Urgent Field Safety Notice
FSN 4-2025
08.09.2025

CHROMSYSTEMS | Diagnostics by HPLC & LC-MS/MS

Please forward to all end users
to forward this information!

Dear Customer,

We are writing to inform you that Chromsystems Instruments & Chemicals GmbH is implementing a corrective measure for the products listed in Table 1. Our records show that you have been supplied with the listed products.

Table 1: Affected products/batches.

Product name	Order no.	Batch no.
MassCheck® Amino Acids, Acylcarnitines incl. Succinylacetone Dried Blood Spot Control Bi-Level	0191	#1425
MassCheck® Amino Acids, Acylcarnitines incl. Succinylacetone Dried Blood Spot Control Level I	0192	#1425
MassCheck® Amino Acids, Acylcarnitines incl. Succinylacetone Dried Blood Spot Control Level II	0193	#1425

Description of the problem, including the identified cause

Information from customer feedback and internal investigations confirm that the concentration of phenylalanine determined using the non-derivatised methods 57000, 57000/F, 57111 and 57111/F is too high for Dried Blood Spot Control Level I (order no. 0192) and too low for Dried Blood Spot Control Level II (order no. 0193).

Therefore, the following adjustment is made to the values for phenylalanine stated on the package insert:

Table 2: New concentrations for phenylalanine

	Substance	Analysis method	Unit	Target value	Range		
0192 #1425	Phenylalanine	LC-MS/MS, non-derivatised:	µmol/L	Original value: 197	138	-	256
				Update: 143	**100**	**-**	**186**
0193 #1425	Phenylalanine	LC-MS/MS, non-derivatised:	µmol/L	Original value: 553	387	-	719
				Update: 707	**495**	**-**	**919**

We assess the risk based on the following considerations

The controls are primarily used to verify the accuracy and precision of the analytical procedure. If the measured values are outside the ranges specified on the control package insert, the measurement system, sample preparation procedure, and calculation of the analysis values must be checked. This can lead to a delay or failure to transmit screening results.

Furthermore, the controls can be used to introduce or adjust a factorisation (relative response factor, RRF). This is usually used to harmonise measured values on devices over time and on different devices and to enable the use of a uniform cut-off value. Using an RRF based on incorrect values adjusts not only the control but also all patient sample results by the same factor. Since the cut-off value is not factorised, there is a risk that metabolic disorders will not be detected in newborn screening due to incorrect RRFs.

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In the scenarios described, patients with a disease for which phenylalanine is used as a marker in newborn screening face a critical situation with serious health consequences if the metabolic disease is not detected or is not detected in time.

What measures should customers/users take?

- Please discard the package insert for 0192 and 0193 #1425 with the release date 21 July 2025 and replace it with the corrected versions with the release dates 1 September 2025 (order no. 0193) and 5 September 2025 (order no. 0192) in the appendix. You can also download the updated package insert from our website (https://chromsystems.com/de/downloadcenter/product-information-leaflets.html).
- If you have used the affected product for phenylalanine factorisation, please consult your treating physician or laboratory manager to determine whether a review of the phenylalanine values is necessary.
- Please ensure that all users of the above-mentioned products and other persons in your organisation who need to be informed are made aware of this "Urgent Field Safety Notice".
- If you have passed on 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 or inform us by email at vigilance@chromsystems.com.
- Please document your actions on the enclosed reply form and send us your response by 22 September 2025.

Disclosure of the information described here

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

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

We apologise for any inconvenience this situation may cause you. If you have any questions, please contact our support team at +49 89 18930-111 or by email at support@chromsystems.com.

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

Kind regards,

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

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Reply form

Product name	Order no.	Batch no.
Dried Blood Spot Control Bi-Level	0191	#1425
Dried Blood Spot Control Level I	0192	#1425
Dried Blood Spot Control Level II	0193	#1425

1. Customer information (to be completed by the customer)	
Organisation	
Address	
Contact name	
Title/Position	
Telephone	
Email	

2. Customer promotion (to be completed by the customer)		
☐ Yes	I have replaced package inserts 0192 and 0193#1425 with release date 21 July 2025 with the updated package inserts.	
☐ Yes ☐ No	Have you used an RRF based on products 0192 and 0192 #1425 to factorise patient sample results? If "yes": clarify with the attending physician or laboratory management whether a retrospective review of the phenylalanine values is necessary .	
☐ Yes ☐ No	Are you aware of any adverse medical events and direct negative effects on patients in connection with the products listed in this safety communication? If "yes": Please provide details of this event:	
☐ Yes ☐ n/a	I have identified and notified my internal and external customers or other affected third parties to whom products affected by this letter have been delivered or may have been shipped.	Enter the date and type of notification or n/a.
☐	I have a question, please contact me.	Brief description of the enquiry:

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By signing, I confirm that I have received security notice FSN 04-2025 and that I have read and understood its contents.	
Name	
Signature	
Date	

Please return the completed form by e-mail or fax by 22 September 2025 to:

email: vigilance@chromsystems.com / fax: +49 89 189 30 199

It is important that your organisation takes the measures 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 corrective actions.

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