BioMajesty

Phospholipids FS*

Diagnostic reagent for quantitative in vitro determination of choline-containing phospholipids in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 5741 99 10 964
R1: 6 x 70 tests
R2: 6 x 70 tests

Method

Enzymatic colorimetric test

Principle

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

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

2 H_2O_2 + 4-Aminoantipyrine + TBHBA $\xrightarrow{\text{Peroxidase}}$ 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. 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. Only freeze once.

Calibrators and Controls

For calibration, the DiaSys TruCal Lipid or DiaSys 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
TruCal Lipid	1 3570 99 10 045	3 x 2 mL
Phospholipids Standard FS	1 5740 99 10 041	3 x 1 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 12.8 mmol/L (992 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**	0.08 mmol/L (6.2 mg/dL) phospholipids
On-board stability	9 days
Calibration stability	2 days

Interferences < 10% by
Ascorbate up to 30 mg/dL
Conjugated bilirubin up to 60 mg/dL
Unconjugated bilirubin up to 60 mg/dL
Hemoglobin up to 500 mg/dL
Lipemia (Intralipid®) up to 1200 mg/dL
For further information on interfering substances refer to Young DS [5].

Precision in serum/plasma			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	0.70	1.83	3.70
Mean [mg/dL]	54.0	142	287
Coefficient of variation [%]	1.62	1.07	0.88
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	0.68	1.83	3.63
Mean [mg/dL]	52.9	142	281
Coefficient of variation [%]	3.07	1.31	0.80

Method comparison in serum/plasma (n=126)	
Test x	DiaSys Phospholipids FS (Hitachi 917)
Test y	DiaSys Phospholipids FS (BioMajesty)
Slope	1.05
Intercept	–0.042 mmol/L (–3.26 mg/dL)
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

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

Reference Range [1]

	mmol/L	mg/dL
Serum/Plasma		
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.

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Literature

1. 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.
2. 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
3. Hilbert T, Lifshitz MS. Lipids and Dyslipoproteinemia. In: Clinical diagnosis and management by laboratory methods. 21st ed. Philadelphia. Saunders Elesevier 2007. p. 200-218
4. Data on file at DiaSys Diagnostic Systems GmbH.
5. 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.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45()): 1240–1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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BioMajesty

Phospholipids FS

Chemistry code 10 574

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.

Analytical Conditions	
R1 volume	120
R2e volume	0
R2 volume	30
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1
Sample vol (U)	1
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	PL
Digits	2
M-wave L.	571
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1	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.I	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

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