

2024-03-28

Target value update for DiaSys controls

Dear DiaSys customers,

Internal measurements for quality assurance have shown, that some target values of the following controls had to be reassigned:

- TruLab N (cat. no.: 5 9000 ...)
- TruLab P (cat. no. 5 9050...)

The affected lots and parameters as well as the new target values and ranges are shown on the next pages. Changed target values are marked grey on the corresponding value sheets.

Download new value sheets with updated target values here:

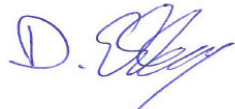
<https://www.diasys-diagnostics.com/service-area/value-sheets/>

Please replace previously used target values by these new target values for all upcoming measurements and inform all affected users.

This is not a subject to report. It is not necessary to announce this customer information to the authorities of the European Union or other authorities outside of the EU.

Please fill in and sign the attached confirmation and send back by fax or scan until 2024-04-15.

Best regards



i.V. David Ehlers
Product Management

CUSTOMER INFORMATION

Control	Reagent Code	Parameter	Lot	New Target Value	New Range
TruLab N	1 1601	CK	32786	143 U/L 2.38 µkat/L	114 – 171 U/L 1.90 – 2.85 µkat/L
	1 1641	CK-MB		31.3 U/L 0.521	25.0 – 37.5 U/L 0.417 – 0.625 µkat/L
	1 2411	GLDH		16.0 0.267 µkat/L	12.8 – 19.2 U/L 0.214 – 0.320 µkat/L
	1 0441	AP, IFCC	33772	65.3 U/L 1.09 µkat/L	49.0 – 81.6 U/L 0.816 – 1.36 µkat/L
	1 0401	AP, DGKC		111 U/L 1.84 µkat/L	82.9 – 138 U/L 1.38 – 2.30 µkat/L
	1 2701 + 2 5010	ALT (GPT) + P5P		48.5 U/L 0.809 µkat/L	37.4 – 59.7 U/L 0.623 – 0.995 µkat/L
	1 2701	ALT (GPT)		48.2 U/L 0.803 µkat/L	37.1 – 59.3 U/L 0.619 – 0.988 µkat/L
	1 2601 + 2 5010	AST (GOT) + P5P		38.2 U/L 0.637 µkat/L	29.4 – 47.0 U/L 0.490 – 0.783 µkat/L
	1 1601	CK		164 U/L 2.73 µkat/L	131 – 197 U/L 2.19 – 3.28 µkat/L
	1 1641	CK-MB	36.0 U/L 0.599 µkat/L	28.8 – 43.1 U/L 0.479 – 0.719 µkat/L	
	1 2411	GLDH	15.5 U/L 0.259 µkat/L	12.4 – 18.7 U/L 0.207 – 0.311 µkat/L	

CUSTOMER INFORMATION

Control	Reagent Code	Parameter	Lot	New Target Value	New Range
TruLab P	1 1601	CK	32787	213 U/L 3.55 µkat/L	170 – 256 U/L 2.84 – 4.26 µkat/L
	1 1641	CK-MB		52.6 U/L 0.877 µkat/L	42.1 – 63.2 U/L 0.702 – 1.05 µkat/L
	1 0441	AP, IFCC	33773	176 U/L 2.93 µkat/L	132 – 220 U/L 2.20 – 3.66 µkat/L
	1 0401	AP, DGKC		264 U/L 4.40 µkat/L	198 – 330 U/L 3.30 – 5.51 µkat/L
	1 2701 + 2 5010	ALT (GPT) with P5P		120 U/L 2.00 µkat/L	92.3 – 147 U/L 1.54 – 2.46 µkat/L
	1 2701	ALT (GPT)		120 U/L 2.00 µkat/L	92.5 – 148 U/L 1.54 – 2.46 µkat/L
	1 2601 + 2 5010	AST (GOT) + P5P		154 U/L 2.57 µkat/L	119 – 190 U/L 1.98 – 3.17 µkat/L
	1 1601	CK		233 U/L 3.88 µkat/L	186 – 280 U/L 3.11 – 4.66 µkat/L
	1 1641	CK-MB		51.9 U/L 0.865 µkat/L	41.5 – 62.3 U/L 0.692 – 1.04 µkat/L