

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

TruLab Protein Level 1 Lot 25179, Cat. No. 5 9500 99 10 046

False assay values for Immunoglobulin E (IgE) and G (IgG) in the target value sheet version 23.07.2018

Date December 19, 2019

Product **TruLab Protein Level 1 Cat. No.: 5 9500 99 10 046**

Lot: Level 1: 25179, expiry date 2021-01

Kit Lot: 40228944, 40231539, 40231551, 40232535, 40233637, 40239855, 50240795, 50241773, 50241987, 50242980, 50243604, 50246421, 50248533, 60128367, 60129040, 60129248, 60129475, 60129650, 60130204, 60130207, 60131564, 60132385, 60133453, 60133454, 60133949, 60134822, 60135358

Explanation Due to a customer complaint, it was determined that the above-mentioned kit lots contain target value sheets with incorrect assay values for IgG and IgE with a deviation of about -2% for IgE and +11% for IgG.

Correct assay values are mentioned below:

Constituent	System	Cat. No.	Assay value	Max. limits	Unit
IgE	DiaSys	1 7239	88.3	70.6 – 106	IU/mL
IgG	DiaSys	1 7212	652 6.52	522 – 782 5.22 – 7.82	mg/dL g/L

Impact on patient results No impact on patient results, since a shift of the control assay value of about -2% for IgE and +11% for IgG in the lower measuring range is seen to be uncritical.

Measures The affected target value sheet was corrected and is provided on the DiaSys website (www.diasys-diagnostics.com).

The incorrect target value sheet of the above mentioned kit lots must not be used anymore and must be exchanged with the corrected target value sheet. It must be checked whether false control values have been used.

Please discuss with the head of laboratory if measurements performed with above mentioned lots should be reviewed.

Please inform all users of the affected products immediately.

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DiaSys has announced the urgent field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers. Please send it back to us by fax or as scan until **January 03, 2020**.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Kind regards,

Christiane Wernz
Technical Product Management