respons®910

# Prealbumin FS*

**Diagnostic reagent for quantitative in vitro determination of prealbumin in serum or plasma on DiaSys respons®910**

## Order Information

**Cat. No. 1 0292 99 10 921**
4 twin containers for 100 tests 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. In very rare cases, samples of patients with gammopathy might give falsified results [7].
5. To avoid contamination and carryover, special care should be taken in combination with Ferritin SR reagent.
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 1.17 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** | 0.01 g/L prealbumin |
| No prozone effect up to 2.9 g/L prealbumin | |
| On-board stability | 6 weeks |
| Calibration stability | 5 days |

| Interfering substance | Interferences < 10% | Prealbumin [g/L] |
|---|---|---|
| **Hemoglobin** | up to 250 mg/dL | 0.245 |
| | up to 250 mg/dL | 0.534 |
| **Bilirubin, conjugated** | up to 30 mg/dL | 0.229 |
| | up to 45 mg/dL | 0.526 |
| **Bilirubin, unconjugated** | up to 40 mg/dL | 0.248 |
| | up to 45 mg/dL | 0.539 |
| **Lipemia** (triglycerides) | up to 2000 mg/dL | 0.246 |
| | up to 2000 mg/dL | 0.516 |
| **Rheumatoid factor** | up to 700 IU/mL | 0.332 |
| 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] | 0.157 | 0.233 | 0.458 |
| Coefficient of variation [%] | 2.64 | 3.51 | 1.46 |
| **Between run (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [g/L] | 0.199 | 0.292 | 0.492 |
| Coefficient of variation [%] | 3.28 | 2.24 | 2.59 |

| **Method comparison (n=136)** | |
|---|---|
| Test x | DiaSys Prealbumin FS (Hitachi 911) |
| Test y | DiaSys Prealbumin FS (respons®910) |
| Slope | 0.992 |
| Intercept | –0.015 g/L |
| Coefficient of correlation | 0.995 |

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

## 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. Clin Chem Lab Med 2007; 45()): 1240–1243.


## Manufacturer


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respons®910

# Prealbumin 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: | PALB |
| Shortcut: | |
| Reagent barcode reference: | 712 |
| Host reference: | 712 |

| Technic | |
|---|---|
| Type: | End point |
| First reagent:[µL] | 200 |
| Blank reagent | Yes |
| Sensitive to light | |
| Second reagent:[µL] | 40 |
| Blank reagent | No |
| Sensitive to light | |
| Main wavelength:[nm] | 380 |
| Secondary wavelength:[nm] | 700 |
| Polychromatic factor: | 1.0000 |
| 1 st reading time [min:sec] | (04:24) |
| Last reading time [min:sec] | 10:00 |
| Reaction way: | Increasing |
| Linear Kinetics<br>Substrate depletion: Absorbance limit | |
| Linearity: Maximum deviation [%] | |
| Fixed Time Kinetics<br>Substrate depletion: Absorbance limit | |
| Endpoint<br>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 | 0.0100 |
| Concentration technical limits-Upper | 1.1700 |
| 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 | 3 |
| Units | g/L |
| Correlation factor-Offset | 0.0000 |
| Correlation factor-Slope | 1.0000 |

| Range | |
|---|---|
| Gender | All |
| Age | |
| SERUM | >=0.200 <=0.400 |
| URINE | |
| PLASMA | >=0.200 <=0.400 |
| 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 | 0.0100 |
| Cal. 2 | 0.0100 |
| Cal. 3 | 0.0100 |
| Cal. 4 | 0.0100 |
| Cal. 5 | 0.0100 |
| Cal. 6 | 0.0100 |
| Drift limit [%] | 2.00 |

| Calculations | |
|---|---|
| Model | Akima Spline |
| Degree | |

* Enter calibrator value