

RECIFE
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Please forward to the enduser of this product!

04 October 2018

Field Safety Notice (FSN)

Closure of the Field Safety Corrective Action

**ClinRep® Complete Kit for Antiepileptics in Serum / Plasma with UHPLC,
order no. 14100**

Dear customer,

we refer to the Field Safety Notice (FSN) provided to you on 28 August 2018 regarding the UHPLC analysis of Lamotrigine with the ClinRep® Complete Kit for Antiepileptics with order no. 14100.

In this FSN we informed you about a customer feedback that reported about an unknown interference with the lamotrigine peak. The feedback refers to a problem with the sample of a patient with multiple co-medication. According to the reported list of co-medication, RECIFE initiated tests and investigations to identify the potential source of interference. The following compounds have been tested:

Omeprazole, Esomeprazole, Tacrolimus, Calcitriol, Midazolam, L-Thyroxine, Lorazepam

This examination has been completed now. As announced in the FSN dated 28 August 2018 we herewith would like to inform you about the outcome. In conclusion no interference caused by the substances mentioned above was found.

Termination of the recommended action to be taken by the user:

Due to the negative interference tests the initial recommendation to check current samples for the reported co-medication, as per FSN dated 28 August 2018, is no longer necessary.

Transmission of this Field Safety Notice:

Please inform all persons in your organisation who need to know this information.

The competent authority (BfArM) has received a copy of this information.

With the enclosed form please confirm the receipt and distribution of this safety information.

We apologise for all inconveniences caused and thank you in advance for your cooperation.
For any further questions please do not hesitate to contact us again.

Contact Person:

Dr. Carmen Alt
Head of Customer Service, PMS

Phone: +49 89 547081-14
E-Mail: alt@recipe.de

Yours sincerely



Dr. Stefan Plank
Head of Regulatory Affairs / QM

Confirmation of Receipt / Declaration for

Field Safety Notice (FSN)

Closure of the Field Safety Corrective Action

ClinRep® Complete Kit for Antiepileptics in Serum / Plasma with UHPLC,
order no. 14100

dated 04 October 2018

Customer-related data

Hospital / Laboratory	
Signature Head of Laboratory (Name)	
Address	
Phone	
Client ID	

Confirmation of Receipt / Declaration

I have read and understood the a.m. „Field Safety Notice“.
All users of this product were also informed.

Date, signature: _____

We kindly ask to return this form by email (customerservice@recipe.de) or fax (+49 89 547081-11) before **31.10.2018**.