

**Attn: Laboratory Manager**

Reference number: CAPA00776

October 30, 2019

**Urgent Field Safety Notice**

Dear Valued Customer,

The purpose of this letter is to notify you that we have initiated a Field Safety Corrective Action for the Syringe Tray Code No. 992678 that is used with the Dako Autostainer instruments (AS480; AS100; S3400; S3800). Our records show that you may have one or more Dako Autostainer instruments without a Syringe Tray.

Product name	Code No.
Autostainer Syringe Tray	992678

**Description of the issue:**

This Field Safety Notice is to ensure that all Autostainer instruments have a Syringe Tray installed. For instruments without a Syringe Tray, there is a remote possibility that the stopcock, syringe pump or the assembly of these items may drip, resulting in a small volume of excess buffer being applied to one or two slide(s) loaded in Rack 3. Presence of a Syringe Tray will prevent any potential dripping from reaching the slide(s) and will remediate this potential issue. The Syringe Tray does not affect the operation of the instrument.

**Potential risk to patients:**

In the event of leakage, the immunohistochemistry intensity score/staining may be affected. Thus, the issue may potentially cause a false negative result. Running on-slide controls, as recommended by the current Autostainer User Guide, would allow detection of potential staining abnormality secondary to dripping. Dako's investigation and risk assessment has concluded that a false negative result may occur with HercepTest and potentially also affect PD-L1 (PD-L1 IHC 22C3 pharmDx and PD-L1 IHC 28-8 pharmDx) in remote to improbable circumstances. If the reduced intensity/staining is not detected by the pathologist, then the diagnostic outcome may be affected.

**Actions to be taken by the user:**

**Within 7 calendar days:**

- Please fill out the attached excel sheet "Autostainer Instrument overview." The sheet is an overview of your Autostainer instruments that may be affected. For each instrument, specify whether:
  - A Syringe Tray has not yet been installed (Request Syringe Tray)
  - A Syringe Tray has been installed
  - The Autostainer instrument has been deinstalled or

- The Autostainer instrument is no longer in your possession.

If you have additional instruments without a Syringe Tray other than those listed, please add the instrument serial number to the excel sheet.

- Return the sheet by email to your local representative.

**If you do have an instrument without a Syringe Tray:**

- a. The Syringe Tray package will be shipped to you as soon as possible when we have received the completed Autostainer Instrument overview.
- b. Upon receipt of the Syringe Tray package, install the Syringe Tray according to the instructions set out in this FSN, see Appendix 1. The Syringe Tray package will also include a Return Form and the installation instruction in English. The Return Form must be signed and returned to your local representative by email to [insert Local Country- OR Distributor contact email] within 7 days after the receipt of the Syringe Tray package. The Return Form can be found in Appendix 2 in your local language.
- c. As set forth in the Dako Autostainer User Guide, use on-slide positive controls.
- d. We recommend a Service Inspection of the instrument if there is indication of buffer leakage from the syringe assembly. Inspection of leakage can be done easily when the tubes are checked for air bubbles in connection with exchange of the buffer bottle.
- e. If there are signs of leakage, check for reduced intensity / weak staining on the positions listed below.

Catalog no.	Model/Instrument	Position
AS480	AUTOSTAINER LINK 48 INSTRUMENT SYSTEM	34
AS100	AUTOSTAINER PLUS LINK INSTRUMENT	35 and 36
S3400	AUTOSTAINER	35 and 36
S3800	AUTOSTAINER PLUS	35 and 36

Please contact your local representative if you have any questions regarding this notification, or if you would like any assistance with completing the Autostainer Instrument Overview or the Return Form.

Please contact your local representative or your local customer service if you have any questions regarding installation of the Syringe Tray, or if you do not have a service agreement and you need a quote for Service Inspection. You can access the support contacts by the following link:

<https://www.agilent.com/en/support/agilent-pathology-support-contacts>.

**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 instrument(s) have been transferred. Please ensure that your organization maintains awareness of this notice and that the recommended steps are completed.

PLEASE NOTE: No other Dako-branded devices are involved in this Field Safety Notice.

**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:



## Appendix 1

### Installation of Syringe Tray

#### Installation Time Estimate

15 minutes

#### Prerequisites

Have the Syringe Tray kit available, Figure 1

Tools (socket and Allen key), bolt, washer and nut are included with the kit

#### Procedure

##### 1) Prepare

- Turn off the instrument
- Move the robot arm by hand to the middle of the instrument, Figure 2
- If present, remove the cable tie from the lower right hole on the syringe bracket, Figure 3
- Place the washer on the bolt, Figure 4
- Place the nut in the socket. It is recommended to stop the nut from sinking down the socket by adding a small piece of material, such as paper, in the hole before the nut is placed in the socket, Figure 4
- Locate the hook on the Syringe Tray, Figure 5



Figure 1.

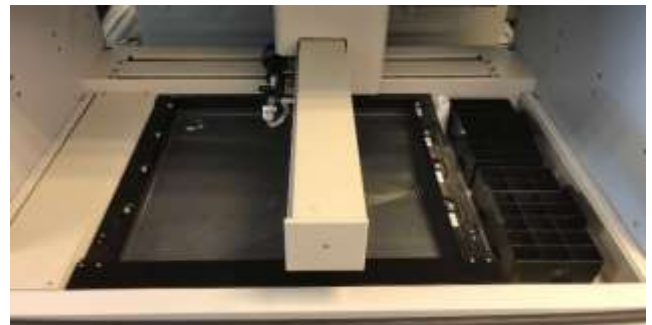


Figure 2.

