BECKMAN COULTER CE

AU

Instructions For Use

TP

TOTAL PROTEIN

REF OSR6132 4 x 25 mL R1, 4 x 25 mL R2
OSR6232 4 x 48 mL R1, 4 x 48 mL R2
OSR6632 4 x 173 mL R1, 4 x 173 mL R2

For *in vitro* diagnostic use only.

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

Photometric colour test for the quantitative determination of total protein in human serum and plasma on Beckman Coulter AU analysers.

OSR6632 for use on the AU5800, AU2700 and AU5400 systems only.

SUMMARY AND EXPLANATION

Reference[1]

The total serum protein is the sum of all circulating proteins and is a major component of blood. Measurements of total protein are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic and nutritional disorders.

A deviation of serum total protein from the reference interval indicates the presence of dysproteinemia or a disorder in water balance. Both conditions can be distinguished by additional performance of serum protein electrophoresis and the determination of haematocrit.

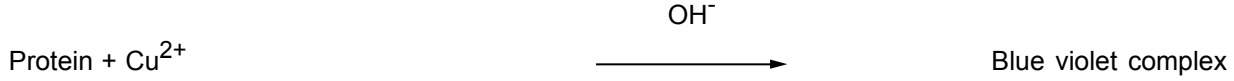
It is also useful in interpreting the significance of the total protein concentration to have more specific knowledge of individual fractions such as albumins and globulins.

METHODOLOGY

Reference[2]

Cupric ions in an alkaline solution react with proteins and polypeptides containing at least two peptide bonds to produce a violet coloured complex. The absorbance of the complex at 540/660 nm is directly proportional to the concentration of protein in the sample.

CHEMICAL REACTION SCHEME



SPECIMEN

TYPE OF SPECIMEN

Serum, EDTA or heparinised plasma.

Stable in serum and plasma for 4 weeks when stored at 2…8°C and 6 days when stored at 15…25°C.[3]

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

Sodium hydroxide	200 mmol/L
Potassium sodium tartrate	32 mmol/L
Copper sulphate	18.8 mmol/L
Potassium iodide	30 mmol/L

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.

GHS HAZARD CLASSIFICATION

Total Protein R1	DANGER	
		
	H314	Causes severe skin burns and eye damage.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P303+P361+P353	IF ON SKIN (or hair): Rinse skin with water.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER or doctor/physician.
		Sodium Hydroxide 1 - 5%
Total Protein R2	DANGER	
		
	H314	Causes severe skin burns and eye damage.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P303+P361+P353	IF ON SKIN (or hair): Rinse skin with water.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER or doctor/physician.
		Sodium Hydroxide 0.5 - 1%
		Copper sulphate 0.5 - 1%

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

REAGENT PREPARATION

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

STORAGE AND STABILITY

The reagents are stable, unopened, up to the stated expiry date when stored at 2…25°C. Once open, reagents stored on board the instrument are stable for 30 days.

AU5800: Once open, reagents stored on board the instrument are stable for 21 days.

CALIBRATION

CALIBRATOR REQUIRED

System Calibrator Cat. No. 66300.

The calibrator total protein value is traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 927c. Recalibrate the assay when the following occur: Change in reagent bottle or significant shift in control values;

Major preventative maintenance was performed on the analyser or a critical part was replaced. Absorption of atmospheric CO_2 by the reagent on board the analyser can impair calibration stability. This effect will vary depending upon the rate of use. Consequently each laboratory should set a calibration frequency in the instrument parameters appropriate to their usage pattern.

QUALITY CONTROL

Controls Cat. No. ODC0003 and ODC0004 or other control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency.

Good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration is performed. Values obtained for the controls should fall within specified limits as defined by the user. 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.

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 analysers automatically compute the total protein concentration of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Reference[1]	
Serum/plasma	
Adults	66 – 83 g/L (6.6 – 8.3 g/dL)
Children (1 - 18 y)	57 – 80 g/L (5.7 – 8.0 g/dL)
New-borns (1 - 30 d)	41 – 63 g/L (4.1 – 6.3 g/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

INTERFERENCES

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

Icterus:	Interference less than 10% up to 24 mg/dL or 410 µmol/L bilirubin
Haemolysis:	Interference less than 10% up to 3 g/L haemoglobin
Lipemia:	Interference less than 10% up to 1,000 mg/dL Intralipid

Eltrombopag and its metabolites may interfere with this assay causing erroneously high patient results.

Refer to Young[4] 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 30 – 120 g/L (3.0 – 12.0 g/dL).

SENSITIVITY

The lowest detectable level in serum on an AU400 analyser was estimated at 0.77 g/L.

The lowest detectable level represents the lowest measurable level of total protein 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 Total Protein OSR6132 assay on the AU640 against another commercially available total protein assay. Results of linear regression analysis were as follows:

y = 1.003x – 1.091	r = 0.999	n = 125	Sample range = 33.24 – 118.26 g/L

PRECISION

The following data was obtained on an AU640 using 3 serum pools analysed over 20 days.

n = 80	**Within-run**		**Total**	
Mean g/L	**SD**	**CV%**	**SD**	**CV%**
35.57	0.18	0.50	0.30	0.84
73.33	0.25	0.34	0.51	0.70
110.80	0.29	0.26	0.71	0.64

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
TP-1N	Total Protein (Serum)

Setting Sheet Footnotes
User defined
† System Calibrator Cat. No.: 66300
* Values set for working in SI units (g/L). To work in g/dL divide by 10.

‡ Depends on usage pattern in the laboratory

REVISION HISTORY

Revised Interferences section.

Preceding version revision history

IFU updated to add Vietnamese language.

Updated Warning and Precautions section

Updated Additional Information section

REFERENCES

1. Thomas L. Total Protein. In: Thomas L, ed. Clinical laboratory diagnostics. Use and assessment of clinical laboratory results. Frankfurt/Main: TH-Books Verlagsgesellschaft, 1998:644-647.

2. Weichselbaum TE. An accurate and rapid method for the determination of proteins in small amounts of blood serum and plasma. Amer J Clin Path 1946; 16:40-48.

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.2:40pp.

4. Young DS. Effects of drugs on clinical laboratory tests, 5thed. AACC Press, 2000.

EC REP Beckman Coulter Ireland Inc., Lismeehan, O'Callaghan's Mills Co. Clare, Ireland (001) 703-527-3887

Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.
www.beckmancoulter.com