respons®920

Prealbumin FS*

Diagnostic reagent for quantitative in vitro determination of prealbumin in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 0292 99 10 921
4 twin containers for 100 determinations each

Method

Immunoturbidimetric test

Principle

Determination of prealbumin concentration by photometric measurement of antigen-antibody-reaction between antibodies against prealbumin and prealbumin present in the sample

Reagents

Components and Concentrations

R1:	TRIS	pH 7.5	100 mmol/L
	NaCl		50 mmol/L
R2:	TRIS	pH 7.8	150 mmol/L
	NaCl		450 mmol/L
	Antibodies (goat) against human prealbumin		< 1%

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. Reagent 1: Warning. H319 Causes serious eye irritation. P280 Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/ attention.
2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
3. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
4. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
5. In very rare cases, samples of patients with gammopathy might give falsified results [7].
6. 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.
7. 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 rotor.

Specimen

Serum, heparin plasma or EDTA plasma

If contaminations are avoided the stability is [1]:

3 days	at	2 – 8°C
6 months	at	–20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys TruCal Protein calibrator set is recommended for calibration. The assigned values of the calibrator have been made traceable to the ERM®-DA470k/IFCC reference material. For internal quality control, a DiaSys TruLab Protein control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal Protein (5 levels)	5 9200 99 10 039	5 x 1 mL
TruLab Protein Level 1	5 9500 99 10 046	3 x 1 mL
TruLab Protein Level 2	5 9510 99 10 046	3 x 1 mL

Performance Characteristics

Measuring range up to 1.5 g/L prealbumin, at least up to the concentration of the highest calibrator (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	0.02 g/L prealbumin
No prozone effect up to 2.6 g/L prealbumin	
On-board stability	12 weeks
Calibration stability	6 weeks

Interferences < 10% by
Conjugated bilirubin up to 40 mg/dL
Unconjugated bilirubin up to 35 mg/dL
Hemoglobin up to 100 mg/dL
Rheumatoid factor up to 500 IU/mL
Lipemia (triglycerides) up to 2000 mg/dL
For further information on interfering substances refer to Young DS [2].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.141	0.347	0.494
Coefficient of variation [%]	3.64	2.18	2.88
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/L]	0.150	0.335	0.520
Coefficient of variation [%]	4.83	3.64	3.37

Method comparison (n=118)	
Test x	DiaSys Prealbumin FS (Hitachi 917)
Test y	DiaSys Prealbumin FS (respons®920)
Slope	1.025
Intercept	–0.013 g/L
Coefficient of correlation	0.998

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

Conversion factor

Prealbumin [g/L] x 18.2 = Prealbumin [µmol/L]

Reference Range [3]

Serum/Plasma: 0.2 – 0.4 g/L (200 – 400 mg/L)

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

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 40-1.
2. 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.
3. Dati F et al. Consensus of a Group of Professional Societies and Diagnostic Companies on Guidelines for Interim Reference Ranges for 14 Proteins in Serum Based on the Standardization Against the IFCC/BCR/CAP Reference Material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
4. Dati F, Metzmann E. Proteins Laboratory Testing and Clinical Use. Holzheim: DiaSys; 2005. p. 42, 333-4.
5. Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W. B. Saunders Company; 1999. p. 500, 1144, 1384-5.
6. Beck FK, Rosenthal TC. Prealbumin: A Marker for Nutritional Evaluation. American Family Physician 2002; 65 (8): 1575-8.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE

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* fluid stable

respons®920

Prealbumin FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	PALB				Auto Rerun		☐
Report Name	:	Prealbumin				Online Calibration		☐
Unit	:	g/L	Decimal Places	:	3	Cuvette Wash		☐
Wavelength-Primary	:	405	Secondary	:	700	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Cubic Spline	Reagent R1	:	PALB R1
M1 Start	:	15	M1 End	:	15	Reagent R2	:	PALB R2
M2 Start	:	33	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	:	*	Calibrator Level 1	:	**
Prozone Limit %	:	97	Prozone Check	:	Lower	Calibrator Level 2	:	**
Linearity Limit %	:	0	Delta Abs./Min.	:	0.00	Calibrator Level 3	:	**
Technical Minimum	:	*	Technical Maximum	:	*	Calibrator Level 4	:	**
Y = aX + b a=	:	1.00	b=	:	0.00	Calibrator Level 5	:	**

*Technical limits are automatically defined by the software via the upper and lower calibrator level.

** Enter calibrator value.

Test Details			Test Volumes			Reference Ranges
Test	:	PALB				
Sample Type	:	Serum				

Sample Volumes

Normal	:	2.00 µL	Dilution Ratio	:	1 X	
Increase	:	6.00 µL	Dilution Ratio	:	1 X	
Decrease	:	2.00 µL	Dilution Ratio	:	2 X	
Standard Volume	:	2.00 µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	200 µL	R1 Stirrer Speed	:	High
RGT-2 Volume	:	40 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	PALB		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (g/L)	Upper Limit (g/L)
Normal	:	0.20	0.40
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other