

CUSTOMER INFORMATION

FIELD SAFETY NOTICE

UPDATE OF TARGET VALUES

Controls and Calibrator

Reassignment of target values for TruLab controls and TruCal U calibrator

Date	February 26, 2016
Products and Lots	TruLab N (cat. no.: 5 9000...), lot 20270 TruLab P (cat. no.: 5 9050...), lot 20271 TruLab Protein Level 1 (cat. no.: 5 9500...), lots 19360 and 20381 TruLab Protein Level 2 (cat. no.: 5 9510...), lots 19361 and 20382 TruLab Urine Level 1 (cat. no.: 5 9170 ...), lots 21056 and 20541 TruLab Urine Level 2 (cat. no.: 5 9180 ...), lots 21057 and 20542 TruCal U (cat. no. 5 9100 ...), lot 20695
Explanation	Internal measurements for quality assurance have shown that some target values for the above mentioned TruLab controls and TruCal U calibrator have to be reassigned.
Impact on patient results	For TruLab controls: No impact on patient results. For calibrator TruCal U lot 20695: Calibration value for AST/GPT has to be reassigned from 105 U/L to 99,8 U/L (-5%). By using this new calibration value also patient results will be shifted by -5%.
Measures	Replace the previously used target values by the new target values communicated in this information on the following pages and inform all affected users about the reassignment. 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 **end of March 2016**.

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

Kind regards

David Ehlers
Product Management

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List of affected products and parameters (1/2)

Control	Lot	Parameter	Method	New Target Value	New Range
TruLab N	20270	Alkaline Phosphatase	IFCC 37°C	92,4 U/L 1,54 µkat/L	69,3 – 116 U/L 1,16 – 1,93 µkat/L
			DGKC, 1970, 37°C	192 U/L 3,20 µkat/L	148 – 236 U/L 2,46 – 3,94 µkat/L
		ALT/GPT	IFCC, with P5P 37°C	38,4 U/L 0,640 µkat/L	29,6 – 47,2 U/L 0,493 – 0,787 µkat/L
		Bilirubin total	Jendrassik-Grof	1,38 mg/dL 23,7 µmol/L	1,02 – 1,74 mg/dL 17,5 – 29,8 µmol/L
		Chloride	Thiocyanate	103 mmol/L 363 mg/dL	93,3 – 112 mmol/L 331 – 397 mg/dL
			ISE direct	102 mmol/L 360 mg/dL	92,4 – 111 mmol/L 328 – 393 mg/dL
		CK	DGKC, IFCC, 37°C	140 U/L 2,34 µkat/L	112 – 168 U/L 1,87 – 2,81 µkat/L
		GLDH	DGKC, 1970, 37°C	13,3 U/L 0,222 µkat/L	10,7 – 16,0 U/L 0,178 – 0,267 µkat/L
		Glucose	Gluc-DH	89,8 mg/dL 4,99 mmol/L	75,5 – 104 mg/dL 4,19 – 5,78 mmol/L
		IgM	Immunoturbidimetric	78,4 mg/dL 0,784 g/L	56,4 – 100 mg/dL 0,564 – 1,00 g/L
Lipase	Colorimetric, 37°C	41,6 U/L 0,693 µkat/L	33,3 – 49,9 U/L 0,555 – 0,832 µkat/L		
TruLab P	20271	Alkaline Phosphatase	IFCC 37°C	198 U/L 3,29 µkat/L	148 – 247 U/L 2,47 – 4,11 µkat/L
			DGKC, 1970, 37°C	408 U/L 6,80 µkat/L	314 – 502 U/L 5,24 – 8,36 µkat/L
		ALT/GPT	IFCC, with P5P 37°C	109 U/L 1,82 µkat/L	83,9 – 134 U/L 1,40 – 2,23 µkat/L
		Chloride	ISE direct	117 mmol/L 414 mg/dL	106 – 127 mmol/L 376 – 451 mg/dL
		CK	DGKC, IFCC, 37°C	455 U/L 7,59 µkat/L	364 – 546 U/L 6,07 – 9,11 µkat/L
		GLDH	DGKC, 1970, 37°C	22,8 U/L 0,381 µkat/L	18,3 – 27,4 U/L 0,305 – 0,457 µkat/L
		Glucose	Gluc-DH	263 mg/dL 14,6 mmol/L	221 – 305 mg/dL 12,3 – 16,9 mmol/L
		IgM	Immunoturbidimetric	96,5 mg/dL 0,965 g/L	69,5 – 124 mg/dL 0,695 – 1,24 g/L
		Lipase	Colorimetric, 37°C	76,6 U/L 1,28 µkat/L	61,3 – 91,9 U/L 1,02 – 1,53 µkat/L
TruLab Protein Level 1	19360	Myoglobin (MYO)	Immunoturbidimetric	56,2 ng/mL 56,2 µg/L	45,0 – 67,4 ng/mL 45,0 – 67,4 µg/L
	20381	Myoglobin (MYO)	Immunoturbidimetric	59,0 ng/mL 59,0 µg/L	47,2 – 70,8 ng/mL 47,2 – 70,8 µg/L
TruLab Protein Level 2	19361	C-Reactive Protein (CRP)	DiaSys Immunoturbidimetric	5,76 mg/dL 57,6 mg/L	4,20 – 7,32 mg/dL 42,0 – 73,2 mg/L
		Myoglobin (MYO)	Immunoturbidimetric	123 ng/mL 123 µg/L	98,4 – 148 ng/mL 98,4 – 148 µg/L
	20382	C-Reactive Protein (CRP)	DiaSys Immunoturbidimetric	6,45 mg/dL 64,5 mg/L	4,71 – 8,19 mg/dL 47,1 – 81,9 mg/L

