

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable against the original IFCC [International Federation of Clinical Chemistry and Laboratory Medicine] formulation from 1998. Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Performance Characteristics

Serum/Plasma

Measuring range from 6 U/L up to 2500 U/L. Linearity < 15 U/L is given within ± 3 U/L, linearity from 15 U/L up to 40 U/L within $\pm 10\%$, linearity > 40 U/L within $\pm 5\%$.
In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection***	4 U/L
Limit of quantitation***	6 U/L
Onboard stability	12 weeks
Calibration stability	3 weeks

Interference by	Interferences $\leq 10\%$ up to	Analyte concentration [U/L]
Ascorbic acid	36 mg/dL	50.3
	36 mg/dL	204
Bilirubin (conjugated)	40 mg/dL	53.3
	75 mg/dL	208
Bilirubin (unconjugated)	50 mg/dL	53.6
	70 mg/dL	197
Hemolysis	24 mg/dL	33.8
	600 mg/dL	219
Lipemia (triglycerides)	1700 mg/dL	46.7
	1700 mg/dL	225

For further information on interfering substances, refer to the literature [7-9].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	21.7	109	279
CV [%]	1.17	0.634	0.798
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	28.6	107	311
CV [%]	3.02	3.23	4.22
Reproducibility (n=75, no. of instruments=3)	Sample 1	Sample 2	Sample 3
Mean [U/L]	54.2	109	1542
CV [%]	3.26	2.74	1.95

Urine

Measuring range 6 U/L up to 2500 U/L. Linearity < 15 U/L is given within ± 3 U/L, linearity from 15 U/L up to 40 U/L within $\pm 10\%$, linearity > 40 U/L within $\pm 5\%$.
In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection***	4 U/L
Limit of quantitation***	6 U/L
Onboard stability	12 weeks
Calibration stability	3 weeks

Interference by	Interferences $\leq 10\%$ up to	Analyte concentration [U/L]
Ascorbic acid	300 mg/dL	255
	300 mg/dL	944
Boric acid	300 mg/dL	245
	300 mg/dL	991
Glucose	2400 mg/dL	269
	2400 mg/dL	912
Protein	320 mg/dL	244
	320 mg/dL	898
Sodium-Oxalate	58 mg/dL	214
	70 mg/dL	913
Urobilinogen	43 mg/dL	252
	43 mg/dL	904

For further information on interfering substances, refer to the literature [7-9].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	42.0	456	1955
CV [%]	0.781	0.475	0.666
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [U/L]	40.6	441	1892
CV [%]	1.41	2.16	2.23
Reproducibility (n=75, no. of instruments=3)	Sample 1	Sample 2	Sample 3
Mean [U/L]	102	482	1577
CV [%]	1.53	1.27	1.20

Serum/Plasma/Urine

Method comparison (n=172)	
Test x	Competitor α -Amylase (cobas c 501)
Test y	DiaSys α -Amylase CC FS (respons [®] 940)
Slope	0.928
Intercept	-1.01 U/L
Coefficient of correlation	0.999

*** according to CLSI document EP17-A2, Vol. 32, No. 8

Conversion Factor

α -Amylase [U/L] x 0.0167 = α -Amylase [μ kat/L]

Reference Range [10]

	Women	Men
Serum/Plasma	< 100 U/L	< 100 U/L
	< 1.67 μ kat/L	< 1.67 μ kat/L
Urine	< 447 U/L	< 491 U/L
	< 7.45 μ kat/L	< 8.18 μ kat/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Moss DW, Henderson AR. Digestive enzymes of pancreatic origin. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company;1999, p.689-98.
2. Thomas L. Clinical Laboratory Diagnostics [Internet]; 2020 [cited 2023 Jun 19]. Available from: <https://www.clinical-laboratory-diagnostics-2020.com/>.
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4. Schumann G, Aoki R, Ferrero CA et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37°C. Clin Chem Lab Med 2006; 44(9): 1146-1155.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
6. Guder WG, da Fonseca-Wollheim F, Heil W, Schmitt Y, Töpfer G, Wissler H, Zawta B. Quality of Diagnostic Samples. 3rd edition; 2010. p. 32-3. p. 66-7.
7. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
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9. Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem. 2001 Jul;38:376-85.
10. Junge W, Wortmann W, Wilke B, Waldenstroem J et al. Development and evaluation of assays for determination of total and pancreatic amylase at 37°C according to the principle recommended by the IFCC. Clin Biochem 2001; 34: 607-15.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



DiaSys Diagnostic Systems GmbH
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www.diasys-diagnostics.com

* Complete Color

** Fluid Stable

α-Amylase CC FS

Application for serum, plasma and urine

Test Details		Test Volumes		Reference Ranges	
Test	: AMY			Auto Rerun	<input type="checkbox"/>
Report Name	: α-Amylase CC			Online Calibration	<input type="checkbox"/>
Unit	: U/L	Decimal Places	: 1	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 415	Secondary	: 700	Special Diluent	<input type="checkbox"/>
Assay Type	: RATE-A	Curve Type	: Linear	Warn after	: 20
M1 Start	: 0	M1 End	: 0	Reagents Used	: 2
M2 Start	: 51	M2 End	: 57	Reagent R1	AMY R1
Sample Replicates	: 1	Standard Replicates	: 2	Reagent R2	AMY R2
Control Replicates	: 1	Control Interval	: 0	Consumables/Calibrators:	
Reaction Direction	: Increasing	React. Abs. Limit	: 2.5000	Blank /Level 0	0
Prozone Limit %	: 0	Prozone Check	: Lower	Calibrator 1	*
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	Calibrator 2	
Technical Minimum	: 6.0000	Technical Maximum	: 2500.0000	Calibrator 3	
Y = aX + b a=	: 1.0000	b=	: 0.0000	Calibrator 4	
Reagent Abs Min	: 0.0000	Reagent Abs Max	: 0.0000	Calibrator 5	

Test Details		Test Volumes		Reference Ranges	
Test	: AMY				
Sample Type	: Serum				
Sample Volumes				Sample Types	
Normal	: 3.00 μL	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum	
Increase	: 6.00 μL	Dilution Ratio	: 1 X	<input type="checkbox"/> Urine	
Decrease	: 2.00 μL	Dilution Ratio	: 1 X	<input type="checkbox"/> CSF	
				<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	
Standard Volume	: 3.00 μL				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 160.00 μL	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 40.00 μL	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: AMY				
Sample Type	: Urine				
Sample Volumes				Sample Types	
Normal	: 3.00 μL	Dilution Ratio	: 1 X	<input type="checkbox"/> Serum	
Increase	: 6.00 μL	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Urine	
Decrease	: 2.00 μL	Dilution Ratio	: 1 X	<input type="checkbox"/> CSF	
				<input type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	
Standard Volume	: 3.00 μL				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 160.00 μL	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 40.00 μL	R2 Stirrer Speed	: High		

Test Details	Test Volumes	Reference Ranges															
Test : <input style="width: 100%;" type="text" value="AMY"/>																	
Sample Type : <input style="width: 50%;" type="text" value="Serum**"/> <input style="width: 50%;" type="text" value="Urine**"/>																	
Reference Range : <input style="width: 100%;" type="text" value="DEFAULT"/>																	
Category : <input style="width: 100%;" type="text" value="Male"/>																	
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* Enter calibrator value
 ** Specimen selected by user
 # Editable by user