

Product Recall

Immediate Action Required

Date Issued

Product

| Product Name | List Number | Lot Number | Expiration Date | UDI Number |
|---|-------------|------------|-----------------|------------|
| Alere NT-proBNP for ARCHITECT Controls | 2R10-10 | 902922185 | 02OCT19 | N/A |
| Alere NT-proBNP for Alinity i Controls | 04S7910 | 10777UP00 | 02OCT19 | N/A |
| | | 10805UP00 | 14DEC19 | N/A |
| Alere NT-proBNP for ARCHITECT Calibrators | 2R10-01 | 902922220 | 02OCT19 | N/A |
| Alere NT-proBNP for Alinity i Calibrators | 04S7901 | 10774UP00 | 01SEPT19 | N/A |
| | | 10801UP00 | 13NOV19 | N/A |

Explanation

The purpose of this letter is to inform you of a product recall for the Alere NT-proBNP Calibrator and Control lot numbers listed above for use on the ARCHITECT and Alinity i systems. No other lot numbers in the field are impacted.

All of the lots listed above demonstrate a time dependent, stability drift in results returned from NT-proBNP testing on both the ARCHITECT and Alinity i systems.

Patient samples and quality control results have been confirmed to be acceptable, however, stability modeling tools have predicted unacceptable performance for these material lots prior to the current dating (expiry) assigned.

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 expiry dating.

Patient Impact

This issue may generate false positive patient results and invalid results that may go undetected.

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