



Urgent Field Safety Notice

Product: Alere Triage[®] NT-pro BNP Test
Catalogue Number: 98700EU
Lot Numbers: Various

August 31, 2018

Dear Valued Customer

The purpose of this notification is to inform you that Abbott (formerly Alere) has identified an issue with the **Alere Triage[®] NT-pro BNP Test (98700EU)** lots shown in Appendix 1 on page 3 of this letter. An increased frequency of elevated NT-pro BNP results has been demonstrated with these lots which may not be detected by your quality control procedures. Note that all of these lots are past their expiration. This action does not affect any other lots of the Alere Triage[®] NT-pro BNP Test, which is now distributed by Quidel Corporation.

The Alere Triage[®] NT-pro BNP Test is a fluorescent immunoassay to be used with the Alere Triage[®] Meter for the quantitative determination of N-terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) in EDTA anticoagulated whole blood and plasma specimens. The test is used as an aid in the diagnosis of individuals suspected of having congestive heart failure (also referred to as heart failure). The test is also used as an aid for the risk stratification of patients with heart failure and the risk stratification of patients with acute coronary syndromes (ACS). The test may also serve as an aid in the assessment of increased risk for cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.

Results from this test should always be interpreted along with clinical findings and other laboratory tests.

Description of the Problem

During internal testing, it was revealed that the lots listed in Appendix 1 exhibit a higher frequency of elevated NT-pro BNP results. These results are not replicated using another method and are considered to be falsely elevated.

If you or your customers have concerns relating to previously reported results using the affected lots listed, please consult with the resident clinical expert or physician at the setting where the test was performed.



Actions to be Taken by the User/Distributor

- Please share this information with customers and users of the kit
- Retain this notification as part of your laboratory Quality System documentation
- To confirm your receipt of this notice, complete the enclosed **URGENT FIELD SAFETY NOTICE REPLY FORM** and return within 10 days via:
 - FAX
 - e-mail
 - Post in prepaid envelope

Contact Details:

We sincerely regret any inconvenience this product performance issue may have caused. Should you have any questions about the information contained in this notification, please contact the Abbott Product Support Care Centers for your region from the contact information in the table below:

Region	Phone	E-Mail Address
Europe & Middle East	+ 44 (0) 161 483 5884	EMEproductsupport@alere.com
Asia Pacific	+ (61) 7 3363 7711	APproductsupport@alere.com
Africa	+ 44 (0) 161 483 5884	ARCISproductsupport@alere.com
Latin America	+ (57) 2 661 8797	LAprодукtsupport@alere.com
France	+ 33 (0)1 39 46 83 18	Techsupport.france@alere.com
Germany/Austria	+ 49 221 271430	TechnicalService.DA@alere.com
Italy	N/A	EMETechsupportIT@alere.com
Spain	+ 34 936008008	EMETechsupportES@alere.com
Switzerland	+ 41 44 782 60 70	serviceCH@alere.com
Norway/Denmark	+ 47 24056810	NODK.TechnicalSupport@alere.com
Sweden/Finland	+ 46 8 544 812 14	SWFI.TechnicalSupport@alere.com

All relevant National Competent Authorities have been advised of this FSCA. In Germany, please contact our European Representative:

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany
Tel.: +49 511 6262 8630
Fax: +49 511 6262 8633

Sincerely,

Ya-Ling King
Director, Quality Assurance
Alere San Diego



Appendix 1: Affected Lots of Alere Triage[®] NT-pro BNP (Catalogue Number 98700EU)

Note: All lots are past their expiration.

Lot Number
K62569B
K62570B
K62571B
K63039B
K62572B
K63051B
K63052B
K63137B
K63138B
K63139B
K63140B
K63176B
K63177B
K63178B
K63179B
K63180B
K63182B
K63183B
K63184B
K63185B
K63763B
K63773B
K63774B
K63775B



Please complete this form even if you did not receive any of the affected product.

Return this form by fax to +35391680102, by emailing a PDF to Field.Safety.Notifications@alere.com OR: send the original document by mail to: Alere International Limited, Parkmore East Business Park, Ballybrit, Galway, Ireland

To satisfy global requirements for regulatory reporting, please complete and return this form within **10 business days of receipt**.

URGENT FIELD SAFETY NOTICE REPLY FORM
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I have been notified by Abbott (formerly Alere) of this issue with Alere Triage[®] NT-pro BNP (Catalogue Number 98700EU).

Please check all relevant boxes:

- I have no record of receipt of this product and therefore will take no further actions.
- I have read this letter and confirm that users of the affected lots of the Alere Triage[®] NT-pro BNP Test in my facilities have been informed.
- I confirm that my facility has forwarded the affected products to other health institutes or customers, the recipients have been informed and this Urgent Field Safety Notice has been forwarded.
- I have read, understood, and have implemented the actions listed above.

Please complete the following information:

DATE:			
AUTHORIZED SIGNATURE:			
PRINT NAME:			
ADDRESS:			
CITY and REGION		PHONE:	
POSTAL CODE:		COUNTRY:	
EMAIL:			