



An Agilent Technologies Company

To Dako Subsidiaries/Distributors only!

Field Action Cover Letter

1. Details on affected product:

Dako Beta-2-Microglobulin PET Kits

Product code: K0052

Affected lots:

Lot 20012249

The total number of distributed affected kits: 113

2. Dako reference number: D00320/CAPA00526

3. Description of the problem:

The purpose of this letter is to inform you that Dako has initiated a Product Removal of one lot of the Dako Beta-2-Microglobulin PET Kit and will take immediate action to replace any kits remaining in your inventory.

Our records show that your company has received the affected lot number of the product noted above and request you stop use of the affected lot.

A stability issue with a single component of the kit, Vial 1 Beta-2-microglobulin Immunoparticles has been identified.

Investigations have shown that a change in the pH value in the Beta-2-microglobulin Immunoparticles (Vial 1) occurred resulting in low or no signal for the 2 lowest standards in the calibration curve.

The identified change in the pH value may affect the accuracy of Beta-2-microglobulin values/results obtained, without any warnings from instruments.

The Beta-2-microglobulin values may be measured up to 20% higher for samples in the clinically elevated ranges.



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3.1 Advise on action to be taken by the Subsidiary/Distributor:

Please be aware that it is now your responsibility to inform the customers who have received the affected lot numbers by completing the following actions:

Customers Notice to the customers.

- Translate the attached *Recall Notification Letter* into your local language.
- Fill in your local contact details in the attached *Recall Notification Letter*

Please return the following to Dako contact: dako.dkvigilance@dako.com

- Within 24 hours, return the attached *Acknowledgement Form* completed by you, confirming that this Field Action letter has been received and that you will act accordingly and comply to all instructions outlined above.
- Within 3 working days, return a copy of the translated *Recall Notification Letter*
- Within 14 working days, return customer confirmation by means of completed *Device Recall Form* or customer email.
- Within 14 working days, notify Dako of the number of kits from your inventory which have been discarded and the amount of kits to be replaced at customer sites.

3.2 Dako Contact:

We regret the need to address you in this way and apologize for any inconvenience caused.

Name: Camilla Hudtloff

Function: Director Quality Assurance

Contact details: dako.dkvigilance@dako.com

Signature:

2015A