

FSN: 01 – FSCA 2026-01

FIELD SAFETY NOTICE

Medical Product: Anti-Annexin V IgG
Product code: ORG 243G
Lot no: 2605614

03.09.2026

Sender: ORGENTEC Diagnostika GmbH, Carl-Zeiss-Str. 49 – 51, 55129 Mainz, Germany
Addressee: To all customers and users

This letter contains important information that requires your immediate and urgent attention. ORGENTEC Diagnostika GmbH is conducting a Field Safety Corrective Action for [REDACTED] ed below.

Identification of the affected medical devices:

Product Name: Anti-Annexin V IgG
Product Code: ORG 243G
Lot Number: 2605614
Intended Use: Anti-Annexin V IgG is an ELISA-based test system for the quantitative measurement of IgG class autoantibodies against annexin V in human serum or plasma samples. This product is intended for professional in vitro diagnostic use only.

Antiphospholipid syndrome (APS, Hughes Syndrome) is a systemic autoimmune disease that causes thromboses, recurrent miscarriage or stillbirths, and stroke. Clinical symptoms are accompanied by specific autoantibodies in the blood, which bind to phospholipids like cardiolipin, or phospholipid-binding proteins like beta-2-glycoprotein I. Autoantibodies against proteins of the coagulation cascade, e.g. prothrombin or annexin V may also be found in patients with APS with otherwise negative phospholipid antibody results. In primary APS autoantibodies against phospholipids appear independently, while in secondary APS phospholipid antibodies are detected in conjunction with other autoimmune diseases, such as lupus erythematosus, rheumatoid arthritis, or Sjögren's syndrome.

Description of the problem:

ORGENTEC has identified a product labeling issue affecting a subset of kits from lot 2605614 of the Anti-Annexin V IgG (ORG 243G) assay.

Investigation has shown that certain Alegria test strips contained an incorrect barcode as Anti-Gliadin IgG (ORG 234G) instead of Anti-Annexin V IgG (ORG

While the microtiter plate frame and kit labeling correctly identify the product as Anti-Annexin V IgG, the barcode printed on the affected test strips may cause the instrument to assign the strip to the wrong assay.

Consequently, results generated from affected strips may be reported as Anti-Gliadin IgG although the measured signal originates from an Anti-Annexin V IgG strip.

Identification of affected test strips:

Affected strips can be identified by checking the barcode and assay name printed on the individual test strips.

Wrong

Barcode begins with **234**
Barcode reads **Gliadin IgG**



Correct

- Number above barcode begins with **243**
- Text below barcode reads **AnnexV IgG**



For kit label, zip-lock bag label and microtiter plate frame may correctly identify the product as Anti-Annexin V IgG. Customers should therefore verify the barcode and assay name printed on the individual test strips.

Strips with correct printed information can be used without restrictions.

Impact on the patient:

Use of an affected test strip may lead to reporting of an Anti-Gliadin IgG result instead of an Anti-Annexin V IgG result. The reported Anti-Gliadin IgG result would not correspond to the analyte actually measured and may lead to misinterpretation of laboratory findings.

[REDACTED] Anti-Annexin V IgG and Anti-Gliadin IgG are generally used as adjunctive tests and are not intended to be used as stand-alone diagnostic tests. Test results are typically interpreted in conjunction with clinical findings, patient history, and additional laboratory investigations. Furthermore, the two assays are used in different clinical settings and address different disease conditions.

[REDACTED] Consequently, several independent factors may contribute to the detection of an incorrect result before clinical decisions are made, including review of laboratory findings, assessment of clinical plausibility, repeat testing, and additional confirmatory investigations. To date no patient harm, adverse event or incorrect diagnosis or inappropriate treatment is known to ORGENTEC. No evidence of serious deterioration of health associated with this issue has been identified.

What measures are to be taken by the addressee?

[REDACTED] Inventory of lot 2605614, Anti-Annexin V IgG (ORG 243G).
[REDACTED] barcode identification and name on the test strips.

- Quarantine affected kits and discontinue their use.
- Review whether patient results have been generated using affected kits from lot 2605614 and assess, in accordance with local laboratory procedures and [REDACTED] judgement, whether repeat testing or further evaluation is required.
- Please inform and forward this notice to affected persons and institutions on which this action has an impact.
- Complete and return the attached Customer Reply Form to your local distributor within 5 business days.

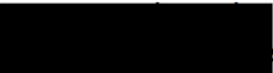
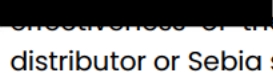
Action Being Taken by The Manufacturer

Corrective and Preventive Actions (CAPA) have been initiated. All remaining inventory of the affected kits have been quarantined by Sebia.

[REDACTED]

[REDACTED]

Transmission of this Field Safety Notice:

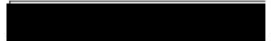
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred. Please  to other organizations on which this action has an impact. Please  on this notice and resulting action for an appropriate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


Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

Yours sincerely:



PMS Manager


E-Mail: vigilance@orgentec.com
ORGENTEC Diagnostika GmbH, Carl-Zeiss-Str. 49 – 51,
55129 Mainz, Germany

Field Safety Notice Customer Reply Form

**<Layout and local contact details may be adapted by the
Distributor/Sebia Subsidiary according to local
communication procedures>**

[Redacted] nber	FSN: 01 – FSCA 2026-01
FSN Date	03.09.2026
Product name / code	Anti-Annexin V IgG / ORG 243G
UDI-DI	04260157082342
Batch/Serial Number (s)	2605614

☐ I confirm receipt of the Field Safety Notice and that I read and understood its content. All measures described in the Field Safety Notice have been implemented. The information and required actions have been brought to the attention of all relevant users and executed.

[Redacted] checked my stock and have ___ kits affected.

☐ I do not have any affected products.

Print Name (and title) _____

Signature _____

Date _____

Customer Number
(optional) _____

[Redacted] nisation
Name _____

Organisation Address _____

Telephone number _____

Email _____

Return acknowledgement to sender

 Email <Pre-filled by Distributor/Sebia Subsidiary>

Postal Address <Pre-filled by Distributor/Sebia Subsidiary>

 Fax <Pre-filled by Distributor/Sebia Subsidiary>

Please return this form within 5 business days of receipt, even if you do not have any of the affected products.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

 on's reply is the evidence we need to monitor the progress of the corrective actions.





