

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

UPDATE OF CALIBRATION AND CONTROL VALUE SHEETS

Calibrator TruCal U, control TruLab N and TruLab P

Interchanged values between methods “Total Protein with sample blank” and “Total Protein without sample blank”

Date	08.04.2021
Product / Lot	TruCal U (cat. no.: 5 9100 ...) Lot 29909 TruLab N (cat no.: 5 9000 ...) Lot 29695 TruLab P (cat. no.: 5 9050 ...) Lot 29696
Kit Lot	TruCal U: 20004021, 20004096, 50268569, 50268726, 50268727, 60144025 TruLab N: 20003973, 50267416, 50268570, 50268728, 50268729, 60144404 TruLab P: 20003974, 50267417, 50268571, 50268907, 50271065, 50271066, 60143754, 60143860, 60143926, 60144405
Explanation	For calibrator TruCal U lot 29909: The calibration value for method “Total Protein with sample blank” has been interchanged with the calibration value for “Total Protein without sample blank” on the corresponding value sheet of the calibrator. For TruLab N Lot 29695 and TruLab P Lot 29696: The target values for method “Total Protein with sample blank” have been interchanged with the target values for “Total Protein without sample blank” on the corresponding value sheets of the controls.
Impact on patient results	For calibrator TruCal U lot 29909: Patient samples measured with method “Total Protein with sample blank” will be found +8.6% falsely high . Patient samples measured with method “Total Protein without sample blank” will be found -9.4% falsely low . For controls TruLab N 29695 and TruLab P 29696: A delayed diagnosis for patient samples may occur since controls might be found outside the confidence interval.
Measures	For calibrator TruCal U lot 29909 and controls TruLab N lot 29695 / TruLab P 29696: Previously measured results should be reviewed by the laboratory management and can be corrected by a recalculation using the factors as follows:

CUSTOMER INFORMATION

Measures
(continued)

Total Protein <i>with</i> sample blank	Result multiplied with factor 0.914
Total Protein <i>without</i> sample blank	Result multiplied with factor 1.094

Replace the previously used target values by the new target values as stated on the updated target value sheet (see attached, marked grey) and inform all affected users about this information.

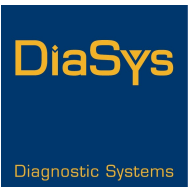
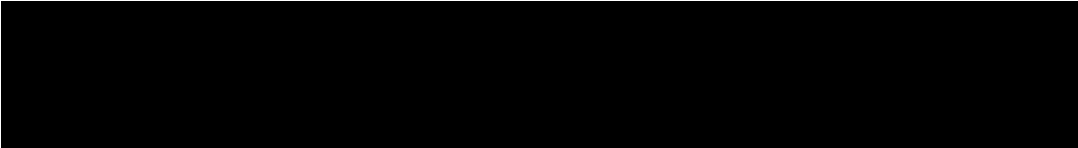
Updated target value sheets can be obtained by using the link below:
<http://www.diasys-diagnostics.com/service-area/value-sheets/>

DiaSys has announced this 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 by fax or as scan until 30.04.2021.

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

Kind regards



Confirmation of receipt

Please confirm that the customer information below is received by your facility:

Urgent Field Safety Notice - Interchanged values between methods "Total Protein with sample blank" and "Total Protein without sample blank"

Herewith I confirm that above named customer information reached me and is forwarded to the users of these DiaSys products.

Customer name: _____

Contact person: _____
(same as signature)

Date / Signature: _____

Please send this fax to DiaSys Diagnostic Systems GmbH (Holzheim / Germany)

Fax-Number: +49-6432-9146-32

Thank you for your efforts!

Empfangsbestätigung

Bitte bestätigen Sie, dass Sie die folgende Kundeninformation erhalten haben.

Dringende Sicherheitsinformation - Vertauschte Werte zwischen den Methoden „Gesamtprotein mit Probenleerwert“ und „Gesamtprotein ohne Probenleerwert“

Hiermit bestätigen wir, dass wir die oben genannte Kundeninformation erhalten und an unsere Kunden weitergeleitet haben.

Name des Distributors: _____

Kontaktperson: _____
(Name des Unterzeichners)

Datum / Unterschrift: _____

Bitte senden Sie das ausgefüllte und unterzeichnete Dokument per Fax an: DiaSys Diagnostic Systems GmbH (Holzheim / Deutschland)

Fax-Nummer: +49-6432-9146-32

Vielen Dank für Ihre Bemühungen!