ORGENTEC

ORGENTEC Diagnostika GmbH • Postfach 100352 • 55134 Mainz

FIELD SAFETY NOTICE, Corrective Action 2019/08/13 ANAscreen

Medical Product: ORGENTEC ANAscreen Alegria®
Product code: ORG 238
Product lot: 1908485
Problem description: Leakage of Alegria® Test Strips

Dear valued customer,

following customer feedback, it has come to our attention that there may be a defect in the foil sealing of test strips from product ORGENTEC ANAscreen Alegria®, ORG 238, lot No. 1908485, which could cause incorrect results for single test strips.
Internal investigation demonstrated that the sealing of the assay strip by the upper metal foil can be untight. This can cause leaking of liquids contained in the strip and may influence the stability of the components. There is a risk for incorrect results.

Test strips of the affected batch of ORG 238, lot 1908485 Alegria® ANAscreen immunoassay kit have to be

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

The IVD product should not be used as it may give incorrect 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. ORGENTEC will provide a free of charge replacement for affected kits.

Summary of observations:

Only a limited number of kits from the product lot 1908485 of ORG 238 are affected. Because the sealing defect is not always visible and cannot be detected easily, all remaining kits should be discarded. Please inform customers who received this lot.

Effect on test result

Affected test strips may give an incorrect result. You may consider retesting of samples analyzed with this product lot, especially if the test results are inconsistent with other observations of the medical status of the patient. It will remain the decision of the lab and the treating physician whether any retesting is appropriate. For retesting, any other lot of ORG 238, ANAscreen can be used.

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

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BIC: COBADEFFXXX

USt-IdNr. DE149058799
Mainz 14 HRB 4300

Geschäftsführer
Ralf Wehen
Dr. Klaus Esperschidt

ORGENTEC Diagnostika GmbH • Postfach 100352 • 55134 Mainz

Corrective and preventive actions
ORGENTEC Diagnostika GmbH has started corrective and preventive actions that will prevent the reoccurrence 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. In case of further questions contact your local distributor.

We apologize for this inconvenience and thank you for your support.

Contact person for further information:

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Corrective Action 2019/08/13
Product: ORGENTEC ORG 238 ANAscreen
Lot: 1908485

Product	Lot	Number of Kits received	Number of kits used up	Number of Kits returned/discarded

Credit Note preferred ◯ **number of kits** _____

Replacement preferred ◯ **number of kits** _____

Problems experience at customer site:

(explain)

_____
Company/Name

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

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