AU

Instructions For Use

PALB
Prealbumin

REF OSR6175 4 x 15 mL R1, 4 x 6.5 mL R2

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

Immuno-turbidimetric test for the quantitative determination of prealbumin in human serum on Beckman Coulter AU analysers.

SUMMARY AND EXPLANATION

Reference[1,2]

Prealbumin (transthyretin), a nonglycosylated tetrameric protein composed of four identical subunits is primarily synthesised in the liver. It binds and transports approximately 10% of both serum thyroxine and triiodothyronine and also plays a significant role in the metabolism of vitamin A by complexing with retinol-binding protein. Because of its relatively short half life, a high tryptophan content, a high proportion of essential to non essential amino acids, and small pool size, prealbumin is an excellent indicator of protein status (levels fall during periods of protein malnutrition).It is a negative acute phase reactant whose levels also fall in inflammation and malignancy as well as in cirrhosis of the liver and protein wasting diseases of the gut or kidneys, because of decreased synthesis and to a lesser extent increased degradation. Other acute phase proteins may be assayed to differentiate whether a decrease in prealbumin is due to malnutrition or inflammation. A number of genetic variants have been described of which most are associated with extracelluar deposition of amyloid fibrils in various tissues. Levels of prealbumin increase in Hodgkin's disease.

METHODOLOGY

When a sample is mixed with R1 buffer and R2 antiserum solution, human prealbumin reacts specifically with the anti-human prealbumin antibodies to yield insoluble aggregates. The absorbance of these aggregates is proportional to the prealbumin concentration in the sample.

SPECIMEN

TYPE OF SPECIMEN

Serum

SPECIMEN STORAGE AND STABILITY

Stable for 6 months when stored at 2…8°C and 3 days when stored at 15…25°C.[3]

Strongly lipemic samples should be avoided.

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

Solution of polymers in phosphate buffered saline	(pH 7.1 – 7.3)
Rabbit anti-human prealbumin antibodies	Variable
Preservative	

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

REAGENT PREPARATION

The reagents are ready for use and can be placed directly on board the instrument

REAGENT STORAGE AND STABILITY

The reagents are stable, unopened, up to the stated expiry date when stored at 2…8°C. Once open, reagents stored on board the instrument are stable for 90 days.

CALIBRATION

CALIBRATOR REQUIRED

Prealbumin Calibrator Cat. No. ODR3029.

The calibrator prealbumin values are traceable to IFCC (International Federation of Clinical Chemistry) standard CRM 470.

Recalibrate the assay every 90 days or when the following occur:

Change in reagent lot or significant shift in control values;

Major preventative maintenance was performed on the analyzer or a critical part was replaced

Following calibration, the resulting curve should be visually reviewed, on the Beckman Coulter analyzer, for acceptability using the software options - Routine, Calibration Monitor, Calibration Curve. Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

QUALITY CONTROL

ITA Control Sera ODC0014, ODC0015 and ODC0016 or other control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration/blanking is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

Please note that the recovery of non-Beckman Coulter controls may vary with reagent lots of immunoassay products, due to the use of non-human materials in the controls.

TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement.

CALCULATIONS

The Beckman Coulter analyzers automatically compute the prealbumin concentration of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Reference[4]

Serum (Adults)	0.2 – 0.4 g/L (20 – 40 mg/dL)

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

PROCEDURAL NOTES

LIMITATIONS

Samples with extremely abnormal optical characteristics, especially turbidity, may produce atypical results. Samples containing Intralipid may cause interference in this assay.

INTERFERENCES

Results of studies conducted to evaluate the susceptibility of the method to interference were as follows:

Icterus:	Interference less than 3% up to 40 mg/dL or 684 µmol/L bilirubin
Haemolysis:	Interference less than 3% up to 5 g/L haemoglobin
Lipemia:	Interference less than 10% up to 225 mg/dL Triglyceride (Avian)**

**Measured at prealbumin concentrations of 10 and 40 (+/- 5) mg/dL.

Refer to Young[5] for further information on interfering substances.

PERFORMANCE CHARACTERISTICS

PERFORMANCE CHARACTERISTICS

Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

LINEARITY

The test is linear within a concentration range of 0.03 – 0.8 g/L (3 – 80 mg/dL).

SENSITIVITY

The lowest detectable level in serum on a DxC 700 AU analyser was estimated at 0.002 g/L.

The lowest detectable level represents the lowest measurable level of prealbumin that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

METHODS COMPARISON

Patient serum samples were used to compare this Prealbumin OSR6175 assay on the AU600 against another commercially available prealbumin assay. Results of linear regression analysis were as follows:

y = 0.963x - 0.018	r = 0.974	n = 70	Sample range = 0.05 – 0.40 g/L

PRECISION

The following data was obtained on a DxC 700 AU using 3 serum pools analysed over 20 days.

n = 80	**Within-run**		**Total**	
Mean g/L	**SD**	**CV%**	**SD**	**CV%**
0.19	0.003	1.81	0.003	1.62
0.36	0.005	1.42	0.005	1.46
0.59	0.011	1.82	0.013	2.21

ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	Description
PLB1G	Prealbumin (Serum)

Setting Sheet Footnotes
User defined

† Prealbumin Calibrator Cat. No.: ODR3029

* Values set for working in SI units (g/L). To work in mg/dL multiply by 100.

REVISION HISTORY

Added new languages

Preceding version revision history

IFU updated to add Vietnamese language.

Updated Additional Information section

REFERENCES

1. Johnson AM, Rohlfs EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia:WB Saunders Company, 1999;500-501.

2. Tietz NW, ed. Clinical guide to laboratory tests, 3rd ed. Philadelphia: WB Saunders Company,1995:608-609.

3. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B, et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. WHO/DIL/LAB/99.1 Rev.2:39pp.

4. Baudner S, Dati F. Standardization of the measurement of 14 proteins in human serum based on the new IFCC/BCR/CAP International reference material CRM 470. J Lab Med 1996;20:145-152.

5. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

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