CHROMSYSTEMS
DIAGNOSTICS BY HPLC & LC-MS/MS

Urgent Field Safety Notice
Urgent safety information
FSN 1-2023
16.10.2023

Please to all end users
of the products!

Dear customer,

our products are continuously optimised and subject to regular quality controls to meet the highest quality standards. The continuous control of our products ensures their high quality, but may lead to corrections in rare cases.

In the course of this research and customer feedback, we have found that the following product has reduced performance :

**Wash Buffer 1 (order no. 47005, batch no. #0122)**

as part of the HPLC reagent kit: **t,t,-Muconic Acid in Urine** (order no. 47000)

Therefore, please be sure to read the following Urgent Field Safety Notice. We also ask you to complete the accompanying response form, as we need proof of receipt of the corrective action.

We apologise for the inconvenience caused by this situation. Chromsystems support is always available to answer any further questions you may have and will deal with your request quickly and reliably.

You can reach us via the hotline + 49 89 18930-111 or by e-mail at support@chromsystems.com.

You are also welcome to contact our field staff.

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

Yours sincerely,

[redacted]

[redacted]
Head of Regulatory Affairs Department
Chromsystems Instruments & Chemicals GmbH



Chromsystems Instruments & Chemicals GmbH
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of the products!

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

Table 1: Affected product / batch.

| Product designation | Order no. | Batch no. |
|---|---|---|
| Wash Buffer 1 | 47005 | #0122 |

## Description of the problem including the identified cause

Some customer complaints report a decrease in the signal for t,t-muconic acid and internal standard when measuring calibrators, controls and patient samples. The internal standard cannot sufficiently compensate for the decrease in signal.

Our internal investigations have shown that the functionality of Wash Buffer 1 with batch number 0122 has deteriorated during storage. This can lead to an incorrect concentration determination of t,t-muconic acid. According to current test results, only lot 0122 is affected.

Affected measurement sequences can be recognised by the fact that the quality control levels show much lower areas than usual.

## We assess risk on the basis of the following considerations

In order to be able to assess the effects of incorrect concentration values on the patient, some examples are discussed below.

Incorrectly set values that are too low result in a person's benzene exposure not being detected. In this case, no action would be taken to protect the person from benzene exposure (e.g. increasing protective measures in the workplace). The patient would suffer adverse effects because no further protective measures are taken for occupational safety.

Incorrectly elevated values would not have any health effects on the patient. In this case, unnecessary occupational safety measures would be taken to protect the person from benzene exposure.

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

- Do not use Wash Buffer 1 (order no. 47005) of batch 0122 for further determinations.
- Discuss with the responsible occupational physician or attending physician whether the determination must be repeated for the person examined.
- Return your remaining stocks of Wash Buffer 1 (order no. 47005) of batch 0122 to us and you will receive a replacement immediately. Please fill in the reply form.
- 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.



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

Please document your actions on the enclosed response form.

Please return the reply by 01.11.2023.

**Passing on the information described here**

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 the products to third parties, please forward a copy of this information or inform us by e-mail at:

regulatory@chromsystems.com

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".

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

Yours sincerely,

[redacted]

[redacted]
Head of Regulatory Affairs Department
Chromsystems Instruments & Chemicals GmbH



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# Reply form

| Product designation | Order no. | Batch no. |
|---|---|---|
| Wash Buffer 1<br>HPLC reagent kit t,t-muconic acid in urine (order no. 47000) | 47005 | 0122 |

| 1. Customer information (to be filled in by the customer) | |
|---|---|
| Organisation | |
| Address | |
| Contact Name | |
| Title/Function | |
| Phone | |
| Email | |

| 2. Customer action (to be filled in by the customer) | | |
|---|---|---|
| ☐ Yes<br>☐ No | Patient data on t,t-muconic acid were obtained using the above batch of Wash Buffer 1.<br><br>If "yes<br>☐ Decision on clinical relevance made with attending physician/occupational physician. | To be completed by the client or enter n/a. |
| ☐ | The information that Wash Buffer 1 (Order No. 47005), Batch 0122 may no longer be used has been brought to the attention of all relevant users and implemented.<br><br>The following number of bottles 47005 of batches 0122 must be exchanged: | To be filled in by the client or enter n/a. |
| ☐ Yes<br>☐ No | Are you aware of any adverse medical events and direct negative effects on patients related to the product listed in this safety communication?<br><br>If "yes": Please provide details of this event (to be completed by the client): | |



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| | | |
|---|---|---|
| ☐ Yes<br>☐ 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. |
| ☐ | I have a question, please contact me. | Short description of the request: |
| With my signature, I acknowledge receipt of Safety Notice FSN 01-2023 and that I have read and understood its contents. | | |
| Name | | |
| Signature | | |
| Date | | |

Please return the completed form by e-mail or fax by 01.11.2023 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 corrective action.



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