

Urgent Field Safety Notice

Please forward to all end users of the products!

FSN Reference number: FSN 2-2020
Gräfelfing, October 28, 2020

Dear Madam or Sir,

We would like to inform you that Chromsystems Instruments & Chemicals GmbH issues a corrective action for the below-mentioned products. Our records show that you have received these affected products.

Table 1: Identification of the affected IVD medical devices

Product description	Order No.	Lot No.
6PLUS I"" Multilevel Saliva Calibrator Set Cortisol Cortisone	73039	3219; 1020
<i>Mass[hrom</i> Cortisol, Cortisone Saliva Control Level 1	0349	3219; 1020
<i>Mass[hrom,D</i> Cortisol, Cortisone Saliva Control Level II	0350	3219; 1020

Problem description including the identified cause

Internal investigations demonstrate that the existing lots #3219 and #1020 on the market of

- **6PLUS** I"" Multilevel Saliva Calibrator Set 73039 and
- *Mass[hrom*® Cortisol, Cortisone Saliva Control Level 1 0349 and Level II 0350

do not meet the stability criteria as specified in the instruction for use for Cortisol and Cortisone at -18 °C over 24 months. Internal investigations show a time-dependent, stability-related deviation from the target values. A continuous degradation of the calibrators and controls is observed.

Using the affected calibrator lots may result in increased results of patient samples for **cortisone**. We currently detect a decrease in **cortisone** in the range of 6 - 15 %, with an average value of 10 % for the Calibrators (order no. 73039) and Control Level II (order no. 0350); this deviation is still within Chromsystems acceptance criteria. Only Control Level 1 (order no. 0349) shows a decrease of approx. 25 % for **cortisone** after 15 months and does not meet the requirements for the product specifications.

The analyte **cortisol** shows only slight degradation of approx. 6 % in the above-mentioned calibrators and controls.

Determination of cortisol and cortisone from saliva by LC/MS-MS is used to monitor cortisol and cortisone levels. The health risk for patients is negligible, as the Calibrators are within acceptance criteria. However, we strongly recommend that you coordinate the decision on clinical relevance with the attending physician(s).

Since the root cause and corrective actions for this problem have not yet been clearly identified, as a corrective measure the shelf lives of the next calibrator and control lots will be reduced to 18 months and the storage temperature will be changed to +2 to +8 °C. Present stability data show that no restrictions are to be expected under these conditions.

What measures should be taken by the addressee

If you have already used the products listed in Table I for your measurements, please check with the attending physician(s) whether it is necessary to review the results of **cortisone**.

- Please stop using the products listed in Table I (do so even if you use them exclusively for cortisol measurements).
- Please destroy the remaining stock of the affected calibrator and controls lot according to your valid laboratory regulations. Chromsystems will replace your stocks with a new lot.
Please note that the new lot has a reduced shelf life of 18 months and a changed storage temperature of +2 to +8 °C. Because of this, your laboratory inventory and ordering system may require adjustment.
- If you have forwarded any of the products mentioned in this letter to another laboratory, please inform that laboratory of the content of this letter and forward a copy.

Please document your measures on the attached document (attachment Response) and return your response until 20.11.2020 (contact details provided in the attachment Response).

Passing on the information described here

Please make sure that all users of the products mentioned above and other persons affected in your organization are informed about this "urgent field safety information". If you have provided third parties with these products, please forward a copy of this information or inform the contact person listed below.

Please follow this notice and the resulting action to ensure the effectiveness of this corrective action. Please retain this information at least until the action has been completed.

Your responsible national authority has been informed and has already received a copy of this "urgent field safety information".

We apologize for the inconvenience caused by this situation. The continuous inspection of our products ensures their high quality. However, this process can also lead to corrections like this being necessary and executed. We would like to thank you in advance for your support in implementing the necessary measures and look forward to continuing our good cooperation.

Contact

Chromsystems Support is available at any time for further questions and will take care of your concerns quickly and reliably. You can contact our Chromsystems-Support directly via our Hotline +49 89 18930-111 or by E-Mail at support@chromsystems.com. You can also contact our field service at any time.

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Chromsystems Instruments & Chemicals GmbH