Prealbumin Assay Kit
（PALB）

Method: Immunoturbidimetric

Cat . No.	Size	Instrument
GB630M	R1:3×20 ml R2:1×20 ml	For Hitachi 717 &ShimadzuCL7200/8000
GS631M	R1:3×20 ml R2:1×20 ml	For Hitachi917 &OlympusAU640/400/600
GT631M	R1:3×20 ml R2:1×20 ml	For TOSHIBA
GB630M/B	R1:3×60 ml R2:3×20 ml	For Hitachi 717 &ShimadzuCL7200/8000
GS631M/B	R1:3×60 ml R2:3×20 ml	For Hitachi917 &OlympusAU640/400/600
GD631M	R1:8×3.8 ml R2:4×2.6 ml	For DATE DIMENSION

INTENDED USE
For the i*n vitro* quantitative determination of Prealbumin (transthyretin) in human serum.

CLINICAL SIGNIFICANCE[1,2,3]
Prealbumin (transthyretin) is a tryptophan-rich 55KDa protein synthesized in liver hepatocytes and functions primarily as a binding and transport protein. The small body pool, short half-life and easy quantification on existing laboratory equipment make Prealbumin the preferred marker of visceral protein status. Measurement of Prealbumin levels in serum may aid in the assessment of the nutritional status of the patient.

ASSAY PRINCIPLE
Neat sample is incubated with assay buffer before the addition of antibody reagent, specific for human prealbumin. The absorbance of the resulting turbid solution is read at 340 nm and is proportional to the concentration of prealbumin in the sample. By constructing a standard curve from the absorbance of known standards, the actual concentration of prealbumin in the sample can be determined.

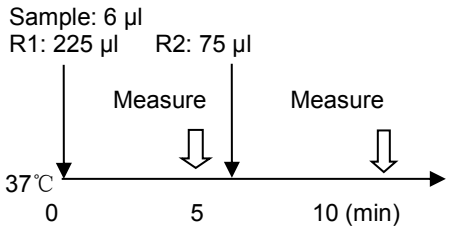
REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris/HCl buffer	80mmol/L
NaCl	240mmol/L
Reagent 2 (R2)	
Tris/HCl buffer	80mmol/L
Anti human albumin antibody	0.25w/v%

SAMPLE COLLECTION AND PREPARATION
Serum samples.
Serum samples stable for 72 hours at 2 -8ºC, or 6 months at -20ºC.

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.

Assay Procedure
Assay mode: END POINT
Wave Length (main/sub): 340 nm / 700 nm



CALIBRATION[4]
Use the specific PALB calibrator GC-PALB.

CALCULATIONS OF RESULTS
Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of PA in the sample is obtained by reading of a value from the calibration curve.

QUALITY CONTROL
Randox Liquid Assayed Specific Protein Controls, Level 1, Level 2 and Level 3 are recommended for daily quality control. Three levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL RANGES[5]
Normal Prealbumin values are age related and a range of 20-40 mg/dl is expected in a normal healthy adult individual.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY
The method is linear up to 500 mg/L. If the concentration in sample is above this concentration, please dilute it with 0.9% NaCl and reassay it. Multiply the result by dilution factor.

PRECISION
The CV of the test should be less than 5%

Intar assay precision			
N=20	level 1	level 2	level 3
Mean(mg/L)	151.35	333.74	500.73
SD	2.98	7.34	9.26
CV(%)	1.90	2.20	1.80

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/L)	155.81	160.28	160.55
$\bar{x}$	158.88		
(Xmax-Xmin)/$\bar{x}$	(160.55-155.81)/155.88*100=3.00%		

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

CE version 2014

INTERFERENCE

Serum analytes other than prealbumin were added to normal serum spiked with prealbumin. The following analytes were tested up to the following levels and found not to interfere:

Bilirubin: up to 1000 μmol/l
Hemoglobin: up to 200 mg/dl
Intralipid: up to 500 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Mears, E. Outcome of a continuous process improvement of a nutritional Care Program incorporating Serum Prealbumin Measurements. Nutritional Investigation, (1996);12 :479-484
2. Tietz, NW.(ed.). Clinical Guide to Laboratory Tests, third reprint Philadelphia, PA:WB Saunders, (1995) : 608-9
3. Hutchinson, DR., Halliwell, RP., Smith, MG. and Parke, DV. Serum “Prealbumin” as an index of liver function in human hepatobiliary disease. Clin Chim Acta, (1981): 114:69-74
4. Hamlin, CR. and Pankowsky, DA. Turbidimetric determination of Transthyretin(Prealbumin) with a centrifugal analyser. Clinical Chemistry, (1986); 33/1:144-146
5. Consensus of a group of Professional societies and Diagnostic companies on Guidelines for interim reference ranges for 14 proteins in serum based on the standardisation against the IFCC/BCR/CAP Reference Material (CRM 470).
   Eur. J. Clin. Chem. Clin. Biochem., (1996); 34: 517-520
6. Glick, MR. et al. Clinical Chemistry, (1986); 32:470-475

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn