Agilent Technologies Denmark ApS
Produktionsvej 42
DK-2600 Glostrup
Denmark

+45 44 85 95 00 telephone
+45 44 85 84 29 facsimile
www.agilent.com
Cvr.: 21852902

Dako
Agilent Pathology Solutions

Attn.: Laboratory Manager
Cc: Chairman Medical Board and Relevant Head of Departments

October 25, 2017

Reference number: CAPA00718

Field Safety Corrective Notification

Dear Valued Customer,

The purpose of this letter is to notify you that we have initiated a Field Safety Corrective Notification for Monoclonal Mouse Anti-Human CDX2, Clone Dak-CDX2, Code No. M3636; Lot(s) 10117361.

Description of the issue:

The Certificate of Analysis (CoA) and the primary labels of the affected vials of M3636 were mislabeled with an incorrect protein concentration value of 292.7 mg/L, which is sixteen times higher than the **correct concentration of 18.3 mg/L.**

To date, Agilent has received only one customer complaint about this issue. The customer detected the issue prior to testing and immediately contacted Agilent. No patient harm was reported, and the customer informed us that they were able to complete the patient's diagnostic testing with minimal delay.

M3636 will perform as expected. There is no change to the concentration itself, just the incorrect concentration stated on the vial label and the CoA. The secondary label (box label) contains the correct concentration of 18.3 mg/L.

If diluted from the incorrect higher concentration of 292.7 mg/L, a decrease in staining intensity resulting in weak staining or negative staining will be seen. This should be easily detectable by both internal positive normal tissue and by the recommended positive external run controls.

Actions to be taken by the user:

Our records indicate that your laboratory has received the affected product. Within 10 calendar days, please take the following actions:

1. Discard any affected vial(s) of Monoclonal Mouse Anti-Human CDX2, Clone Dak-CDX2, Code No. M3636, from the affected lot(s). The vials should be discarded in accordance with the precautions in the Instructions For Use.

Agilent Technologies Denmark ApS
Produktionsvej 42
DK-2600 Glostrup
Denmark

+45 44 85 95 00 telephone
+45 44 85 84 29 facsimile
www.agilent.com
Cvr.: 21852902

Dako
Agilent Pathology Solutions

2. Confirm that you have received this information by completing and returning the enclosed Device Recall Form to Dako QA Vigilance by Dako.dkvigilance@agilent.com with your Sales Representative on copy.
    a. You will receive replacements after we have received the completed form from you.
    b. Please note that the Device Recall Form is required to request replacement product(s) for any unused/partially used items which are discarded.
3. Review previous assay runs and patient results where the affected lot(s) was used. Determine whether the lot(s) was appropriately validated at the correct dilution and/or whether an incorrect dilution could have been used in a run without appropriate positive and negative run controls. If there were runs at the incorrect dilution without appropriate run controls, it is possible the results might have had false decreased staining intensity or false negative staining. If so, the results should be considered inconclusive and a retest should be run with the dilution calculated from the correct concentration of 18.3 mg/L.
4. Contact your sales representative if you have any questions regarding this notification, or if you would like assistance with the Device Recall Form.
5. Please contact your sales representative if you have any doubt or question about the affected lots numbers since there are other lot numbers affected globally. Please note, the only affected lot number in Singapore is **10117361**.

Transmission of this notice:
We kindly ask you to inform those who need to be aware of this notification within your organization or any other organization to which the affected or potentially affected product(s) have been transferred. Please ensure that your organization maintains awareness of this notice and the recommended steps until the corrective actions have been completed.

Thank you for your attention to this matter. We apologize for any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure patient and customer satisfaction.

PLEASE NOTE: No other Dako branded devices are involved in this recall.

Reporting to authorities:
The undersigned confirms that the appropriate Regulatory Agency has been notified.

Contact:
Name: Asger Dahlgaard
Function: Complaint and Vigilance Manager
Contact details: Dako.dkvigilance@agilent.com
Signature: [redacted]

Agilent Technologies