
Urgent Field Safety Notice

Adaption of reference ranges for calibrators

concerning
Dihydrotestosterone ELISA, order no. EQ 6152-9601-1, lot no. E220621BF, E220621BV, E220712RV, E220712SL, E220719AV, E220804DB, E220825AT, E220825BO, E220825CE, E220907BG, E220920BP, E221010BL, E221221SA, E230112CH, E230112DB

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24 May 2023

From:
EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany
www.euroimmun.com

To:
Users and distributors

Identification of the medical/IVD products concerned:
Dihydrotestosterone ELISA, order no. EQ 6152-9601-1, lot no. E220621BF, E220621BV, E220712RV, E220712SL, E220719AV, E220804DB, E220825AT, E220825BO, E220825CE, E220907BG, E220920BP, E221010BL, E221221SA, E230112CH, E230112DB

Dear customers,

EUROIMMUN has initiated a field corrective action for the product specified above. This notification contains important information for your immediate attention.

Description of the problem and the determined cause:
The measuring signals (OD values) for the calibrators included in tests kits of the Dihydrotestosterone ELISA, order no. EQ 6152-9601-1, lot numbers as above, may yield values outside the acceptable reference ranges over time. The measured concentrations for the controls included in the test kit will be within the acceptable ranges stated on the quality control certificate, and results for patient samples will not be affected.
The respective incubations are invalid, as indicated in the lot-specific quality control certificate, and the test results must not be used. Final results may be delayed. All valid results determined previously using the above-mentioned lots are not affected and remain valid.

Measures to be taken:
The reference ranges for the calibrators must be adapted. The following reference ranges should be used for the remaining shelf life of the above-mentioned lots of the Dihydrotestosterone ELISA.

Calibrator 1, 1 pg/ml, Valid range: **>0.600** O.D.
Calibrator 7, 2500 pg/ml, Valid range: **<0.500** O.D.

O.D. Calibrator 1 > O.D. Calibrator 2 > O.D. Calibrator 3 > O.D. Calibrator 4 > O.D. Calibrator 5 > O.D. Calibrator 6 > O.D. Calibrator 7

Evaluate invalid test runs again using the corrected reference ranges.
Both controls provided in the test kit must be investigated in each test run, and the results obtained must be within the acceptable ranges stated on the quality control certificate.

The results should always be interpreted together with clinical findings and further diagnostic tests.

To confirm receipt of this safety information, please send the completed reply form by fax to the following number: +49 (0) 451 2032 7065. We kindly ask that you return the form as soon as possible and **by 23 June 2023 at the latest.**

Information to be passed on:
This notice must be forwarded to all users and distributors of the above-mentioned product.

Thank you for your cooperation! We apologise for any inconvenience this may cause.

For further information, please do not hesitate to contact EUROIMMUN using the contact details below.

Contact:

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Please send back the customer reply as specified on the document.