



## Performances

Les données exemplaires citées en bas peuvent varier légèrement en cas de conditions de mesure déviantes.

Domaine de mesure jusqu'à 2000 U/L. En cas d'activité plus élevée, mesurer les spécimens une seconde fois après une dilution manuelle avec du NaCl (9 g/L) ou avec la fonction rerun.	
Limite de détection***	3 U/L
Stabilité à bord de l'analyseur	4 semaines
Stabilité de calibration	2 semaines

Substance interférente	Interférences ≤ 10 % jusqu'à	Concentration de l'analyte [U/L]
<b>Acide ascorbique</b>	30 mg/dL	96,3
<b>Bilirubine</b> (conjuguée)	70 mg/dL	86,3
	70 mg/dL	194
<b>Bilirubine</b> (non conjuguée)	70 mg/dL	84,3
	70 mg/dL	192
<b>Hémoglobine</b>	550 mg/dL	63,6
	550 mg/dL	229
<b>Lipémie</b> (Triglycérides)	1000 mg/dL	82,4
	1000 mg/dL	150

Pour plus d'information au sujet des interférences, voir Young DS [7,8].

Précision			
Intra série (n=20)	Échantillon 1	Échantillon 2	Échantillon 3
Moyenne [U/L]	77,3	526	914
CV [%]	1,64	1,80	1,26
Inter série (n=20)	Échantillon 1	Échantillon 2	Échantillon 3
Moyenne [U/L]	73,1	475	933
CV [%]	2,63	2,12	2,21

Comparaison de méthodes (n=118)	
Test x	α-Amylase CC FS de DiaSys (Hitachi 917)
Test y	α-Amylase CC FS de DiaSys (respons <sup>®</sup> 910)
Pente	0,967
Ordonnée à l'origine	0,766 U/L
Coefficient de corrélation	0,999

\*\*\* selon CLSI, document EP17-A, Vol. 24, No. 34

## Facteur de Conversion

α-Amylase [U/L] x 0,0167 = α-Amylase

## Valeurs Usuelles [9]

	Femmes	Hommes
<b>Sérum/Plasma</b>	< 100 U/L	< 100 U/L
	< 1,67 µkat/L	< 1,67 µkat/L

Chaque laboratoire devrait vérifier si les valeurs usuelles sont transmissibles à sa propre population patiente et déterminer ses propres valeurs de référence si besoin.

## Références Bibliographiques

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\* Complete Color = Coloration Complète

\*\* Fluid Stable = Liquide & Stable

## α-Amylase CC FS

### Application for serum and plasma 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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	AMY
Shortcut:	
Reagent barcode reference:	015
Host reference:	

Technic	
Type:	Linear kinetic
First reagent:[μL]	160
Blank reagent	Yes
Sensitive to light	
Second reagent:[μL]	40
Blank reagent	Yes
Sensitive to light	
Main wavelength:[nm]	405
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
1 st reading time [min:sec]	07:48
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance li	1.0000
Linearity: Maximum deviation [%]	100
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [μL]	0 (no hemolysis)
Cleaner	
Sample [μL]	0
Technical limits	
Concentration technical limits-Lower	3
Concentration technical limits-Upper	2000
SERUM	
Normal volume [μL]	3
Normal dilution (factor)	1
Below normal volume [μL]	6
Below normal dilution (factor)	1
Above normal volume [μL]	3
Above normal dilution (factor)	6
URIN	
Normal volume [μL]	3
Normal dilution (factor)	1
Below normal volume [μL]	6
Below normal dilution (factor)	1
Above normal volume [μL]	3
Above normal dilution (factor)	6
PLASMA	
Normal volume [μL]	3
Normal dilution (factor)	1
Below normal volume [μL]	6
Below normal dilution (factor)	1
Above normal volume [μL]	3
Above normal dilution (factor)	6
CSF	
Normal volume [μL]	3
Normal dilution (factor)	1
Below normal volume [μL]	6
Below normal dilution (factor)	1
Above normal volume [μL]	3
Above normal dilution (factor)	6
Whole blood	
Normal volume [μL]	3
Normal dilution (factor)	1
Below normal volume [μL]	6
Below normal dilution (factor)	1
Above normal volume [μL]	3
Above normal dilution (factor)	6

Results	
Decimals	1
Units	U/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	All
Age	
SERUM	>= <=100
URINE	
PLASMA	>= <=100
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.001
Cal. 2	0.003
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X
Degree	1

\* Enter calibrator value