Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064, USA

Product Correction

Urgent - Immediate Action Required

Cc: Chairman Medical Board and relevant Head of Departments

Date Issued June 11, 2019

Product

Product Name	List Number (LN)	Lot Number	Expiration Date	UDI Number
ARCHITECT Ceruloplasmin	6K91-30	71050Y600	31AUG2019	(01)00380740010829 (17)190831(10)71050Y600
		80015Y600	31AUG2019	(01)00380740010829 (17)190831(10)80015Y600
		80098Y600	31DEC2019	(01)00380740010829 (17)191231(10)80098Y600
		80302Y600	30APR2020	(01)00380740010829 (17)200430(10)80302Y600
		80406Y600	31MAY2020	(01)00380740010829 (17)200531(10)80406Y600
		80485Y600	30SEP2020	(01)00380740010829 (17)200930(10)80485Y600
		80487Y600	30SEP2020	(01)00380740010829 (17)200930(10)80487Y600
		90105Y600	31DEC2020	(01)00380740010829 (17)201231(10)90105Y600
		90170Y600	31DEC2020	(01)00380740010829 (17)201231(10)90170Y600
Alinity c Ceruloplasmin Reagent Kit	09P9320	90080Y600	30NOV2019	(01)00380740150716 (17)191130(10) 90080Y600

Explanation The purpose of this letter is to inform you that Abbott has received the attached Field Safety Notice from SENTINEL DIAGNOSTICS, the manufacture of the ARCHITECT Ceruloplasmin assay and Alinity c Ceruloplasmin Reagent Kit. Sentinel has confirmed that the EDTA specimen collection tube type (Dipotassium and Tripotassium) did not meet the sample storage stability claim listed in the package insert and is no longer acceptable for use. Based upon this testing, the specimen storage information is being revised.

Patient Impact Please refer to the attached Sentinel Field Safety Notice.

Necessary Actions	• Please review the attached Sentinel Field Safety Notice and follow the required actions. • Complete and return the Customer Reply Form.
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). 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.

SENTINEL
DIAGNOSTICS

Field Safety Notice
N. 03_2019

Product Name	List Number (LN)	Lot Number	Expiration Date
Ceruloplasmin	6K91-30	All	N/A
Alinity c Ceruloplasmin	09P9320	All	N/A

Date: June 5, 2019

Details on affected devices:

The purpose of this letter is to inform you of an update to the "SPECIMEN COLLECTION AND HANDLING" section of the Instructions for Use (IFU) for the ARCHITECT Ceruloplasmin assay and to the "SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS" section of the Instructions for Use (IFU) for the Alinity c Ceruloplasmin assay . Based upon recent specimen storage testing, the **EDTA specimen type is no longer acceptable for use.**

Description of the problem:

Package insert of the Ceruloplasmin assay lists the EDTA as suitable anticoagulant for sampling collection tube. However, the EDTA sample tube storage claims are not met with the new studies performed.
In particular, the stability claims of 2 weeks at 2-8°C and 8 days at room temperature are NOT confirmed, both for Dipotassium and for Tripotassium EDTA.

Patient Impact:

There is a potential for incorrect patient results when the EDTA specimen type is used.

Actions to be taken:

Immediately discontinue the use of EDTA plasma samples when using the Ceruloplasmin assay.

Transmission of this Field Safety Notice:

- 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.
- Please retain this letter for your laboratory records.

Mario Fangareggi
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Patricia Dupé [redacted]
Head of Quality System