URINARY PROTEIN
Multi-Purpose (MPR) Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL363UP	3 x 50 ml	UP 1	2 - 8°C
	1 x 50 ml	UP 2	
	5 x (1 x 3 ml)	Urinary Protein– Standard set	

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Urinary Protein in urine on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: [3]

Only a small amount of protein is present in normal excreted urine (20–150 mg/day). Albumin comprises most of the excreted protein. Loss of normal selectivity results in glomerular proteinuria. This will result in the detection of proteins with increasingly greater molecular mass. Tubular proteinuria is characterised by the appearance of low molecular mass proteins in urine. This is caused by diminished tubular reabsorbtion of the low molecular mass proteins.

PRINCIPLE OF THE TEST: [1, 2]

This reagent is a turbidimetric procedure in which benzethonium chloride is used as the protein-denaturing agent. Benzethonium chloride denatures proteins present in urine, resulting in the formation of a fine suspension which is qualified turbidmetrically at 525nm. . The reagent has been modified to overcome the problem of high concentration effect, where very hugh concentrations of protein in urine can cause low reading. The reagent is suitable for determination of proteins in CSF.

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Both reagents: clear colourless liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Label Elements:

DANGER

H314 – Causes severe skin burns and eye damage.

Precautionary Statements:
P264 – Wash thoroughly after handling.
P280 – Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 – IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340 – IF INHALED – Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Handling precautions:
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument applications are available upon request.

COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent 1	Sodium Hydroxide	530 mmol/l
	EDTA	74 mmol/l
Reagent 2	Benzethonium Chloride	115 mmol/l
Standard 1	Urinary Protein	125 mg/l
Standard 2	Urinary Protein	250 mg/l
Standard 3	Urinary Protein	500 mg/l
Standard 4	Urinary Protein	1000 mg/l
Standard 5	Urinary Protein	2000 mg/l

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, components are stable until expiry date stated on the label.
Prepare a standard series by dilution with 0.9% NaCl:

Dil	NaCl	1/16	1/8	¼	½	Nil
Con	0	125	250	500	1000	2000

TYPE OF SPECIMEN:

Use urine as specimen.
It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification.
Stability: if urine specimen cannot be analysed immediately, it should be refrigerated or frozen after collection. In addition, specimens not analysed within 2 hours of collection should have a chemical preservative (boric acid) added to the collection container.

TEST PROCEDURE:

Materials required but not supplied:

Description	Catalog. No.	Description	Catalog. No.
Urine Control Level 1	GL909	Photometer	N/A
Urine Control Level 2	GL919	General Laboratory Equipment	N/A

Assay procedure:
Wavelength: λ: 505 nm
Temperature: 37°C
Optical path: 1 cm light path.

Allow reagents to reach working temperature before use.

	Blank	Calibrator (Cal)	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	60 µl
Calibrator (Cal)	----	60 µl	----
Gently mix and Incubate at 37°C Measure the Optical Density (OD) after 5 minutes @ 37°C (OD1), against the reagent blank			
Reagent 2	400 µl	400 µl	400 µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD) after 10 minutes @ 37°C (OD2) , against the reagent blank			

Note: Use saline as standard 0.

Calibration:
Using standards set provided, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory QC Programme.

CALCULATION:

- Calculate the ΔAbs for all calibrators (ΔAbs = OD2-OD1) and construct a calibration curve.
- Calculate the ΔAbs for each sample. Determine the corresponding concentration from the calibration curve.

(Conversion factor: Qty in mg/l = Qty in mg/dl x 10)

EXPECTED VALUES [3]:

	Mg/dl	Mg/l
Urine	< 15	< 150mg/24h
CSF	15 – 45	150 - 450

Each laboratory should establish its own reference range. Urinary Protein results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
This assay is linear across the calibration range.
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Sensitivity:
The Lowest Detectable Level was estimated at 6.24 mg/l (0.624 mg/dl).

Precision:

Within Run N = 20	Mean (mg/l)	SD	% CV	Between Run N = 20	Mean (mg/l)	SD	% CV
Level 1	255	1.78	0.70	Level 1	258	6.68	2.59
Level 2	498	3.23	0.65	Level 2	500	9.17	1.83

Method Comparison:
Using 50 samples, a comparison, between this Urinary Protein test (y) and another commercially available test (x), gave the following results:

y = 1.009x + 8.274	r = 0.999	Sample range: 5 to 2076 mg/l

BIBLIOGRAPHY:

1. Young DS. Effects of Drugs on Clin. Lab. Test. 3rd edition 1990; 3:296-300.
2. Watkins I, Jenkins L, Clin. Chem. 1987:333217-8.
3. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 38-39, 342 and 718-719.

SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
CE	CE Mark - Device comply with the Directives 98/79/EC		
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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