

Firma XYZ GMBH
z. H. Herr Mustermann
Musterstr. 10

41460 Musterhausen

Neuss, 6. Februar 2019

Urgent Field Safety Notice

Dear customer,

according to our records you have received the following product from us:

Product name: **IgG4 Food-Screening – Conjugate Kit**

Product number: **101010PG**

Lot number: **2841511PG4, 2822910PG4, 2811910PG4, 2801710PG4**

Problem: Elevated OD Values, false positive results

Measure: **Recall of the affected lot**

Description of the problem:

When using the affected kit lots in screening tests for IgG4 antibodies in human serum or plasma against food allergens elevated OD values or false positive test results can occur.

In a root cause analysis it could be demonstrated that the problem is caused by the anti-IgG4-HRP conjugate in the conjugate kit.

Other kit lots are not affected.

Patient Risk:

Patients may be tested falsely positive for IgG4 antibodies against food allergens which could be a hint of a potential food intolerance. As a consequence patients would be recommended a special diet.

Test results shall generally be assessed together with the clinical situation and the anamnesis of the patient and shall be verified with a confirmatory test in case of doubt.

The patient risk can thus be judged as low.

Corrective Actions:

All defective kits in the market could be assigned to the affected customers and will be recalled by Dr. Fooke-Achterrath Laboratorien GmbH.

The German authority Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) will be informed by Dr. Fooke-Achterrath Laboratorien GmbH about this Urgent Field Safety Notice.

Actions to be taken by the customer:

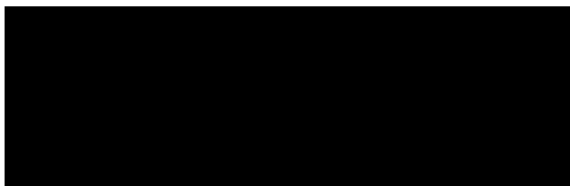
1. Check your inventory and identify kits of the affected lot(s).
2. Do not use kits of the affected lot(s) any more.
3. Send us back all affected kits free of charge.
4. If you have further delivered the product within or outside your organisation, please, forward this Urgent Field Safety Notice to the respective persons.
5. Please check the validity of all test results you have obtained with these kit lots and repeat the tests in case of doubt.
6. Please fill in the attached letter of acknowledgement and send it back to us at your earliest convenience.
7. Please keep this Urgent Field Safety Notice with your documentation.

In case of questions please contact

Dr. Margrit Fooke-Achterrath
Tel.: +49 (0) 2131 – 2984 – 0
Email: mfooke@fooke-labs.de

With kind regards

Dr. Fooke-Achterrath Laboratorien GmbH



Letter of Acknowledgement for the Urgent Field Safety Notice

Please send the filled and signed letter at your earliest convenience to Dr. Fooke-Achterrath Laboratorien GmbH:

by Fax-Nr.: +49 (0)2131 – 2984 – 184,

by Email as scanned document (PDF format): information@fooke-labs.de

**by Mail: Dr. Fooke-Achterrath Laboratorien GmbH,
Habichtweg 16, D-41468 Neuss, Germany**

Herewith I confirm that I have received the Urgent Field Safety Notice for **IgG4 Food-Screening - Conjugate Kit** with lots **2841511PG4, 2822910PG4, 2811910PG4, 2801710PG4**.

- ☐ I have read the information and taken the recommended actions.
- ☐ I have no kits of the affected lot in my inventory.
- ☐ I have _____ kits of the affected lot in my inventory and will send them back to Dr. Fooke-Achterrath Laboratorien GmbH.

Name of responsible Person:

Function:

Organisation:

Address:

Telephone Number:

Email:

Date / Signature:
