

**Please forward to the end user of the device!**

25. November 2015

## Urgent Field Safety Notice

### Termination of the safety measures

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

#### Absender:

Bio-Rad Laboratories GmbH, [REDACTED], Heidemannstrasse 164, 80939 München, Deutschland,  
[REDACTED]

#### Identifikation der betroffenen Medizinprodukte:

Produkt	Art.-#	Charge	Expiry Date
Urinary Metanephrines by HPLC	195-5411	116802 (Pilot)	2015-01-02
Urinary Metanephrines by HPLC	195-5411	125347	2015-08-08
Urinary Metanephrines by HPLC	195-5411	126678	2015-08-08
Urinary Metanephrines by HPLC	195-5411	126924	2016-02-28
Urinary Metanephrines by HPLC	195-5411	127066	2016-02-28
Urinary Metanephrines by HPLC	195-5411	127298	2016-04-05
Urinary Metanephrines by HPLC – Automated Method on ASPEC™	195-5412	125110 (Pilot)	2015-01-02
Urinary Metanephrines by HPLC – Automated Method on ASPEC™	195-5412	125344	2015-08-08
Urinary Metanephrines by HPLC – Automated Method on ASPEC™	195-5412	126687	2015-08-08
Urinary Metanephrines by HPLC – Automated Method on ASPEC™	195-5412	126929	2016-02-28
Urinary Metanephrines by HPLC – Automated Method on ASPEC™	195-5412	127085	2016-04-05

Dear valued customer,

We would like to inform you that conducted studies on the topic of possible falsely negative results have been concluded.

In summary studies confirm that our products are safe and that there is no significant risk for producing falsely negative results.

In order to ensure that the values determined by our products are correct we would like you to take the below listed actions.

**Safety measures:**

1. Adaption of the HPLC Analysis

In order to suppress the detection of potential other interfering substances within the sample the detector potential needs to be adjusted from 0,69V to **0,60V**.

2. Revocation of the safety measures

The safety measures recommended in the Urgent Field Notice of the 14.10.2015 dealing with the **individual review of all samples within the normal range** concerning the peak size of the internal standard **is no longer required**.

3. Replacement of the Instructions for Use

The CD-ROM containing the Instructions for Use for respective Kits have been amended accordingly. Please make sure that respective analyses in your laboratory will be conducted with the modified parameters and replace all Instructions for Use and eventually Quick Guides etc. with the adapted/latest versions.

**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.

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.



**Bio-Rad  
Laboratories GmbH**

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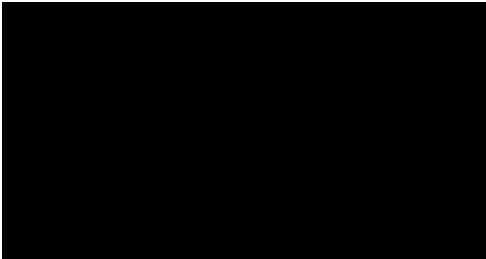
**Contact person:**

Kurt Pawlitschko  
QC Manager

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Heidemannstrasse 164  
80939 München, Germany  
Telefon: +49 (0) 89 31884-0  
E-Mail: [kurt\\_pawlitschko@bio-rad.com](mailto:kurt_pawlitschko@bio-rad.com)

Best regards,

**Bio-Rad Laboratories GmbH**





## Important Field Safety Notice Receipt Confirmation to

### Urgent Field Safety Notice Termination of the safety measures

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#### 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 **December 10, 2015** via fax to following number:  
**+49 (0) 89 31884 - 100**

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