SBio MICRO PROTEIN KIT

(Pyrogallol Red Method)

(For invitro diagnostic use only)

REF	90620075	90632150
Pack Size	75 ml	2 x 150 ml

CE

8°C 2°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	S Micro Protein Standard (100 mg/dl)	Pyrogallol Red Pyrogallol Red Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	This way up	EC REP Authorised Representative in the European Community
Date of Manufacture	REF Catalogue Number	L1 Micro Protein Reagent		

INTENDED USE

Micro Protein Kit is used for the determination of proteins in urine and CSF.

PRINCIPLE OF THE TEST

Proteins, in an acidic medium, combine with Pyrogallol Red and Molybdate to form a blue purple coloured complex. Intensity of the colour formed is directly proportional to the amount of proteins present in the sample.

Proteins + Pyrogallol Red + Molybdate —(Acidic Medium)→ Blue Purple Coloured Complex

CLINICAL SIGNIFICANCE

Protein is the main component of muscles, organs, and glands. Every living cell and all body fluids, except bile and urine, contain protein. The cells of muscles, tendons, and ligaments are maintained with protein. Two major groups of proteins in the blood are albumin and globulin. High protein levels may be caused by severe dehydration, diseases of the blood, such as multiple myeloma, Hodgkin's lymphoma, leukemia, macroglobulinemia, or hemolytic anemia, an autoimmune disease, such as rheumatoid arthritis, lupus, autoimmune hepatitis, kidney disease, liver disease and tuberculosis. Low levels may be caused by a poor diet (malnutrition), severe burns, kidney disease, liver disease.

PRESENTATION

	75 ml	2 x 150 ml
L1 : Micro Protein Reagent	75 ml	2 x 150 ml
S : Micro Protein Standard (100 mg/dl)	3 ml	5 ml

COMPOSITION

Sycinic Acid 70 mM, Sodium Benzoate 3.5 mM & Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8° C till the expiry mentioned on the labels.

REAGENT PREPARATION

Reagents are ready to use.

For doing the High Sensitivity Assay dilute the Micro Protein Standard (S) 1+4 with normal saline before use. Prepare fresh each time.

SAMPLE REQUIRED

Urine and CSF is required.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

TEST PROCEDURE

Wavelength / filter : 600 nm (Hg 623 nm)/Red
Temperature : R.T.
Light path : 1 cm

MATERIAL REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Waterbath, Stopwatch/Timer.

High Linearity Assay:

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

Addition of Reagent	B (ml)	S (ml)	T (ml)
Micro Protein Reagent (L1)	1.0	1.0	1.0
Distilled water	0.01	-	-
Micro Protein Standard (S)	-	0.01	-
Sample	-	-	0.01

Mix well and incubate at R.T. for 5 minutes. Measure the absorbance of the Standard (Abs. S) and Test Sample (Abs. T) against Blank, within 30 minutes.

High Sensitivity Assay:

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

Addition of Reagent	B (ml)	S (ml)	T (ml)
Micro Protein Reagent (L1)	1.0	1.0	1.0
Distilled water	0.05	-	-
Diluted Standard (S)	-	0.05	-
Sample	-	-	0.05

Mix well and incubate at R.T. for 5 minutes. Measure the absorbance of the Standard (Abs. S) and Test Sample (Abs. T) against Blank, within 30 minutes.

CALCULATIONS

High Linearity Assay:

$$\text{Micro Proteins in mg/dl} = \frac{\text{Abs.T}}{\text{Abs.S}} \times 100$$

High Sensitivity Assay:

$$\text{Micro Proteins in mg/dl} = \frac{\text{Abs.T}}{\text{Abs.S}} \times 20$$

Convert the Micro Protein concentration into mg/L by multiplying with factor “10”. Multiply the Micro Protein concentration (mg/L) with 24 hours urine volume collected in liters.

QUALITY CONTROL

The following process is recommended for QC during the assay of Micro Protein. *Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:

The High Linearity procedure is linear upto 400 mg/dl and the High Sensitivity procedure is linear upto 80 mg/dl. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

Method comparison:

Comparative studies were done to compare our reagent with another commercial Micro Protein Assay. No significant differences were observed. Details of the comparative study are available on request.

REFERENCE RANGE

Urine : 28 - 140 mg/24 hours.
Urine (Random) : 1 - 35 mg/dl
CSF : 10 - 40 mg/dl

It is recommended that each laboratory establish its own normal range representing its patient population.

NOTES

Protect reagents from bright light. Proteins are reported to be stable in the sample for 3 days at 2-8° C. In case the exact wavelength is not available and one obtains low absorbances, for the High Linearity Assay, one can use 0.02 ml of the sample instead of 0.01 ml to obtain higher absorbances. However in this case the linearity of the assay drops to 200 mg/dl from 400 mg/dl. High concentration of chelating agents and traces of detergents may interfere. Hence their presence should be avoided and good clean glassware should be used. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

(1) Watanabe, N, et al (1986), Clin Chem., 32,1551. (2) Data on file: SBio.

Mfd. for:

Singapore Biosciences PTE Ltd.

11 Yishun Street 51, # 04-23, The Criterion, Singapore 767971.

EC REP

CMC Medical Devices & Drugs S.L.,
C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain.

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