TOTAL PROTEIN (URINE) Assay Kit (UP)

Method: Pyrogallol Red

Cat .No.	Size	Instrument
GB370S	2×50 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS371S	2×50 ml	For Hitachi917 & OlympusAU640/400/600
GT371S	2×50 ml	For TOSHIBA

INTENDED USE

For the *in vitro* quantitative determination of total protein in urine or cerebrospinal fluid.

CLINICAL SIGNIFICANCE[1]

Determination of Total Protein in urine and cerebrospinal fluid is valuable in the diagnosis of renal and central nervous system disorders respectively. Urinary protein elevations are commonly seen in the following conditions: strenuous exercise, fever and hypothermia, nephrosis and diabetic nephropathy and urinary tract infections. Determination of total protein in cerebrospinal fluid aids in the diagnosis of such conditions as meningitis, CNS tumours and cerebral haemorrhage.

ASSAY PRINCIPLE[2]

Pyrogallol red complexes with proteins in an acid environment containing molybdate ions. The resulting blue-coloured complex absorbs maximally at 600 nm. Therefore the optical density at 600 nm is directly proportional to the protein concentration of the samples.

SAMPLE COLLECTION AND PREPARATION[3,4]

Urine or cerebrospinal fluid samples.
Urine: 24 hour collection, urine samples are stable for 24 hours at 2-8℃, or for 3 months when frozen .
Cerebrospinal fluid: Test in half an hour after collection.(Note: samples without adding preservatives)

REAGENT COMPOSITION

Contents	Concentration of Solutions
Colour Reagent	
Pyrogallol red	60 μmol/L
Disodium molybdate	40 μmol/L
Succinic acid	150 μmol/L
Sodium oxalate	1 mmol/L
Sodium benzoate	3 mmol/L
Calibrator	1g/L

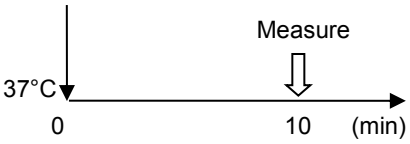
STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 917)
Assay Mode: End Point 15
Wave Length (main/sub): 600 nm/700 nm

Sample:10 μl
R1: 300 μl



1. Mix 10 μl sample with 300 μl R1 and incubate at 37°C for 10 minutes
2. Measure the absorbance of the sample (Asample) and calibrator (Acalibrator) against reagent blank.

CALCULATION

$$\text{Concentration} = \frac{\Delta A_{sample}/\text{min}}{\Delta A_{calibrator}/\text{min}} \times \text{Calibrator value}$$

To determine 24 hours Urinary Protein, measure the 24 h urine volume in ml and assay the urine for protein content(g/l) as per procedure. Calculate the 24h Urinary Protein using the follow formula:

Protein (g/24h)= Urinary Protein(g/l)×TV/1000

Where TV=24h urine volume in ml
1000=Converts ml/day to l/day

CALIBRATION

Gcell Urinary Protein Calibrator (1g/l) provided with the kit is recommended for calibration when testing urine.

QUALITY CONTROL

Gcell Urinary Protein Quality Control level 1 and level 2 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

REFERENCE VALUE

Cerebrospinal fluid: 0.15-0.45 g/L
Urine: 0.028-0.141g/24h or 0.01-0.14 g/L
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 1.4 g/L. If sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

CE Revised 01DEC11 version 1102

PRECISION

The CV of the test should be less than 10%.

Intra assay precision		
N=20	Level1	Level 2
Mean (g/L)	0.099	0.5005
SD	0.0045	0.0083
CV	4.52%	1.65%
Inter assay precision		
N=5	Level1	Level 2
Mean (g/L)	0.100	0.499
SD	0.0038	0.0046
CV	3.80%	0.92%

SENSITIVITY

The minimum detectable concentration of Urinary Protein with an acceptable level of precision was determined as 0.0055 g/L.

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Urea: 1000 mg/dl
Direct bilirubin: 3 mg/dl
Ascorbic Acid: 60 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
$Y=0.943X-0.001$, $R^2=0.997$; 50 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Pesce, A.J.,Kaplan, L.A.: Methods in Clinical Chemistry(1987)
2. Watanabe, N., Kamei, S., Ohkubo, A., Yamanaka, M., Ohsawa, S., Makino, K., Clin. Chem., 1986;32/8:1551
3. Laboratory Test Handbook, Jacobs et al. ed 2.
4. Orsonneau, J., Dowet, P., Massoubre, C., Lustenberger, P., and Bernard, S., Clin. Chem., 1989;35/11:2233

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

CE