This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Notification No. 13A2X00197218100

**Revised: February 2021 (6th edition)
*Revised: January 2017 (5th edition)

This package insert must be read carefully prior to use.

Total protein assay kit for blood tests
(Classification No.: 30181001)

QUALIGENT TP

General Precautions **

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. For the effects of an administered drug on the measured value, carefully read the Precautions for Use in the package insert of the drug, especially the section about the effects on laboratory test results. Please also read carefully the "2. Interfering Substances," in the "Procedural Precautions" section, as well as "2. Precautions for Assessment" in the "Assessment of Assay Results" section, of this package insert.
4. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
5. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
6. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
7. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component : Ingredients
TP Coloring Solution:
Copper sulfate (II) pentahydrate

Intended Use

Measurement of total protein in serum or plasma

Total protein is the general term for all proteins with various functions. Changes of the total protein level reflect change of physiological function and damage or disease affecting organs/tissues of the body.

Assay Principle

1. Assay Principle
Protein in the samples reacts with the Biuret reagent to form a red-purple complex. The total protein level is determined by measuring the absorbance of this red-purple complex.

$$\text{Protein} \xrightarrow{\text{Biuret reagent}} \text{Complex (red-purple color)}$$

2. Features
The measurement is hardly affected by turbidity of the solution.

Procedural Precautions **

1. Properties of Samples and Sampling Methods
1) Samples
Serum and plasma (heparin plasma, EDTA plasma, citrated plasma and NaF-EDTA plasma) may be used.
2) Storage of samples
If the isolated serum or plasma sample cannot be tested on the same day, specimens should be stored as follows[4]:
2–10°C: for tests within 1 mouth
≤ -20°C: for tests after more than 1 month.
Bring samples to room temperature (15–30°C) before use.

2. Interfering substances
Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), formazin turbidity (up to 3000 FTU), or ascorbic acid (up to 50 mg/dL). Hemolyzed samples result in artifactual elevation of the protein level.

3. Others
1) Always use Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, Seronorm Human or Anaserum ALB・TP Standard Solution for calibration.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) **

1. Preparation of reagents
Reagent: TP Coloring Solution is ready to use.

2. Assay Procedure
This product is compatible with Hitachi 9000 series and LABOSPECT series automated analyzers. Assay procedure is indicated below.

$$\underset{2.1\ \mu L}{\text{Sample}} + \underset{180\ \mu L}{\text{Reagent}} \xrightarrow[10\ \text{min}]{37°C} \text{Measurement (Absorbance※)} \longrightarrow \text{Calculation of concentration}$$

※Absorbance: The difference in absorbance between 700 nm and 546 nm
Calibration material: Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, Seronorm Human or Anaserum ALB・TP Standard Solution (Manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results **

1. Reference standard range[2]
6.6–8.1 g/dL (Within the JCCLS common standard)

2. Precautions for Assessment

There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance *

1. Sensitivity

1) Reagent blank: absorbance being equal to or lower than 0.05
2) Sensitivity: The absorbance is 0.21–0.25 per 6 g/dL of albumin.

2. Accuracy: 90–110% of the expected assay value

3. Within-run Reproducibility:

Coefficient of variation ≤ 3%

(Test methods used for 1. –3. are in-house methods.)

4. Measurement Range[5]: (On a Hitachi 9000 series automated analyzer)

0.3–12 g/dL

5. Correlation[5]

1) Serum N=70 r=0.979 y=0.94x＋0.43
Control method: Approved in vitro diagnostic (Biuret test)
2) Plasma N=150 r=0.999 y=1.02x –0.11
Control method: Approved in vitro diagnostic (Biuret test)

6. Standard Material

SRM927 (NIST)

Precautions for Use or Handling *

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
2) The TP Coloring Solution is an alkaline solution. If it is accidentally ingested or comes into contact with the eyes or skin, immediately rinse the area with water and seek medical treatment, if necessary.

2. Precautions for Use

1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.

4. Other precautions

1) Do not use the containers for other purposes.
2) Do not take apart the reagent cartridge before use.

Storage and Shelf Life *

1. Storage temperature: room temperature (1–30°C)

2. Shelf life: 2 years from the date of manufacture (The expiration date is printed on the outer package.)

Packaging *

Name	Package		
QUALIGENT TP	Set (Cassette for Hitachi 9000 series)	TP Coloring Solution 1 × 27.0 mL	× 2
	L set (Set for Hitachi LABOSPECT series)	TP Coloring Solution 1 × 46 mL	× 2

References **

1) Gornall, A.G., et al.: J. Chem, 177, 751, 1949.
2) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 35th ed. Tokyo: Kanehara Shuppan; 2020. Japanese.
3) Akiyoshi M., Shimizu F. (supervising editors): Clinical laboratory methods and diagnosis course 14, Tokyo: Ishiyaku Shuppan; 1972. Japanese.
4) Sasaki M. et al.: Sampling of constituents of the human body, Tokyo: Kodansha; 1972. Japanese.
5) SEKISUI MEDICAL CO., LTD. In house data. Japanese.

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