respons®910

Phospholipids FS*

Diagnostic reagent for quantitative in vitro determination of choline-containing phospholipids in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 5741 99 10 921
4 twin containers for 120 tests each

Method

Enzymatic colorimetric test

Principle

$$\text{Phosphatidyl choline} + H_2O \xrightarrow{\text{Phospholipase D}} \text{Choline} + \text{Phosphatidic acid}$$

$$\text{Choline} + 2\ O_2 + H_2O \xrightarrow{\text{Choline oxidase}} \text{Betaine} + 2\ H_2O_2$$

$$2\ H_2O_2 + \text{4-Aminoantipyrine} + \text{TBHBA} \xrightarrow{\text{Peroxidase}} \text{Chinone dye} + 4\ H_2O$$

Reagents

Components and Concentrations

R1:	Tris buffer	pH 8.0	75 mmol/L
	TBHBA		3 mmol/L
	Choline oxidase		≥ 3 kU/L
R2:	Tris buffer	pH 8.0	75 mmol/L
	4-Aminoantipyrine		6 mmol/L
	Peroxidase		≥ 30 kU/L
	Phospholipase D		≥ 3.0 kU/L

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. The reagents contain biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent trays. Avoid formation of foam. Do not shake the reagents.

Specimen

Serum and plasma

Stability [4]

5 days	at	20 – 25°C
1 month	at	2 – 8°C
1 month	at	–20°C

Discard contaminated specimen. Freeze only once.

Calibrators and Controls

For calibration the DiaSys TruCal Lipid calibrator or the Phospholipids Standard FS is recommended. The assigned values of the calibrator or standard are traceable to a primary standard material. For internal quality control DiaSys TruLab L control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
Phospholipids Standard FS	1 5740 99 10 041	3 x 1 mL
TruCal Lipid	1 3570 99 10 045	3 x 2 mL
TruLab L Level 1	5 9020 99 10 065	3 x 3 mL
TruLab L Level 2	5 9030 99 10 065	3 x 3 mL

Performance Characteristics

Measuring range up to 10.7 mmol/L (829 mg/dL) phospholipids (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	0.09 mmol/L (6.98 mg/dL) phospholipids
On-board stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences < 10%	Phospholipids [mmol/L]
Ascorbate	up to 30 mg/dL	2.39
Hemoglobin	up to 600 mg/dL	1.47
	up to 600 mg/dL	2.77
Bilirubin, conjugated	up to 25 mg/dL	1.04
	up to 30 mg/dL	2.87
Bilirubin, unconjugated	up to 65 mg/dL	1.00
	up to 50 mg/dL	2.77
Lipemia (triglycerides)	up to 2000 mg/dL	0.96
	up to 2000 mg/dL	2.66
For further information on interfering substances refer to Young DS [1].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	0.94	2.30	3.78
Mean [mg/dL]	72.9	178	293
Coefficient of variation [%]	2.48	2.07	1.73
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	0.66	2.16	3.76
Mean [mg/dL]	51.2	167	291
Coefficient of variation [%]	3.73	2.63	3.02

Method comparison (n=134)	
Test x	DiaSys Phospholipids FS (Hitachi 917)
Test y	DiaSys Phospholipids FS (respons®910)
Slope	1.028
Intercept	–0.002 mmol/L (-0.155 mg/dL)
Coefficient of correlation	0.999

** according to NCCLS document EP17-A. vol. 24. no. 34

Conversion factor

Phospholipids [mg/dL] x 0.0129 = Phospholipids [mmol/L]

Reference Range [2]

Serum/Plasma	mmol/L	mg/dL
Newborn:	0.90 – 2.19	70 – 170
Infant:	1.29 – 3.55	100 – 275
Child:	2.32 – 3.81	180 – 295
Adult:	1.61 – 3.55	125 – 275

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

Literature

1. 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.
2. Pennell C. et al. Reference information for the clinical laboratory. In: Burtis CA. Ashwood ER. editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1788-1846.
3. Subbajah P.V. Determination and Clinical Significance of Phospholipids. In Rifai N. Warnick G.R Dominiczak M.H. Handbook of lipoprotein testing. 2 nd ed. AACC Press 2000. p. 521-36.
4. Hilbert T. Lifshitz MS. Lipids and Dyslipoproteinemia. In: Clinical diagnosis and management by laboratory methods. 21st ed. Philadelphia. Saunders Elesevier 2007. p. 200-218.
5. Data on file at DiaSys Diagnostic Systems GmbH.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45()): 1240–1243.

Manufacturer

DiaSys Diagnostic Systems GmbH
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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:	PL
Shortcut:	
Reagent barcode reference:	061
Host reference:	061

Technic	
Type:	End point
First reagent:[µL]	200
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	50
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	570
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
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	0.0900
Concentration technical limits-Upper	10.7000
SERUM	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	2.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	mmol/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	>=1.61 <=3.55
URINE	
PLASMA	>=1.61 <=3.55
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	0.004
Cal. 2	0.030
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value