Dako
An Agilent Technologies Company

Customer Address
Name
Country

Date: December 11, 2013

Field Safety Notice/Recall Notification

The purpose of this letter is to inform you that Dako has initiated a recall of *HER2* CISH pharmDx™ Kit, Code SK109.

The following products are affected by this recall:

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.

Our records show that you/your company have received the affected device lot 00092789.

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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Actions to be taken by the user:

Further use of any remaining product should cease immediately.

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

It is your responsibility to determine the impact of this change in performance on patient results from the affected lots.

Communication:

Please ensure that this notice is distributed within your organization as appropriate and to the relevant organizations, where the affected or potentially affected products have been transferred. 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 to customers* to document the usage or disposal of affected lot and to request a replacement for the affected product.

Please note that you must complete and return this form even if you do not have any products to dispose. Your local sales representative can assist you in completing this. The information is essential in order for us to maintain the necessary records relating to recalleffectiveness, which is required by the authorities.

Please contact your **local** Dako sales representative if you have any questions or require any assistance regarding this recall. We sincerely regret any inconvenience that this action may cause but we appreciate your understanding as we take action to ensure patient and customer satisfaction.

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

Dako Contact:

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Function: Quality Compliance Manager

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Signature: