Agilent
Dako

Attn.: Laboratory Manager

«Account_Name»
«Shipped-to Account Number»
«Address1»
«City», «Postal_Code»
«State», «Ctry»

Reference number: CAPA00753 MMMM DD, 2018

Urgent Field Safety Notice

The purpose of this letter is to notify you that we have initiated a Field Safety Corrective Action (FSCA) for a specific lot of FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 1294, Ready-to-Use (Dako Omnis), Code No. GA090. Our records show that your laboratory has received the affected lot:

Lot No. 10122642	Release date: March 15th, 2017	Expiration date: January 31th, 2018

Description of the issue:

Agilent has determined that the lot listed above may have been contaminated with CDX2 antibody. The issue was first noticed in an internal study using the affected lot, where unexpected nuclear staining of colon epithelium was observed. Based on our analysis, the trace amount of antibody should not affect stability of the GA090. Only tissue with high CDX2 expression such as normal colon tissue may show false positive staining.

To date, Agilent has not received any customer complaints on this issue. The nuclear staining was seen only for some vials of the affected lot. It is important to emphasize that the manual and Autostainer versions of this product are not affected.

Affected results

Our investigations have shown that the contamination issue with CDX2 antibody should not affect the staining on patient specimens as the intended use of GA090 is to semi-quantitatively detect human progesterone receptor (PR) status on invasive breast carcinoma specimens. This means that the issue of unexpected nuclear staining will mainly affect colon tissue and not breast tissue, and therefore should not lead to false positive results.

In the Instructions for Use (IFU), colon tissue is recommended as an external negative tissue control. Using colon as a negative tissue control with the affected vials could result in rejection of otherwise valid patient test results due to the unexpected nuclear staining which would alert the pathologist to do a rerun.

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. Confirm that you have received this information by completing and returning the below return form to your local country sales representative [insert local country/distributor contact email].
2. If you used colon tissue, where the affected lot was used, you should review previous assay runs and patient results to ensure that the PR status is concordant to the result expected. If needed, please contact your local country sales representative to arrange a replacement solution for you.

3. Contact your local country sales representative if you have any questions regarding this notification, or if you would like assistance with the return 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.

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

Reporting to authorities (only applicable for EEA countries):

Please be aware that the relevant National Competent Authorities have been advised of this safety notice.

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 safety and customer satisfaction.

Sincerely,

Asger Dahlgaard
Complaint and Vigilance Manager
dako.dkvigilance@agilent.com
Signature:

Attn.: Laboratory Manager

«Account_Name»
«Shipped-to account number»
«Address1»
«City», «Postal_Code»
«State», «Ctry»

Return Form for Customers

Agilent Reference Number: CAPA00753

Fill in this Return Form to confirm receipt of the enclosed Field Safety Notice, regarding FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 1294, Ready-to-Use (Dako Omnis), Code No. GA090.

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The Return Form must be completed within 10 days from receipt and emailed to [insert local country/distributor contact email]. Please be aware that the signature must be in handwriting.

Acknowledgement:				
1. I have read and understood the Field Safety Notice and the instructions stated in this letter:			Yes ☐ No ☐	
2. Do you have any affected items in your in stock? Please check your inventory before answering this question. If the answer to this question (question 2) is yes, please fill in the quantity of affected items in your inventory as well as the quantity of replacement items required in the table below.			Yes ☐ No ☐	
Product code	Product name	Lot	Number of items discarded	Number of items to be replaced
GA090	FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 1294, Ready-To-Use (Dako Omnis)	10122642		
Date				
Name of person completing this form				
e-mail address				
Phone number		+		
Signature				