Microprotein Kit
CliniQuant - FSR
Pyrogallol Red Method, End Point

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Dye Reagent	R2 Microprotein Standard
MTPFSR-01	2 x 25ml	2 x 25ml	1 x 3ml

INTENDED USE
This reagent is intended for quantitative determination of protein concentration in human urine and CSF.

CLINICAL SIGNIFICANCE
Glomeruli behaves as ultrafilters for plasma proteins. The degree of filtration depend on their molecular size and their plasma concentration. The proportion of proteins excreted in urine depends on the absorption capacity of the renal tubules.

PRINCIPLE OF THE METHOD
Dye pyrogallol combines with molybdenum acid to form a red colored complex with absorbance maxima at 470 nm. This complex combines with protein under acidic conditions shifting its absorbance maxima to longer wavelength 600 nm. The concentration of the protein is obtained by measuring absorbance at 620 nm.

KIT COMPONENTS
Composition
R1- Dye Reagent : Pyrogallol Red 0.058 mmol/l, Sodium Molybdate 0.12mmol/l
R2- Microprotein Standard : 100 mg/dl, Human Serum Albumin 100 mg/dl

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

REAGENT PREPARATION, STORAGE & STABILITY
Reagent is ready to use. Keep away from direct light sources.
Stability: up to expiration date on labels at 2-8 °C.
Stability since first opening of vials: preferable within 60 days at 2-8 °C.

REAGENT DETERIORATION
1. Discard any turbid reagent or failure to recover control values within the assigned range.
2. Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS
1.Reagent contains acid. Do not mouth pipette. It is recommended to handle carefully, avoiding contact with skin and ingestion. If spilled, thoroughly wash affected areas with plenty of water.
2.Specimens should be considered infectious and handled appropriately.
3.Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN
Use fresh urine specimens. Urine specimens when stored at 4°C are stable for 2-3 days. Addition of chemical preservative merthiolate (0.2 mmol/l) is recommended for urine specimens during delay in analyses due to transportation.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc. (mg/dl)	100 (mg/dl)
Filter - 1 (nm)	620
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	21.3
Reference High	119.6
Linearity Limit	400

TEST PROCEDURE

Dispense	Blank	Standard	Sample
Reagent 1	1ml	1ml	1ml
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Mix, incubate for 10 min at 37°C. Read absorbance of standard (As) and samples (Ax) against reagent blank.			

RESULT CALCULATION
Urine: proteins mg/dl = Ax/As x Concentration of Standard

To determine the 24 hours urinary protein, measure the 24 hours urine total volume in ml (TV) and assay the urine protein content (mg/dl). Calculate the 24hr urinary protein using the formula:

Protein (mg/day) = protein (mg/dl) x TV /100
where : TV = 24 hours urine total volume in ml
100= converts ml/day to dl/day

CE
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SI conversion factor: 1 mg/dl x 0.01 = 1 g/l

EXPECTED VALUES

Urine: 21.3 - 119.6 mg/day (24 hours sample)

CSF: 8- 43 mg/dl

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal and assayed abnormal Urine controls, to confirm the validity of the test and assure the accuracy of patient result.

Using the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 400 mg/dl.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 2.4 mg/dl.

The limit of quantification is 7.4 mg/dl

3. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	16.41	0.59	3.62
sample 2	57.28	1.05	1.83

Inter-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	16.65	0.83	4.99
sample 2	56.4	2.04	3.62

LIMITATIONS

Samples with values above 400 mg/dl should be diluted with 0.9% saline, re-run and results multiplied by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 695 – 700.

2. Data on file: Meril Diagnostics.

IFU/MTPFSR01/01

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged
EC REP	Authorized European Representative in the European Community		