

19 June 2023

Subject:

Important information

MassCheck® Drugs of Abuse Testing Urine Control Set Level I (order no. 0410, batch 0623)

Response required

Dear customers,

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

Shelf life *MassCheck®* Drugs of Abuse Testing Urine Control Set Level I (Best.-Nr. 0410) after reconstitution (available from May 2023):

Recent stability studies contradict the information in the package insert of Lot 0623. The following table shows the correct shelf lives after reconstitution compared to those in the supplied package insert:

Storage temperature	Substance	Storage life previously	Storage life corrected
+2 to +8 °C	All analytes (except those mentioned below)	1 week	1 week
	7-Aminonitrazepam	1 week	1 day
	7-Aminoclonazepam 7-Aminoflunitrazepam		
below -18 °C	All analytes (except those mentioned below)	3 months	3 months
	7-Aminonitrazepam	9 days	2 weeks
	7-Aminoclonazepam	2 week	
	7-Aminoflunitrazepam	3 week	
	Nitrazepam Nordiazepam	3 months	2 months
	2C-B Chlordiazepoxide	2 months	3 months
below -70 °C	All analytes	3 months	3 months

Please complete the attached response form to acknowledge receipt of the corrective action.

We apologise for any inconvenience this situation may cause you.

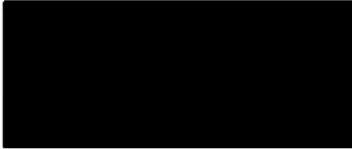
CHROMSYSTEMS

DIAGNOSTICS BY HPLC & LC-MS/MS

Our Chromsystems support staff is available at all times to answer any further questions you may have and will deal with your request quickly and reliably. You can reach our Chromsystems support via the hotline + 49 89 18930-111 or by e-mail at support@chromsystems.com. You are also welcome to contact one of our local Chromsystems representatives.

We look forward to further cooperation.

With kind regards



Chromsystems Instruments & Chemicals GmbH
Am Haag 12, 82166 Graefelfing/Munich, Germany

Phone: +49 89 18930-0
Fax: +49 89 18930-299
E-mail: Product.Management@chromsystems.de
www.chromsystems.com



Trade Register Court Munich no. HRB 92 351



Response from user to Chromsystems

Name of method	Order no.	Lot no.
MassCheck® Drugs of Abuse Testing Urine Control Set Level I	0410	0623

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)		
<input type="checkbox"/> Yes	The information that the shelf life of some analytes varies at different storage temperatures is brought to the attention of all relevant users.	To be filled in by the client or enter n/a.
<input type="checkbox"/> Yes	I have received the new package insert (Update to 16.06.2023) and replaced the previous package insert. (in electronic and/or printed form).	To be filled in by the client or enter n/a.
<input type="checkbox"/> Yes	Already reconstituted and aliquoted samples are used by me according to the modified shelf lives.	To be filled in by the client or enter n/a.
<input type="checkbox"/> Yes <input type="checkbox"/> n/a	I have identified and notified my customers or other affected third parties to whom methods affected by this letter have been delivered or may have been sent.	Enter the date and type of notification or n/a.
I hereby acknowledge receipt of this customer information and that I have read and understood its contents.		
Name / Signature		
Date		

Please return the completed form by e-mail or fax by 03.07.2023 to:

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