

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the Molar Extinction Coefficient. Use DiaSys TruLab N and P 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

Performance Characteristics

Measuring range up to 2000 U/L. In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection***	2 U/L
Onboard stability	4 weeks
Calibration stability	4 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	80.8
Bilirubin (conjugated)	60 mg/dL	83.0
Bilirubin (unconjugated)	60 mg/dL	85.0
Lipemia (triglycerides)	1800 mg/dL	36.6

Hemoglobin interferes at low concentrations.
For further information on interfering substances, refer to Young DS [8,9].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	39.5	149	234
CV [%]	2.19	2.18	1.35
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	38.9	145	218
CV [%]	2.86	2.47	3.73

Method comparison (n=115)	
Test x	DiaSys Pancreatic amylase CC FS (Hitachi 917)
Test y	DiaSys Pancreatic amylase CC FS (respons [®] 920)
Slope	1.01
Intercept	-0.650 U/L
Coefficient of correlation	0.999

*** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor

Pancreatic amylase [U/L] x 0.0167= Pancreatic amylase [µkat/L]

Reference Range [10]

	Women	Men
Serum/Plasma	< 53 U/L	< 53 U/L
	< 0.88 µkat/L	< 0.88 µkat/L

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

Literature

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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
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Complete Color

** Fluid Stable

Pancreatic amylase CC FS

Application for serum and plasma

Test Details		Test Volumes		Reference Ranges	
Test	: PAMY			Auto Rerun	<input type="checkbox"/>
Report Name	: Pancreatic Amylase			Online Calibration	<input type="checkbox"/>
Unit	: U/L	Decimal Places	: 1	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 405	Secondary	: 700	Total Reagents	: 2
Assay Type	: RATE - A	Curve Type	: Linear	Reagent R1	: PAMY R1
M1 Start	: 0	M1 End	: 0	Reagent R2	: PAMY R2
M2 Start	: 26	M2 End	: 33		
Sample Replicates	: 1	Standard Replicates	: 3	Consumables/Calibrators:	
Control Replicates	: 1	Control Interval	: 0	Blank/Level 0	: 0
Reaction Direction	: Increasing	React. Abs. Limit	: 2.50	Calibrator 1	: *
Prozone Limit %	: 0	Prozone Check	: Lower		
Linearity Limit %	: 0	Delta Abs./Min.	: 0.00		
Technical Minimum	: 2.00	Technical Maximum	: 2000.00		
Y = aX + b	a = 1.00	b =	0.00		

* Enter calibrator value.

Test Details		Test Volumes		Reference Ranges	
Test	: PAMY				
Sample Type	: Serum				
Sample Volumes				Sample Types	
Normal	: 4.00 μ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
Increase	: 8.00 μ L	Dilution Ratio	: 1 X		
Decrease	: 2.00 μ L	Dilution Ratio	: 1 X		
Standard Volume	: 4.00 μ L				
Reagent Volumes and Stirrer Speed					
RGT-1 Volume	: 160 μ L	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 40 μ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: PAMY				
Sample Type	: Serum				
Reference Range	: DEFAULT				
Category	: Male				
Reference Range				Sample Types	
	Lower Limit		Upper Limit	<input checked="" type="checkbox"/> Serum <input type="checkbox"/> Urine <input type="checkbox"/> CSF <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other	
	(U/L)		(U/L)		
Normal	: #		#		
Panic	: #		#		

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