

Customer Notification

Date: 24.02.2020

Product: Estradiol ELISA
Cat.-No.: DEH3355
Lot-Number: H 024, H 025, H 026

Dear valued Demeditec customer,

Internal stability studies indicate that after a kit duration of four months, the values found in the normal value range could be detected higher than expected. Higher concentration ranges (>100 pg/ml) seem to be excluded from this effect. The values measured within the first four months gave reasonable results. Thus the results of the measured samples within this period should be reliable.

This effect is caused by a raw component that has been replaced in subsequent batches. The problem has been identified due to our production and QC processes and the information is used as a preventive measure to avoid measuring incorrectly increased measurement results. Therefore it is important that the kits of the affected lots must not longer be used and discarded immediately. Of course we support you in replacing the remaining kits.

Therapeutic consequences should not be made solely on the basis of the values determined with this test, but only taking into account all clinical observations and other diagnostic methods.

Since estradiol is not considered individually, but always in connection with the clinical picture and examination as well as other laboratory diagnostic tests, the health risk is minimal.

What is to be done?

- Please check your stock situation and discard all unused kits immediately from the affected lots
- Please use the attached form on page 3, sign and send back to us
- Please inform your customers and forward this notice to affected persons and institutions
- We do not expect issues with the results of the patient samples, nevertheless please check them again. In case the results are higher than expected, the samples should be re-tested.
- Please tell us if you have experienced any problem with these lots and specify the details

Transmission of this customer notification:

This notice has to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected product has been transferred. Please be aware of this notice and the resulting action for an appropriate period to ensure effectiveness of the preventive action. In case of further questions contact your local distributor.

Contact person for further information:

ppa. Dr. Manfred Czapp
Authorized Signatory
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
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Fax: +49-(0)431-71922-55
E-mail: czapp@demeditec.de
Web: www.demeditec.com

A large black rectangular redaction box covering several lines of text in the contact information section.

Response Form

Send to
 Demeditec Diagnostics GmbH
 Lise-Meitner-Str. 2
 24145 Kiel
 Germany
 Email: czapp@demeditec.de
 FAX: +49 (0)431-71922-55

Demeditec Estradiol ELISA
 Product code: DEH3355
 Product lot: H 024, H 025, H 026
 Problem description: Risk of elevated estradiol results in the as normal value
 declared concentration range

Please check the following points and confirm:

- I have received and understood the customer notification from 20.02.2020.
- I confirm that I have forwarded this information to the end-users.

| Product | Lot | Number of Kits received | Number of kits used up | Number of Kits returned/discarded |
|--------------------|---------------------|-------------------------|------------------------|-----------------------------------|
| Estradiol, DEH3355 | H 024, H 025, H 026 | | | |

Company Name: _____

Company Address: _____

Date: _____

Contact Person: _____

Signature: _____

Email address: _____

Please complete and return this Response Form until 28.02.2020!