ORGENTEC Diagnostika GmbH • Carl-Zeiss-Str. 49 – 51 • D 55129 Mainz

Dear Valued Customer

FIELD SAFETY NOTICE, Corrective Action 2018/10/31 Anti-Annexin V IgM

Product: ORG 243M - Alegria® Anti-Annexin V IgM

Lot: 1812037

Problem description: Risk of increased positive or false positive results

Following customer feedback, internal investigation of Anti-Annexin V IgM, ORG 243M, lot 1812037 demonstrates a risk for incorrect quantification of patient samples in single Alegria strips. Using this lot may lead to wrongly increased positive or false-positive results for this parameter.

Test strips from the affected batch of ORG 243M, Alegria® Anti-Annexin V IgM immunoassay kits have to be

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

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:

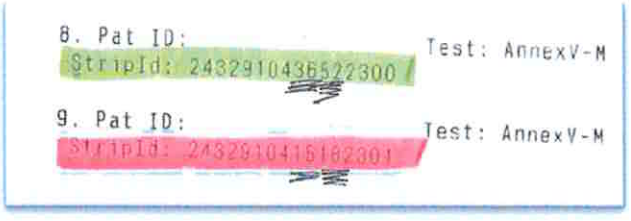
1. **Identification of ORG 243M, Lot 1812037 test strips**

To identify already tested kits, the product strip's barcode on the printout can be used.
Anti-Annexin V ORG 243M, Lot 1812037 (expiry date 10-2019)
strip's code is 243 2 910 xxxxxxxxx

2. **Identification of affected test strips**

Affected Alegria strips with false quantification can be identified in the Alegria result printout checking the strip ID.
The **correct** strip ID is 243 2 910 4 **36 52** xxxx (x=consecutive individual strip number). All tests done with this strip IDs are **correct**.

Affected strips will show different numbers on positions 9-12, for example 243 2 910 4 **15 18** xxxx.
All tests done with this strip IDs are **affected**.



Example for false strip ID on printout

3. Effect on test result

Affected Alegria strips will show a wrong (too high) quantification of a correctly positive results.
Affected Alegria strips can show a false positive assessment of a correctly negative samples.

A false-positive or elevated test result does not pose a risk to the patient in context with the guidelines for APS 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 this batch 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 is appropriate. For retesting, any other lot of Anti-Annexin V ORG 243M can be used.

4. 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
- Please tell us, if you have experienced any problem with this lot and specify the details

5. Corrective and preventive actions

ORGENTEC Diagnostika GmbH implemented corrective and preventive actions that prevent the re-occurrence of this error. Preventive actions were applied to all Alegria® products.

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.

Contact person for further information:

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Corrective Action 2018/10/31
Product: ORG 243M Alegria® Anti-Annexin IgM
Lot: 1812037

Delivery	Lot	Number of kits received	Number of kits used up	Number of kits returned	Number of kits discarded
	1812037				

Problems experience at customer site:

(explain)

_____
Company/Name

_____ _____
Date **Signature** **Stamp**