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Dako
Agilent Pathology Solutions

Attn.: Laboratory Manager

«Account_Name»
«Address1»
«Address2»
«City», «Postal_Code»
«State», «Ctry»

Reference number: **CAPA00741**

February X, 2018

Field Safety Notice

Dear Valued Customer,

The purpose of this letter is to notify you that we have initiated a Field Safety Corrective Action for the following products:

- **Monoclonal Mouse Anti-Pneumocystis Jiroveci Clone 3F6**, Code No. M0778 Lot Nos. 20010445, 20030858, and 20042555.
- **Monoclonal Mouse Anti-Human Leukaemia, Hairy Cell Clone DBA.44**, Code No. M0880, Lot Nos. 20033445, 20040767, and 20042272.

Description of the problem:

The primary labels of the affected vials of M0778 and M0880 were mislabeled with an incorrect concentration. The Instructions For Use is not affected.

- For M0778 the concentration was written to be 30 mg/L. **The correct concentration is 75 mg/L.**
- For M0880 the concentration was written to be 187 mg/L. **The correct concentration is 485 mg/L.**

The ~2.5-fold higher concentration in the vials will have no consequence on the quality of M0778 and M0880 and the products are expected to perform as usual.

If diluted according to the label, the higher concentration will, in a worst case scenario, result in stronger signals than expected and may lead to increased background staining and/or false positive staining. Positive and negative run controls would detect any problems with staining in this case. However, we recommend that you review your records to determine if retests are required. To date, we have received no customer complaints concerning the affected products.

Actions to be taken by the user:

Our records indicate that your laboratory has received one or both affected product(s). Within 10 calendar days, please take the following actions:

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1. Discard any affected bottle(s) of **Monoclonal Mouse Anti-Pneumocystis Jiroveci Clone 3F6**, Code No. M0778 Lot Nos. 20010445, 20030858, and 20042555 and **Monoclonal Mouse Anti-Human Leukaemia, Hairy Cell Clone DBA.44**, Code No. M0880, Lot Nos. 20033445, 20040767, and 20042272.
2. Bottles can be discarded in accordance with the precautions in the Instructions For Use.
3. Confirm that you have received this information, by completing and returning the enclosed Device Recall Form to the email stated in the Device Recall Form.

   The entire Device Recall Form must be completed, if replacement product(s) is requested for any unused product(s) you have discarded.
4. Review previous assay runs and patient results where the affected lot(s) was used. Determine if these assay runs were diluted based on the incorrect concentration on the label and whether the results might have had false increased staining signal, increased background, and/or false positive staining. It is highly likely that this would have been previously detected due to the increased signal/background on positive/negative controls, including internal tissue controls. However, if assays were incorrectly diluted, but not detected at the time, the results should be considered inconclusive and a retest should be run.

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 than the mentioned two are involved in this Field Safety Corrective Action.

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

Instruction for Customers

The following actions must be taken within 10 calender days:

- Please fill out the fields below to record affected devices in your laboratory and return the form to [Insert e-mail address for Subsidiary contact person] with your sales representative on copy. Note that all fields must be filled in.
- **Unused and partially used Monoclonal Mouse, Anti-Pneumocystis Jiroveci Clone 3F6**, **code no. M0778** will be replaced with the Ready-to-Use version for Autostainer Link 48, IR635. Replacement of **unused and partially used Monoclonal Mouse, Anti-Human Leukaemia, Hairy Cell Clone DBA.44, code no. M0880** will be provided.
- If replacement is needed, you will receive the replacement product after Agilent has received the Device Recall Form filled in by you, and only if unused /partially used items are discarded.

Customer Information			
Date			
Country			
Institution Name			
Customer Account Number			
Customer Address			
Customer Signature			
Usage and replacement of the affected M0778 and / or M0880 Partially used items are considered as unused. See example of how to fill out on page 2.			
Product Code(s)			
Affected Recall Lot Number(s)			
Items / Kits Used (pcs)			
Items / Kits Discarded (Unused) (pcs)			
Required number of replacements (pcs)			

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Example of how to fill out the last section

A customer received M0778 and M0880 products from the lot no(s) affected, as follows:

- **One M0778** bottle from lot no. **20030858** and **one M0778** bottle lot no. **20042555**. Both were used.
- **One partially used M0880** bottle from lot no. **20033445**. Partially used items are considered as unused. Customer discarded the partially unused M0880 bottle.

This example is how the customer should fill out the below section:

Product Code(s)	M0778	M0778	M0880
Affected Recall Lot Number(s)	**20030858**	**20042555**	**20033445**
Items / Kits Used (pcs)	1	1	0
Items / Kits Discarded (Unused) (pcs)	0	0	1
Required number of replacements (pcs)	0	0	1