PROTEINS HS

HS 0100 CH	2 x 50 ml
HS 0500 CH	4 x 125 ml

INTENDED USE

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

SUMMARY OF TEST

The renal excretion of moderate quantities of proteins could be an index of a beginner renal pathology, especially in diabetic subjects. The presence of light chain immuno-globulins could be an index of kidney myeloma.
The present method, based on the pigment pyrogallol red according to Watanabe, permits a reliable quantification also of proteins classes different than albumin.

PRINCIPLE OF THE METHOD

Proteins combine with pyrogallol red to form a color complex, the absorbance of which is measured at 600 nm. Sodium dodecylsulphate is added to increase accuracy in measuring proteins other than albumine (Watanabe).

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.

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

Composition: succinate buffer 0.05 M pH 2.50, pyrogallol red 0.04 mM, sodium molibdate 0.13 mM, sodium oxalate 1 mM, sodium benzoate 0.35 mM, SDS 0.1 mM.

Standard: proteins solution 100 mg/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 micro-pipettes. 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

HS R1: Warning. May cause damage to organs (H371).
Do not breath vapours (P260). Wash hands thoroughly after handling (P264). Do not eat, drink or smoke when using this product (P270).

Standard: It is not classified as hazardous.

SPECIMEN

Urine, cerebrospinal fluid. Stable 3 days at 2-8°C.

TEST PROCEDURE

Wavelenght:	600 nm (allowed 580 ÷ 620 nm)
Lightpath:	1 cm
Temperature:	25, 30 or 37°C

dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml
water	5 μl	-	-
standard	-	5 μl	-
sample	-	-	5 μl

Mix, incubate at 25, 30 or 37°C for 5 minutes.
Read absorbances of standard (As) and samples (Ax) against reagent blank.

RESULTS CALCULATION

Urine, cerebrospinal fluid:
proteins mg/dl = Ax/As x 100 (standard value)

EXPECTED VALUES

Cerebrospinal fluid: 14 - 45 mg/dl
Urine: 28 - 141 mg/24 h

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 a reliable and compatible urine based control material is needed.

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity
the method is linear up to 500 mg/dl.
If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)
the limit of detection is 0.3 mg/dl.

Interferences
no interference was observed by the presence of:
ascorbic acid   ≤ 500 mg/dl

Precision

intra-assay (n=10)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	37.10	0.74	2.00
sample 2	103.40	1.27	1.20

inter-assay (n=20)	mean (mg/dl)	SD (mg/dl)	CV%
sample 1	38.01	0.79	2.00
sample 2	100.09	2.46	2.00

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

Proteins HS Chema = x
Proteins competitor = y
n = 88

$y = 0.97x - 0.54$ mg/dl $r^2 = 0.978$

WASTE DISPOSAL

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

REFERENCES

Watanabe et al. - Clin.Chem. 32/8, 1551-1554 (1986).

MANUFACTURER

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SYMBOLS

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

CE