

Customer Notification

Date: 20.11.2023

Product: Estradiol free in Saliva ELISA
Cat.-No.: DESLV4188
Lot-Number: 68K103

Dear valued Demeditec customer,

following a complaint, we were made aware of an error in the filling volume of the TMB substrate solution for the Estradiol free in Saliva ELISA (DESLV4188). Instead of the stated 25 ml, only 14 ml are contained in the vial.

The test can be performed correctly according to the package insert, however, due to the reduced volume of the TMB substrate solution, the entire plate cannot be used, but a maximum of 70 wells.

What is to be done?

- Please check your stock situation and discard all unused kits immediately from the affected lots.
- Demeditec will supply replacement kits.
- Please use the attached form on page 2, sign and send back to us

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
Tel: +49-(0)431-71922-32
Fax: +49-(0)431-71922-55
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Web: www.demeditec.com

Signature: 



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 free in Saliva ELISA
 Product code: DESLV4188
 Product lot: 68K103
 Problem description: TMB substrate solution volume too low

Please check the following points and confirm:

- I have received and understood the customer notification from 20.11.2023.
- I confirm that I have forwarded this information to the end-users.

Product	Cat.-No.-	Lot	Number of Kits received	Number of kits used up	Number of Kits returned/discarded
Estradiol free in Saliva	DESLV4188	68K103			

Company Name: _____

Company Address: _____

Date: _____

Contact Person: _____

Signature: _____

Email address: _____

Please complete and return this Response Form until 30.11.2023!