



Axis-Shield Diagnostics Ltd
Luna Place, The Technology Park,
Dundee, DD2 1XA, UK.

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	902917627	19DEC2018	(01)05055845400404(17)181219(10)902917627
	2R10-10	902918346	16FEB2019	(01)05055845400404(17)190216(10)902918346

Explanation

The purpose of this letter is to inform you of a product recall for the Alere NT-proBNP for ARCHITECT Control lot numbers listed above, and to provide instructions on what actions your laboratory must take.

Axis-Shield has identified a stability issue that may lead to Quality Control values falling outside of expected ranges prior to assigned expiry date

Patient Impact

A potential delay may exist in the reporting of patient results due to Quality Control values falling outside of expected ranges. Internal testing on patient samples showed no atypical bias for the impacted lots, therefore if Quality Controls are in range, patient results are not impacted.

Necessary Actions

If....	Then...
You HAVE an alternate control lot available in inventory	Immediately discontinue use of the control lot number(s) listed above and switch to the alternate control lot. Destroy any remaining inventory of impacted material according to your laboratory procedures.
You do NOT have an alternate control lot available in inventory and the current lot continues to generate valid QC results	Immediately order a replacement control lot. You may continue to use the control lot number(s) listed above while following your current laboratory QC procedures. Once you receive the replacement control lot, destroy any remaining inventory of impacted material according to your laboratory procedures.

**Necessary
Actions
Continued**

- Please retain this letter for your laboratory records.

To prevent reoccurrence:

- New replacement Alere NT-proBNP for ARCHITECT lots should be used.
- Reporting of patient results using impacted material must follow your local quality control procedures

**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.
