PROTEIN URINE (uPROTEIN)

PYROGALLOL RED

Intended use:
Protein in the sample reacts with pyrogallol red and molybdate in acidic medium forming a coloured complex which can be measured by spectrophotometry.

Composition:

A. Reagent. Pyrogallol red 60 umol/L, sodium molybdate 40 umol/L, succinate 50 mmol/L, pH 2.3, detergent.
Harmful (Xn): R20/21/22: Harmful by inhalation, in contact with skin and if swallowed. R68/20/21/22: Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed. S36/37: Wear suitable protective clothing and gloves. S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S. Protein (Urine) Standard. Bovine albumin. Concentration is given on the label. Concentration value is traceable to the Standard Reference Material SRM 927 (National Institute of Standards and Technology, NIST)

Preparation and stability:
Reagent (A): Store at 15-30ºC.
Protein (Urine) Standard (S): Store at 2-8ºC, once opened.
Reagent and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.
Indications of deterioration:
Reagent: Presence of particulate material, turbidity, absorbance of the blank over 0.150 at 600 nm.
Standard: Presence of particulate material, turbidity.
Reagent and Standard are provided ready to use.
Onboard Stability: 2 weeks.

Specimen:
Urine collected by standard procedures. Collect a 24-hour urine specimen, measure the volume and store at 2-8ºC. Stable for 8 days. Cerebrospinal fluid (CSF) collected by standard procedures. Do not use samples with blood. Stable for 4 days at 2-8ºC

Limitations - interference:
Criterion: Recovery within ±10% of initial value.
Icterus: No significant interference up to an index I of 26 (approximate conjugated and unconjugated bilirubin concentration: 26 mg/dl).
Hemolysis: No significant interference up to an index H of 1000 (approximate haemoglobin concentration: 1000 mg/dl).
Lipemia (Intralipid): No significant interference up to an index L of 1000 (approximate triglycerides concentration: 2000 mg/dl). There is poor correlation between turbidly and triglycerides concentration. Rheumatoid factors < 180 lU/l do not interfere.

Measuring/reportable range:
70 - 4000 mg/L
At higher concentrations, dilute the sample with 0.9% NaCl (e.g. 1 + 1). Multiply the result by the appropriate factor (e.g. 2).

Expected values:
Urine: Less than 150 mg/24-h
Cerebrospinal fluid:
Children: 300-1000 mg/L
Adults: 150-450 mg/L
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference range. For diagnostic purposes the uPROTEIN results should always be assayed in conjunction with the patient's medical history, clinical examinations and other findings.

Analytical sensitivity (lower detection limit)
Detection limit: 70 mg/L
The lower detection limit represents the lowest measurable uPROTEIN concentration that can be distinguished from zero. It is calculated as three standard deviations of 21 replicates of the lowest standard.

Testing procedure:
Applications for automated systems are available on request.
Materials provided
Working solutions as described above Additional materials required
Calibrators and controls as indicated below
0.9% NaCl,

Manual procedure:	
Wavelength:	600 nm
Temperature:	+37°C
Cuvette:	1 cm
Zero adjustment:	against reagent blank

	Sample/ Calibrator
Sample/Calibrator	10 µl
R1	500 µl
Mix, and incubate for 10 minutes. And read absorbance A_2.	
Calculation:	
(A_{sample} / $A_{standard}$) C Standard (mg/L) x 24h urine volume (L) = C Sample (mg/24h protein)	

Imprecision:
Reproducibility was determined using human samples and controls in an internal protocol (n = 20). The following results were obtained:

Repeatibility (within run):

Mean concentration	CV	n
800 mg/L	3.0 %	20
1600 mg/L	2.1 %	20

Reproducibility (run to run):

Mean concentration	CV	n
800 mg/L	3.2 %	25
1600 mg/L	3.0 %	25

Method comparison:
A comparison of the BIOANALYTIC uPROTEIN (y) with a commercial obtainable assay (x) gave the following result (mg/L). y = 1.07 x + 2.01; r = 0.99

Quality Control:
BIOANALYTIC URIN CON L1 5 x 1 ml
BIOANALYTIC URIN CON L2 5 x 1 ml

Calibration:
Standardization: This uPROTEIN method was calibrated against an international standard defined for uPROTEIN.
S1: BIOANALYTIC uPROTEIN CAL. SET

Literature:
1. Watanabe N et al. Urinary Protein as measured with a pyrogallol red-molybdate complex, manually and in a Hitachi 726 automated analyzer. Clin Chem 1986; 32:1551-1544.
2. Orsonneau JL et al. An improved pyrogallol red-molybdate method for determining total urinary protein. Clin Chem 1989; 35:2233-2236.
3. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2005.
4. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
5. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.

Order information (Cat No.) :

B21300	B25300	B28300	B31300	B34300	B37300
B21301	B25301	B28301	B32300	B34301	B80300
B22300	B27300	B30300	B33300	B35300	
B24300	B27301	B30301	B33301	B36300	

Manufacturer
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SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions

ISO 9001:2015
ISO 13485:2016