

1 July, 2014

[Recipient's Name]
[Company]

[Recipient's Address]

Customer Notification

Dear Valued Customer,

The purpose of this letter is to inform you that Dako is taking an action to correct the calibration settings in certain Autostainer Link 48 (AS480) instruments, with DakoLink™ software, version 4.0. Other Autostainer instruments are **not** affected by this correction. Our records show that one of the potentially affected instruments is installed at your laboratory.

No action is required on your part. You can continue to use the Autostainer Link 48 (AS480) instrument as normal.

Our investigation has confirmed that this issue affects some Autostainer Link 48 instruments. We have identified the specific instruments which are affected and confirmed that the following instrument in your laboratory is affected by this correction:

Issue	Instrument	Software version	Serial Number
Dakolink™ software calibration settings	Autostainer Link 48 (AS480)	4.0 (initially released March 2013)	Subsidiaries to customize the letter, by listing the specific serial number(s) for the instrument(s) at the customer sites.

Description of the problem:

Dako has found a software defect in the calibration routine of DakoLink 4.0. The defect may cause the Autostainer control software to use old calibration settings. Our investigations have shown that this will only occur in circumstances where the DakoLink software has been upgraded from 3.1 to 4.0. **and** where an instrument has had a Preventive Maintenance or a



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waste pump has been replaced, since installation of the Dakolink 4.0 software. In very unlikely circumstances, the software defect may lead to premature rejection of reagent bottles, which has no patient impact; or inadequate aspiration of reagent, which may lead to incorrect patient results.

Dako's investigation and risk assessment has concluded that the risk to patients is remote.

Dako's actions:

Dako has developed a software work-around to correct the calibration settings, which will address this issue permanently.

Your local Field Service team will contact you to schedule a visit to do the following:

- Determine whether the affected instrument has been impacted by the software defect. If yes, correct the calibration settings to address the issue;
- Determine whether back-office analysis of instrument data is needed to identify slides that could be affected by inadequate aspiration;
- In the rare event that off site analysis of data is required, we will request written permission to download and investigate the data off site.
- If the data analysis shows that some slides may have been affected by inadequate aspiration we will work with you to manage the situation.

It is anticipated that the field service visit will last approximately 1.5 hours, so please consider this when scheduling the appointment. The Field Service Engineer will leave you with a record of the visit and document changes made to the instrument in your service record.

Actions to be taken by the user:

You may continue to use the Autostainer Link 48 (AS480) instrument as normal.

Communication:

Please ensure that this notification is distributed within your organization as appropriate so that there is no confusion on the availability of the instrument.



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Dako Contact:

Please contact your **local** Dako representative if you have any questions or require any assistance regarding this Customer Notification.

We sincerely regret any inconvenience that this may cause, and we appreciate your understanding as we take action to ensure patient and customer satisfaction.

Name:

Function:

Contact details:

Signature: