



Agilent Pathology Solutions

## Attn.: Laboratory Manager

April 24, 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 mislabelled 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](mailto: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 organisation or any other organisation to which the affected or potentially affected product(s) have been transferred. Please ensure that your organisation 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 apologise 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](mailto:Dako.dkvigilance@agilent.com)

Signature:

A handwritten signature in blue ink, appearing to read "Asger Dahlgaard".



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