



An Agilent Technologies Company

Danish Medicines Agency
Axel Heides gade 1
2300 Copenhagen S
Denmark

15 Nov, 2012

To whom it may concern:

Field Safety Corrective Report – Dako Denmark A/S initiated Field Safety Notice of In Vitro diagnostic medical device – CoverStainer Slide Rack CS10330 – no adverse incidents have been reported.

Reporting firm and Manufacturer's name:

Manufacturer: Dako Denmark A/S
Produktionsvej 42
DK-2600 Glostrup
Denmark

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Report date: November xx, 2012
Name of distributor: See distributor list, attachment 1



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IVD Medical Device

Commercial Name: CoverStainer Slide Rack
(Part used with CoverStainer CS100)
Model/Catalogue number: CS103 / CS10330
Class of Device: IVD General (not listed in Annex II and nor for selftesting)

Nomenclature system and text:

Related to CoverStainer CS100
GMDN code: 33617;
Slide stainer, Automated

Serial No.: CS10330 does not have SN, all is replaced.
Software version: Not applicable
Manufacturing /Expiring date: Not applicable
Accessories/Associated devices: Not Applicable
Notified Body (NB) ID Number: Not Applicable

Description of FSCA

Background information and reason for the FSCA

Dako Denmark A/S is legal Manufacturer of the instrument CoverStainer model CS100. The Device in question is a **CoverStainer Rack CS10330** delivered with the instrument which can be ordered and replaced when wear and tear is observed in connection with the routines of maintenance or the process preparation of the CoverStainer.

Based on an investigation it has been concluded that the expected life time of the CoverStainer racks (CS 10330) does not meet the set requirements. The consequence can be that slides are falling out of the rack during the staining process. 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, though no such reporting have been received.

Description and Justification of the Action:

The rack problem originates from variations in the manufacturing process. Therefore Dako has chosen to improve the rack by changing the manufacturer and the manufacturing process in order to further improve product quality. The new rack design has been improved to further secure the correct slide position in order to deliver consistent staining quality.

Dako Denmark A/S will notify the customers voluntarily and replace the racks free of charge.

The risk analysis made for the main device has already handled the described problem.

Based on the complaint history, experience from the market and the daily routines in a laboratory, the likelihood of the potential risk is to be regarded as low. By replacing the racks in the field with racks of the new design we regard and expect this potential risk to be further reduced.



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Advice on actions to be taken by the distributor and the User:

The distributor will be responsible for:

- Sending customer notice letter to end user
- Follow up at the end users and returning Product Recall Form (see attachment 3)

Dako Denmark will ensure that the replacement is shipped to End User, or in some cases to the distributor. The distributor will then be responsible for sending the replacement to the End User.

Field Safety Notice (FSN) in English: See attachment 2

Time schedule for implementation of the different actions: December 2012

Affected EEA countries and Candidates by this FSCA:

NO, FI, SE, DK, DE, NL, BE, FR, ES, IT, GB, PL

Affected countries outside the EEA:

USA, Mexico, Brazil, Chile, Canada, Equador, China, Japan, Australia, Taiwan, Republic of Korea, Israel, Turkey, Saudi Arabia, Russia

Comments: No comments

For further information please contact the undersigned

Yours Sincerely
Dako Denmark A/S

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- Encl.: 1) Distributor List
2) Field Safety Notice (Customer Notice Letter)
3) Product Recall Form to customers (Acknowledgement form)