Attn.: Laboratory Manager

4T

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

Dako reference number:

Field Safety Notice

The purpose of this letter is to inform you that Dako has initiated a field safety notice of APAAP, Mouse Monoclonal Code No. D0651.

APAAP, mouse Monoclonal Code No. D0651 **Lot no. 20013724** is affected by this field safety notice.

Description of the problem:

This Notification has been initiated due to a defect in **Lot no. 20013724**. More specifically, the product has been diluted 10 times more than specified in the product specification. The cause has been identified as limited to a human error. Correction and corrective actions have been implemented.

Due to one complaint received from a customer using the affected lot, Dako has become aware of this issue which may potentially cause weak staining and false negative test results. If appropriate positive controls and good laboratory practice have been used, then detectibility of this issue would be high.

Advise on action to be taken by the user:

The device listed above is subject to device destruction and replacement.

Our records show that you/your company have received the affected device APAAP, Mouse Monoclonal Code No. D0651 **Lot no. 20013724:**

1. Further use of any remaining products should cease/stop
2. Destroy the affected product APAAP, Mouse Monoclonal Code No. D0651 **Lot no. 20013724**
3. Please confirm that you have received this information by returning the attached, fully completed Device Recall Form and return it to Dako QA Vigilance, by dako.dkvigilance@dako.com

Please note: The Device Recall Form is required to request replacement product for any unused product you have destroyed.

This information is required by the regulatory authorities and Dako is required to inform them of the progress of this recall. It is therefore essential that you complete this action even if you do not have any remaining product in your inventory.

Please contact your Dako representative if you have any questions regarding this recall, completing the Device Recall Form or would like assistance with any of our products.

Transmission of this Notice:

This notice needs to be passed on to all those who need to be aware within your organization or any organization, where to the affected or potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please complete and return the attached Device Recall Form for the affected device.

Please note that you must complete and return this form even if you do not have any product left. Your local sales representative can assist you in completing this form. This information is essential in order to maintain field safety notice effectiveness information required by the authorities.

Please contact your Dako sales representative if you have any questions regarding this field safety notice, any of our products, or would like assistance with the field safety notice. We regret 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 devices are involved in this field safety notice.

Reporting to authorities:

The undersigned confirms that the appropriate Regulatory Agency has been notified.

Dako Contact:

Name:Barbara Drago

Function: Quality Assurance; Complaint and Vigilance Manager

Contact details: Dako.dkvigilance@dako.com

Signature:

Dako
An Agilent Technologies Company

Device Recall Form to customers

Instructions for Customers

The following actions must be taken within 10 calender days:

- Please fill in the below fields and return the form by email to **Dako QA Vigilance, by email dako.dkvigilance@dako.com**.
- Note that all fields must be filled-in.
- If replacement of APAAP, Mouse Monoclonal (D0651) is needed, you will receive the product after Dako has received this filled in Device Recall Form.

Fill in the following to record affected devices and request replacements – if needed.

Customer Information

Country	1T
Institution Name	1T
Account Number	1T
Your Name	1T
Job Title	1T
Department	1T
Phone Number	1T
Email Address (optional)	1T

Usage of APAAP, Mouse Monoclonal Affected Lots

List the number of items from the affected lot. Partially used items is considered as unused.

Product Code	D0651		
Lot Number Affected	20013724		
Items Used			
Items Unused			

Product Disposal — *Only discard the affected D0651 lot no. 20013724 product*

List the number of unused items discarded.

Product Code	D0651		
Lot Number Affected	20013724		
Items Discarded			

Replacement Request — *Only if D0651 lot no. 20013724 are unused*

List the number of items you require to replace.

Product Code	D0651		
Lot Number Affected	20013724		
Required number of replacements			

Customer Signature *(Only mandatory for US, Brazil and Canada)*

Dako reference number:

ACKNOWLEDGEMENT FORM for Subsidiaries

Dear Dako Recall contact person,

Please fill in this Acknowledgement Form, and return it to QA Vigilance, by email dako.dkvigilance@dako.com, no later than 48 hours from receipt of the Field Safe Notice.

I hereby confirm that I have received the Field Safe Notice concerning APAAP, Mouse Monoclonal No. D0651 Lot no. 20013724.

Company: _____

Country: _____

Name: _____

Date: _____