Dako
An Agilent Technologies Company

«INCIDENT_CUSTOMER»«AddressBlock»

Att.: «CONTACTNAME» / Laboratory Manager

Dako reference number: *CAPA00475*

Urgent Medical Device Field Safety Notice

Dear Valued Customer,

Based on findings of a defective part in some Autostainer instruments, Dako has initiated this Field Safety Notice concerning Autostainer instruments for customers using HercepTest™. Your laboratory may continue to use the instrument(s) in accordance with the guidance set forth below. Your local Dako representative will contact you regarding this notification.

The following instrument(s) are affected by this Field Safety Notice:

Catalog no.	Model no.	Serial Number
«Catalog»	«Item»	«I1_Serial»
		«I2_Serial»
		«I3_Serial»
		«I4_Serial»
		«I5_Serial»
		«I6_Serial»
		«I7_Serial»
		«I8_Serial»
		«I9_Serial»
		«I10_Serial»

Description of the problem:

Dako has determined that a defect in the stopcock component of the syringe assembly (see figure 1) in some Autostainer instruments may, under some circumstances, cause leakage of excess buffer onto slide position 35 and 36 (for AS480 slide position 34) due to the stopcock's standby location over these position(s).

Catalog no.	Model/Instrument	Do not use position for HercepTest™
AS100	AUTOSTAINER PLUS LINK INSTRUMENT	**35 and 36**
AS480	AUTOSTAINER LINK 48 INSTRUMENT SYSTEM	**34**
S3400	AUTOSTAINER	**35 and 36**
S3800	AUTOSTAINER PLUS	**35 and 36**

You may continue to use your instrument(s). However, Dako recommends to discontinue the use of HercepTest™ in the slide position 34, 35 and 36, depending on make and model of the instrument(s) in your facility.

In addition, we recommend that you pay special attention to any indication of this leakage or compromised staining.

- When staining using the HercepTest™ protocols, excess leakage from the syringe assembly may dilute the antibody and reduce IHC staining quality and potentially affect the score.
- If the compromised HercepTest™ staining is not detected by the operator or pathologist, it could potentially be misinterpreted as a negative test result, which could contribute to an incorrect diagnosis. Positive test results will not be affected by this defect.

We are not aware of any cases of patient misdiagnosis at this time and no other reagent protocols are impacted by this defect. As part of Dako's ongoing quality control procedures, we have identified the faulty population of stopcocks, and all stopcocks are now screened for this issue prior to deployment.

Please understand that although your instrument(s) has been identified as having a defective stopcock, it may not be affected by this defect. Leakage of excess buffer occurs only in remote circumstances even when using a stopcock that has been identified as defective.

Dako understands the importance of this recall and is fully committed to resolving the problem. As such, Dako requests your full cooperation to enable our personnel to come onsite to review the data in your instrument(s) to determine whether HercepTest™ has been used for staining slides in the affected position(s).

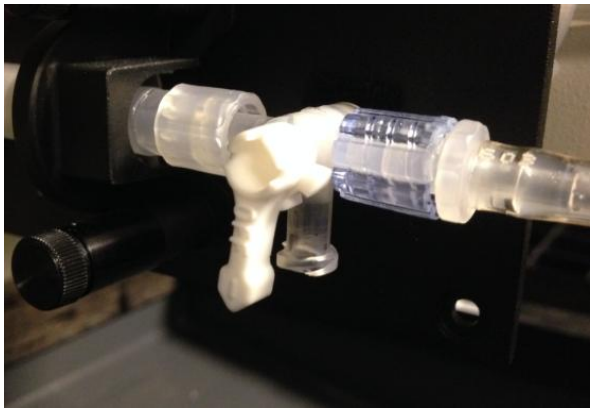

Figure 1. Picture of stopcock spare part to Autostainer

We advise you to take the following actions:

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

- Discontinue the use of HerceptTest™ on the affected slide position(s).
- As set forth in Dako's staining protocol, use on-slide positive controls.
- Watch for any indication of buffer leakage from the syringe assembly. This can be done easily when the tubes are checked for air bubbles in connection with exchange of the buffer bottle.
- Check for weak staining in regards to HercepTest™ in the affected slide position(s). As advised in the IFU for HercepTest™ please contact Dako Technical Support Department to report unusual staining.

Dako's Actions:

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Your local Dako representative will contact you within the next few weeks in order to determine whether HercepTest™ has been used for staining slides in the affected slide position(s).

Dako has identified a longer term corrective action to install a drip tray under the stopcock. Your local Dako representative will contact you when the drip tray is available.

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 where the potentially affected instrument(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.

Please complete, sign and return the attached product recall form as soon as possible.

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

Dako Contact:

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Best regards

Rosanne Welcher

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