Pariksha Biotech
A game changer in IVD

Microprotein Estimation Kit

High-Q Microprotein-ML

(Pyrogallol Red Method)

HIGH®
Command on Quality

Intended Use:
For the quantitative estimation of Microprotein in Human Urine and CSF

Summary and Clinical Significance:
Urine is formed by ultrafiltration of plasma across the glomerular capillary wall. Proteins with a relative molecule mass > 40 000 are almost completely retained, while smaller substances easily enter the glomerular filtrate.

Most CSF protein originates by diffusion from plasma across the blood- CSF barrier. Elevated levels occur as a result of increased permeability of the blood-CFS barrier or with increased local synthesis of immunoglobulins. Turbidimetric methods using trichloroacetic acid (TCA) or sulfosalicylic acid (SSA) require precipitation of the protein in the sample; the resulting turbidity may be unstable and flocculate. Dye-binding methods such as Protein measurements in urine are used in the diagnosis and treatment of disease conditions such as renal or heart diseases, or thyroid disorders, which are characterized by proteinuria or albuminuria. CSF protein measurements are used in the diagnosis and treatment of conditions such as meningitis, brain tumors, and infections of the central nervous systems.

Principle:

When the Pyrogallol Red-Molybdate Complex binds to basic amino acid groups of protein molecules, there is a shift in reagent absorbance. The increase in absorbance at 578nm (570–630nm) is directly proportional to protein concentration in the sample.

Storage and Stability:

All the reagents must be stored at 2-8^{0}C and are stable till the expiry date mentioned on the labels. Microprotein Reagent should be protected from light as the reagent is photosensitive.

Reagent Composition:

Pyrogallol Red - 75 mmol/L

Succinic Acid - 60 mmol/L

Sodium Molybdate - 10mMol/L

Activators and Stabilizers

Specimen:
Urine:
Use random or 24 hour urine specimens.

Cerebrospinal Fluid (CSF):
No special additives are required. Blood in a CSF specimen invalidates the protein value. Centrifuge samples containing precipitate before performing the assay. Collection and preparation.Specimens may be stored at temperatures between +2°C and +8°C for 48 hours.

Procedure:

Pipette into test tubes labeled Blank (B) Standard (S) and Test (T) as follows:

Reagent	B	S	T
Microprotein Reagent	1.00 ml	1000 µl	1000 µl
Microprotein Standard (Conc. 100 mg/dl)	-	20 µl	-
Sample	-	-	20 µl

Mix well and incubate for 5 min. at 37°C.

Read absorbance of Standard (S) and Test (T) against Blank (B) at 578 nm or with red filter (570 – 630 nm) within 20 min. Final Colour is stable for 20 min at Room Temperature.

Calculations:

$$\text{Microprotein Conc. (mg/dl)} = \frac{\text{Abs. of Test}}{\text{Abs. of Standard}} \times 100$$

Estimation of Total Microprotein in Urine:

Procedure:

1. Measure and record 24 hours urine volume in litres.
2. Determine the Microprotein concentration in mg/dl using High-Q Microprotein - ML Kit.
3. Convert the Microprotein Concentration in to mg/L by multiplying with factor "10".
4. Multiply the Microprotein concentration (mg/L) with 24 hrs. Urine Volume.

Formula:

Total Microprotein excreted / 24 hrs = Microprotein Concentration in mg/dl X 10 X volume of 24 hrs urine collected in litres.

Example:

24 hours urine volume = 1.8 L

Urine Microprotein Conc. Determined by High-Q Microprotein Kit = 15 mg/dL.

Total Microprotein excreted in urine/24 hours based on the above formula =15 x 10 x 1.8 = 270 mg/24 hours.

Above example falls in abnormal range (Pathological and indicates disease).

System Parameters

Reaction Type (Mode):		END POINT
Wave Length	:	578 nm (570–630)
Flow Cell Temp.	:	37°C
Sample Volume	:	20 µl
Reagent Volume	:	1000 µl
Standard Conc.	:	100
Unit	:	mg/dL
Blanking with	:	Reagent
Low Normal (CSF)	:	10
High Normal (CSF)	:	50
Linearity	:	250

Pariksha Biotech
A game changer in IVD

Microprotein Estimation Kit

High-Q Microprotein-ML

(Pyrogallol Red Method)

HIGH®
Command on Quality

Quality Control:

To ensure adequate Quality Control, the use of Commercial Urine/CSF Reference Control materials are recommended with each assay batch. Use of Quality Control material checks both the instrument and reagent functions.

Limitations & Interference

No significant interference was observed from conjugated and unconjugated bilirubin concentration up to 20 mg/dl, haemoglobin up to 50 mg/dl , Ascorbic Acid ,Creatinine, GlucosePhosphorus, Urea, Magnesium,Sodium Citrate, Caffeine, Cefazolin Sodium,Chlorpromazine Calcium. L-Dopa, Gentamicin Sulfate, Sodium Oxalate and Uric Acid.

Normal Range:

Urine 28.0 –141 mg/24 hrs

Random Urine: Less than 10 mg/dL

CSF 10 – 50 mg/dL

It is recommended that laboratories establish their own normal range.

Notes:

1. The Microprotein Reagent should not be exposed to light (photosensitive).
2. Use fresh tubes / cuvettes and microtips to avoid protein contamination.
3. Read results within 20 minutes as the final colour stability is 20 minutes.
4. If the sample value exceeds 250 mg/dl, dilute sample 1:1 with saline and multiply results with the dilution factor 2 .

Precision and Corellation:

Inter assay and Intra assay %CV were evaluated at three different pooled serum samples..

Mean inter assay CV %(n=20) 1.9%

Mean intra assay CV %(N=20) 1.8%

Values from 100 serum samples obtained with High-Q Microprotein - ML kit were compared with the values obtained from three other manufacturers similar kits and the correlation factor was r =0.99

References:

1. Watanabe, N, clinchem 32, 8, 1551-1554 (1986)

Ordering Information:

Ref./Cat. No.	Pack Size	Presentation
P-MPR - 25	25 ml	Mono Liquid Reagent
P-MPR - 50	2 x 25 ml	

PRODUCT FEATURES:

- **Single Liquid Reagent.**
- **Linearity 250 mg/dl.**
- **Superior over sulphosalicylic acid method.**
- **5 minutes End Point Assay.**
- **Results correlate with Benzethonium Chloride method.**
- **Detects Microprotein as low as 4 mg/dL.**
- **Tailor made for tropical Conditions. With Lipid Clearing Factor (LCF).**
- **No significant interference was observed from conjugated and unconjugated bilirubin concentration up to 20 mg/dl, haemoglobin up to 50 mg/dl , Ascorbic Acid, Creatinine, Glucose, Phosphorus, Urea, Magnesium, Sodium Citrate, Caffeine, Cefazolin Sodium, Chlorpromazine Calcium. L-Dopa, Gentamicin Sulfate, Sodium Oxalate and Uric Acid.**
- **Available as Multi purpose Reagents and System Packs**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

+91 7075706709 info@parikshabio.com www.parikshabio.com

AN ISO 13485 Certified Company

Rev # 2