

**Quantitative determination of Protein in Urine / CSF**  
**Only for *In Vitro* Diagnostic use**

- Bring all reagents, standard and samples to room temperature 18 - 28°C, prior to analysis.

**ORDER INFORMATION**

REF	Cont.
MTP 25	1 X 25 mL
MTP 100	2 x 50 mL

**CLINICAL SIGNIFICANCE**

In healthy persons, the urine contains no protein or only a trace amount of protein; normally the glomeruli prevent 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 concentration of protein in cerebro-spinal fluid (CSF) can be cause by infections and intracranial pressure.

**Method**

Photometric test.

**PRINCIPLE**

Protein in the sample reacts with pyrogallol red and molybdate in acid medium forming a coloured complex which can be measured by spectrophotometry.

Protein + Pyrogallol Red-Molybdenum Complex → Protein Pyrogallol Red-Molybdenum Complex.

**REAGENT**

Reagent I : Pyrogallol red Solution  
Protein (Urine) Standard : Bovine albumin 100 mg/dL.

**REAGENT PREPARATION**

The Reagent is ready to use.

**REAGENT STORAGE AND STABILITY**

The Reagent is stable till expiry when stored at 2 - 8°C. Store protected from light.

**WARNING AND PRECAUTIONS**

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

**WASTE MANAGEMENT**

Please refer to local legal requirements.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- NaCl solution 9 g/L
- General laboratory equipment

**SAMPLE COLLECTION AND PRESERVATION**

**Urine** collected by standard procedures. Collect a 24-hour urine specimen. Measure the volume and store at 2-8°C. Stable for 8 days.  
**Cerebrospinal fluid (CSF)** collected by standard procedures. Do not use samples with blood. Stable for 4 days at 2-8°C.

**ASSAY PROCEDURE**

**Operating Instructions**

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.

AUTOMATED PARAMETERS	
Wavelength	600 nm
Reaction Type	End Point
Cuvette	1 cm light path
Reaction Temperature	37°C
Reaction Type	Increasing
Measurement	Against Reagent Blank
Sample Volume	20µl
Reagent Volume	1000µl
Incubation	10 minutes
Blank Absorbance Limit	< 0.500
Low Normal	150 mg/L
High Normal	450 mg/L
Linearity	200 mg/L

**MANUAL ASSAY PROCEDURE**

**Pipette into Test Tubes**

	BLANK	STD	SAMPLE
Sample	-	-	20µl
Standard	-	20µl	-
Reagent	1000µl	1000µl	1000µl

- Mix & Incubate for 10 min. at 37°C .Measure absorbance of Sample (AT) and Standard (AS) against Reagent Blank at 600 nm.

**SAMPLE DILUTIONS**

- This method is linear upto a concentration of 200 mg/L.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

**CALCULATION**

Urine 24 h=	$\frac{A(\text{Sample})}{A(\text{standard})} \times 1000$ (Standard conc.)x vol. (L) urine 24 h= mg protein/24
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CSF	$\frac{A(\text{Sample})}{A(\text{standard})} \times 1000$ (Standard conc.)= mg/L protein in the sample
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**CALIBRATORS AND CONTROLS**

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

**PERFORMANCE CHARACTERISTICS**

**WITHIN RUN**

Sample	Mean Concentration	SD	CV %
Control 1	49.69	2.09	4.20%
Control 2	150.63	2.49	1.65%

**RUN TO RUN**

Sample	Mean Concentration	SD	CV %
Control 1	5046	2017	4.30%
Control 2	151.64	2.59	1.70%

#### LINEARITY

The method is linear upto a concentration of 200 mg/L. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

**Limit of detection:** The limit of detection for Urine Protein is 10 mg/L.

#### METHOD COMPARISON

A comparison of Accucare Urine Protein with a commercially available assay (x) using 20 samples gave following results:  $R^2 = 0.9900$

#### REFERENCE VALUES

Urine	Less than 150 mg/24-h
Cerebrospinal fluid:	
Children	300-1000 mg/L
Adults	150-450 mg/L

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

#### LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.











#### INTERFERENCE

- Ascorbic Acid: No interference found upto 500 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

#### BIBLIOGRAPHY

- Orsonneau JL et al. An improved Pyrogallol Red-Molybdate Method for Determining Total Urinary Protein. Clin Chem 1989 (35):2233-2236.

#### GLOSSARY OF SYMBOL

	Consult Instruction for Use		Lot Number
	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		For <i>in vitro</i> Diagnostic use only
	Keep away from sunlight		Content of the kit



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