CHROMSYSTEMS

Urgent Field Safety Notice

FSN 3-2020

02. November 2020

Please forward to all end users of the products!

Dear customer,

Our products are continuously optimised and are subject to comprehensive quality control measures, aimed at ensuring the highest product quality possible. As part of these investigations, we discovered the stability of the following products to be lower than indicated in the product information leaflet:

3PLUS1® Multilevel Plasma Calibrator Set - 75128 (Lot #2219 and Lot #2320)
MassChrom® Amino Acid Analysis Plasma Control Level I-III (0471-0473, Lot #2019)

Please review the Urgent Field Safety Notice and complete and return the Reply Form as we are required to document receipt of the corrective action.

We apologise for any inconvenience this may cause.

Please contact Chromsystems Support if you have any questions and we will endeavour to respond as quickly as possible. You can reach us on the hotline + 49 89 18930-111 or by e-mail at support@chromsystems.com. Alternatively, you can contact your local sales representative.

Regards,

Dr. Ralf Fischer
Head of Regulatory Affairs Department
Chromsystems Instruments & Chemicals GmbH

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Please forward to all end users of the products!

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.

Product description	Order No.	Lot No.
3PLUS1® Multilevel Plasma Calibrator Set	75128	2219; 2320
MassChrom® Amino Acid Analysis Plasma Control Level I	0471	2019
MassChrom® Amino Acid Analysis Plasma Control Level II	0472	2019
MassChrom® Amino Acid Analysis Plasma Control Level III	0473	2019

Table 1

Problem description including the identified cause

Internal investigations demonstrate that the existing lots on the market, as shown above in *Table 1*, do not meet the stability criteria after reconstitution as specified in the instruction for use for the analytes asparagine, homocystine and methionine at storage temperature of < - 18 °C. Internal investigations show a time-dependent, stability-related deviation from the target values.

These analytes show a maximum deviation of -25 % for asparagine, of -26 % for homocystine and of -23 % for methionine from the target values after 3 months of storage at < - 18 °C.

Using the affected calibrator lots may result in increased results of patient samples for asparagine, homocystine and/or methionine, if reconstituted calibrators and controls were used after being stored longer than 6 weeks at < -18 °C.

Determination of levels of asparagine, homocystine and methionine are used for identifying metabolic diseases. If reconstituted calibrators and controls were stored more than 6 weeks at < -18 °C before use, we strongly recommend that you coordinate the decision on clinical relevance of the results with the attending physician(s).

Since the root cause for this problem has not yet been clearly identified, as a corrective measure the in-use stability (after reconstitution) at < -18 °C of asparagine, homocystine and methionine will be reduced to 6 weeks. All other analytes included in the calibrators 75128 and controls 0471, 0472, 0473 are NOT affected by this restriction.

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What measures should be taken by the addressee

If you have already used the products listed in *Table 1* for your measurements, please check with the attending physician(s) whether it is necessary to review the results of **asparagine, homocystine** and **methionine**.

Please stop using the reconstituted products listed in Table 1 that were stored more than 6 weeks (and less than 3 months) at < -18 C for measurements of asparagine, homocystine and methionine.

Please destroy remaining stocks of the reconstituted calibrators and controls that are stored more than 6 weeks at < -18 °C and were intended to be used in measurements of asparagine, homocystine and methionine according to your valid laboratory regulations. Chromsystems will replace your stocks.

Please note calibrators and controls will now have a reduced in-use stability (after reconstitution) for asparagine, homocystine and methionine of 6 weeks at < -18 °C. For all other analytes, in-use stability is not changed. 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 following Reply Form and return it until 20.11.2020 (contact details provided on page 6).

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".

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02. November 2020 – **reply form**

Please forward to all end users of the products!

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3PLUS1® Multilevel Plasma Calibrator Set	75128	2219; 2320
MassChrom® Amino Acid Analysis Plasma Control Level I	0471	2019
MassChrom® Amino Acid Analysis Plasma Control Level II	0472	2019
MassChrom® Amino Acid Analysis Plasma Control Level III	0473	2019

Customer Details

Organization	
Address	
Contact Name	
Title/Function	
Phone	
E-mail	

Customer Action (To be filled out by the customer or check N/A)

☐ I confirm receipt of this Field Safety Notice and that I have read and understood its content.

☐ Yes
☐ No
☐ N/A

Patient data for asparagine, homocystine and methionine were generated AND reconstituted calibrators and controls used for these measurements were stored more than 6 weeks at < -18 °C.

If Yes: Decision on clinical relevance of asparagine, homocystine and methionine results was made with attending physician.

If No: No further actions to be taken by user.

Continued on page 5

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02. November 2020 – **reply form**

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Customer Action (To be filled out by the customer or check N/A)

☐ Yes
☐ N/A

The information that reconstituted calibrators and controls must not stored more than 6 weeks at < -18 °C if intended for measurements of asparagine, homocystine and methionine has been brought to the attention of all relevant users, and has been executed.

☐ Yes
☐ N/A

The following amount of reconstituted calibrators and controls has been destroyed since they were intended for measurements of asparagine, homocystine and methionine and were stored more than 6 weeks at < -18 °C.

The following products and quantities have been destroyed:

☐	☐	☐	☐	☐
75128 #2219	75128 #2320	0471 #2019	0472 #2019	0473 #2019

☐ Yes
☐ N/A

Are you aware of any adverse medical events related to the products listed in this FSN?

☐ Yes
☐ N/A

I have identified and notified my customers or others to whom products affected by this letter have been or may have been sent.

Date and type of notification

☐

I have a query, please contact me.

Brief description of query:

↓ **Continued on page 6**

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02. November 2020 – **reply form**

Please forward to all end users of the products!

Date / Name _____ / _____

Signature _____

Please send the completed form by E-mail or Fax until 20.11.2020 to:

E-mail: regulatory@chromsystems.com / Fax: +49 89 189 30 199

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

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