Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden, Germany

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Cc **Chairman Medical Board and relevant Head of Departments**

Date Issued May 16, 2019

Product

Product Name	List Number	Lot Numbers	UDI
Alinity c Complement C3 Reagent Kit	09P56	All	N/A
Alinity c Immunoglobulin A Reagent Kit	09P61		
Alinity c Immunoglobulin G Reagent Kit	09P62		
Alinity c Immunoglobulin M Reagent Kit	09P63		
Alinity c Apolipoprotein A1 Reagent Kit	09P46		
Alinity c Complement C4 Reagent Kit	09P57		
Alinity c Haptoglobin Reagent Kit	09P59		
Alinity c Apolipoprotein B Reagent Kit	09P47		
Alinity c Transferrin Reagent Kit	08P38		

Explanation

The purpose of this letter is to inform you of an update to the **REAGENTS** and **SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS** sections of the Instructions for Use (IFU) for the Alinity 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, please contact your local area Customer Service. 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 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
Complement C3	09P56	No longer acceptable	8 days		3 days			≤ 50	50
Immunoglobulin A	09P61	No longer acceptable	8 months	8 months	7 days	7 days	25	≤ 75	
Immunoglobulin G	09P62	No longer acceptable	8 months	4 months	7 days	7 days	50	≤ 50	
Immunoglobulin M	09P63	No longer acceptable	4 months	2 months	7 days	7 days		≤ 75	
Apolipoprotein A1	09P46	No longer acceptable						≤ 80	
Complement C4	09P57	No longer acceptable					45	≤ 50	50
Haptoglobin	09P59	No longer acceptable					36	≤ 50	
Apolipoprotein B	09P47							≤ 80	
Transferrin	08P38						21	≤ 50	

*Polyethylene glycol