



**Bio-Rad
Laboratories GmbH**

Postfach 45 01 33 • 80901 München
Heidemannstraße 164 • 80939 München
Telefon +49 (0)89 318 84-0
Telefax +49 (0)89 318 84 100
www.bio-rad.com

Please forward to the end user of the device!

October 8, 2015

Urgent Field Safety Notice

Urinary Metanephtrines by HPLC (Cat. # 195-5411)
Urinary Metanephtrines by HPLC – Automated Method on ASPEC™ (Cat. # 195-5412)

Addressor:

Bio-Rad Laboratories GmbH, Susanne Karg, Heidemannstrasse 164, 80939 München, Deutschland,
Tel.: +49 (0) 89 31884-290, Fax: +49 (0) 89 31884-100, E-Mail: susanne_karg@bio-rad.com

Details of affected devices:

Product	Ref.-N°	Lot N°	Expiry
Urinary Metanephtrines by HPLC	195-5411	116802 (Pilot)	2015-01-02
Urinary Metanephtrines by HPLC	195-5411	125347	2015-08-08
Urinary Metanephtrines by HPLC	195-5411	126678	2015-08-08
Urinary Metanephtrines by HPLC	195-5411	126924	2016-02-28
Urinary Metanephtrines by HPLC	195-5411	127066	2016-02-28
Urinary Metanephtrines by HPLC	195-5411	127298	2016-04-05
Urinary Metanephtrines by HPLC – Automated Method on ASPEC™	195-5412	125110 (Pilot)	2015-01-02
Urinary Metanephtrines by HPLC – Automated Method on ASPEC™	195-5412	125344	2015-08-08
Urinary Metanephtrines by HPLC – Automated Method on ASPEC™	195-5412	126687	2015-08-08
Urinary Metanephtrines by HPLC – Automated Method on ASPEC™	195-5412	126929	2016-02-28
Urinary Metanephtrines by HPLC – Automated Method on ASPEC™	195-5412	127085	2016-04-05

Description of the problem:

Within the latest generation of Bio-Rad *Urinary Metanephtrines by HPLC* Reagent Kits an internal standard based on a capsaicin-metabolite (HMBA) is used in order to determine analytical HPLC values.

If HMBA is present in the 24-hour urine sample the internal standard of the test can be potentially affected and falsely low values may arise.



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Hence, as described in the instructions for use in chapter 3.2 *Specimen Collection and Handling*, patients have to abstain from food and drugs which contain capsaicin (e.g. hot pepper) one day prior to collecting the urine.

In context of complaint handling we noticed that there exists the risk that this information of the instruction may be overlooked or misunderstood by the users. As a result, the requirement that capsaicin-containing products must be strictly avoided a day before and during collection of the urine might possibly not be passed along to the patient by the physician in charge.

As a consequence, we will successively add supplementary indications to package inserts of above mentioned product numbers regarding HMBA interference and its consequential provisions. Additionally our Bio-Rad service employees will advert to this circumstance intensely during test implementation.

Advise on action to be taken by the user:

Please ensure that the following information will be distributed to the appropriate divisions in your house until then:

- HMBA in the urine sample may cause false low measurement results in the determination of Normetanephrine, metanephrine and 3-methoxytyramine.
- Patients are not allowed to consume any capsaicin-containing foods and medication one day prior to and during the collection of the urine.

Please confirm with the physicians in charge that the dietary restrictions have been strictly followed. In case of suspicion of a violation of the restrictions by capsaicin uptake in any form 1 day prior or during to collecting the urine, we recommend the retesting of patients with negative results under compliance to the dietary restrictions.

Inform physicians in charge by inter alia, customizing your specifications according to this announcement.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Responsible authorities received a copy of this information.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please refer to the attached form. By returning the form to us, you confirm that you have reviewed and forwarded the safety information.

We apologize for any inconvenience and would like to thank you in advance for your cooperation. If you have any additional questions please contact us.



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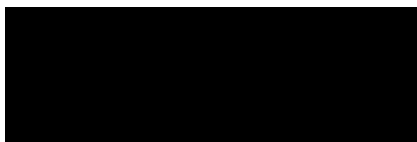
Contact reference person:

Kurt Pawlitschko
QC Manager

Bio-Rad Laboratories GmbH
Heidemannstrasse 164
80939 Munich, Germany
Tel.: +49 (0) 89 31884-0
E-Mail: kurt_pawlitschko@bio-rad.com

Best regards,

Bio-Rad Laboratories GmbH



Susanne Karg
Bio-Rad Laboratories GmbH
(Safety Officer Medical Devices)



Dr. Reiner Krey
Bio-Rad Laboratories GmbH
(Manufacturing Operations Manager)



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Important Field Safety Notice Receipt Confirmation to

Urgent Field Safety Notice

Urinary Metanephrines by HPLC (Cat. # 195-5411)

Urinary Metanephrines by HPLC – Automated Method on ASPEC™ (Cat. # 195-5412)

CUSTOMER DETAILS

Hospital / Laboratory	
Signed Laboratory Management (Name)	
Address	
Telephone number	
Customer number	

ACTION

DECLARATION:

I read and understood the Field Safety Notice (Safety Notice).

All users of the device and all physicians in charge were informed as well.

Date: _____

Signature: _____

- Please return signed confirmation until **November 10, 2015** via fax to following number:
+49 (0) 89 31884 - 100

Please contact your local Bio-Rad service for further questions or support.