



**DIAGNOSTIC KIT  
FOR DETERMINATION OF  
TOTAL PROTEINS CONCENTRATION  
IN URINE**

**OS – URINE PROTEINS**

**INTRODUCTION**

In healthy people with properly functioning kidneys proteins are actively reabsorbed in the proximal tubules and only small amounts proteins (several mg per day) are excreted in urine. The measurement of total proteins concentration in urine are used in the diagnosis and treatment of disease conditions such as renal or heart diseases, or thyroid disorders, which are characterized by proteinuria or albuminuria.

The measurement of total proteins in cerebrospinal fluid (CSF) is especially useful in detecting increased permeability of the blood-brain barrier and to detection increased intrathecal synthesis of immunoglobulins. Increase the concentration of protein in CSF may indicate brain tumors. Intracerebral hemorrhage, brain injury, bacterial and viral encephalitis and multiple sclerosis.

**METHOD PRINCIPLE**

Direct, colorimetric method with pyrogallol red.

At an acidic pH the protein amino acid groups, with the pyrogallol red-molibdate complex, form a coloured compound which colour intensity is proportional to the concentration of proteins in the sample.

**REAGENTS**

**Package**

1-Reagent 2 x 53.5 ml

The reagent when stored at 15-30°C is stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and evaporation, avoid contamination!

**Concentrations in the test**

Succinate buffer 50 mmol/l  
 Pyrogallol red 0.06 mmol/l  
 Sodium molibdate 0.04 mmol/l  
 Detergent 2 %

**Warnings and notes**

- Product for in vitro diagnostic use only.
- The reagents must be used only for purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not use after expiry date.
- Do not interchange caps.
- Do not freeze reagent.
- Reagent should be mixed before use by gently inverting the bottle several times.
- The appearance of turbidity or control sera values outside the manufacturer's acceptable range may indicate of reagent instability.
- The reagent contains < 0.1% sodium azide as a preservative. Avoid contact with skin and mucous membranes.

**SPECIMEN**

Urine. Collect samples in accordance with the NCCLS procedure reported in literature.

Cerebrospinal fluid. Centrifuge before analysis. To correct interpretation of results CSF specimen must be collected and analysed simultaneously with a blood sample.

Urine sample can be stored up to 2 days at 2-8°C.

CSF sample can be stored up to 3 days at 2-8°C, 6 months at -20 °C. Nevertheless it is recommended to perform the assay with freshly collected samples!

**PROCEDURE**

This reagent may be used in automatic analysers Olympus AU400/AU640.

1-Reagent is ready to use.

For reagent blank 0.9% NaCl is recommended.

**APPLICATION**

Reagent ID: 070

Specific Test Parameters									
General	LIH	ISE	Range						
Test name:	UP				Type:	Urine/Other	Operation:	Yes	
Sample: Volume	4	μL	Dilution	0	μL	Pre-Dilution Rate:	1		
Reagents: R1 Volume	200	μL	Dilution	0	μL	Min OD		Max OD	
R2 Volume	0	μL	Dilution	0	μL	L	-2.0000	H	2.5000
Wavelength:	Pri: 600		Sec:			Reagent OD Limit:			
Method:	END					First L	-2.0000	First H	2.5000
Reaction Slope:	+					Last L	-2.0000	Last H	2.5000
Measuring Point 1: First	0		Last	27		Dynamic Range:			
Measuring Point 2: First			Last			L	5.5	H	250
Linearity:		%				Correlation Factor:			
No-Lag-Time:						A	1.000	B	0.000
						On-board Stability Period:			

Specific Test Parameters									
General	LIH	ISE	Range						
Test name:	UP				Type:	Urine/Other			
Value/Flag:	#		Level L:	#	Level H:	#			
Normal Ranges:									
	Sex	Age L	Age H			L		H	
		Year	Month	Year	Month				
1.	#	#	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#	#	#
7.	None Selected					#	#	#	#
8.	Out of Range					#	#	#	#
Panic Value:			L	#	H	#	Unit:	mg/dl	Decimal Places: 2

Calibration Specific							
General	ISE						
Test name:	UP				Type:	Urine/Other	
Calibration Type:	2AB	Formula:	Polygonal	Counts:	1	Process:	CONC
Point 1:	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H		
Point 2:	#		**	-2.0000	2.5000		
Point 3:	#		*	-2.0000	2.5000		
Point 4:							
Point 5:							
Point 6:							
Point 7:							
1-Point Cal.Point:	<input type="checkbox"/>	with CONC-0	Slope Check:	None	Advanced Calibration:	#	
MB Type Factor:			Calibration Stability Period:				

- # User defined
- \* Calibrator value
- \*\* Saline should be used as calibrator 1

**Calculation**

For the calculation of proteins excreted over 24 hours, multiply the concentration (mg/dl) by the volume (dl) of the 24 hours urine.

**REFERENCE VALUES <sup>5,8</sup>**

<b>urine (adults)</b>	< 15 mg/dl (0.15 g/l)	
<b>urine 24-h (adults)</b>	< 100 mg (0.10 g)	
<b>cerebrospinal fluid</b>	mg/dl	g/l
0 – 4 weeks	20 – 80	0.20 – 0.80
1 month – adults	15 – 45	0.15 – 0.45

It is recommended for each laboratory to establish its own reference ranges for local population.

## QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY URINE CONTROL LEVEL 1 (Cat. No 5-161) and LEVEL 2 (Cat. No 5-162) with each batch of samples.

For the calibration of automatic analysers systems are recommended the CORMAY URINE PROTEINS CALIBRATORS (Cat. No. 5-181).

The calibration curve should be prepared every 9 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

## PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers Olympus AU400 and Hitachi 911. Results may vary if a different instrument is used.

- **Sensitivity:** 5.5 mg/dl.
- **Linearity:** up to 250 mg/dl.  
If total proteins concentration exceeds 250 mg/dl dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.
- **Specificity / Interferences**  
Inorganic phosphate, calcium and magnesium ions, creatinine, urea, uric acid, glucose, sodium citrate, sodium oxalate and sodium ascorbate do not significantly interfere with the test (< 2%).

- **Precision**

Repeatability (run to run) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	34.29	1.31	3.82
level 2	126.07	3.50	2.78

Reproducibility (day to day) n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	25.4	0.59	2.32
level 2	43.0	0.85	1.98

- **Method comparison**

A comparison between total protein values determined at Olympus AU400 (y) and at ADVIA 1650 (x) using 44 samples gave following results:

$$y = 1.0287x + 4.1389 \text{ mg/dl};$$

$$R = 0.9943 \quad (R - \text{correlation coefficient})$$

## WASTE MANAGEMENT

Please refer to local legal requirements.

## LITERATURE

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## MANUFACTURER

**PZ CORMAY S.A.**  
22 Wiosenna Street,  
05-092 Łomianki, POLAND  
tel.: +48 (0) 22 751 79 10  
fax: +48 (0) 22 751 79 14  
<http://www.cormay.pl>

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