N.S. BIO-TEC

Micro proteins

Colorimetric, Endpoint

INTENDED FOR USE:
For the quantitative determination of Micro Proteins in urine and cerebro-spinal fluid (CSF)

PRINCIPLE :
The Proteins, at acid pH values, bind pyrogallol red in presence of molybdate and forms a colored complex, which colour intensity is directly proportional to the amount of proteins in the sample

SPECIMEN COLLECTION:
Urine 24/h and cerebro-spinal fluid.
Urine may be stored at: - 20°C up to 1 year.
During drawing of cerebro-spinal fluid, avoid haemolysis.
The cerebro-spinal fluid may be stored 72 hours in refrigerator or 6 months at: - 20°C
Shake and bring the samples at room temperature (+15-25°C) before using

REAGENT COMPOSITION:

R2	Buffer Pyrogallol Sodium molybdate Sodium oxalate	100 mmol/L < 0.1 mmol/L < 1 % < 1 %
R1	Albumin/Globulins	50mg/dL

PACKAGE : Collection & Storage .
Store at room temperature (+15-25°C)
Stable until the expiration date reported upon the package.
After the unsealing and the taking of the reagent, it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacteric contamination

PRECAUTION & WARNING:
Avoid pipette by mouth .
The preparation , according to current regulation . is classified as not dangerous.
The total concentration of non active components (preservatives , detergents ,stabilizers) is below the minimum required for citation .
Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes The samples must be handle as potentially infected from HIV or Hepatitis .

REAGENT PREPATION AND STABILITY :
Ready to use liquid reagent. Stable until the date reported on the label.
The Reagent is limpid and yellow/orange.
Do not store the reagent (A) in refrigerator: the colouring could precipitate.
The Reagent is limpid and red

REQUIRED MATERIALS NOT PROVIDED :
General Laboratory Equipment and instrumentations.

PROCEDURE :

Wavelength	600nm (598-610)
Optical path :	1 cm light path
Temperature :	+37ºC
Reading :	Against blank reagent
Assay type :	Endpoint

Pipetting in tubes :

	BLANK	STANDARD	SAMPLE
Reagent (A)	1000 µL	1000 µL	1000 µL
Distilled Water	25 µL		
Calibrator		25 µL	
Sample Urine			25 µL

Mix, incubate for 5 min at 37°C or 15 min at room temperature (+15-25°C); read sample and standard extinction against blank reagent
Colour is stable at least 15 min.
Volumes can be proportionally modified.
This methodology describes the manual procedure to use the kit.
For automated procedure, ask for specific application

CALCULATION :

$$\textbf{URINE : PT (mg/24h)} = \frac{\text{(A) sample Urine}}{\text{(A) Calibrator}} \times 50 \times \frac{\text{Vol. Urine ml}}{100}$$

$$\textbf{CSF : PT (mg/dL)} = \frac{\text{(A) sample CSF}}{\text{(A) Calibrator}} \times 50$$

A = Extinction
Calibrator Concentration = 50 mg/dL

EXPECTED VALUES:
Proteins in urine : 28 -150 mg/24h
Proteins in urine random: < 10 mg/dL
Protein in CSF: 14 - 45 mg/dL
(baby: 40 - 120 mg/dL – Adults>60 years: 15 - 60 mg/dL).
The above mentioned values are to be considered as a reference. It is strongly recommended that each laboratory establish its own normal range according to its geographic area, according to IFCC protocol

WASTE DISPOSAL :
The disposal of the product must be in accordance with local regulation concerning waste disposal .

QUALITY CONTROL :
It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

PERFORMANCE :

MEASURE INTERVAL INEARITY :	0-250mg/dl
DETECTION LIMIT (2DS):	0.025mg/dl
SENSITIVITY:	1mg/dl=0.02433A at 600nm

INTER-ASSAY PRECISION: n=20

CSF		C.V.=2.1 %
Normal Urine		C.V.=2.8 %
Pathologic Urine		C.V.=2.9 %

INTRA-ASSAY PRECISION: n=20

CSF		C.V.4%
Normal Urine		C.V.6.4%
Pathologic Urine		C.V.5.4%
CORRELATION	r = 0.9971	n=20
LIN. REGRESSION	y = 1.0205 × - 0.0488	n=20

INTERFERENCE:

Interferences are negligible up to :	
Glucose 500 mg/dl	NaCl 350 mEq/L
Creatinine 25 mg/dl	Urea 200 mg/dL

METHOD LIMITATIONS:
For concentration higher than 250 mg/dl repeat the measure on a sample diluted 1:5 with saline solution e multiply the results by 5.
In drawing of Urine/24h, do not use Benzoic Acid or Hydrochloric Acid as antibacterial agents, because they could interfere giving falsely low results
For a thorough evaluation of the interfering substances , consult:
Fujita,Y,Mori,I,Kitano,Bunseki kagatu 32:E379-386, 1983

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