

# Bioway Chemistry Reagent Series

## The Serum Prealbumin Detection Kit

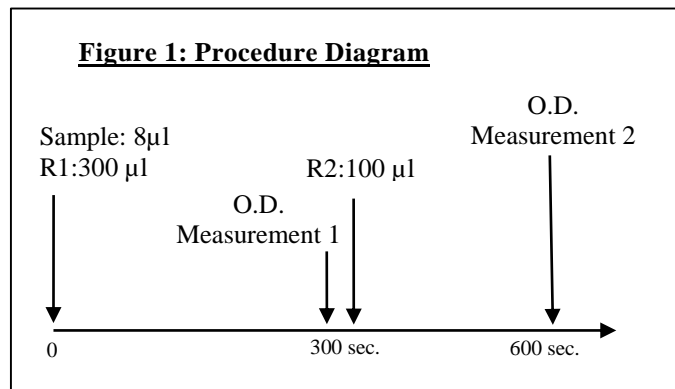
Detection of Prealbumin in Human Serum or plasma on Chemistry Analyzers



Cat. No. R047K11

Prealbumin Detection Kit

### SUMMARY OF TEST PROCEDURE



\*Refer to Figure 1 and the package insert for detail

**Table 1: Instrument Parameters\***

Calibration method	5 point non-linear	Slope of reaction	increase
Wavelength	Pr:340 nm Se: 700 nm	Sample volume	8 µl
Test method	2 point end	R1 volume	300 µl
Reaction temperature	37°C	R2 volume	100 µl

### INTENDED USE

**Bioway Chemistry Reagent Series Prealbumin Reagent Kit** (the Kit) is an immunoturbidimetric assay intended for *in vitro* quantitative detection of prealbumin (PALB) in human serum on automated clinical chemistry analyzers.

### SUMMARY AND EXPLANATION

Prealbumin (transthyretin) transports the thyroid hormones thyroxin and triiodothyronine, and also vitamin A through an association with retinol-binding protein. PALB is a negative acute phase reactant with decreased levels found in inflammation, malignancy, cirrhosis of liver, and protein-wasting diseases of the gut or kidneys. Increased levels of PALB have been reported in Hodgkinson's disease. PALB can be used as an indicator of nutritional status due to its fast response to protein deficiency, its short half-life and the abundance of tryptophan and a high essential to non-essential amino acid ratio.

### TEST PRINCIPLES

The Kit utilizes immunoturbidimetry to measure the prealbumin level in human serum or plasma. During the test, PALB in the sample binds with the specific anti-PALB antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of PALB in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

### MATERIALS PROVIDED

#### Reagents:

<b>R1</b>	Polyethylene Glycol-6000, buffer, Sodium azide < 0.1%
<b>R2</b>	anti-PALB antibodies, Polyethylene Glycol-6000, buffer, sodium azide < 0.1%

### MATERIALS NEEDED BUT NOT PROVIDED

- Automated chemistry analyzer.
- PALB calibrator set (available for purchase) and control set (commercially available).

### INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

### STORAGE AND STABILITY

Store the reagents at 2-8°C. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8°C after opening.

### PRECAUTIONS

- The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
- Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

### SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum or Heparin plasma samples.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 8° C for up to 1 days or at -80° C for up to 1 months. Avoid repeated freezing and thawing.

### TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

**Calibration:** 5 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

**Test procedure:** see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

- Add 8 µl of sample and 300 µl of R1; mix well and incubate at 37°C for 300 seconds.
- Take optical density measurement OD 1 just before addition of R2.
- Add 100 µl of R2, mix well and incubate at 37°C.
- Take optical density measurement OD 2 at 600 seconds.
- Calculate  $\Delta OD = OD 2 - OD 1$

### RESULT

The PALB value can be obtained by using the calculated  $\Delta OD$  to find the corresponding value on a calibration curve prepared with known values.

### EXPECTED VALUES

150 - 350 mg/L.

It is recommended for each laboratory to establish its own expected values.

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### QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

### LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

### PERFORMANCE CHARACTERISTICS

**Linearity:** 20 – 560 mg/L ( $R \geq 0.990$ )

**Precision:** Within Run:  $CV \leq 4\%$ ;  
Run-to-Run:  $CV \leq 6\%$

**Interference:** no interference detected for: Bilirubin (200 mg/dL), and hemoglobin (3 g/L).

**Reagent Blank Absorbance:** at 340nm wavelength and 10 mm optical diameter, O.D.  $\leq 0.20$

### REFERENCES

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3. Oppenheimer, J.H., .Role of Plasma Proteins in the Binding, Distribution and Metabolism of the Thyroid Hormones,. N. Engl. J. Med., 278:1153, (1968).
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5. Prealbumin in Nutritional Care Consensus Group. Measurement of visceral protein status in assessing protein and energy malnutrition: standard of care. *Nutrition*. 1995; 11:169–71.

Not Intended for Sale in the United States.

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