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Cvr.: 21852902

Dako
Agilent Pathology Solutions

Attn.: Laboratory Manager

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

Reference number: CAPA00722 October 5, 2017

Field Safety Corrective Action

The purpose of this letter is to notify you that we have initiated a Field Safety Corrective Action for specific lots of FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis), Code No. GA084. Our records show that your laboratory has received the following affected lot(s):

[This sentence must be deleted: - Lot no(s) not provided to the customer must be removed]:

Lot. No.	Lot. No.	Lot. No.
10127880	10127400	10125849

Description of the issue:

Agilent has determined that the lot(s) listed above have shown weak non-specific nuclear and cytoplasmic/stromal staining in known negative samples. The issue was first noticed in an internal Agilent study using one of the affected lots, where false-positive nuclear staining was seen in a subset of the negative samples, and was not seen on negative tissue run controls. The staining was misinterpreted by a trained breast pathologist as ER-positive. Further testing has shown that all of the above lots are affected. In these lots, some, but not all, breast cancer samples will show weak false-positive staining in some nuclei. Because of this, use of these lots could result in a false-positive result in patient tissue and may not be detected by run controls.

To date, Agilent has not received any customer complaints on this issue. The false-positive results were seen only for GA084 in an internal Dako Omnis study, and only for the affected three lots. It is important to emphasize that the manual and Autostainer versions of this product are not affected.

Affected results

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Based on our investigations, there is a high possibility that the non-specific nuclear staining in some specimens which could be mistaken for specific staining in some situations. Using a known negative run control that is not affected and a patient sample with ER that is erroneously scored above 1%, as staining above 1+ or 1% is considered positive, will present the greatest risk of a false-positive result. This would be more likely if the negative tissue run control was cell pellets or non-breast cancer FFPE, as these negative controls are less likely to show the non-specific staining. In these situations, the non-specific staining is not easily detectable by a trained pathologist and could result in false ER-positive test results.

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 Ready-to-Use GA084 vial(s) from the affected lot(s). The vials should 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 QA Vigilance by email to dako.dkvigilance@agilent.com with your sales representative on copy.
    a. Choose the type of replacement product you want to receive on the Device Recall Form. You will receive replacements after we have received the completed form from you. Please note that replacements are also offered for products that have already been used.
3. Review previous assay runs and patient results where the affected lot(s) were used. Consider re-staining and analyzing specimens with increased non-specific staining or borderline results, especially with very low intensity staining.
4. 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:

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Name: [redacted]
Function: [redacted]
Contact details: Dako.dkvigilance@agilent.com
Signature: [redacted]

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Agilent Reference Number: CAPA00722

Device Recall Form for Customers

Instruction for Customers

The following actions must be taken within 10 calendar days:

- Please fill out the fields below to record affected devices in your laboratory and return the form to QA Vigilance, via email , to dako.dkvigilance@agilent.com with your sales representative on copy. Note that all fields must be filled in.
- Replacement for both used and unused vial(s) of specific lots of FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Dako Omnis), Product Code GA084 will be provided. You will receive the replacement items after Agilent has received the completed Device Recall Form filled from you. Thank you.

Customer Information			
Date			
Country			
Institution Name			
Customer Account Number			
Customer Address			
Customer Signature			
Usage of the affected GA084 vial(s) See example of how to fill out on page 3.			
Affected Recall Lot Number(s)			
Items / Kits Used (pcs)			
Items / Kits Unused/Discarded (pcs)			

Offered Replacement Products
See example of how to fill out on page 3.

You can choose between following replacement products

- Estrogen Receptor, Clone EP1 product variants M364301, IR084 or IS084
- Estrogen Receptor, Clone 1D5 product variants IR657 or IS657

Note:

- Two vials of M364301 are equal to 1 vial of GA084.

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Two vials of IS084 or IS657 are equal to 1 vial of GA084.		
Order Your Replacement Product(s) in pieces equal to the number of product you received.		2 vials x M364301
		1 vial x IR084
		2 vials x IS084
		1 vial x IR657
		2 vials x IS657

Example of how to fill out the last sections

A customer received GA084 products from the lot no(s) affected, as follows:

- Two GA084 vials from lot no. YYYYYYY. Both used.
- One GA084 vial from lot no. XXXXXX. Partially used items are considered as unused. Customer discarded the partially unused GA084 vial (1).

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

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Usage and replacement of the affected GA084			
Affected Recall Lot Number(s)	YYYYYYY	XXXXXX	Total
Items / Kits Used (pcs)	2	0	
Items / Kits Discarded (Unused) (pcs)	0	1	
Required number of replacements (pcs)	2	1	Total: 3

Offered Replacement Products
You can choose between following replacement products

- Estrogen Receptor, Clone EP1 product variants M364301, IR084 or IS084
- Estrogen Receptor, Clone 1D5 product variants IR657 or IS657

Note:

- Two vials of M364301 are equal to 1 vial of GA084.
  Two vials of IS084 or IS657 are equal to 1 vial of GA084.

Order Your Replacement Product(s) in pieces equal to the number of product you received.	3	2 vials x M364301
		1 vial x IR084
		2 vials x IS084.
		1 vial x IR657
		2 vials x IS657

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