Instructions For Use

GENESIS

Micro Total Protein (M-TP) (Colorimetric Method)

Cat no.	size
1113 101	2*50
1113 102	2*100
1113 103	4*100

INTENDED USE

Micrototal protein reagent is intended for the in-vitro quantitative, diagnostic determination of total protein in human cerebrospinal fluid (CSF) and urine on both automated and manual systems.

DIAGNOSTIC CHARACTERISTICS

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.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

Proteins react in acid solution with pirogallol red and molybdate to form a colored complex.
The intensity of the color formed is proportional to the protein concentration in the sample.

COMPOSITION

Reagent (R)	Pyrogallol red Sodium molybdate	50 µmol/L 0,04 mmol/L
(Standard Protein)		150 mg/dL

STORAGE AND STABILITY.

- Store at 2-8ºC
- The kit are stable until the expiration date on the label when stored tightly closed.

REAGENT PREPARATION

- Reagent Ready to use.

ADDITIONAL EQUIPMENT

− Analyzer, spectrophotometer able to read at 578 nm

SPECIMEN

- Use Urine and CSF free from blood contamination.

Stability:-

- Urine 24 h: Stability 8 days at 2-8ºC.
- Cerebrospinal fluid (CSF): Stable 4 days at 2-8ºC.

PRECAUTIONS AND WARNINGS

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

PROCEDURE

1. Assay conditions:

Wavelength: . . . . . 578 nm
Optical path:……..1 cm
Assay type:…… End Point

2. Pipette into a cuvette:

	Reagent Blank	Standard	Sample
Reagent (R)	1.0 mL	1.0 mL	1.0 mL
Standard	-----	20 µL	------
Sample	-----	-----	20 µL

3. Mix and incubate for exactly 10 minutes at 15 - 25 °C. Measure absorbance of specimen (Aspecimen) and standard(Astandard) against reagent blank.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

CALCULATIONS

CSF or Urine protein conc.(mg/dL) =

$$\frac{A(specimen)}{A(standard)} \times \text{Standard conc}$$

REFERENCE VALUES

Urine (24 hrs)	20 – 145 mg/day
Urine (random)	< 10 mg/dL
CSF	15 – 45 mg/dL

QUALITY CONTROL

It is recommended to use the Control Serum level I And II to verify the performance of the measurement procedure.
Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS

Measuring range:

- Detection limit 0.944 mg/dL
- Linearity limit 400 mg/dL.

If the concentration is greater than linearity limit, dilute the sample 1/2 With NaCl 9 g/L and multiply the result by 2.

Precision:

	Intra-assay (n= 20)		
Mean (mg/dL)	22.0	53.6	101.4
SD	3.7	4.0	5.2
CV (%)	2.28	0.75	0.51

Inter-assay (n= 20)		
21.6	49.9	101.8
18.3	26.1	166.1
7.35	5.22	16.43

Sensitivity: 1mg/L = 0.00026 (A).

Accuracy: Results obtained using Genesis reagents (y) did not show systematic differences when compared with other commercial reagents (x). The results obtained using 50 samples were the following: Correlation coefficient $(r)^2$: 0.9338 Regression equation: y = 0.4294x – 5.4159 The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

- Bilirubin (< 5 mg/dL) does not interfere.
- Hemoglobin may affect the results.
- Other drugs and substances may interfere.
- Positive interferences in urine of patients under treatment with aminoglycosids-gentamicine or tobromycine-reported with other pyrogallol tests have been shown to have no influence with this specific formulation.
- CSF contaminated by red cells from a traumatic lumbar puncture or intracerebral hemorrhage will increase protein concentrations by ≈ 10 mg/L for every 1000 erithrocytes.

BIBLIOGRAPHY

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CE

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