Abbott Laboratories
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Urgent Field Safety Notice
Product Correction
Immediate Action Required

Date Issued	April 07, 2014

Product

Product	List Number (LN)	Lot Numbers	
Lipase Reagent	7D80	43827UQ12	43994UQ07
		43819UQ03	44596UQ08
		44449UQ05	44775UQ09
		44127UQ06	44930UQ11
		44334UQ07	

Explanation

The Lipase reagent package insert for the lots above has incorrect information regarding the required cuvette SmartWash for Triglyceride. The insert indicates that the Triglyceride cuvette SmartWash assay parameter is not required on ARCHITECT System Software version 7.00 or higher; however, the **Triglyceride SmartWash IS required for the Lipase assay on all software versions**. The insert is correct beginning with lot 45200UQ12.

The *c*Systems assay disks contain the correct Lipase SmartWash parameters. This issue only impacts ARCHITECT *c*8000 and *c*4000 systems. ARCHITECT *c*16000 performs a check to ensure Triglyceride and Lipase are on separate lines.

Patient Impact

Patient results could potentially be impacted if the cuvette SmartWash for Triglyceride is not configured in the Lipase reagent parameters.

Necessary Actions

1. Verify that Lipase assay parameters (Assay: Lip, Number: 1029) on your ARCHITECT *c*Systems are configured for a **Trig (Triglyceride) Cuvette SmartWash with 345 volume of 10% Detergent B** per the table below.
2. If the Lipase SmartWash for Triglyceride is not configured, **immediately update the Lipase SmartWash parameter by adding a Trig (Triglyceride) Cuvette SmartWash with 345 volume of 10% Detergent B** per the table below.

Configure assay parameters — SmartWash

COMPONENT	REAGENT / ASSAY	WASH	Volume	Replicates
R1	ACETM	0.5% AcidWash	345	1**
R1	LIP00	10% Detergent B	345	2
R1	All	10% Detergent B	345	2
R2	LIP00	10% Detergent B	345	2
R2	All	10% Detergent B	345	2
Cuvette	Uric	10% Detergent B	345	
Cuvette	Trig	10% Detergent B	345	
Cuvette	Chol	10% Detergent B	345	
Cuvette	Uric-U	10% Detergent B	345	
Sample Probe		0.5% AcidWash		

**Reagent Probe SmartWashes must be configured in order listed.

- *For additional information on configuring cuvette SmartWashes, refer to Section 2 of the ARCHITECT Systems Operation Manual.*
- *Using Diagnostic Procedure 6117 Remove Trig SmartWash will NOT remove the Triglyceride cuvette SmartWash from the Lipase assay.*

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Please retain a copy of this letter for your laboratory records. If you have forwarded any of the lots above to another laboratory, please provide a copy of this letter to them.

Contact Information

We sincerely regret any inconvenience this may cause 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. Customers outside the U.S., please contact your local area Customer Service.

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