Total Protein Kit

CliniQuant - FSR

Biuret Method, End Point

Meril Diagnostics

For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Total Protein Reagent	R2 Total Protein Standard
TPRFSR-01	4 x 50ml	4 x 50ml	1 x 5ml
TPRFSR-02	2 x 500ml	2 x 500ml	2 x 5ml

INTENDED USE

This reagent is intended for quantitative determination of proteins concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

Serum Total Protein is useful in monitoring change in the protein levels due to diseases. Increased levels are found in dehydration due to inadequate water intake or to excessive water loss as in severe vomiting, diarrhoea, Addison' s disease and in multiple myeloma.

PRINCIPLE OF THE METHOD

Proteins peptidic bonds react with Cu(II) in alkaline solution to form blue-purple complex, the absorbance of which is measured at 546 nm. Each Cu(II) can complex up to 6 peptidic bonds.

$$\text{Proteins} \xrightarrow[\text{alkaline medium}]{Cu^{2+}} \text{Blue color complex}$$

KIT COMPONENTS

Composition

R1 - Total Protein Reagent : Cupric Sulphate 12.01 mmol/l, Potassium sodium tartarate 31.8 g/l, Potassium Iodide 54.21 mmol/l, Sodium Hydroxide 200 mmol/l

R2 - Total Protein Standard : 6.0 g/dl, BSA 60g/l, Sodium Azide 0.1%

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent is ready to use. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Upon opening of kit, store Reagent R1 at 15 -30 °C and standard at 2-8 °C.

Stability since first opening of reagent bottle: preferable within 60 days at 15 -30 °C.

REAGENT DETERIORATION

1. Discard the reagent if absorbance exceeds 0.2 at 546 nm against distilled water.
2. Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS

1. Reagent contains strong alkali. Do not mouth pipette. It is suggested to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use unhemolysed serum or plasma. Plasma specimens may obtain 0.4 g/dl high due to fibrinogen. Serum/ plasma is stable for 7 days at 2-8 °C and 1 month at -20 °C.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc.	6 (g/dl)
Filter – 1 (nm)	546
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	6.0
Reference High	8.3
Linearity Limit	15

CE
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TEST PROCEDURE

Dispense	Blank	Standard	Sample
Reagent 1	1ml	1ml	1ml
Distilled water	20 µl	-	-
Standard	-	20 µl	-
Sample	-	-	20 µl
Mix, incubate for 5 min at 37°C. Read absorbance of standard (As) and samples (Ax) against reagent blank.			

RESULT CALCULATION

Serum/plasma:

Proteins g/dl = Ax/As x Concentration of Standard

SI conversion factor: 1 g/dl x 10 = 1 g/l

EXPECTED VALUES

6.0 – 8.3 g/dl OR 60 – 83 g/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 15.0 g/dl.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.05 g/dl.

The limit of quantification is 0.1 g/dl.

3. Interferences

Gross hemolysis, lipaemia and icteric specimens may cause falsely elevated results, a sample blank be set by adding 20 µl sample in 1ml saline.

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	g/dl	g/dl	%
sample 1	6.66	0.02	0.33
sample 2	4.91	0.03	0.62

Inter-assay precision

	Mean	SD	CV
n = 20	g/dl	g/dl	%
sample 1	6.52	0.24	3.70
sample 2	4.83	0.22	4.50

5. Methods Comparison

Comparison was done between reference Total Protein Reagent and CliniQuant - FSR Total Protein Reagent (test)

N = 36 $y = 0.973x + 0.267$

$r^2 = 0.963$

LIMITATIONS

Samples with values above 15 g/dl should be diluted with 0.9% saline, re-run and results multiplied by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 695 – 700.

2. Data on file: Meril Diagnostics.

IFU/TPRFSR01/00

06-11-2018

Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community