



## Urgent Field Safety Notice Product Correction

Immediate Action Required

**Date Issued** October 10, 2016

**Product**

Product Name	List Number (LN)	Lot Number	Expiration Date	UDI
ARCHITECT Lactic Acid	9D89-21	31497UN14	17-Oct-2016	Not Applicable
		09353UN15	12-Feb-2017	
		45216UN15	12-May-2017	
		14596UN15	30-Jul-2017	
		37055UN15	12-Oct-2017	
		14782UN16	21-Apr-2018	

**Explanation**

Abbott has identified negative interference from the drug N-Acetyl Cysteine (NAC) with the ARCHITECT Lactic Acid reagent (LN 9D89-21).

The table below outlines the levels of interference observed at NAC concentrations of 80 mg/L (0.49 mmol/L) and 800 mg/L (4.9 mmol/L).

NAC Concentration	Lactic Acid Target	Observed % of Target
80 mg/L (0.49 mmol/L)	9.5 mg/dL (1.05 mmol/L)	- 6.4%
	19.6 mg/dL (2.18 mmol/L)	- 4.0%
800 mg/L (4.9 mmol/L)	9.5 mg/dL (1.05 mmol/L)	- 33.8%
	19.6 mg/dL (2.18 mmol/L)	- 27.9%

**Patient Impact**

Patients undergoing treatment with NAC may have falsely depressed Lactic Acid results

**Necessary Actions**

- Please review this letter with your Medical Director
- Taking the above information into consideration, you may continue to use ARCHITECT Lactic Acid reagent (LN 9D89-21)
- Please 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
- 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.