PROTEINS HS

HS 0500 CH 4 x 125 ml

SUMMARY OF TEST

The renal excrection of moderate quantities of proteins could be an index of a beginner renal pathology, especially in diabetic subjects. The presence of light chain immunoglobulins could be an index of kidney myeloma.
The present method , based on the pigment pyrogallol red according to Watanabe, permit a reliable quantification also of proteins classes different than albumin. Moreover, because to the extended dynamic range and to the absence of pigment fixation on labware, the method is easily appicable to automatic analyzers.

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 at 15-25°C.
Keep away from direct light sources.

Reagent A: 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 15-25°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 15-25°C.
Stability since first opening of vials: ≥ 60 days at 15-25°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

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	2 ml	2 ml	2 ml
water	10 µl	-	-
standard	-	10 µl	-
sample	-	-	10 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/dl

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 1 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 = 0.978

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. Refer to special instructions/safety data sheets.

REFERENCES

Watanabe et al. - Clin.Chem. 32/8, 1551-1544 (1986).

MANUFACTURER

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SYMBOLS

CE