

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

Serum/Plasma

Measuring range up to 1740 U/L. Linearity is given within ± 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***	2 U/L
Onboard stability	6 weeks
Calibration stability	6 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [U/L]
Ascorbic acid	30 mg/dL	23.5
Bilirubin (conjugated)	54 mg/dL	24.0
Bilirubin (unconjugated)	54 mg/dL	23.7
Hemolysis	600 mg/dL	37.1
Lipemia (triglycerides)	2000 mg/dL	25.3

For further information on interfering substances, refer to the literature [9,10].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	26.3	115	252
CV [%]	0.897	0.645	0.609
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	44.9	142	247
CV [%]	1.40	0.859	0.591

Method comparison (n=135)	
Test x	DiaSys Pancreatic amylase CC FS (Hitachi 917)
Test y	DiaSys Pancreatic amylase CC FS (BioMajesty® JCA-BM6010/C)
Slope	1.01
Intercept	0.958 U/L
Coefficient of correlation	0.999

Urine

Measuring range up to 3480 U/L. Linearity is given within ± 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
Onboard stability	6 weeks
Calibration stability	6 weeks

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	43.6	124	80.6
CV [%]	0.806	1.53	0.373
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	43.9	125	81.1
CV [%]	1.41	1.95	1.58

Method comparison (n=100)	
Test x	DiaSys Pancreatic amylase CC FS (Hitachi 917)
Test y	DiaSys Pancreatic amylase CC FS (BioMajesty® JCA-BM6010/C)
Slope	1.03
Intercept	-2.99 U/L
Coefficient of correlation	0.999

Conversion Factor

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

Reference Range [11]

	Women	Men
Serum/Plasma	< 53 U/L	< 53 U/L
	< 0.88 µkat/L	< 0.88 µkat/L
Urine	< 319 U/L	< 356 U/L
	< 5.3 µkat/L	< 5.9 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.



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* Complete Color

** Fluid Stable

Pancreatic amylase CC FS

Chemistry code 10 055

Application for serum, plasma, urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	2
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	PAMY
Digits	1
M-wave L.	410
S-wave.L	694
Analy.mthd.	RRA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	2	1
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re. absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	21
M-DET.P.m	32
M-DET.P.n	42
S-DET.P.p	0
S-DET.P.r	0
Check D.P.l.	21
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	1.6
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999