CHROMSYSTEMS
DIAGNOSTICS BY HPLC & LC-MS/MS

Urgent Field Safety Notice
FSN 3-2025
25.03.2025

Urgent safety information
Please forward to all
end users of the products!

Dear valued customer,

This letter is to advise you that Chromsystems Instruments & Chemicals GmbH is taking corrective action on the products listed in Table 1. Our records show that you have been supplied with the listed products.

Table 1: Affected products.

Product designation	Order no.	UDI-DI
Internal Standard Mix MassChrom® Amino Acids and Acylcarnitines from Dried Blood (non derivatized)	57004 57004/FR	04250317517715 04250317549129
Associated assays	**Order no.**	**Basic-UDI-DI**
MassChrom® Amino Acids and Acylcarnites from dried blood (non derivatized) (with and without determination of succinylacetone)	57000 57000/F	4250317NBS9Z

Description of the problem including the suspected cause

Information from customer feedback and internal investigations identified sporadic, but substantial interference on the internal standard of glutarylcarnitine (C5DC-d6). This effect is not batch-specific. The interference is suspected to be caused by additives in plastic materials used during sample preparation and has been observed to lead to up to 4-fold increased internal standard intensities. Increased intensities of the internal standard caused by such interference can result in the determination of false low concentrations for glutarylcarnitine (C5DC).

We assess the risk on the basis of following considerations

C5DC serves as marker for Glutaric acidemia Type I (GA 1; also known as Glutaryl-CoA dehydrogenase deficiency). Affected newborns can be identified by increased concentrations of C5DC in dried blood spots. Since this increase can be quite mild, falsely decreased concentrations determined in the case of C5DC-d6 interference may lead to false negative screening results. The risk of this is very low, since GA 1 is a rare disorder with a prevalence of approximately 1 in 100,000 live births and the interference has only been observed very sporadically (less than 1% of investigated samples affected in our internal investigation). Even though the risk of occurrence is low, the potential negative effects on affected patients that are not identified in the screening program can be severe. We therefore ask you to please follow the measures listed below for determination of glutarylcarnitine (C5DC) using the products listed in Table 1.

What measures are to be taken by the customer/user?

- Monitor the intensities of internal standard C5DC-d6 (in products 57004 and 57004/FR) for anomalies. If intensities are increased beyond the usual spread, a re-injection may not be sufficient to obtain a valid result. Instead, please **repeat the sample preparation** and measurement for the respective sample.
- If you have used 57004 or 57004/FR - Internal Standard MassChrom® Amino Acids and Acylcarnitines from Dried Blood (non derivatised) of any batch for screening of patient samples, please check with the attending physician(s) whether it is necessary to review the results of glutarylcarnitine (C5DC). A re-evaluation for outliers in the C5DC-d6 intensities may be required.

Chromsystems
Instruments & Chemicals GmbH
Am Haag 12
82166 Gräfelfing/Germany
Telefon: +49 89 18930-0
Telefax: +49 89 18930-199
mailbox@chromsystems.com
www.chromsystems.com

Urgent Field Safety Notice
FSN 3-2025
25.03.2025

Urgent safety information
Please forward to all
end users of the products!

- Please ensure that all users of the above products and other persons in your organisation who need to be informed are made aware of this "Urgent Safety Information".
- If you have given any of the products mentioned in this letter to another laboratory, inform that laboratory of the contents of this letter and forward a copy or inform us by e-mail at regulatory@chromsystems.com.
- Please document your actions on the enclosed response form and please return the reply form by 11.04.2025.

Passing on the information described here

Please follow this notice and the resulting action to ensure the effectiveness of the corrective action and keep this information at least until the action is completed.

The competent national regulatory authority has been informed of this "Urgent Safety Information".

If you have any questions, please contact our support team at +49 89 18930-111 or by e-mail at support@chromsystems.com.

We apologise for the inconvenience caused by this situation and ask for your understanding that we take this action to ensure the safety and satisfaction of our customers and patients. Chromsystems support is always available to answer any further questions you may have and will deal with your request quickly and reliably.

We thank you in advance for your support in carrying out the necessary measures and look forward to continuing our good cooperation.

Yours sincerely,

Dr. P. Karsten
Regulatory Affairs Specialist

Dr. M. Resch
Regulatory Affairs Specialist

Chromsystems
Instruments & Chemicals GmbH
Am Haag 12
82166 Gräfelfing/Germany
Telefon: +49 89 18930-0
Telefax: +49 89 18930-199
mailbox@chromsystems.com
www.chromsystems.com

Urgent safety information
Please forward to all
end users of the products!

Reply form

Product designation	Order no.
Internal Standard Mix MassChrom® Amino Acids and Acylcarnitines from Dried Blood (non derivatized)	57004 57004/FR

1. Customer information (to be filled in by the customer)

Organisation	
Address, Country	
Contact Name	
Title/Function	
Phone	
Email	

2. Customer action (to be filled in by the customer)

☐	The information that the intensities of internal standard C5DC-d6 (in products 57004, 57004/FR) have to be monitored for anomalies and if intensities are unusually increased, sample preparation and measurement for the respective sample must be repeated has been implemented and brought to the attention of all relevant users.	To be completed by the client or enter n/a.
☐ Yes ☐ No	Are you aware of any adverse medical events and direct negative effects on patients related to the product listed in this safety communication? If "yes": Please provide details of this event (to be completed by the client):	
☐ Yes ☐ n/a	I have identified and notified my customers or other affected third parties to whom products affected by this letter were shipped or may have been shipped.	Enter the date and type of notification or n/a.

Urgent safety information
Please forward to all
end users of the products!

☐	I have a question, please contact me.	Short description of the request:
With my signature, I acknowledge the receipt of Safety Notice FSN 03-2025 and that I have read and understood its contents.		
Name		
Signature		
Date		

Please return the completed form by e-mail or fax by 11.04.2025 to:

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

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

Your organisation's response is the evidence we need to monitor the progress of the corrective action.