**Attn.: Laboratory Manager**

**«Account\_Name»**

**«Address1»**

**«Address2»**

**«City», «Postal\_Code»**

**«State», «Ctry»**

Reference number: CAPA00657 June 14, 2017

**Field Corrective Action**

The purpose of this letter is to notify you that we have initiated a Field Corrective Action for Monoclonal Mouse Anti-Human Cytokeratin, High Molecular Weight, Clone 34βE12, Code No. M0630, Lot No(s):

Lot no. 10115298 (M063001-2)

Lot no. 10115412 (M063029-2)

**Description of the problem:**

The primary (vial) labels of the affected vials of M0630 were mislabeled with an incorrect concentration of 11.2 µg/ml. Additionally, you might have received a Certificate of Analysis (CoA) stating the same incorrect concentration. **The correct concentration is 23.5 µg/ml.**

M0630 will perform as expected, and there is no change to the actual concentration of the product. Although the vial label shows an incorrect concentration, the secondary (box) label contains the correct concentration of 23.5 µg/ml.

If diluted from the incorrect lower concentration of 11.2 µg/ml, the result would be a higher concentration. This may cause stronger signals than expected, and may lead to increased background staining. Positive and negative run controls would be useful to detect any problems with staining in this case. If the increased staining might lead to any doubt in the interpretation of the results, we recommend that you perform a retest.

## 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 bottle(s) of Monoclonal Mouse Anti-Human Cytokeratin, High Molecular Weight, Clone 34βE12, Code No. M0630, Lot No(s) [to be inserted]. Bottles can 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 Dako QA Vigilance by [Dako.dkvigilance@agilent.com](mailto:Dako.dkvigilance@agilent.com) with your sales representative on copy.
   1. The entire Device Recall Form must be completed, if replacement product(s) is requested for any unused product(s) you have discarded.
3. Review previous assay runs and patient results where the affected lot(s) was used. Determine if these assay runs were diluted based on the incorrect concentration on the label and whether the results might have had false increased staining signal, increased background, and/or false positive staining. It is highly likely that this would have been previously detected due to the increased signal/background on positive/negative controls, including internal tissue controls. However, if assays were incorrectly diluted, but not detected at the time, the results should be considered inconclusive and a retest should be run with the dilution calculated from the correct concentration of 23.5 µg/ml L.

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:**

Name: Asger Dahlgaard

Function: Complaint and Vigilance Manager

Contact details: Dako.dkvigilance@agilent.com

Signature: