Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064

Urgent Field Safety Notice
Product Recall

Urgent - Immediate Action Required

cc **Chairman Medical Board and relevant Head of Departments**
Date Issued **May 24, 2019**

Product

Product Name	List Number	Lot Number	UDI
ARCHITECT BNP Calibrators	8K28-02	44K79318	[redacted]
		44K80818	[redacted]
		44K82118	[redacted]
		44K82618	[redacted]
		44K85119	[redacted]
	8K28-03	44K79418	[redacted]
		44K81018	[redacted]
		44K82018	[redacted]
		44K85219	[redacted]
	8K28-09	44K84119	N/A
ARCHITECT BNP Controls	8K28-11	44K78918	[redacted]
		44K80918	[redacted]
		44K82718	[redacted]
	8K28-12	44K79518	[redacted]
		44K81118	[redacted]
		44K82818	[redacted]
		44K84219	[redacted]

Explanation

The purpose of this letter is to inform you of a product recall for the ARCHITECT BNP Calibrator and Control lot numbers listed above. The lots listed above demonstrate a time dependent, stability drift in patient and control results returned from ARCHITECT BNP testing.

Root cause and corrective action for this issue has not yet been identified, however, as an interim mode of control, all future calibrator and control lots will have shortened expiration dating. Actions are being taken to mitigate and/or prevent any further reduction of product expiration dating and maintain product supply.

Until root cause is determined and corrective actions are implemented, new calibrator and control lots will have a proactively shortened expiration date of 165 days from date of

manufacture.

Patient Impact

Use of impacted calibrator lots may result in falsely elevated patient results. Use of impacted control lots may result in invalid patient results due to controls out of range.

Necessary Actions

Destroy any remaining inventory of the following:

Product Name	List Number	Lot Number
ARCHITECT BNP Calibrators	8K28-02	44K79318
		44K80818
		44K82118
		44K82618
	8K28-03	44K79418
		44K81018
		44K82018
ARCHITECT BNP Controls	8K28-11	44K78918
		44K80918
		44K82718
	8K28-12	44K79518
		44K81118
		44K82818

If…	**Then…**
You do NOT have alternate calibrator and/or control lots available in inventory and you have generated a valid calibration curve	Immediately order replacement calibrator and/or control lots. You may continue to use valid calibration curves generated with the above calibrator lots as long as controls not listed above remain within range. The control lots listed above CANNOT be used to validate the calibration curves. Destroy any inventory of the above lots according to your laboratory procedures.
You HAVE alternate calibrator and/or control lots available in your inventory	Discontinue use of the impacted lots immediately and switch to the alternate calibrator and/or control lots. Destroy any remaining inventory of the calibrator and/or control lots according to your laboratory practices.

Necessary Actions continued

Adjust the expiration date of the following lots:

Product Name	List Number	Lot Number	From expiration date…	To expiration date…
ARCHITECT BNP Calibrators	8K28-02	44K85119	22JAN2020	**06JUL2019**
	8K28-03	44K85219	22JAN2020	**06JUL2019**
	8K28-09	44K84119	17DEC2019	**31MAY2019**
ARCHITECT BNP Controls	8K28-12	44K84219	17DEC2019	**31MAY2019**

If…	**Then…**
You are currently using or have inventory of these lots	Adjust the expiration date as instructed above. As this is a manual change in expiration date, the ARCHITECT software will continue to track to original dating as assigned during the manufacture of these lots. Manual tracking of the newly assigned expiration dates will have to be performed for each individual instrument, kit, and laboratory. Obtain replacement calibrator and/or controls prior to adjusted expiration to maintain testing.

- All future calibrator and control lots will have shortened expiration dating and will require adjustments to your laboratory inventory and order management practices. Please contact your local Abbott representative for assistance and advice on optimization of workflow in your laboratory.
- Complete and return the Customer Reply Form.
- If you have forwarded any of the products listed within this letter to other laboratories, please inform them of this Product Recall and provide 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.