



An Agilent Technologies Company

Field Safety Notice

Device name: CoverStainer Slide Rack
Device number: CS10330
Date: November 13th 2012

Dear Dako Customer,

We would like to thank you for your business with Dako and your confidence in our solutions to help our patients, hospitals and diagnostic laboratories around the world in our relentless fight against cancer.

On September 2010, Dako introduced the H&E CoverStainer (CS100). Since then we have installed more than 100 units worldwide. Clinicians and pathologists have been overall pleased with the throughput and quality of the stains.

As with any new product on the market we have been closely monitoring and tracking the performance of the instrument. While we knew that the functionality of the instrument is performing well in general, there have been some observations with the plastic racks that hold the slides through the staining process which require our attention. In our relentless stewardship, Dako has decided to voluntarily replace all of the racks at our own expense. Dako will start the replacement process immediately in order to provide a higher standard of operational performance and to enhance our overall H&E solution.

In the coming days we will send you the new replacement racks at no cost with easy to follow instructions regarding this Field Safety Notice. The new rack design has been enhanced to ensure correct slide position during the staining process.

Again, Dako is committed to the relentless fight against cancer, and greatly appreciates your partnership in this endeavor. Should you have questions or need technical support, please contact your local Dako representative.

Dako Denmark A/S

Produktionsvej 42
DK-2600 Glostrup
Denmark

Tel. · 45 44 85 95 00
Fax · 45 44 85 95 95
www.dako.com

CVR No. 33 21 13 17

Details of affected product:

Device Brand name: CoverStainer Slide Rack
Item No: CS10330

Dako reference number: SR 3023763

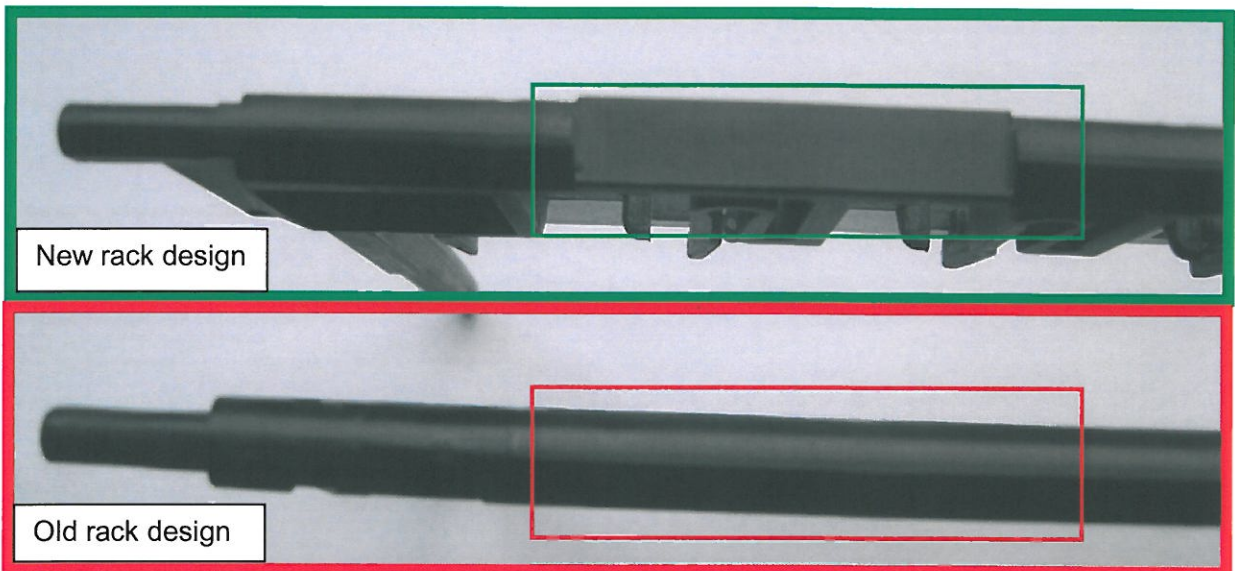
Description of the problem:

This Field Safety Notice has been initiated because the expected life time of the CoverStainer slide racks (CS 10330) does not meet established performance requirements, originating from variations in the manufacturing process. The result can be that slides are falling out of the rack during the staining process. While this has been observed at only a few customer sites, the corrective action includes all CoverStainer installations.

Slides falling out of the rack during the staining process would require a new slide preparation and staining process to be initiated. In the rare event, the patient would need to be called in for a new sample to be taken.

Dako has chosen to correct the rack situation by using a new manufacturer and has improved the rack design to secure correct slide position in the rack.

The new rack design has visible changes which makes it easy to distinguish from the old rack design. The images below show a barcode surface which is present on the new rack (green) but not on the old rack (red).





An Agilent Technologies Company

Action to be taken by the user:

Based on the above, the CoverStainer slide rack (CS 10330) is subject to a voluntary replacement and our records show that your laboratory utilizes those racks.

Dako therefore recommends that further use of the CoverStainer slide rack should cease and be discarded immediately upon receipt of the new racks. New racks will be shipped free of charge to you immediately after this letter has been sent.

Please fill in the Product Recall form attached to this letter and send it back to Dako Denmark.

Transmission of this Notice:

This notice needs to be passed on to all those who need to be informed of the situation within your organization or to any other organization, where the affected or potentially affected devices have been transferred to. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness of this notice and the resulting action for an appropriate period of time to ensure effectiveness of the corrective action.

Reporting to Authorities

The undersigned confirms that the appropriate Regulatory Agency has been notified.

Dako Contact:

We regret the need to address this to you in this way and apologize for any inconvenience caused.

Should you have any questions please contact your local Dako representative or

Global Solution Manager: Göran Mattsson

Email: göran.mattsson@dako.com

Cell: (+45) 2199 5899

Annika Berg
CVP Global RA/QA
Dako Denmark A/S