Total Protein

CYPRESS DIAGNOSTICS

CE

IVD

Biuret. Colorimetric
Liquid

Store at 2-8 °C

Configuration

REF	HB0190	HB0190A	HB0190M
VOL	2 x 125 mL	8 x 125 mL	8 x 30 mL
Reagent 1	2 x 125 mL	8 x 125 mL	8 x 30 mL
Standard	1 x 5 mL	4 x 5 mL	-

Intended use

The Cypress Diagnostics kit Total Protein is an in vitro diagnostic medical device intended to be used for the quantitative measurement of total protein in human serum or plasma. The device is not automated. The measurement of total protein is intended to be used as part of a routine health checkup (screening) and as an aid in the diagnosis of liver, kidney or other disorders. This kit is intended to be used by healthcare professionals in a laboratory-based testing environment.
For *in vitro* diagnostic use only. For professional use only.

Clinical significance

Through osmotic pressure, serum protein is involved in the maintenance of normal distribution of water between blood and tissues. The several fractions of serum protein vary independently and widely in disease. Low protein is primary caused by malnutrition, impaired synthesis, loss (as by hemorrhage) or excessive protein catabolism. Elevated protein levels are caused mainly by dehydration.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

Protein together with a basic copper-sulphate solution containing tartrate (Biuret Reagent) form a violet blue color complex. The intensity of the color formed is proportional to the total protein concentration in the sample.

Reagent composition

Reagent 1	BIURET Potassium-Sodium-Tartrate (20 mmol/L) Sodium Hydroxide (500 mmol/L) Potassium Iodide (25 mmol/L) Copper (II) Sulphate (7 mmol/L)
Standard	Albumin Aqueous (see value on label) *BSA (50 g/L)

**This is a material of animal origin, but the risk of this material was assessed as non-hazardous and non-critical in the Risk Analysis*

Precautions

- Reagent 1: Danger. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H412: Harmful to aquatic life with long lasting effects. P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash hands and exposed skin thoroughly after handling. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P501: Dispose of contents/container in an appropriate container observing applicable local regulations.
- All body fluid samples should be considered potentially infectious materials and the appropriate precautions should be taken. Wear personal protective equipment such as gloves, safety glasses, lab coats or aprons when working with possible biohazard contaminants.
- Use Good Laboratory Practices (GLP) when handling this product.
- Please refer to the MSDS, available on our website, for further information.

Preparation

The reagent and standard are ready for use.

Storage, stability and disposal

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.
Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 546 nm ≥ 0,22, the reagent should be discarded.
Do not use the product if deterioration or contamination is suspected or beyond the expiration date or open container stability period. Dispose unused or deteriorated product and waste in compliance with local regulations.

Additional material required but not provided

- Spectrophotometer or colorimeter. Minimum analyzer specifications:
  Measuring at 546 nm (530-550)
  Linear measuring range: 0 - 2 AU
- Cuvettes, matching the analyzer used (1,0 cm light path)
- General laboratory equipment

Samples

Sample type: human serum or plasma. Stability: 1 month at 2-8 °C.

Procedure

Make sure the reagents and samples are at room temperature.
1. Wavelength 546 nm (530-550); Temperature 37 °C/15-25 °C; Cuvette (1 cm light path).
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

For Blank	1 mL R1 Biuret
For Standard [Note 4]	25 µL Standard + 1 mL R1 Biuret
For Sample	25 µL Sample + 1 mL R1 Biuret
Mix and incubate for 5 min. at 37 °C or 10 min. at room temperature (15-25 °C). Measure the absorbance (A) of sample and standard against the blank. The color is stable for at least one hour.	

Calculation

$$\text{Total Protein (g/dL)} = \frac{A_{Sample} - A_{Blank}}{A_{Standard} - A_{Blank}} \times stand.conc.\,(g/dL)$$

Conversion Factor: g/L = 10 x g/dL

Quality control

Control sera are recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration.
Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). If other controls (not manufactured by Cypress) are used, they have to be validated by the user as they can vary. Prepare and measure these controls the same as samples. Measure at least one replicate per control.
If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Reference values

Adults	6,6 - 8,3 g/dL (66 - 83 g/L)
Newborns	5,2 - 9,1 g/dL (52 - 91 g/L)

These values are for orientation purpose. Each laboratory should establish its own reference range.

Performance characteristics

Measuring range: from 0,008 g/dL (detection limit) to 15 g/dL (linearity limit). If the obtained results are greater than 15 g/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

Precision:

	intra-assay (n=20)		inter-assay (n=20)	
Mean (g/dL)	6,46	4,77	6,52	4,78
SD	0,129	0,092	0,162	0,114
CV (%)	1,99	1,92	2,49	2,39

Sensitivity: 1 g/dL = 0,056 AU

Accuracy: Results obtained using CYPRESS DIAGNOSTICS reagents did not show systematic differences when compared with other commercial reagents.
The results of the performance characteristics depend on the analyzer used.

Interferences

No interference of hemoglobin (22 mg/dL). A list of drugs and other interfering substances with total protein determination has been reported by Young et al.

Notes

1. For best use of this kit on a Cypress Diagnostics analyzer, we kindly advise to follow the application sheets of the respective analyzer. Please log in to our website (www.diagnostics.be) as a registered user to download the latest application sheets, which are located under the section of the corresponding analyzer. Compatible Cypress analyzers: CYANSmart, CYANStart, CYANExpert 130, CYANVision
2. In case other instruments (not manufactured by Cypress Diagnostics) are used, the laboratory is responsible to validate the reagents in this kit on those analyzers before testing patient samples.
3. For this kit, application sheets for the following Mindray analyzers are available (see website): BS-120, BS-200, BS-200E
4. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In this case, it is recommended to use a serum based Biochemistry calibrator (HBC03).

Cypress Diagnostics: Nijverheidsstraat 8 • 2235 Hulshout • Belgium
www.diagnostics.be • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be

Bibliography

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2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press 1995.
3. Young DS. Effects of diseases on Clinical Lab. Tests, 4th ed AACC 2001.
4. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
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Notice: Any serious incident that has occurred in relation to the device shall be reported to Cypress Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

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Cypress Diagnostics: Nijverheidsstraat 8 • 2235 Hulshout • Belgium
www.diagnostics.be • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be