Customer Address
Name
Country

Dako reference number: *Notification CAPA 00509*

Date:

Urgent Medical Device Recall Notification

Dear Valued Customer,

It has come to our attention that a problem occurs in the Omnis software module, known as the Test Request Distributor (TRD). The Test Request Distributor (TRD) is intended to distribute patient case, appropriate parts information, track changes and transform test requests from a Laboratory Information System (LIS), True Positive ID (TPID) or manual entries, to connected Dako systems. TRD connected to LIS or TPID does not support updates to an existing test request. Consequently, the test executed on the slide does not match the updated information in LIS/TPID, or that noted on the slide label.

Based on our findings, Dako has initiated a Voluntary Medical Device Recall to Dako Omnis customers who are using the Dako Omnis connected to an LIS or to TPID. Your laboratory may continue to use the instrument in accordance with the guidance set forth below. Your local Dako representative will contact you regarding this notification.

Customers affected by this Medical Device Recall Notification must have the following:

1) An Omnis software configuration with TRD versions 1.3.0 (part of Dako Omnis Upgrade pack 1.5) and TRD version 1.4.0 (part of Dako Omnis upgrade pack 2)

2) An Omnis set-up connected to LIS or TPID

Other Dako instruments connected to the LIS or TPID through the Omnis software set-up will also be affected (Artisan™ Link, Artisan™ Link Pro, Autostainer Plus Link Instrument, Autostainer Link 48).

Description of the problem:

If a user requests slides from the LIS or TPID, and subsequently updates a request by changing the test, this update will be rejected by the Omnis software module known as TRD. Due to this rejection, the LIS and slide label printed from the LIS system will display the updated test with

the requested change, but the Omnis system will execute the initial test, not reflecting the change.

The system will not warn the user that the test request was not changed according to the update from LIS or TPID. Test requests updated in the above described manner will also be rejected by the TRD when the DakoLink Products (Artisan™ Link, Artisan™ Link Pro, Autostainer Plus Link Instrument, Autostainer Link 48) are connected through the TRD to the LIS/TPID.

You may continue to use your instrument(s), but we strongly advise that you do not update test requests when the Dako Omnis is connected to a LIS or TPID.

Please note that we are not aware of any patient misdiagnosis at this time.

Dako understands the importance of this issue, and is fully committed to resolving the problem. As such, we request your cooperation to ensure that everyone in your laboratory is made aware of this issue.

We advise you to take the following actions:

You may continue to use your instrument(s), but please take the following actions:

- Do not update a test request in LIS or TPID after it has been created.
- Instead, delete the test request and request a new one with the desired protocol.
- If tests are requested, and labels are printed from the Dako Omnis, the tests are executed properly.

If you are concerned that your laboratory may have deviated from the recommendations listed, we kindly ask you to contact your local Dako representative.

Dako's Actions:

Your local Dako representative will contact you within the next week to make sure you have read and understand this notification.

We are working on a long-term corrective action and will inform you when it is available.

Transmission of this Notice:

We kindly ask that you inform those within your organization of this notification. This includes any organizations where the potentially affected instruments have been transferred. Please ensure that your organization maintains awareness of this notice, and the recommended steps

until the corrective actions have been completed.

Please complete, sign, and return the attached acknowledgement form within one week of receiving this letter.

If you have any questions regarding this notification or would like assistance, please contact your Dako sales representative. We apologize for any inconvenience that this action may cause, and appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

Dako Contact:

Name: Per Andersen

Function: Global Solution Manager

Dako Omnis Solution
Global Marketing

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Best regards

Name:

Function:

Contact details:

Signature