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Attn: Laboratory Manager

CUSTOMER DETAILS

Reference number: CAPA00729

December 17, 2018

Urgent Field Safety Notice

Dear Valued Customer,

The purpose of this letter is to notify you of a Field Safety Corrective Action (FSCA) regarding slide racks that are used with the Dako Autostainer instruments (AS480; AS100; S3400; S3800). We are updating our Autostainer Link Basic User Guide with respect to slide leveling. Our records show that your laboratory has received the following affected device:

Product name	Code No.
Autostainer Slide Racks	S3704

Description of the issue:

Agilent has identified an additional correction to the risk of slide rack leveling failures as described in the current Autostainer User Guides. Such failures have the potential to impact staining quality with weak/uneven staining, which may lead to false negative test results. We are updating the Autostainer Link Basic User Guide to include an additional mitigation to the slide rack leveling risk. Although the current User Guides already addresses the importance of regular slide levelness checks and the use of on-slide controls, we have identified an additional action to mitigate the potential for out-of-level slide racks. Slide racks may be affected by repeated exposure to the heat of the hot water bath of the PT Link leading to the risk of level failures. We have determined that a limit of 175 uses of each slide rack will further reduce the risk of out-of-level slides. Following this update to the guide will ensure your slide racks are not used beyond their ability to withstand the hot water bath and are replaced at a frequency appropriate for your workflow.





Update of the User Guide:

The user instructions: Autostainer Link Basic User Guide will be updated regarding the **following (as provided in more detail in the Appendix to this letter)**:

- Storage of slide racks.
- The slide rack shall be aligned and resting on the sink frame when loading the slide rack.
- The slide rack can tolerate 175 PT Link pre-treatment cycles.
- Dispose slide racks that fails the slide position test or that have been subjected to 175 PT Link cycles.

Clinical Significance:

If use of your slide racks is in excess of 175 PT Link pre-treatment cycles, then there is the possibility that out-of-level slide racks may lead to weak/uneven staining, which potentially leads to false negative test results and may impact patient treatment. If on-slide controls are run, as recommended by the Autostainer User Guide, the failure should have been detected.

Risk associated with previous use of affected device:

If our recommendations, stated in the current Autostainer User Guide, are followed, the likelihood of risk to patients is remote.

Actions to be taken by the user:

Within 10 calendar days, please take the following actions:

1. Carefully read the updates stated in this notification letter and appendix.
2. Confirm that you have received this information by completing and returning the enclosed Return Form to your local sales representative by email to cruinnfsngroup@cruinn.ie.
3. Continue the use of the Dako Autostainer in accordance with this notification.

Please contact your local sales representative if you have any questions regarding this notification, or if you would like any assistance.

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.

Reporting to authorities (only applicable for EEA countries):

Please be aware that the relevant National Competent Authorities have been advised of this safety notice.





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 safety and customer satisfaction.

Sincerely,

Asger Dahlgaard

Complaint and Vigilance Manager

dako.dkvigilance@agilent.com

Signature:

A handwritten signature in blue ink that reads "Asger Dahlgaard". The signature is written in a cursive style with a large, stylized initial "A".





Attn.: Laboratory Manager

CUSTOMER DETAILS

Return Form for Customers

CAPA00729

Agilent Reference Number:

Fill in this Return Form to confirm receipt of the enclosed Field Safety Notice regarding Autostainer Slide Racks, Code No. S3704.

The Return Form must be completed within 10 days from receipt and emailed to cruinnfsngroup@cruinn.ie

Acknowledgement:	
<i>I have read and understood the Field Safety Notice and the instructions stated in this letter:</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Date</i>	
<i>Name of person completing this form</i>	
<i>E-mail address</i>	
<i>Phone number</i>	+
<i>Signature in handwriting</i>	



APPENDIX

Based on the changes, we recommend the following:

- *Label the slide rack with expiry date before being put into use for tracking of PT Link cycles. (see below for instructions on how to calculate the expiry date).*
- *Qualify every slide rack before being put into use by performing the slide position test. (see below for instructions on how to perform the slide position test).*
- *Place the slide label so both sides or no sides of the label are in contact with the slide rack.*
- *When not in use, store the rack in position that avoids: direct sunlight, extreme temperatures, and stacking of the racks.*
- *If the slide rack is accidentally dropped on the floor, check the levelness of each slide position by performing the slide position test.*
- *When loading the rack in the instrument ensure that the slide rack is aligned and rests on the sink frame.*
- *Regularly check the levelness of each slide position by performing the slide position test, at least every 3 months.*
- *Discard slide racks that fail the slide position test or have been subjected to 175 PT Link pre-treatment cycles.*

Procedures

Slide rack expiry calculation examples:

*Lab 1 has 2 sets of racks for each Autostainer and starts the instrument up to 3 times per day. The lab is closed Saturday and Sunday and on 11 public holidays. An average month has $(365-11-2*52)/12 = 21$ working days/month.*

*Expiry date lab 1: $175 \text{ [cycles/rack]} * 2 \text{ [racks]} / 3 \text{ [cycles/day]} / 21 \text{ [days/month]} = 5.6$ months.*

Expiry date for lab 1 should be set to five months from initial use.

Lab 2 has 3 sets of racks for each Autostainer and starts the instrument up to 2 times per day. The lab only closes 10 days per year and is open Saturday and Sunday. An average month has $(365-10)/12 = 30$ working days/month.

*Expiry date lab 2: $175 \text{ [cycles/rack]} * 3 \text{ [racks]} / 2 \text{ [cycles/day]} / 30 \text{ [days/month]} = 8.8$ months.*

Expiry date for lab 2 should be set to eight months from initial use.

Slide Position test

Place blank slides with slide labels into the Autostainer Link rack that was also used in the PT Link. Ensure that the slide label is in contact with both sides of the slide rack or, if you are using small labels, that the slide label is centered between the slide holders.

Load the rack into the Autostainer Link.



Use the level supplied with the instrument to check every slide position. The level indicator for each position must be within the **second** circle ring on the level. See illustration below.

Agilent recommends discarding slide racks if one or more of the slide positions do not pass the slide position test.

When all 12 positions have been tested successfully, the rack should be labeled with a new QC label specifying date of the next slide position test.

