



## TP Reagent Kit (Biuret Colorimetric Method)

### Instructions for Use

REF CC1079

### PRODUCT NAME

TP Reagent Kit (Biuret Colorimetric Method)

### PACKAGE SPECIFICATION

|                               |              |             |             |
|-------------------------------|--------------|-------------|-------------|
| R: 1×10 mL                    | R: 1×20 mL   | R: 1×50 mL  | R: 2×30 mL  |
| R: 2×35 mL                    | R: 2×40 mL   | R: 2×45 mL  | R: 2×50 mL  |
| R: 2×55 mL                    | R: 2×60 mL   | R: 4×20 mL  | R: 4×30 mL  |
| R: 4×35 mL                    | R: 4×40 mL   | R: 4×45 mL  | R: 4×50 mL  |
| R: 4×55 mL                    | R: 4×60 mL   | R: 5×20 mL  | R: 6×20 mL  |
| R: 6×30 mL                    | R: 6×35 mL   | R: 6×40 mL  | R: 6×45 mL  |
| R: 6×50 mL                    | R: 6×55 mL   | R: 6×60 mL  | R: 8×20 mL  |
| R: 10×20 mL                   | R: 2×100 mL  | R: 6×100 mL | R: 12×25 mL |
| R: 2×2000 mL                  | R: 4×1000 mL | R: 5×120 mL |             |
| Calibrator (Optional): 1×1 mL |              |             |             |

### INTENDED USE

This test kit is designed for *in vitro* quantitative measurement of serum or plasma total protein in human. The total protein concentration is mainly used for complementary evaluation of liver hepatic function clinically. For professional and laboratory use only.

### PRINCIPLE

The reagent is designed according to the candidate reference method recommended by the American Academy of Clinical Chemistry (AACC). The principle of the kit is that the peptide bonds (-CONH-) in proteins would form purple orchid complex with divalent copper ions (Ca<sup>2+</sup>) in alkaline solution. Moreover, the absorbance (ΔA) of the reaction mixture is positively proportional to the protein concentration of the sample.

### COMPONENTS

| Kit contents          | Reagent components                              | Concentration |
|-----------------------|-------------------------------------------------|---------------|
| Reagent               | NaKC <sub>2</sub> H <sub>3</sub> O <sub>4</sub> | 22 g/L        |
|                       | CuSO <sub>4</sub>                               | 3.5 g/L       |
|                       | KI                                              | 3.5 g/L       |
|                       | NaOH                                            | 20 g/L        |
| Calibrator (Optional) | Albumin (aqueous matrix)                        | 65-75 g/L     |

As for multi-component kit, the components are not exchangeable.

Calibrator traceability: Traceable to international Standard Reference Material (SRM) 909c.

### STORAGE AND VALIDITY

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.

Please refer to the label on the reagent kit for the production date and expiration date.

### APPLICABLE DEVICES

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd.,

models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc. models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

### SAMPLE REQUIREMENTS

Serum and plasma with heparin anticoagulant are recommended. Sample should be separated in time after collection to avoid hemolysis. Serum are stable for 6 days at 20-25°C, for 4 weeks at 4-8°C and for 1 year at -20°C.

### TEST PROCEDURE

- Preparation: Use directly;
- Conditions: (different parameters to be set on the machine can be obtained according to different testing instruments)

|                              |                       |                                 |        |
|------------------------------|-----------------------|---------------------------------|--------|
| Primary/secondary wavelength | 546nm/700nm           | Calibration type                | linear |
| Sample/R1                    | 6/300 μL              | Time of Mixture of Serum and R1 | 10min  |
| Method                       | One point end assay   | Reaction time                   | 10min  |
| Calibration Method           | Two-point calibration | Direction                       | Upward |

(The absorbance A read by the device = A<sub>Primary wavelength</sub> - A<sub>Secondary wavelength</sub>)  
Operation steps:

| Substance Added    | Blank tube | Test tube |
|--------------------|------------|-----------|
| R1                 | 300 μL     | 300 μL    |
| Sample             | -          | 6 μL      |
| ddH <sub>2</sub> O | 6 μL       | -         |

Mixed, incubated at 37°C for 10 min, then zero calibration and read the absorbance A of each tube.

- Calibration: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
- Quality control: Randox QC serum are recommended. QC value should be within the range of the preset value. If not, please follow the below steps to check:
  - Check whether the parameter setting and light source are correct;
  - Check whether the cuvettes and the sample probe are contaminated;
  - Check whether the ddH<sub>2</sub>O are polluted, because bacterial growth cause incorrect results;
  - Check the reaction temperature;
  - Check the expiration date of the kit.
- Calculation of results:  
C<sub>sample</sub>=C<sub>standard</sub> × A<sub>sample</sub> / A<sub>standard</sub>

### REFERENCE RANGE

65-85 g/L

The reference range is for reference purposes only. It is recommended to set its own reference range in each laboratory.

