



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.