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AUDIT

URINARY PROTEIN
Hitachi® Liquid Reagent

KIT SPECIFICATIONS:

Name	Quantity	Reagent	Storage
U.P	2 x 40 ml	UP 1	2-8°C
	2 x 20 ml	UP 2	
	1 x 2 ml	URINARY PROTEIN – Standard	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of urinary protein in urine, on Hitachi® 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 quantified turbidmetrically at 525nm.** The reagent has been modified to overcome the problem of high concentration effect, where very high concentrations of protein in urine can cause low reading. The reagent is suitable for determination of proteins in CSF. The amount of suspension formed is directly proportional to the amount of urinary protein in the sample.

Proteins + benzethonium chloride ⟶ Fine suspension

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.

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:

This assay is designed to run on Hitachi® clinical chemistry analysers. Refer to relevant user's manual or Laboratory internal practice for routine maintenance procedures. *All information is encoded in the barcode. If analyser fails to read or if the barcode is damaged, enter the series of numbers beneath the barcode.*

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	Urinary Protein	200 mg/dl

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, unopened component is stable until expiry date stated on the label.
Stability On Board the Instrument: 28 days.

TYPE OF SPECIMEN: [3]

Use urine as specimen.

Centrifuge samples containing precipitates before performing the assay.

Non centrifuged samples may produce elevated results.

It is recommended to follow NCCLS 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 can not 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.
Urine Control	QC1067
Saline solution 0.9 g/l NaCl	N/A
General Laboratory Equipment	N/A

Assay procedure:
Refer to relevant user's manual for instructions on instrument start-up, loading components and samples, calibration, sample testing procedures, calculating and reporting results.

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.
- 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.
- At intervals established by the Laboratory's QC Programme.

CALCULATION:

The analyser automatically calculates the Urinary Protein concentration in the sample.
(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

*values obtained from centrifuged samples
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:
- Reassay using, when available, "Rerun" function. Refer relevant user's manual for instructions.
- *Or*, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Sensitivity:
The Lower Detectable Level was estimated at 6.24 mg/l

Precision:

Within Run N = 20	Mean *(mg/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(mg/l)*	*SD*	*% CV*
Level 1	237	10.40	4.39	Level 1	254	5.88	2.32
Level 2	425	8.38	1.97	Level 2	430	8.50	1.98

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

y = 1.005x – 4.677	r = 0.999	Sample range: 5 to 2009 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 33(2):17-8.
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 Audit Diagnostics systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	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

CE

HITACHI 704/717/911/912/917/MODP® ARE REGISTERED TRADEMARKS OF NISSEI SANGYO CO. LTD., JAPAN.

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Urinary Protein Hitachi® Instruments Settings

AUDIT

HITACHI 911 / 912 / 917 / MODP®

All information is encoded in the barcode. If analyser fails to read or if the barcode is damaged, enter the series of numbers beneath the barcode.

HITACHI 704®: (Temperature: 37°C)

CHEMISTRY PARAMETERS	
TEST CODE	**[UP]**
ASSAY CODE	[2(2 POINT] - [15] - [32]
SAMPLE VOLUME	[20]
R1 VOLUME	[300] - [__] - [NO]
R2 VOLUME	[150] - [__] - [NO]
WAVELENGTH	[505]
CALIB. METHOD	[NON-LINEAR] - [4] - [6]
STD (1) CONC. POS.	[__] - [__]
STD (2) CONC. POS.	[__] - [__]
STD (3) CONC. POS.	[__] - [__]
STD (4) CONC. POS.	[__] - [__]
STD (5) CONC. POS.	[__] - [__]
STD (6) CONC. POS.	[__] - [__]
UNITS	[__]
SD LIMIT	[999]
DUPLICATE LIMIT	[500]
SENSITIVITY LIMIT	[0]
ABS LIMIT (INC/DEC)	[0] - [INCREASE]
PROZONE LIMIT	[32000] - [UPPER]
EXPECTED VALUE	[__] - [__]
INSTRUMENT FACTOR	[1.00]

[__] User Defined.

HITACHI 717®: (Temperature: 37°C)

CHEMISTRY PARAMETERS	
TEST CODE	**[UP]**
ASSAY CODE	[2(2 POINT] - [22] - [50]
SAMPLE VOLUME	[20] - [0]
R1 VOLUME	[250] - [__] - [NO]
R2 VOLUME	[125] - [__] - [NO]
WAVELENGTH	[505]
CALIB. METHOD	[NON-LINEAR] - [4] - [6]
STD (1) CONC. POS.	[__] - [__]
STD (2) CONC. POS.	[__] - [__]
STD (3) CONC. POS.	[__] - [__]
STD (4) CONC. POS.	[__] - [__]
STD (5) CONC. POS.	[__] - [__]
STD (6) CONC. POS.	[__] - [__]
SD LIMIT	[999]
DUPLICATE LIMIT	[300]
SENSITIVITY LIMIT	[0] - [INCREASE]
ABS LIMIT (INC/DEC)	[32000] - [UPPER]
PROZONE LIMIT	[0] - [0]
EXPECTED VALUE	[__] - [__]
PANIC VALUES	[__] - [__]
INSTRUMENT FACTOR	[1.00]

[__] User Defined.

HITACHI 911®: (Temperature: 37°C)

CHEMISTRY PARAMETERS		
TEST CODE		**[UP]**
ASSAY CODE		[2 POINT END] - [10]
WAVELENGTH (SUB-MAIN)		[505]
ASSAY POINT		[15] - [31]
DILUTION		
SAMPLE VOLUME (µL)		[20] - [__]
ABS LIMIT		[0] - [INCREASE]
PROZONE LIMIT		[0] - [LOWER]
REAGENT (µL)	R1	[250] - [0] - [0]
	R2	[0] - [0] - [0]
	R3	[125] - [0] - [0]
	R4	[0] - [0] - [0]
CALIBRATION TYPE		[SPLINE] - [6] - [0]
SD LIMIT		[999]
DUPLICATE LIMIT		[500]
SENSITIVITY LIMIT		[0]
SI ABS. LIMIT		[-32000] - [32000]
UNIT		[__] - [__]
INSTRUMENT A		[1.00]
FACTOR (Y=AX+B) B		[0] - [0]
STD 1		[__] - [__]
STD 2		[__] - [__]
STD 3		[__] - [__]
STD 4		[__] - [__]
STD 5		[__] - [__]
STD 6		[__] - [__]

[__] User Defined.