Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois, 60064

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued May 16, 2019

Product

Product Name	List Number	Lot Numbers	UDI
ARCHITECT Complement C3	9D96	All	N/A
ARCHITECT Immunoglobulin A	9D98		
ARCHITECT Immunoglobulin G	9D99		
ARCHITECT Immunoglobulin M	1E01		
ARCHITECT Apolipoprotein A1	9D92		
ARCHITECT Complement C4	9D97		
ARCHITECT Haptoglobin	9D91		
ARCHITECT Apolipoprotein B	9D93		
ARCHITECT Transferrin	1E04		

Explanation

The purpose of this letter is to inform you of an update to the **REAGENTS** and **SPECIMEN COLLECTION AND HANDLING/ PREPARATION FOR ANALYSIS** sections of the Instructions for Use (IFU) for the ARCHITECT products listed above.

Based on recent fibrinogen interference testing, the EDTA specimen type is no longer acceptable for use with the assays listed in Section 1 of Appendix A.

For Complement C4 only, greater than 10% negative interference was observed on samples containing elevated fibrinogen concentrations >1512 mg/dL in lithium heparin tubes and >859 mg/dL in sodium heparin tubes. Heparin samples below these fibrinogen concentrations did not show interference. Results should be evaluated by comparing to other clinically relevant information. For all other assays listed in Appendix A, no interference was observed on heparin tubes at fibrinogen levels up to 1776 mg/dL.

Additionally, based on recent testing, the specimen storage information is being revised for the assays shown in Section 2 of Appendix A.

Lastly, the active ingredient concentrations are being updated for assays shown in Section 3 of Appendix A. **NOTE:** These concentration changes are informational only; there is no change to reagent formulations.

Until the IFU is updated, all reagent kits will include a kit stuffer with this information.

Patient Impact	There is a potential for falsely depressed results due to fibrinogen interference with EDTA specimens for the products listed in Section 1 of Appendix A. For Complement C4, there is a potential for falsely depressed results due to fibrinogen interference with heparin tubes at the concentrations listed above in the Explanation section.
Necessary Actions	• Immediately discontinue the use of EDTA plasma samples when using any of the products listed in Section 1 of the table in Appendix A. • Please review this letter with your Medical Director and follow your laboratory procedures. • 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.
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.

Appendix A: Updates to the **REAGENTS** and **SPECIMEN COLLECTION AND HANDLING/ PREPARATION FOR ANALYSIS** sections

Assay	LN	SECTION 1	SECTION 2				SECTION 3		
		EDTA Specimen Type	Current Maximum Storage Time		Revised Maximum Storage Time		Reagent Concentration		
			2 - 8°C	20 - 25°C	2 - 8°C	20 - 25°C	PEG* (g/L) R1	Serum (%) R2	TRIS (mmol/L) R2
ARCHITECT Complement C3	9D96	No longer acceptable	8 days		3 days			≤ 50	50
ARCHITECT Immunoglobulin A	9D98	No longer acceptable	8 months	8 months	7 days	7 days	25	≤ 75	
ARCHITECT Immunoglobulin G	9D99	No longer acceptable	8 months	4 months	7 days	7 days	50	≤ 50	
ARCHITECT Immunoglobulin M	1E01	No longer acceptable	4 months	2 months	7 days	7 days		≤ 75	
ARCHITECT Apolipoprotein A1	9D92	No longer acceptable						≤ 80	
ARCHITECT Complement C4	9D97	No longer acceptable					45	≤ 50	50
ARCHITECT Haptoglobin	9D91	No longer acceptable					36	≤ 50	
ARCHITECT Apolipoprotein B	9D93							≤ 80	
ARCHITECT Transferrin	1E04						21	≤ 50	

*Polyethylene glycol