



Product Recall

Immediate Action Required

Date Issued 09 MARCH 2020

Product

Product Name	List Number	Lot Number	Expiration Date	UDI Number
Aleré NT-proBNP	2R10-01	902929466	03APR2020	N/A
		902929915	06MAY2020	N/A
Aleré NT-proBNP	04S7901	10976UP00	03APR2020	N/A
		10991UP00	06MAY2020	N/A
Aleré NT-proBNP	2R10-10	902929465	03APR2020	N/A
		902929899	05MAY2020	N/A
Aleré NT-proBNP	04S7910	10975UP00	03APR2020	N/A
		10989UP00	05MAY2020	N/A

Explanation

The purpose of this letter is to inform you of a product recall for the Aleré NT-proBNP Calibrator and Control lot numbers listed above for use on the ARCHITECT or Alinity i systems.

All of the lots listed above demonstrate higher than expected quality control variation and / or patient sample returns when testing on the ARCHITECT and Alinity i systems.

Internal testing has confirmed this is due to an unacceptable stability drift in quality control values, when compared to the initial market release values of the calibrator lots listed.

If Calibrators and Controls with the same assigned expiry date are used together the Control values may not be elevated as the material may have similar stability drift.

Patient Impact

This issue may generate falsely elevated patient results that may go undetected if quality controls do not detect the shift.

Necessary Actions

Immediately discontinue use of the affected calibrator and / or control lots listed and switch to the alternate material lot(s) you have available.

Immediately destroy any remaining inventory of the affected calibrator and / or controls lots listed according to your laboratory procedures.

Immediately order replacement material(s) if you do not have unaffected material available.

Please retain this letter for your laboratory records.

To prevent reoccurrence:

New replacements lots of Alere NT-proBNP Calibrator and Controls for use on the ARCHITECT and /or Alinity i systems, should be used. These will have shortened dating.

Please take this into consideration when reordering.

**Contact
Information**

We sincerely regret any inconvenience this may have caused your laboratory. If you, or any of the healthcare providers you serve, have any questions regarding this information, please contact your local area Customer Service.