

LIQUID URINE CONTROL - LEVEL 2 (LIQ URN CONTROL 2)

CAT NO. UC5074 **LOT NO.** 1297UC
SIZE 10 x 10 ml **EXPIRY:** 2025-07-28
GTIN: 05055273207569

INTENDED USE

The Randox Liquid Urine Control Level 2 is intended for in vitro diagnostic use, in the quality control of Amylase, Calcium, Chloride, Cortisol, Creatinine, Glucose, hCG pregnancy, Magnesium, Microalbumin, Osmolality, pH, Phosphate Inorganic, Potassium, Protein Total, Sodium, Specific Gravity, Urea and Uric Acid (Urate) on clinical chemistry systems. The Liquid Urine Control is for the control of accuracy.

Creatinine assays in the Liquid Urine Controls may not be suitable for use on some Vitros systems.

SAFETY PRECAUTIONS AND WARNINGS

The Quality Control material is derived from human urine obtained from volunteer donors. It is recommended that this product is handled with the same precautions used for patient samples.

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on www.randox.com.

Please dispose of all biological and chemical materials according to local guidelines.

STORAGE AND STABILITY

UNOPENED: The Liquid Urine Control is stable to the expiration date printed on individual labels, when stored refrigerated at +2°C to +8°C.

OPENED: The Liquid Urine Control is stable for 30 days at +2°C to +8°C when opened, if kept capped in original container and free from contamination. After use, any residual product should NOT BE RETURNED to the original vial.

PREPARATION FOR USE

The Liquid Urine Controls are supplied ready for use.

MATERIALS PROVIDED

Liquid Urine Control - Level 2 10 x 10 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Not applicable.

VALUE ASSIGNMENT

Each batch of Liquid Urine Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd.

EC	REP
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Randox Teoranta, Meenmore,
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Rev. 31 Oct '23 me

METHOD		LIQ URN CONTROL 2					
Lot. No.	1297UC	Cat. No.	UC5074				
Size	10 x 10ml	Expiry	2025-07-28				
Analyte	unit	Target	low	high	1SD	2SD	methods
Amylase	U/L	37.9	30.3	45.5	3.8	7.6	Roche liquid Pnpg7
	U/L	40.7	32.6	48.8	4.05	8.1	Randox Liquid Ethylidene pNPG7
Calcium	mg/dl	7.82	7.05	8.59	0.39	0.77	Cresolphthalein complexone
	mg/dl	7.58	6.81	8.35	0.39	0.77	Arsenazo III
Chloride	mmol/l	77.8	66.1	89.5	5.85	11.7	ISE indirect
	mmol/l	73.2	62.2	84.2	5.5	11	ISE direct
Cortisol	nmol/l	82.3	61.7	103	10.3	20.6	Roche Cobas e series
	µg/dl	2.96	2.22	3.7	0.37	0.74	
	nmol/l	38.8	29.1	48.5	4.85	9.7	Abbott Architect (5P02)/ Alinity (8P45)
	µg/dl	1.4	1.05	1.75	0.18	0.35	
Creatinine	mg/dl	73.5	58.8	88.2	7.35	14.7	Jaffe rate blanked comp. (-26 µmol/l)
Glucose	mg/dl	22.9	18.4	27.4	2.25	4.5	Glucose oxidase
	mg/dl	23.2	18.6	27.8	2.3	4.6	Hexokinase
Magnesium	mg/dl	6.49	5.2	7.78	0.65	1.29	Xylidyl Blue
Microalbumin	mg/l	24.2	18.6	29.8	2.8	5.6	Immunoturbidimetric
Osmolality	mOsm/kg	438	350	526	44	88	Freezing point depression
pH	pH units	6.13	5.52	6.74	0.31	0.61	pH meter
Phosphate Inorganic	mg/dl	26.6	21.3	31.9	2.65	5.3	Phosphomolybdate UV
Potassium	mmol/l	28.2	24	32.4	2.1	4.2	ISE direct
	mmol/l	29.1	24.7	33.5	2.2	4.4	ISE indirect
Sodium	mmol/l	77.8	68.5	87.1	4.65	9.3	ISE direct
	mmol/l	80.2	70.6	89.8	4.8	9.6	ISE indirect
Specific Gravity	N/A	1.03	0.82	1.24	0.1	0.21	Roche Uriscys 1100 / 1800 / 2400
Total Protein	mg/l	153	122	184	15.5	31	Turbidimetric
	mg/l	190	152	228	19	38	Pyrogallol Red
Uric Acid (Urate)	mg/dl	9.37	7.49	11.25	0.94	1.88	Uricase Peroxidase with ascorbate oxidase @ 546nm
Urea	mg/dl	920	733	1107	93.5	187	Urease kinetic