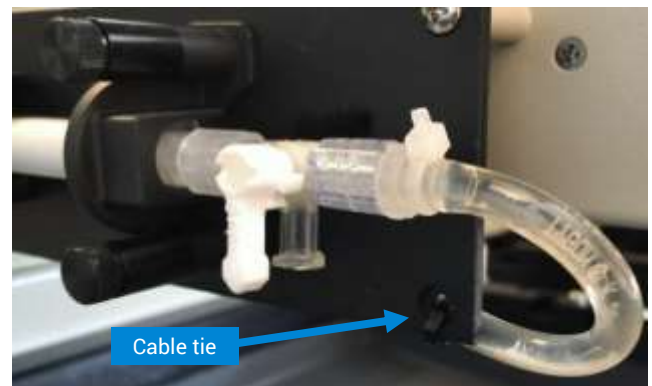


Figure 3.



Figure 4.



Figure 5.

### 2) Mounting

- With your right hand, slide the hook part of the Syringe Tray Bracket over the Distance rod, Figure 6
- With your left hand, install the small bolt and washer from the syringe side in the lower hole, Figure 7
- Use the socket to mount the nut from the backside, Figure 8
- Use the Allen key and socket to hand tighten the bolt/nut, Figure 8
- Figure 9 depicts the final solution

### 3) Test

- Turn on the instrument
- Test for leakage by priming the system with buffer or water while visually inspecting the syringe tray

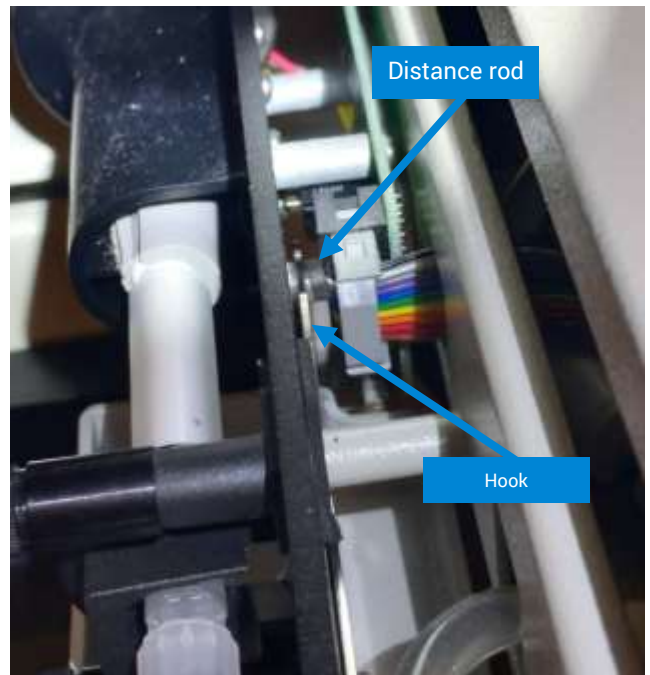


Figure 6.



Figure 7.



Figure 9.



Figure 8.

**Note:** To prime the stopcock (when needed), tilt the Syringe Tray by pushing the tray against the syringe, and down. The tray will be tilted back to the horizontal position, by spring force, and snap-locked in this position. Figure 10

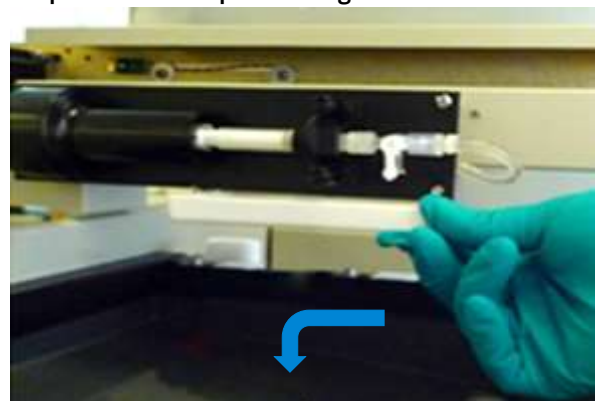


Figure 10.

**APPENDIX 2**

**Return Form for Customers**

**Agilent Reference Number: CAPA00776**

**ONLY SIGN ONCE ALL SYRINGE TRAYS ARE INSTALLED**

Fill in this Return Form to confirm receipt of the Field Safety Notice and to confirm that the actions are performed with regard to the Dako Autostainer instruments (AS480; AS100; S3400; S3800) without a Syringe Tray.

The Return Form must be signed and returned to your local representative by email within 7 days after the receipt of the Syringe Tray package.

<b>Acknowledgement:</b>	
I have read and understood the Field Safety Notice and the instructions. I have installed a Syringe Tray on each of the affected Autostainer instruments.	
Date	
Name of person completing this form	
Signature in handwriting	

*Only sign once all syringe trays are installed*

**ONLY SIGN ONCE ALL SYRINGE TRAYS ARE INSTALLED**