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Your reference

Our Reference

Date
03/13/2019

Urgent Field Safety Notice

Date: March 13th, 2019

Product: *recom*Scan setcard for *recom*Line Helicobacter 2.0 IgG/IgA

Subject: *recom*Scan setcard *recom*Line Helicobacter 2.0 Rev001 Build002.stc: the antigen HpaA is not included in the assessment

Corrective action: **recall of the incorrect setcard *recom*Line Helicobacter 2.0 Rev001 Build002.stc, replacement by correct Rev001 Build003.stc**

Dear Sir/Madam,

You might possibly use an incorrect *recom*Scan setcard for the *recom*Line Helicobacter IgG/IgA 2.0. In Rev001 Build002 of the setcard the antigen HpaA is not included in the assessment of the sample. **Only the assessment in IgA is concerned by this issue.** In the summation of the point values the two points for a positive HpaA are not added. All other antigens are assessed correctly.

As a consequence of a missing HpaA assessment, false negative results might be generated. An analysis of the performance data in this regard revealed a probability of occurrence of 0.7%. A risk for patients is given.

The failure has been identified and resolved. Corrective measures are initiated.

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Recommendations for the user:

Please check which build of the *recom*Line Helicobacter 2.0 setcard is installed with your *recom*Scan version by following the provided instructions.

- Build001 contains a correct assessment for HpaA und therefore produces correct results. No exchange of the setcard is necessary
- Build002 is incorrect.
    - In case you do not use *recom*Line Helicobacter IgG/IgA 2.0 please delete the setcard.
    - In case you do use *recom*Line Helicobacter IgG/IgA 2.0 please install the new setcard (Rev001 Build003) according to the enclosed directions. For further information please contact Mikrogen's technical support (phone +49 89 54801139 or email tech.support@mikrogen.de).

- Please ensure that this notice will be passed to all staff members within your organization and to all of your customers affected.

The German 'Federal Institute for Drugs and Medical Devices' (BfArM) and the corresponding authority in your country will be informed about this notice by Mikrogen.

Please confirm receipt of the Urgent Field Safety Notice with the Fax Reply below. Mikrogen apologizes for any inconvenience caused.

For any further questions please feel free to contact me.

Sincerely,

Dr. Stefan Ammer
Safety Representative for Medical Devices

Fax Reply

Please return the filled fax reply form to Mikrogen: **Fax No. +49 89 54801-100**

I herewith confirm the receipt of the Urgent Field Safety Notice concerning *recom*Scan Interpreter für *recom*Line Helicobacter 2.0 Rev001 Build002.

Company
Contact
Street, No.
City
Postal Code

_____
Signature / Stamp