



Agilent Pathology Solutions

Attn.: Laboratory Manager

May 4, 2017

«Account_Name»

«Address1»

«Address2»

«City», «Postal_Code»

«State», «Ctry»

Reference number: CAPA00639

Field Safety Notification

Dear Valued Customer,

The purpose of this letter is to notify you that we have initiated a Field Safety Notification for Monoclonal Mouse Anti-Human MutS Protein Homolog 2, CloneFE11, Code No. M3639; Lot No(s) [to be inserted].

Description of the problem:

The primary labels of the affected vials of M3639 were mislabeled with an incorrect concentration of 180 mg/L, which is ten times higher than **the correct concentration of 18 mg/L**.

M3639 will perform as expected. There is no change to the concentration itself, just the incorrect concentration stated on the vial label. The secondary label contains the correct concentration of 18 mg/L.

If diluted from the incorrect higher concentration of 180 mg/L, a decrease in staining intensity or false 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 bottle(s) of Monoclonal Mouse Anti-Human MutS Protein Homolog 2, CloneFE11, Code M3639, lot no. [to be inserted]. Bottles can be discarded in accordance with the precautions in the Instructions For Use.
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.
3. Review previous assay runs and patient results where the affected lot(s) was used. Determine if these assay runs were incorrectly diluted and



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whether 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 mg/L.

The Device Recall Form is required to request replacement product(s) for any unused product(s) you have destroyed.

Contact your sales representative if you have any questions regarding this notification, or if you would like assistance with the Device Recall Form.

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.

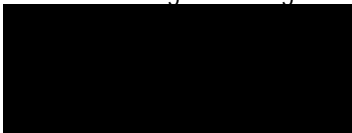
Contact:

Name: Asger Dahlgaard

Function: Complaint and Vigilance Manager

Contact details: Dako.dkvigilance@agilent.com

Signature:





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Device Recall Form to customers

The following actions must be taken within 10 calendar days:

- Please fill in the below fields and return the form to **QA Vigilance**, by email dako.dkvigilance@agilent.com with your sales representative on copy. Note that all fields must be filled-in.
- If replacement of Monoclonal Mouse Anti-Human MutS Protein Homolog 2, CloneFE11, Code No. **M3639** is needed, you will receive the product after Agilent has received this filled in Device Recall Form.
- If you do not have any remaining M3639 vials in your laboratory please fill-in "0" (zero) to the Device Recall Form.

Fill in the following to record affected devices. Request replacements, if needed.

Customer Information

Institution Name	2T
Account Number	2T
Date	2T
Address	2T
Country	2T

Product Disposal — Only discard the affected M3639 vials.

List the number of items from the affected lot. Partially used items are considered as unused.
List the number of unused items discarded:

Lot Number(s) Affected	_____	_____	_____
Items Discarded	_____ each	_____ each	_____ each
Items Used	_____ each	_____ each	_____ each
Item Unused	_____ each	_____ each	_____ each

Replacement Request – Only if any M3639 vials are unused

Request the number of M3639 vials you require to replace with the affected vials according to the received Field Safety Notification.

Lot Number(s) Affected	_____	_____	_____
Required number of replacements	_____ each	_____ each	_____ each



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Customer Signature *(Mandatory only for US, Canada and Brazil)*