

Dear Valued Customer

FIELD SAFETY NOTICE, Corrective Action 2017/08/30 MCV

Product: ORG 248 Alegria® Anti-MCV

Lots: 1705292, 1706145, 1706561, 1707197

Problem description: Risk of false positive results

Following customer feedback internal investigation demonstrates a decrease in activity of the calibrator (cut-off control) over time for the four lots listed above. Using those four lots may lead to false-positive results for this parameter.

Affected batches of ORG 248 Anti-MCV immunoassay kits for Alegria need to be returned to the manufacturer. The IVD product should not be used as it 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 and status:

When tested under temperature stress conditions, the calibrator showed a significantly lower activity in the kits. This leads to a higher quantification in the calculation of the optical density values. This effect bears the risk that some negative sample-values will be above the cut-off and will be read as positive.

The root-cause of the problem has not been identified, yet. However, we are working hard on a solution to start supply again. Our ORG 548 anti-MCV ELISA microplates were not affected.

A false-positive test does not pose a risk to the patient in context with the guidelines for rheumatoid arthritis as it is only one part of the clinical diagnostic scheme. Still, you may consider retesting the sample.

Especially, if a physician has found results which have been generated by using these batches to be inconsistent with other observations about the medical status of a patient. It will remain the decision of the lab and the treating physician whether any retesting with alternative products is appropriate.

To identify already tested kits, the product strip's barcode can be used.
Alegria® ORG 248 Alegria® anti-MCV,

Lot 1705292 (expiry date 2018-06-30) strip's code is 248-1-80663154-xxxx
Lot 1706145 (expiry date 2018-06-30) strip's code is 248-1-80663253-xxxx
Lot 1706561 (expiry date 2018-06-30) strip's code is 248-1-80662950-xxxx
Lot 1707197 (expiry date 2018-07-31) strip's code is 248-1-80762849-xxxx

For retesting, we recommend the ELISA ORG 548 anti-MCV. We are transiently increasing our production capacities for these products to match the higher demand.

What is to be done?

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

Transmission of this Field Safety Notice:

This notice needs 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 resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact person for further information:

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Product: ORG 248 Alegria® anti-MCV

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Delivery	Lot	Number of Kits received	Number of kits used up	Number of Kits returned
	1705292			
	1706145			
	1706561			
	1707197			

Problems experience at customer site:

(explain)

Company/Name

Date

Signature

Stamp