PROTEINS (TOTAL)

TP 0100 CH	2 x 50 ml
TP 0500 CH	4 x 125 ml
TP 1000 CH	4 x 250 ml

INTENDED USE

Reagent for quantitative in vitro determination of total proteins in biological fluids.

SUMMARY OF TEST

The two general causes of alterations of serum total proteins are a change in the volume of plasma water and a change in the concentration of one or more of the specific proteins in the plasma. Hyperproteinemia is noted in dehydration due to inadequate water intake or to excessive water loss as in severe vomiting, diarrhea, Addison's disease, or diabetic acidosis. Hemodilution (increase in plasma water volume) occurs with water intoxication or salt retention syndromes, during massive intravenous infusions.

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 520-560 nm. Each Cu(II) can complex up to 6 peptidic bonds. Tartrate salt is a stabilizer and iodide ions are added to prevent self-reduction of alkaline cupric complex.
For automatic analyzers, set the reference wavelenght to 600-700 nm.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

TP R1 **0100: 2 x 50 ml (liquid) blue cap**
0500: 4 x 125 ml (liquid) blue cap
1000: 4 x 250 ml (liquid) blue cap

Composition: cupric sulphate 6 mM, sodium-potassium tartrate 21 mM, potassium iodide 6 mM, NaOH 0.75 M.

Standard: proteins solution 6 g/dl - 5 ml

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Use reagent ready to use.
Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: preferably within 60 days at 2-8°C.

PRECAUTIONS

TP R1: Warning. Causes serious eye irritation (H319).

Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

Standard: It is not classified as hazardous.

SPECIMEN

Either serum or plasma may be used, but serum is preferred. A fasting specimen is not required but may be desirable to decrease lipemia. Hemolysis should be avoided. Tightly stoppered samples of serum are stable for 1 week at room temperature or 1 month at 2-8°C.
Specimens that have been frozen and thawed should be thoroughly mixed before assay.

TEST PROCEDURE

Wavelenght: 540 nm (allowed 520 ÷ 560 nm)
Lightpath: 1 cm
Temperature: 25, 30 or 37°C

dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml
water	10 µl	-	-
standard	-	10 µl	-
sample	-	-	10 µl

Mix, incubate at 25, 30 or 37°C for 10 minutes.
Read absorbances of standard (As) and samples (Ax) against reagent blank.

RESULTS CALCULATION

Serum, plasma:

proteins g/dl = Ax/As x 6 (standard value)

EXPECTED VALUES

Ambulatory adult: 6.3 - 8.3 g/dl
Recumbent adult: 6.0 - 7.8 g/dl
(after age of 60 years, levels are approximately 0.2 g/dl lower)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QUANTINORM CHEMA
with normal or close to normal control values
QUANTIPATH CHEMA
with pathological control values.
If required, a multiparametric, human based calibrator is available:
AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity
the method is linear up to 12 g/dl.
If the limit value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)
the limit of detection is 0.1 g/dl.

Interferences
no interference was observed by the presence of:

hemoglobin	≤ 350 mg/dl
bilirubin	≤ 20 mg/dl
lipids	≤ 200 mg/dl

Precision

intra-assay (n=10)	mean (g/dl)	SD (g/dl)	CV%
sample 1	5.03	0.10	2.00
sample 2	5.54	0.10	1.80

inter-assay (n=20)	mean (g/dl)	SD (g/dl)	CV%
sample 1	5.12	0.11	2.20
sample 2	5.31	0.17	3.20

Methods comparison
a comparison between Chema and a commercially available product gave the following results:

Proteins total Chema = x
Proteins total competitor = y
n = 97

$y = 1.02x - 0.11$ g/dl $r^2 = 0.97$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Flack C.P. and Woollen J.W. - Clin.Chem. 30, 559 (1984).
Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

MANUFACTURER

Chema Diagnostica
Via Campania 2/4
60030 Monsano (AN) - ITALY - EU
phone +39 0731 605064
fax +39 0731 605672
e-mail: mail@chema.com
website: http://www.chema.com

SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

CE