



Agilent Pathology Solutions

Attn.: Laboratory Manager

«Account_Name»
«Address1»
«Address2»
«City», «Postal_Code»
«State», «Ctry»

Reference number: CAPA00728

December 22, 2017

Field Safety Notice

Dear valued customer,

The purpose of this letter is to notify you that we have initiated a Field Safety Corrective Action concerning the Artisan instruments: Artisan Classic (AR100), Artisan Link (AR210), and Artisan Link Pro (AR310). Our records show that your laboratory has received the following affected instrument(s):

[insert device details]

Instrument	Catalog No.	Serial No.

Description of the issue:

As part of a device history file (DHF) review for the Artisan instrument, a fume test has been conducted. The fume test was set up to measure the emission of formaldehyde from the Artisan instrument. Results for the fume test showed that the emission of formaldehyde exceeds the threshold limits set by Ireland.

Potential user risk:

To date, Agilent has received no customer complaints on this issue. The risk of formaldehyde exposure from the Artisan instrument is difficult to assess due to various





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factors, such as: laboratory configuration, how long the user is near the instrument, the ventilation of the laboratory, and which assays are run (since only five specific Artisan assays, which are listed below, produce these fumes). Nonetheless, prolonged user exposure to formaldehyde could potentially increase the risk of user harm which is why formaldehyde exposure should be kept at a minimum.

It is important to note that you may continue to use your instrument(s). However, we recommend that you place your instrument(s) in a highly ventilated area until a solution has been implemented. Agilent is currently working on a solution which will minimize the formaldehyde exhaust from the Artisan instrument.

If it is not possible to place your instrument(s) in a highly ventilated area, we recommend that you do not run the following protocols on your Artisan instrument(s):

- AR166 Artisan Gomori's Green Trichrome Stain Kit
- AR167 Artisan Gomori's Trichrome Stain Kit
- AR173 Artisan Masson's Trichrome Stain Kit
- AR179 Artisan Reticulin/Nuclear Fast Red Stain Kit
- AR182 Artisan Reticulin/No Counterstain Stain Kit

Please be aware that no solution will be implemented for the Artisan Classic (AR100), as this product has been discontinued. If you have an active Artisan Classic (AR100) instrument in your laboratory, we recommend that you follow the guideline as mentioned above and place the instrument in a highly ventilated area when in use.

Actions to be taken by the user:

Within 10 calendar days, please take the following actions:

1. Confirm that you have received this information by completing and returning the enclosed Return Form to QA Vigilance by email to dako.dkvigilance@agilent.com with your sales representative on copy.
2. Contact your sales representative if you have any questions regarding this notification, or if you would like assistance with the Return Form.

Actions to be taken by Agilent:

We are currently working on a corrective action that will minimize the emission of formaldehyde from the Artisan instruments. A solution is expected to be ready for implementation in the beginning of July 2018. Your local Agilent representative/Distributor will contact you when a solution 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 which could have affected instruments installed. Please ensure that your organization maintains awareness of this notice and the recommended steps until the corrective actions have been completed.





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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 act to ensure patient and customer satisfaction.

Please note: No other Dako-branded devices are involved in this Field Safety Corrective Action.

Reporting to authorities:

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

Contact:

Name: Asger Dahlgaard

Function: Complaint and Vigilance Manager

Contact details: dako.dkvigilance@agilent.com

Signature:

A handwritten signature in blue ink, appearing to read "Asger Dahlgaard".