9975 Summers Ridge Road
San Diego, CA 92121, USA

18 October 2012

URGENT FIELD SAFETY NOTICE

Correction to Instructions for Use

Re:	**Alere Triage® BNP**	**Catalogue No. 98000XREU**
	Alere Triage® Profiler SOB™ Panel	**Catalogue No. 97300EU**
	Alere Triage® D-dimer	**Catalogue No. 98100EU**
	Alere Triage® CardioProfiler™ Panel	**Catalogue No. 97100CPEU**
	Alere Triage® Cardiac Panel	**Catalogue No. 97000HSEU**
	Alere Triage® TOX + MTD	**Catalogue No. 94400EU**

Dear Customer,

The purpose of this letter is to communicate a field correction regarding the product instructions for use.

Our records indicate that you have received one or more of the aforementioned kits from Alere, Inc.

For the Triage Cardiac family of products the precision sections of the product instructions for use (IFU) have been revised to reflect the Quality Control specifications. This provides clarity around the precision expected for these products.

For the Triage TOX+MTD product the Threshold Validation section of the product IFU has been revised to reflect the Quality Control specifications. This provides clarity around the expected product performance at concentrations that are 50% above and below the threshold for each analyte.

The IFU is supplied as a CD-ROM in each kit, and is labeled with a sticker: *"Updated product insert"*

CUSTOMER REQUIRED ACTION

- **Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice.**
- **Please ensure that all users of the device have received the Urgent Field Safety Notice.**

DISTRIBUTOR REQUIRED ACTION

- **Complete and FAX the enclosed Verification Form within 10 days to confirm your receipt of this notice.**
- **Please ensure that all users of the device have received a copy of the Urgent Field Safety Notice.**
- **Monitor the effectiveness of the communication by receipt of the Verification Form.**
- **Once the Verification Forms have been received from your customers, please notify Alere International Ltd that the notification is complete.**

Please note that the relevant National Competent Authorities have been advised of this Field Safety Corrective Action. Should you have any questions about the information contained in this notification, please contact:

Alere San Diego, Inc.
9975 Summers Ridge Road
San Diego, CA 92121
U.S.A.
Triage.support@alere.com

In Germany you may contact our European Representative:

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

Sincerely,

[redacted]
Vice President
Global Regulatory & Clinical Affairs
Alere, Inc.

Please complete this form even if you do not have any involved product and Fax Back to <INSERT FAX NUMBER HERE>.
(Or scan and email to <INSERT E-MAIL ADDRESS>)

Customer/Distributor Verification Form
Urgent Field Safety Notice

We acknowledge receipt of the Alere San Diego, Inc. Urgent Field Safety Notice dated, October 18, 2012 for the following products:

- **Alere Triage® BNP, Catalogue No. 98000XREU**
- **Alere Triage® Profiler SOB™ Panel, Catalogue No. 97300EU**
- **Alere Triage® D-dimer, Catalogue No. 98100EU**
- **Alere Triage® CardioProfiler™ Panel, Catalogue No. 97100CPEU**
- **Alere Triage® Cardiac Panel, Catalogue No. 97000HSEU**
- **Alere Triage® TOX + MTD, Catalogue No. 94400EU**

I have read, understood and implemented the required actions.

DATE*: _____

AUTHORIZED SIGNATURE*: _____

PRINT NAME*: _____

TITLE: _____ DEPARTMENT: _____

INSTITUTION*: _____

ADDRESS*: _____

CITY*: _____ STATE*: _____ PHONE*: _____

POSTAL CODE*: _____ COUNTRY*: _____

EMAIL: _____

☐ Completed by Alere Technical Services or Alere Field Representative on behalf of the above named customer

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt to <CONTACT PERSON> at Fax Number <INSERT FAX NUMBER> .

*** Mandatory field**