



## Urgent Field Safety Notice Product Recall

Immediate Action Required

**To** Chairman Medical Board and relevant Head of Departments.

**Date Issued** August 29, 2018

**Product**

Product Name	List Number	Lot Number	Expiration Date	UDI Number
Alere NT-proBNP for ARCHITECT Controls	2R10-10	902917627	19DEC2018	[REDACTED]
		902918346	16FEB2019	[REDACTED]

**Explanation**

Abbott received the attached letter from Axis-Shield Diagnostics, the manufacturer of the Alere NT-proBNP for ARCHITECT Controls. 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**

Please refer to the attached letter from Axis-Shield.

**Necessary Actions**

- Please review the attached Axis-Shield letter carefully and follow the instructions.
- Complete and return the Abbott Customer Reply Form.
- Contact Abbott Customer Service for assistance if needed.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall 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, please contact your local area Customer Service.