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List of affected products and parameters (2/2)

Control	Lot	Parameter	Method	New Target Value	New Range
TruLab Urine Level 1	21056	Microalbumin (ALB)	DiaSys Immunoturbidimetric	6,87 mg/L 0,687 mg/dL	4,95 – 8,79 mg/L 0,495 – 0,879 mg/dL
		Creatinine (CREA)	DiaSys Jaffe, w/o compensation	64,3 mg/dL 5,68 mmol/L	48,9 – 79,7 mg/dL 4,32 – 7,05 mmol/L
		Total Protein (TP) lots before lot 21168	DiaSys Pyrogallol red	4,20 mg/dL 42,0 mg/L	3,19 – 5,21 mg/dL 31,9 – 52,1 mg/L
	20541	Microalbumin (ALB)	DiaSys Immunoturbidimetric	7,77 mg/L 0,777 mg/dL	5,59 – 9,95 mg/L 0,559 – 0,995 mg/dL
		Total Protein (TP) <i>only for lots before lot 21168</i>	DiaSys Pyrogallol red	4,06 mg/dL 40,6 mg/L	3,09 – 5,03 mg/dL 30,9 – 50,3 mg/L
		Creatinine (CREA)	DiaSys Jaffe, w/o compensation	64,4 mg/dL 5,69 mmol/L	48,9 – 79,9 mg/dL 4,33 – 7,06 mmol/L
TruLab Urine Level 2	21057	Creatinine (CREA)	DiaSys Enzymatic PAP	155 mg/dL 13,7 mmol/L	118 – 192 mg/dL 10,4 – 17,0 mmol/L
			DiaSys Jaffe, w/o compensation	144 mg/dL 12,7 mmol/L	109 – 179 mg/dL 9,67 – 15,8 mmol/L
	20542	Creatinine (CREA)	DiaSys Enzymatic PAP	149 mg/dL 13,2 mmol/L	113 – 185 mg/dL 10,0 – 16,3 mmol/L
			DiaSys Jaffe, w/o compensation	138 mg/dL 12,2 mmol/L	105 – 171 mg/dL 9,26 – 15,1 mmol/L
TruCal U	20695	AST/GOT	IFCC, with P5P 37°C	99,8 U/L 1,66 µkat/L	