

ORGENTEC Diagnostika GmbH • Postfach 100352 • 55134 Mainz

FIELD SAFETY NOTICE, Corrective Action 2019/03/18

Medical Product: ORGENTEC ENAcombi ELISA

Product code: ORG 514

Product lot: 1900397

Problem description: Risk of elevated or false positive Anti-Sm antibody results

Dear Valued Customer,

following customer feedback, internal investigation of ENAcombi ORG 514, lot 1900397 demonstrates a risk for incorrect and/or false positive quantification of patient samples measured for anti-Sm antibodies in this assay. ENAcombi contains other antigen-specific antibody tests (anti-SS-A, anti-SS-B, anti-RNP/Sm, anti-Scl-70, anti-Jo-1) which are not affected and show correct results.

ENAcombi ORG 514, lot 1900397 immunoassay kits have to be

- returned to the manufacturer or
- destroyed at distributor/end user

The IVD product should not be used as the anti-Sm antibody testing may give imprecise results. The kits will be reimbursed by the ORGENTEC distributor in your country.

Enclosed with this notice is a return protocol with relevant information for returning the product. All costs and reimbursement will be covered by ORGENTEC Diagnostika GmbH.

Summary of observations:

Anti-Sm antibody results obtained with ENAcombi ORG 514, lot 1900397 immunoassay kits may be false elevated or false positive. Sm antigen coated cavities in the immunoassay kit are contaminated with SS-A antigen. This can cause false positive results for Anti-Sm antibodies if the sample contains anti-SS-A antibodies.

Validity of already obtained measurements can be checked by combination of assay result data:

- If a sample shows positive results for Sm, but clear negative results for SS-A, the Sm result is correct
- If a sample shows positive results for Sm and elevated/positive results for SS-A, the Sm result is incorrect

In case of incorrect Sm results, the sample has to be retested for presence of Anti-Sm antibody. Other ENAcombi ORG 514 immunoassay kit lots can be used, they were tested and did not show this problem. An elevated test result per se does not imply a risk for treatment of the patient, as detection of antibodies only supports clinical diagnosis. According to current regulations they alone do not constitute a clinical diagnosis.

What is to be done?

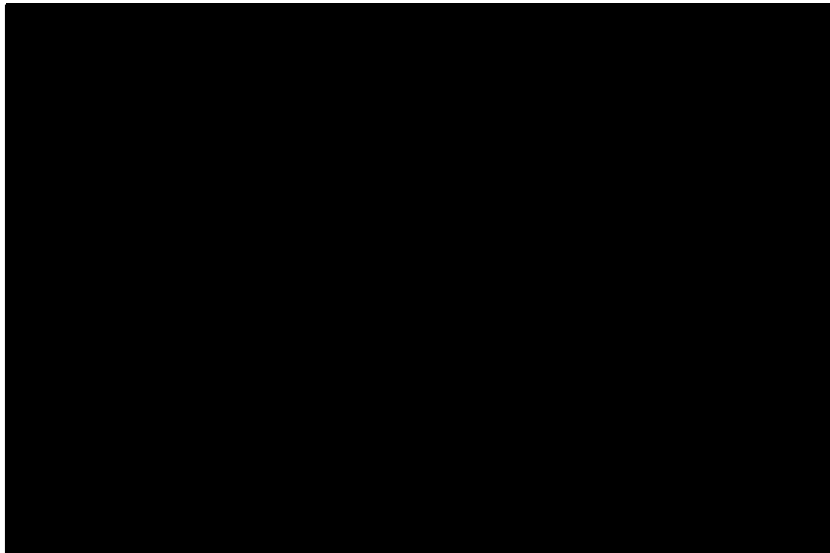
- Please send back or discard all unused kits
- Please use the attached form on page 3, sign and send back to us
- Please inform your customers and forward this notice to affected persons and institutions
- Please tell us if you have experienced any problem with this lot and specify the details

Corrective and preventive actions

ORGENTEC Diagnostika GmbH started corrective and preventive actions that prevent the re-occurrence of this error. Previous lots of ENAcombi ORG 514 were checked and did not show this problem. QC release criteria will be adapted to prevent re-occurrence of this problem for new Kit lots of ENAcombi ORG 514.

Transmission of this Field Safety Notice:

This notice has to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred. Please be aware of this notice and the resulting action for an appropriate period to ensure effectiveness of the corrective action. In case of further questions contact your local distributor.

Contact person for further information:

Send to: ORGENTEC Diagnostika GmbH • Postfach 100352 • 55134 Mainz

FAX: +49 61 31 / 92 58 58
EMAIL: cs@orgentec.com

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Problem description: Risk of elevated or false positive Anti-Sm antibody results

Product	Lot	Number of Kits received	Number of kits used up	Number of Kits returned/discarded
ENACombi, ORG 514	1900397			

Problems experience at customer site:

(explain)

Company/Name

Date

Signature

Stamp