URINE CSF PROTEIN (2-8ºC)

CATALOGUE NUMBER	KIT SIZE (mL)
MPRUCP1	2x50ml / 1x5ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
This reagent is intended for the quantitative determination of total protein in urine and cerebrospinal fluid.

Clinical Significance:
Urine does not contain any protein in healthy individuals. In the kidney the glomeruli prevent the passage of protein from the blood to the glomerular filtrate. Glomerular injury causes increased permeability to plasma proteins, resulting in proteinuria, which refers to the presence of protein in the urine. A persistent finding of proteinuria is the single most important indication of renal disease. Elevated concentrations of protein in CSF can be caused by infections and intracranial pressure.

Test Principle:
Proteins react in acid solution with pyrogallol red and molybdate to form a coloured complex. The intensity of the colour formed is proportional to the protein concentration in the sample and can be measured spectrophotometrically.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Reagent R1	Succinate Buffer	50 mmol/l
	Sodium Molybdate	0.04 mmol/l
	Pyrogallol Red	0.05 mmol/l
Urine/CSF Protein Standard	Albumin/Globulin aqueous primary standard	1000 mg/l

Reagent Preparation and Stability:
R1: Liquid, ready to use
Standard: Liquid, ready to use
R1 and Standard are stable to the expiry date when stored unopened at 2 - 8ºC and protected from light. Once opened store tightly closed at 2 - 8ºC and protect from light and contamination. Do not use reagents after the expiry date. Dispose of reagents carefully in line with local guidelines.

Sample Collection, Preparation and Stability:
Single urine specimen or 24 hour collection samples may be used, but collected in containers without preservative.
CSF collected as standard. Any haemolysis present invalidates the sample for protein analysis.
Urine and CSF samples are stable for 48 hours at 2 - 8ºC.

Assay Procedure:

WAVELENGTH	578 – 600 nm
TEMPERATURE	25-37ºC
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample	-	-	20 µl
Standard	-	20 µl	-
Reagent	1000 µl	1000 µl	1000 µl
Mix and incubate for 10 minutes at assay temperature. Read the absorbance (Δ Abs) of Sample/Standard against the Reagent Blank. The colour is stable for 30 minutes.			

Calculation:
Urine 24h:

$$\text{Concentration (mg Protein/24h)} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Concentration of Standard x vol (L) urine}$$

CSF:

$$\text{Concentration (mg/L Protein)} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Concentration of Standard}$$

Performance Characteristics:
Measuring range:
9.4 – 4000 mg/l.
Where results are above the linearity limit, dilute samples in a ratio of 1+3 with Normal saline, re-assay and multiply the result by 4.

Interferences:
Criterion: Recovery within +/- 10% of initial value.
Icterus: No significant interference up to 20 mg/dl of Bilirubin.
Haemolysis interferes with the assay.

Limitations:
Protein U&CSF Standard: handle carefully as this is prone to contamination. Use clean disposable tips for dispensing the calibrator supplied.
The result from this test should not be used as the sole criteria for the diagnosis of renal disease or disorders associated with elevated protein in CSF, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Reference Range:

Urine (24h)	< 150 mg/l
	Children 300 – 1000 mg/l
CSF	Adults 150 – 450 mg/l

Each laboratory should establish its own mean reference range according to the population.

Automated systems:
Contact Prestige Diagnostics Technical Department for applications on a wide range of automated analysers.

References:

1. Orsonneau JL et al. An improved Pyrogallol Red-Molybdate method for determining total urinary protein. Clin Chem 1989; 35: 2233-2236.
2. Koller A. Total serum protein. Kaplan A. et al. Clin Chem The C.V Mosby Co. St Louis. Toronto. Princeton 1984; 1316-1324 and 418.
3. Bablok W. et al. A General Regression Procedure for Method Transformation. Clin Chem Clin Biochem 1988; 26: 783-790.
4. Tietz NS (Ed) Clinical Guide to Laboratory tests, 3rd ed 1995. PA: W B Saunders; 1995: 518-522.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Keep away from sunlight

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