

FIELD SAFETY NOTICE, Corrective Action FSCA 2021-06 ORG 903MX

**Medical Product: ORGENTEC Anti-HSV-1 IgM Abs,
Product code: ORG 903MX
Product lot: 2008176, shelf life: 2021-Okt-03
Problem description: Risk for false negative results**

Dear Valued Customer,

Stability tests of our product Anti-HSV-1 IgM Abs, ORG 903MX, lot 2008176, show that with increasing aging of the lot the measured value of human serum samples decreases. This may lead to false negative results. The internal control of the assay does not show a decrease in values, so the error is not indicated by the control.

Due to a possible risk when using the affected lot, we kindly ask you to control your stock and not to continue using products from this lot. All other product lots Anti-HSV-1 IgM Abs, ORG 903MX can be used further, they have been checked and show the correct performance.

Please discard/destroy unused kits of the affected lot 2008176 that you have in stock, and also any in use kits of the affected lot on site in the customer's lab.

All costs and refunds will be covered by ORGENTEC Diagnostika GmbH. ORGENTEC will offer a free replacement for affected kits. Attached to this notification is a response form with all necessary information.

Summary of observations:

Retesting has shown that batch 2008176 quantifies too low with increasing age and as a result human samples may be found false negative. As the error cannot be detected due to a valid control result, we kindly ask you to control your stock and to stop using products from this batch.

What is to be done?

- Please discard all unused kits
- Please provide evidence of the destruction by using 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

Effect on the test result

Results obtained with the affected test strips may be false negative. Repeated testing of a sample could be an option if the test result does not match the clinical suspicion of the doctor or the previous PCR results.

The decision whether a follow-up test is necessary is left to the laboratory and the treating physician. Retesting can be done with any other batch of Anti-HSV-1 IgM Abs, ORG 903MX.

Corrective and preventive actions

ORGENTEC Diagnostika GmbH started corrective and preventive actions that shall prevent the re-occurrence of this error.

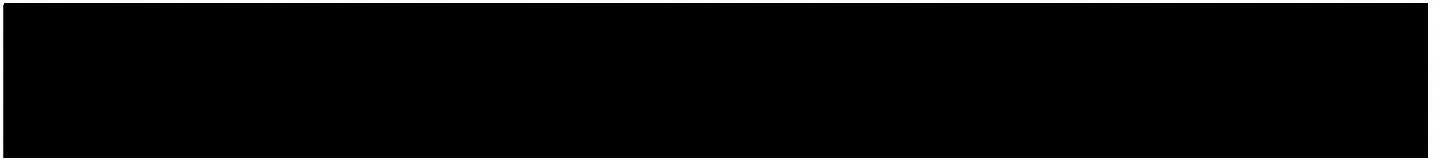
Transmission of this Field Safety Notice:

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.

We apologize for the inconvenience caused to you and thank you for your support in carrying out this measure. In case of further questions contact your local distributor.

Contact person for further information:

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Problem description: Risk for false negative results

Delivery	Lot	Number of Kits received	Number of kits used up	Number of Kits discarded

Credit Note preferred number of kits _____

Replacement preferred number of kits _____

Problems experience at customer site:

(explain)

Company/Name

Customer ID

