Important Safety Notice

Date: 30.10.2018

Product: beta-2-Microglobulin ELISA
Cat.-No.: DE7610
Lot-Number: Listed on page 2 (Annex I)

Dear valued Demeditec customer,

This important safety notice is to inform you that we have observed an issue in the package insert of beta-2-Microglobulin ELISA coded DE7610. Demeditec Diagnostics is sending this letter to inform you about this mistake and to provide assistance with this issue.

Issue:
Unfortunately, we found a mistake in the English version of the package insert supplied with the affected lots which is important for the calculation of results in urine samples. The following sentence was missing in chapter *12 Calculation of Results*:
"*Due to different dilution, urine results have to be divided by 10 after calculation.*"
The serum samples are diluted 1:100 and the urine samples 1:10. The concentrations of serum samples may be estimated directly from the calibrator curve while the urine results have to be divided by 10 after calculation.

Please note that all information about the calculation of results for serum and plasma samples are still correct and reliable!

Impact:
The calculation according to the package insert would lead to 10-times increased urine results and to an accumulation of falsely elevated values resulting in further detailed investigations of the patient.
Beta-2-microglobulin secretion in urine indicates renal filtration disorders. As stated in the package insert this assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually. Each laboratory should establish its own ranges.
Up to now we did not receive any complains about results of urine samples.

Actions/Resolution:

- Block all affected kits on stock that were supplied from Demeditec
- Identifying and information of all end-users who purchased the affected kit
- If the kit hasn´t been used yet, it is possible to change the package insert and use Version 05-01/18. In that case the correct quality of this product is guaranteed.
- Please check with the end users whether they have used urine as sample type

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- The urine values measured so far should be re-evaluated taking into account this important safety notice.

Please share this information with your customers and return the completed Response Form (on page 3) by Email or Fax within 10 days so we are assured that you have received this important communication.

If you have any questions, please do not hesitate to contact us.
We apologize for all inconveniences caused by this issue and thank you for your further trust in our products.

Yours sincerely,

ppa. Dr. Manfred Czapp

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Annex I

Lot	Expiry Date
1808512	30.11.2019
1802545	30.09.2019
1718395	31.03.2019
1713439	31.01.2019
1704876	31.10.2018
1713023	31.10.2018
1622512	31.07.2018
1606074	30.11.2017
1621294	30.11.2017
1700166	30.11.2017
1505118	28.05.2017
V15-010850205	28.08.2016
V14-165940244	28.05.2016
V14-036640209	28.09.2015
V13-162431541	28.06.2015
5BM31525	28.12.2014
5BM24006	28.09.2014

Response Form

To
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24145 Kiel
Germany
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FAX: +49 (0)431-71922-55

Please check the following points and confirm:

- O I have received and understood the important safety notice from 30.10.2018.
- O I confirm that I have forwarded this information to the end-users.
- O I have checked the stock situation and we have ___ kits from the affected kit lots on stock.
- O The end users have used the following sample types:
  - O Urine
  - O Serum or Plasma
  - O Unknown

Company Name: _____

Company Address:_____

Date: _____

Contact Person: _____

Signature: _____

Email address: _____

Please complete and return this Response Form until 09.11.2018!