STANDARD DIAGNOSTICS, INC.

Tel : 82-31-899-2800 Fax : 82-31-899-2840
65, Borahagal-ro, Giheung-gu, Yongin-si,
Gyeonggi-do, Republic of Korea

Urgent Field Safety Notice – Recall

- **General information**

Affected product information	**Name** : Panbio Q Fever IgM ELISA **Cat. No.** : 06PE20 **Lot No.** : 264006
FSCA Reference (FSCA identifier)	14091604F-1
Date of Notice	September, 2014
Attention	Distributors and Users who have or use the affected products.

Warning - Do not use the lot (#264006) of Panbio Q fever IgM ELISA

This letter is to inform you of the field safety corrective actions regarding kit performance degradation in the concerned lot. Please see the detailed information on this issue.

- **Details**

Reason for this Field Action

Lot #264006 met specification at the time of release. Standard Diagnostics, Inc. (Manufacturer) performed stability monitoring and identified that the lot has degradation prior to expiry date. A customer complaint was also received. The values of positive control, calibrator and cut-off were out-of internal manufacturing range due to instability of serum used in production. The calibrator instability could lead to a fluctuating cut-off value with consequential potential risk of false positive/negative results.

Risk analysis was performed. The instructions for use (IFU) describe that the clinical diagnosis must be interpreted with clinical signs and symptoms of the patient. The results from this kit are not by themselves diagnostic and should be considered in association with other clinical data and patient symptoms.
Despite test limitations indicated in IFU, we concluded that it is required to implement this field action for the lot because of risk of false positive or negative results.

Advise on action to be taken by the distributor and the user

In order to mitigate potential risks, **we decided to perform a voluntary recall process for the lot# 264006 again. Clients will be offered a refund as reimbursement.**

We request distributors and users to follow the instructions.

For distributors

1) Distribute Field Safety Notice to users.
2) Quarantine all affected products and discard them at your site per local guideline.
3) Collecting the verification form from users.
4) After collection, use the reconciliation form (Annex 1.) and return to manufacturer, along with the collected verification form.
5) Proceed with refund of the kits distributed to the affected end-users.

SD
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For users

1) Upon the receipt of field safety notice, **do not use the affected products and discard them per local guideline.**
2) In order to confirm all affected products are discarded, we ask you to fill out the verification form (Please refer to Annex 2.)
3) Please send a copy of signed verification form to the distributor by email indicating in Annex 2. (for returning form, PDF format is preferred)
4) After the distributor confirms the receipt of verification form, refund will be made.

Note.) For additional assistance or inquiry in relation to recall (refund), please contact the distributor.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (If appropriate)
Please transfer this notice to other organizations on which this action has an impact. (If appropriate)
This field action has been reported to the relevant competent authorities.

We apologize for the inconvenience. Thank you for your attention and for your cooperation in this matter.

If you have any questions, feel free to contact distributor or e-mail to manufacturer (Sean Kim, TS Manager – sean.kim@alere.com).

Sincerely,

23 Sep. 2014

Taesuk, Kim
Quality Management Representative
Standard Diagnostics, Inc.

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Annex 1. Reconciliation Form – Recall (For Distributors)

• **Concerned Product information**

Product name	Catalogue Number	Lot numbers
Panbio Q Fever IgM ELISA	06PE20	264006

• **Distributor information**

***Company name**	
***Respondent name**	
***Physical address**	
***Email address**	
***Tel.**	
***Fax.(if available)**	

** Indicates required fields*

Reconciliation Status

• **Status affected products (Quantity) at distributor's site**

Total received	Distributed	Quarantined

Required actions :

1) *Discard quarantined products per local guideline.*
2) *Collect all verification form distributed to users.*
3) *Provide the manufacturer (SD) with signed reconciliation form and the collected verification form from users.*

sean.kim@alere.com

☐ I discarded all affected kits as per local guideline. (please tick, if applicable)

• **Reconciliation Status (please clarify in the "Remaining" if you didn't receive the returned verification form)**

Total FSN distributed	Collected	Remaining

☐ I have read, understood and implemented the required actions. (please tick, if applicable)

Date *Signature*

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Annex 2. Verification Form – Recall (For Users)

• **Affected Product information**

Product name	Catalogue Number	Lot numbers
Panbio Q Fever IgM ELISA	06PE20	264006

• **Users information**

***Company name**	
***Respondent name**	
***Physical address**	
***Email address**	
***Tel.**	
***Fax.(if available)**	

** Indicates required fields*

• **Status of affected products (Quantity)**

Total received

Required actions :

1) *Discard quarantined/unused products per local guideline.*
2) *Return the form to distributor for reimbursement after the signature below.*

Once a verification form is returned, the reimbursement will be made.

Please tick the box and fill the blank

☐ I discarded all affected kits as per local guideline.

☐ I wish to get a refund as reimbursement.

To meet regulatory requirements, thank you for completing this form (pdf format is preferred). Please return this form by e-mail within 10 working days to the following e-mail address:

Richard.mcilvenny@alere.com

☐ I have read, understood and implemented the required actions.

Date *Signature*