LiquiMAX Microprotein-SLR
(Pyrogallol Red Method)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVMPR - 50	2 x 25 ml	Mono Liquid Reagent
AVMPR - 100	4 x 25 ml	

INTENDED USE:
LiquiMAX Microprotein is an in-vitro diagnostic kit is use for the quantitative determination of Microprotein in Human Urine and CSF.

PRODUCT FEATURES:
1. Single Liquid Reagent.
2. Linearity 250 mg/dl.
3. Superior over sulphosalicylic acid method.
4. 5 minutes End Point Assay.
5. Results correlate with Benzethonium Chloride method.
6. Detects Microprotein as low as 4 mg/dl.
7. Available as Multi purpose Reagents and System Packs

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.

PRINICIPLE:
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 & STABILITY:
All the reagents must be stored at 2-8°C and are stable till the expiry date mentioned on the labels. Microprotein Reagent should be protected from light as the reagent is photosensitive.

KIT COMPONENTS
1. Microprotein Reagent
2. Microprotein Standard : Concentration as stated on the label

COMPOSITION:
Pyrogallol Red - 75 mmol/L
Succinic Acid - 60 mmol/L
Sodium Molybdate - 10mMol/L
Activators and Stabilizers

REAGENT RECONSTITUTION & STABILITY
Reagent are liquid stable no need for reconstitution.
When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED
Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION
Discard any turbid reagent if blank reagent absorbance exceeds 0.8 at 578 nm against distilled water.

WARNING & PRECAUTIONS
- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION AND STORAGE
Urine: Use random or 24 hour urine specimens. Use no preservatives.

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.

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

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

Reagent	B	S	T
1. Microprotein Reagent	1.00ml	1000 µl	1000 µl
2. Microprotein Standard (Conc. 100 mg/dl)	-	20 µl	-
3. 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:
Microprotein Conc. (Mg/dl) $= \frac{\text{Abs. of Test}}{\text{Abs. of Standard}} \times 100$

ESTIMATION OF TOTAL MICROPROTEIN IN URINE:
1. Measure and record 24 hours urine volume in litres.
2. Determine the Microprotein concentration in mg/dl using LiquiMAX Microprotein - SLR 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 = 2.0L
Urine Microprotein Conc. Determined by GenX Microprotein Kit = 15 mg/dl.
Total Microprotein excreted in urine/24 hours based on the above formula =15 x 10 x 2.0 = 300 mg/24 hours.
Above example falls in abnormal range (Pathological and indicates disease).

EXPECTED VALUES

Urine 21.3 – 119.6 mg/24 hrs

CSF 10 – 50 mg/dl

It is recommended that laboratories establish their own normal range.

QUALITY CONTROL & CALIBRATION:

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.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 250 mg/dl

2. Sensitivity/ Limit of Detection (LOD)

The Lowest Detectable Level was estimated 2 mg/dl.

3. Interferences

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.

Intra -Assay n = 40	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	25.4	0.24	1.81
Sample 2	58.9	0.60	1.01
Sample 3	103	1.50	1.45

Inter -Assay n = 40	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	25.6	0.24	1.81
Sample 2	58.9	0.49	0.80
Sample 3	103	0.65	0.63

5. Method Comparison:

A comparison of the LiquiMAX Microprotein (y) with a commercial obtainable assay (x) gave the following result : y = 1.113 x – 0.278; r = 0.990

LIMITATIONS

Measuring range: 2-250 mg/dl. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

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 .

REFERENCES:

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

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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