



Ref. LTR-83452-00-A

Rome, 10/03/2016

**AGGIORNAMENTO VALORI DI RIFERIMENTO****Controlli e Calibratori**

Ri-assegnazione dei valori di riferimento per i controlli TruLab e TruCal U calibratore

Data, 26/02/2016

Prodotti e lotti: TruLab N (cat. No.: 5 9000...) lot. 20270  
TruLab P (Cat. No.: 5 9050...) lot. 20271  
TruLab Protein Level 1 (cat. No.:5 9500...) lotti 19360 e 20381  
TruLab Protein Level 2 (cat. No.:5 9510...) lotti 19361 e 20382  
TruLab Urine Level 1 (cat. No.:5 9170...) lotti 21056 e 20541  
TruLab Urine Level 2 (cat. No.: 5 9180...) lotti 21057 e 20542  
TruCal U (cat. No.: 5 9100...) lot. 20695

Spiegazione i test interni effettuati in base al programma di controllo della qualità hanno mostrato che alcuni valori di riferimento per i suddetti prodotti devono essere ri-assegnati.

**Impatto sui**

risultati dei pazienti Per i TruLab controlli: nessun impatto sui risultati dei pazienti.  
Per i TruCal U calibratori lot. 20695: i valori di calibrazione per AST/GPT devono essere ri-assegnati da 105 U/L a 99,8 U/L (-5%). Usando questo nuovo valore di calibrazione anche i risultati dei pazienti saranno slittati del - 5%.

Misure sostituire i valori di calibrazione precedentemente utilizzati ed usare come riferimento i nuovi valori allegati a questa nota ed informare tutti gli utenti che sono coinvolti.

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

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

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