

Single Registration Number (SRN): N/A



Urgent Product Recall

Immediate Action Required

Date Issued

March 9, 2022

Product

Note: This Product Recall impacts the following product (lots) distributed within South Korea.

Product Description	List Number	Lot Number	UDI
Alere NT-proBNP for ARCHITECT	2R10-25	11372UP00	(01) 05055845400398 (17) 220705 (10) 11372UP00
Alere NT-proBNP for ARCHITECT	2R10-25	11419UP00	(01) 05055845400398 (17) 220909 (10) 11419UP00
Alere NT-proBNP for Alinity i Reagent Kit	04S7920	11362UP00	(01) 05055845400435 (17) 220527 (10) 11362UP00
Alere NT-proBNP for Alinity i Reagent Kit	04S7920	11371UP00	(01) 05055845400435 (17) 220604 (10) 11371UP00
Alere NT-proBNP for Alinity i Reagent Kit	04S7920	11424UP00	(01) 05055845400435 (17) 220809 (10) 11424UP00

Explanation

Core Diagnostics received the attached letter from Axis-Shield Diagnostics, the manufacturer of the Alere NT-proBNP for ARCHITECT and Alinity i Reagent Kits. Axis-Shield Diagnostics has identified that the lot numbers listed above have been distributed within the South Korean market prior to receiving regulatory approval for a product change.

Impact on Patient Results

Please refer to the attached letter from Axis-Shield Diagnostics.

Necessary Actions to be Taken by Customer

- Please review the attached Axis-Shield Diagnostics letter carefully and follow the instructions.
- An Abbott representative will be in contact with you to coordinate the activities necessary to return the products listed in the table above.
- 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.
- Contact Abbott Customer Service for assistance if needed.
- Complete and return the Abbott Customer Reply Form.
- Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have questions regarding this information, please contact your local area Customer Service.