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Your reference

Our Reference

Date  
03/13/2019

Page 1

## Urgent Field Safety Notice

Date: March 13<sup>th</sup>, 2019

Product: *recomScan* setcard for *recomLine* Helicobacter 2.0 IgG/IgA

Subject: *recomScan* setcard *recomLine* Helicobacter 2.0 Rev001 Build002.stc: the antigen HpaA is not included in the assessment

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

Dear Sir/Madam,

You might possibly use an incorrect *recomScan* setcard for the *recomLine* 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.

**Recommendations for the user:**

Please check which build of the *recomLine Helicobacter 2.0* setcard is installed with your *recomScan* 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 *recomLine Helicobacter IgG/IgA 2.0* please delete the setcard.
  - In case you do use *recomLine 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](mailto: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

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**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 *recomScan* Interpreter für *recomLine Helicobacter 2.0 Rev001 Build002*.

Company  
Contact  
Street, No.  
City  
Postal Code

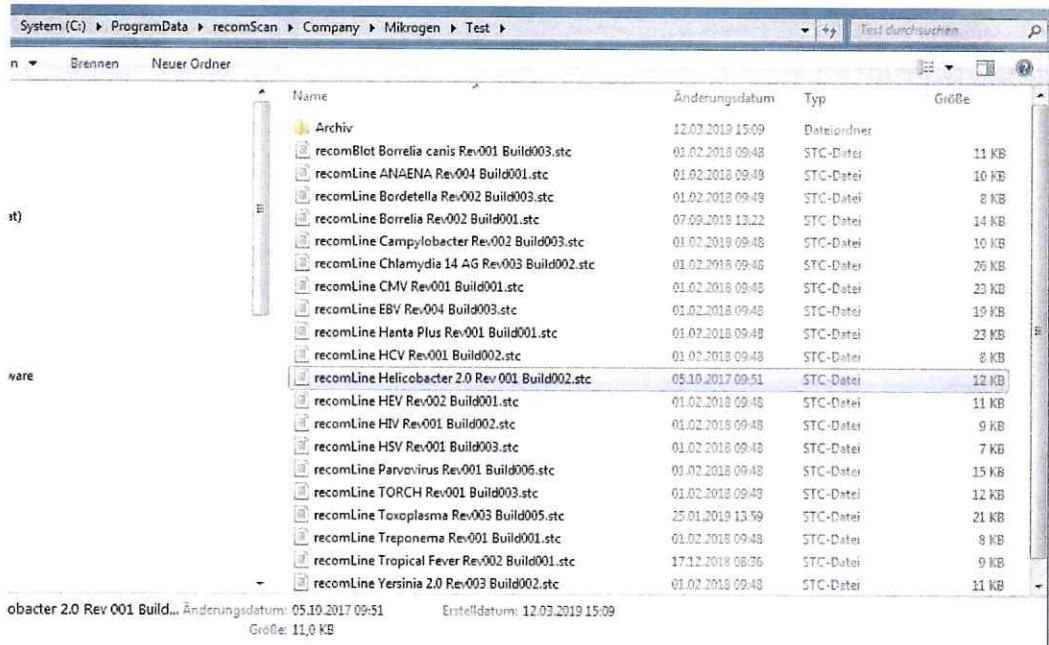
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Signature / Stamp

## Instruction to check and exchange the *recomScan* setcard *recomLine Helicobacter 2.0 Rev001 Build002.stc*

### Locating the installed setcard file on the system:

- Navigate to the *recomScan* Application Data (C:\ProgramData\recomScan):
  1. Click on Windows Start and navigate to the entry 'Mikrogen', sub-entry 'recomScan'
  2. Click on 'recomScan ApplicationData' and a window will open containing the folder 'Company'
  3. Inside the folder 'Company' navigate to 'Mikrogen' and then 'Test' (see screenshot below)



- Inside the folder 'Test' (and potential other folders like backups which could contain the setcard) find the setcard for *recomLine Helicobacter 2.0*.

### Recommended actions:

- All copies of *recomLine Helicobacter 2.0 Rev001 Build002* have to be deleted from all existing *recomScan* installations (Filename: *recomLine Helicobacter 2.0 Rev001 Build002.stc*)
- All copies of *recomLine Helicobacter 2.0 Rev001 Build001* can still be used on all existing *recomScan* installations (Filename: *recomLine Helicobacter 2.0 Rev001 Build001.stc*)
- In case the *recomLine Helicobacter 2.0 Rev001 Build002* was deleted and the customer is using *recomLine Helicobacter 2.0*, install and configure the provided setcard *recomLine Helicobacter 2.0 Rev001 Build003* (Filename: *recomLine Helicobacter 2.0 Rev001 Build003.stc*). For this purpose, copy the new setcard to the folder 'Test' of your *recomScan* installation and execute the setcard change tool in the folder 'Test' to adapt the setcard to your language and the used result presentation (CutOff-Index, CutOff%, PlusMinus).

*Note: The difference between *recomLine Helicobacter 2.0 Rev001 Build001* and *Build003* is the usage of a different separator (, instead of ;) in some result texts which created a problem with LIS connections.*