

Urgent Field Safety Notice

Date: May 30th 2018

Product: *recomLine* ANA/ENA IgG (Art. Nr. 6072) of the lot LAE121701

***recomLine* ANA/ENA IgG of the lot LAE121701: one test kit can contain incorrect test strips**

Safety precaution: **Recall of affected *recomLine* ANA/ENA IgG of the lot LAE121701**

Dear Madam/Sir,

You may have received a *recomLine* ANA/ENA IgG test kit of the lot LAE121701 with incorrect test strips. The test strips may be too short. Incorrect test strips have a length of 10 cm, correct ones have a length of 10.5 cm. As a consequence, the dsDNA band is missing on incorrect test strips.

On the basis of production records it was possible to determine that of the 285 test kits of the *recomLine* ANA/ENA IgG lot LAE121701 284 contain correct test strips. However, Mikrogen cannot exclude with 100% certainty that one test kit contains incorrect test strips with missing dsDNA band.

Merely one single test kit with the strip tube numbers LAEd 487/3 and LAEd 487/4 could contain test strips which are too short.

Test implementation with incorrect *recomLine* ANA/ENA IgG test strips can lead to false negative results for systemic lupus erythematosus. A risk for the patient is given.

Recommendations for the user:

Test kits of the affected lot LAE121701 have already been used:

- Please check the numbers of the used strip tubes. These are printed on the label of the red screw cap of the strip tube. All numbers **except for LAEd 487/3 and LAEd 487/4** contain correct test strips and produce correct results. These test strips do not need any further examination.
- In case the tube numbers cannot be retraced or you have performed assays with test strips of the tubes **LAEd 487/3 and LAEd 487/4** please check the length of the test strips. Test strips with a length of 10.5 cm are correct and produce correct results. Test strips with a length of 10 cm are incorrect. Please repeat these tests and inform your customer(s). Please contact us for FOC replacement of the test kit.



Test kits of the affected lot LAE121701 are still on stock:

- Please check the labels on the red screw caps of the strip tubes. All numbers **except for LAEd 487/3 and LAEd 487/4** contain correct test strips.
- If your test kit contains strip tubes **LAEd 487/3 and LAEd 487/4** please contact us.
- Please ensure that this notice will be passed to all staff members within your organization and to all of your customers affected.

The corresponding authorities of the affected countries 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 contact the safety representative Dr. Stefan Ammer, phone +49 89 54801-172, E-mail: stefan.ammer@mikrogen.de

Sincerely,

Dr. Stefan Ammer
Safety Representative for Medical Products

Fax Reply

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

I herewith confirm the receipt of the Urgent Field Safety Notice concerning *recomLine* ANA/ENA IgG (Art. Nr. 6072), Lot LAE121701

Company
Contact
Street, No.
City
Postal Code

Signature / Stamp