Urgent Field Safety Notice

Alere TESTPACK + Plus STREP A with OBC (505715J, 505796J)

FSCA-identifier: FSCA#2016-001

Type of action: Device destruction/replacement

Date: 18th May 2016

Dear valued customer,

The purpose of this letter is to inform you that Alere Medical Co., Ltd. is initiating a recall of the following product:

Details on affected devices:
The following devices and lot numbers are affected:

Alere TESTPACK + Plus STREP A with OBC, Catalog Number 505715J, 505796J

505715J	55331K100	55485K100	56356K100	57538K100
	58123K100	58809K100	59588K100	59677K100
505796J	55012K100	55298K100	56053K100	56557K100
	57082K100	57091K100	57946K100	58322K100
	58334K100	58514K100	59045K100	59046K100
	59703K100	59925K100	60018K100	60616K100

Description of the problem:
Alere TESTPACK + Plus STREP A with OBC, Catalog Number 505715J, 505796J

The listed lots of Alere TESTPACK + Plus STREP A with OBC kit contain swabs (Swab Lot FCQQ00, GJAN00, AN3P00) that are defective. The swab shaft of the defective lot has a yellow coloration (normally white) and can be easily broken if bent. This is due to acceleration in the aging of the plastic which is currently being investigated. Should the shaft of the swab break while a sample is being taken from the throat, there is an increased risk of injury due to choking hazard or scratching of the oral mucosa.

Advise on action to be taken by the user/distributor:

- Discontinue use immediately and discard these lots
- Return the attached Customer Verification Form for replacement or credit
- 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 Verification Form and return within 10 days.

Please FAX or e-mail the completed Reply Form to:

Alere Medical Co., Ltd.
Fax: +81-(0)47-311-5751
Email: QA.IMJ@Alere.com

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to any other organisations or customers on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference:

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:

Alere Product Support Care Centers

Region	Phone	E-Mail Address
Europe & Middle East	+44 (0) 161 483 9032	EMEproductsupport@alere.com
Asia Pacific	+ (61) 7 3363 7711	APproductsupport@alere.com
Africa, Russia & CIS	+ (972) 8 9429 683	ARCISproductsupport@alere.com
Latin America	+ (57) 2 661 8797	LAproductsupport@alere.com

Sincerely,

Aki Asahina
Quality System Manager
Alere Medical Co., Ltd.

Please complete this verification form even if you do not have any involved product and
Fax Back to Technical Service at Fax Number +81-(0)47-311-5751
or email to QA.IMJ @alere.com.

Customer/Distributor Verification Form
URGENT MEDICAL DEVICE RECALL

We acknowledge receipt of the Alere Medical Co., Ltd, URGENT MEDICAL DEVICE RECALL dated May 17th, 2016 for the following product:

- **Alere TESTPACK + Plus STREP A with OBC,**

505715J	55331K100	55485K100	56356K100	57538K100
	58123K100	58809K100	59588K100	59677K100
505796J	55012K100	55298K100	56053K100	56557K100
	57082K100	57091K100	57946K100	58322K100
	58334K100	58514K100	59045K100	59046K100
	59703K100	59925K100	60018K100	60616K100

Please check the appropriate boxes:

☐ I have no record of receipt of this product and therefore will take no further actions.

☐ I have read and understand the letter and have followed the recommended actions.

☐ I have forwarded this notification to our customers/consignees to which we have provided product.

DATE*: _____

AUTHORIZED SIGNATURE*: _____

PRINT NAME*: _____

TITLE: _____ DEPARTMENT: _____

FACILITY*: _____

ADDRESS*: _____

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

POSTAL CODE*: _____ COUNTRY*: _____

EMAIL: _____

*** Mandatory field**

To satisfy global requirements for regulatory reporting, please complete and return this form within 10 business days of receipt to Technical Services at +81-(0)47-311-5751 or email to QA.IMJ @alere.com.