Dako
An Agilent Technologies Company

To Dako Subsidiaries/Distributors only!

Recall Cover Letter

Date: December 11, 2013
Dako reference no.: CAPA00422

1. Details on affected product:

Product	Code	Lot	Expiry date
HER2 CISH pharmDx™ Kit	SK109	00092789	2014-03-31

No other Dako products or other lots are subject to this recall.

2. Dako reference number:

Customer Complaints: SR3076149, SR3076401, SR3076773

3. Description of the problem:

This notification has been initiated as weak and inhomogeneous red signals have been observed when using HER2 CISH pharmDx™ Kit lot 00092789.

If you/your company have followed the recommended quality control procedures according to the Instructions for Use (IFU), slides with weak and inhomogeneous signals would not pass quality control and would therefore not be subject to further evaluation.

If the recommended quality control procedures have not been followed, there is a risk of incorrect red signal count. That could lead to underestimation of the HER2/CEN-17 ratio and potentially false negative results.

The Quality Control section of the Instruction for Use states that:

1. Signal must be clear, well balanced in intensity, distinct and easy to evaluate
2. Normal cells within the sample allow for an internal control of the staining run
   - Normal cells should have 1-2 clearly visible red signals indicating that the HER2 DNA Probe has successfully hybridized to the HER2 amplicon.
   - In case of tissue sectioning, some normal cells will have less than the expected 2 signals of each color.
   - Failure to detect signals in normal cells indicates assay failure, and results should be considered invalid.

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3.1 Actions to be taken by the Subsidiary/Distributor:

Our records show that you have customers who have received the affected product. To help you identify affected customers, we have attached a list with customer names/order numbers to this letter.

Further use of any remaining product should cease immediately.

The product listed above is subject to disposal and replacement.

Please be aware that it is now your responsibility, in your local language, to inform the customers, who have received the affected products by completing the following actions:

- Translate the attached *Field Safety Notice/Recall Notification* into your local language
- Fill in the customer name and address in the header of the *Field Safety Notice/Recall Notification*
- Fill in your local contact details in the attached *Device Recall Form to customers*
- Send to all affected customers:
    - The translated *Field Safety Notice/Recall Notification*
    - The *Device Recall Form to customers*

Return the following to Dako Contact:

- Within **24 hours** the *Acknowledgement form* completed by you to acknowledge that the letter has been received and that you will act accordingly and comply to all the instructions outlined above.
- Copy of the translated *Field Safety Notice/Recall Notification*
- Customer completed *Device Recall Form to customers*

3.2 Dako Contact:

We regret the need to address you in this way and apologize for any inconvenience caused.

Name: Jette Kjeldal

Function: Quality Compliance Manager

Contact details: jette.kjeldal@dako.com
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Signature: