-Jun-19	[redacted]
		45337UN17	14-Jul-19	[redacted]
		84994UN17	12-Oct-19	[redacted]
		24856UN17	13-Nov-19	[redacted]
		41652UN18	29-Jan-20	[redacted]
		99639UN18	26-Feb-20	[redacted]
		99661UN18	13-Apr-20	[redacted]
		78493UN18	25-Jul-20	[redacted]
		95220UN18	7-Sep-20	[redacted]
		31428UN18	31-Oct-20	[redacted]
		33784UN18	11-Jun-20	[redacted]
	7D70-31	36339UN17	6-Jan-19	[redacted]
		97389UN17	9-Mar-19	[redacted]
		12922UN17	3-May-19	[redacted]
		43616UN17	9-Jun-19	[redacted]
		45338UN17	14-Jul-19	[redacted]
		84993UN17	1-Sep-19	[redacted]
		08788UN17	12-Oct-19	[redacted]
		24857UN17	13-Nov-19	[redacted]
		41651UN18	29-Jan-20	[redacted]
		99640UN18	26-Feb-20	[redacted]
		99662UN18	13-Apr-20	[redacted]
		33783UN18	9-May-20	[redacted]
		33785UN18	11-Jun-20	[redacted]
		78859UN18	25-Jul-20	[redacted]
		95341UN18	7-Sep-20	[redacted]
		31429UN18	31-Oct-20	[redacted]

Explanation	This letter is to inform you of a Product Correction which impacts ARCHITECT Magnesium (LN 7D70). Abbott internal testing has identified that the **Magnesium urine application** demonstrates depressed urine result recovery. All samples >0.5mEq/L fail the linearity acceptance criteria for the bias specification and demonstrate depressed recovery of up to 37%. The specific cause of the negative bias/depressed results is currently under investigation. Note: The depressed result recovery issue **does not** affect the ARCHITECT Magnesium (LN 7D70) serum/plasma application.
Patient Impact	Urine magnesium results may be impacted; internal data shows up to 96% of results are impacted. There is no patient impact to Magnesium plasma/serum results.
Necessary Actions	If you are currently using the ARCHITECT Magnesium (LN 7D70) urine application: • **Immediately** discontinue use of the ARCHITECT Magnesium (LN 7D70) urine application. • You may continue to use the serum/plasma application for the ARCHITECT Magnesium (LN 7D70). • 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. • Complete and return the Customer Reply Form. • 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. • As an alternative to the current urine application, you may use Abbott ARCHITECT (enzymatic) Magnesium LN 3P68, urine application, where available. **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 1-877-4ABBOTT (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).