### EXPLANATION OF TEST RESULTS

Hemolysis interferes the assay and should be avoided as much as possible during the operation.

### LIMITATIONS

When hemoglobin ≤ 500 mg/dL, vitamin C ≤ 30 mg/dL, bilirubin ≤ 40 mg/dL, triglyceride ≤ 1000 mg/dL, there is no interference to the assay.

### PERFORMANCE CHARACTERISTICS

- Appearance

The reagent is blue and clear liquid. There are possibly small amount of undissolved particles in the solution that will not affect the test.

- Blank Absorbance

The blank absorbance of reagent A<sub>546nm</sub> ≤ 0.200.

### 3. Accuracy

The relative deviation should not exceed ±5%

### 4. Linear Range

Serum linearity: [30.0, 120.0] g/L:

- Linear correlation coefficient r should not be less than 0.995;
- Comparative linear deviation should not exceed ±6.0%.

### 5. Analytical sensitivity

The absorbance difference (ΔA) of the 70 g/L sample should not be less than 0.150.

### 6. Precision

#### 6.1 Repeatability (within-run precision)

When repeat test sample with concentration of (70.0 ±10.0) g/L using same kit, the CV should not exceed 2%.

#### 6.2 Between-run precision

When repeat test sample with concentration of (70.0 ±10.0) g/L using different batches of kits, the CV should not exceed 5%.

## PRECAUTIONS

### 1. General Precautions

- For *in vitro* diagnosis only.
- When used for clinical diagnosis, please make comprehensive judgment based on the assay results, clinical symptoms and other examination results, etc.
- Please use this product according to the IFU.

### 2. Precautions for operation

- Please dispose of the specimen as if it were a hazardous substance that may be infected with HIV, HBV, HCV, etc. To avoid or reduce the risk of infection, please use disposable gloves.
- In case of accidental contact with the eyes or mouth, or with the skin, rinse immediately and thoroughly with water and seek medical advice if necessary.

### 3. Precautions for use

- Please store the reagents according to the storage method and avoid freezing. The quality of reagents may change after freezing, please do not use them.
- Please do not use reagents that have expired. The results of expired reagents may be inaccurate.
- Please avoid adding reagents halfway through the test.
- Please avoid direct sunlight during operation.
- Do not use if the reagent is turbid.

### 4. Precautions for waste disposal

Samples and waste fluids are potentially biologically infectious. Operators should comply with laboratory safety regulations and dispose of waste fluids according to local regulations for medical waste, infectious waste, and industrial waste.

### 5. Other precautions
















- On automatic biochemistry analyzers, the linearity range is related to the ratio of sample volume used to reagent volume and the time of measurement.
- The volume of reagents and samples can be changed proportionally according to the requirements of different instruments.
- Do not use the reagent bottles for other purposes.
- Hemoglobin and bilirubin can cause interference. The former at 1.0 g/L can cause a positive interference of 1.8 g/L. The latter 300 mg/L can cause a positive interference of 2.0 g/L. Serum blank elimination can be carried out by replacing it with biuret reagent without copper sulfate.
- Cyclic anhydride would bind to copper ions in the reagent and precipitate, the supernatant can be removed by centrifugation and measured without affecting the results.
- The result of calculation with k-value is not as reliable as that using the calibration measurement value of standard substance.
- Do not mix reagents of different batches.

## REFERENCE

H. Shang, et. al.: National Clinical Test Operation Procedures (4<sup>th</sup> ed.). People's Health Publishing House. 2015: 200-203.

## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on TP Reagent Kit (Biuret Colorimetric Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

| Key to symbols used                                                               |                                                                                       |                                                                                     |                                                                          |                                                                                     |                           |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------|
|    | Manufacturer                                                                          |    | Use-by date                                                              |    | Catalogue number          |
|   | Date of manufacture                                                                   |   | Batch code                                                               |   | Temperature limit         |
|  | <i>In vitro</i> diagnostic medical device                                             |  | Keep away from sunlight                                                  |  | Biological risks          |
|  | Consult <i>instructions for use</i> or consult <i>electronic instructions for use</i> |  | Do not use if package is damaged and consult <i>instructions for use</i> |  | Authorized representative |
|  | CE mark                                                                               |  | This way up                                                              |  | Do not re-use             |



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