

Please forward this information to the end user of the product!

Urgent Field Safety Notice

FSN 2021-01-18, 22th January 2021

ClinCal® Whole Blood Calibrators for Immunosuppressants

Order nos. 9933, 9033 and 9028

Dear customer,

this notice informs about an important safety information regarding the calibration of Immunosuppressants in whole blood. RECIPE has implemented a corrective action for products your institution received according to our documentation (see Table 1 and 3).

Table 1: ClinCal® Calibrators

Product name	Order nos.	Lot	Expiry date
Whole Blood Calibrator Set for Immunosuppressants, Level 0 - 6	9933	1428	2021-10
Whole Blood Calibrator Set for Immunosuppressants, Level 0 - 3	9033	1379	2022-09
Only in combination with 9033 and 9933: Whole Blood Calibrator for Immunosuppressants, Level 7	9028	1457	2021-11

Reason for this customer information:

For the previously assigned target values of tacrolimus and sirolimus of the above-mentioned products deviations from the respective European Reference Materials ERM-DA110a and ERM-DA111a were determined. For cyclosporine A and everolimus, deviations of the target values to the respective Certified Reference Materials of Cerilliant CRM C-093 and E-068 were determined. The deviations depend on the individual analyte and level.

The corrections of the target values to the certified reference materials are summarised for each analyte and concentration level (see Table 2):

Table 2: Correction of the target values in % to the certified reference materials

Order nos.	9933						9033			9028
Lot	1428						1379			1457
Level	L 1	L 2	L 3	L 4	L 5	L 6	L 1	L 2	L 3	L 7
Cyclosporine A	- 14	- 9	- 6	- 4	- 3	- 3	- 14	- 6	- 3	- 3
Tacrolimus	+ 4	- 2	- 4	- 5	- 6	- 6	+ 4	- 4	- 6	- 6
Sirolimus	- 2	- 8	- 11	- 13	- 14	- 14	- 1	- 11	- 13	- 14
Everolimus	- 12	- 15	- 16	- 17	- 18	- 18	- 11	- 16	- 18	- 18

We updated the target values in order to harmonise these with the certified reference materials.

The updated product data sheets 9933_1428-1, 9033_1379-2 and 9028_1457-2 replace the previous versions and were attached to this mailing.

Internal quality controls

Using the updated target values of the calibrators may lead to a shift in the quality controls. Therefore, the target values of the following ClinChek® Whole Blood Controls have been adjusted:

Table 3: ClinChek® Controls

Product name	Order nos.	Lot	Expiry date
Whole Blood Control for Immunosuppressants, Level I - III	8830-8833	1509	2022-12
Whole Blood Control for Immunosuppressants, Level IV, V	8903	1428	2021-10

The updated product data sheets 8833_1509-1 and 8903_1428-1 replace the previous versions and were attached to this mailing.

Health risk evaluation:

RECIPE has not received any reports on clinical adverse events. Laboratory findings must always be assessed in the context of clinical symptoms, body weight-based dosing, other laboratory findings and the patient's medical history. We do not think reviewing previously obtained results is necessary.

Actions taken for the customer/end-user:

- Please discuss this information with your medical director
- Use the new determined target values (released on 18.01.2021) for calibration
- The control values and ranges must be reviewed and adjusted accordingly
- Please keep this letter with your records
- Please complete the attached form "Confirmation of Receipt" and return the form by 05.02.2021 at the latest

Dissemination of this urgent field safety notice:

Please make sure that all users of the above mentioned products as well as other persons in your organisation who need to be informed are made aware of this "Urgent Field Safety Notice". In case you have supplied the products to third parties, please forward a copy of this information to the responsible person.

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

We thank you for your cooperation. Please contact us in case you have questions.

Person of contact:

Dr. Carmen Alt
Head of Customer Support, Safety and Surveillance
Phone +49 (0) 89 547081-0, Email customersupport@recipe.de

Please complete the confirmation of receipt FSN 2021-01-18 and return the completed form by **05.02.2021 at the latest** to:

customersupport@recipe.de or FAX: +49 (0)89 547081-11.

RECIPE is required to provide proof of receipt of the urgent field safety notice.

Confirmation of Receipt FSN 2021-01-18

ClinCal® Whole Blood Calibrators for Immunosuppressants

Product name	Order nos.	Lot	Expiry date
Whole Blood Calibrator Set for Immunosuppressants, Level 0 - 6	9933	1428	2021-10
Whole Blood Calibrator Set for Immunosuppressants, Level 0 - 3	9033	1379	2022-09
Whole Blood Calibrator for Immunosuppressants, Level 7	9028	1457	2021-11

ClinChek® Whole Blood Controls for Immunosuppressants

Product name	Order nos.	Lot	Expiry date
Whole Blood Control for Immunosuppressants, Level I - III	8830-8833	1509	2022-12
Whole Blood Control for Immunosuppressants, Level IV, V	8903	1428	2021-10

Customer-related Information:

Hospital/Laboratory	
Signature Laboratory Management (Name)	
Address	
Phone/Email	
Customer ID	

Confirmation of Receipt / Statement

I have read and understood the above information FSN 2021-01-18. Other users supplied with products listed in this notice were identified and have been informed.

Date, Signature: _____