

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

CAT NO. UC5074 **LOT NO.** 1162UC
SIZE: 10 x 10 ml **EXPIRY:** 2022-07-28
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 (HIV1, 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.



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MEAN OF ALL INSTRUMENTS (LIQ URN CONTROL 2)

Lot. No. 1162UC Cat. No. UC5074

Size 10 x 10 ml Expiry 2022-07-28

Analyte	unit	Target	Range		1SD	2SD	methods
			low	high			
Amylase	U/l	32.8	26.3	39.4	3.27	6.53	Randox Liquid Ethylidene pNPG7
	U/l	31.2	24.9	37.4	3.14	6.27	Roche liquid stable pNPG7
	U/l	34.8	27.9	41.7	3.46	6.92	Beckman Synchron AMY7
	U/l	26.8	21.5	32.2	2.67	5.33	Siemens 2-chloro-pNPG3
Calcium	mmol/l	1.92	1.73	2.11	0.10	0.19	Arsenazo III
	mg/dl	7.70	6.93	8.47	0.39	0.77	
	mmol/l	1.86	1.67	2.05	0.10	0.19	NM-BAPTA
	mg/dl	7.45	6.69	8.21	0.38	0.76	
	mmol/l	1.94	1.75	2.13	0.10	0.19	Cresolphthalein complexone
mg/dl	7.78	7.01	8.55	0.39	0.77		
Chloride	mmol/l	68.5	58.3	78.8	5.12	10.24	ISE direct
	mmol/l	72.5	61.6	83.4	5.44	10.88	ISE indirect
Cortisol	nmol/l	79.9	59.9	99.9	10.01	20.01	Roche Cobas e series
	µg/dl	2.88	2.16	3.60	0.36	0.72	
Creatinine	mmol/l	6.31	5.05	7.57	0.63	1.26	Alkaline picrate no deproteinization
	mg/dl	71.3	57.1	85.5	7.10	14.20	
	mmol/l	6.85	5.48	8.22	0.68	1.37	Roche Creatinine Plus
	mg/dl	77.4	61.9	92.9	7.75	15.50	
	mmol/l	6.77	5.41	8.13	0.68	1.36	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	76.5	61.1	91.9	7.70	15.40	
Glucose	mmol/l	1.23	0.98	1.48	0.12	0.25	Glucose oxidase
	mg/dl	22.2	17.7	26.7	2.25	4.50	



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Glucose	mmol/l	1.32	1.06	1.58	0.13	0.26	Hexokinase
	mg/dl	23.8	19.1	28.5	2.35	4.70	
hCG pregnancy	N/A	NEG	-----	-----	-----	-----	Randox One Step 37°C
Magnesium	mmol/l	2.38	1.90	2.86	0.24	0.48	Xylidyl Blue
	mg/dl	5.78	4.62	6.94	0.58	1.16	
	mmol/l	2.46	1.97	2.95	0.25	0.49	Methylthymol blue
	mg/dl	5.98	4.79	7.17	0.60	1.19	
Microalbumin	mg/l	26.0	20.8	31.2	2.61	5.21	Immunoturbidimetric
Osmolality	mOsm/kg	424	339	510	42.67	85.33	Freezing point depression
pH	pH units	6.10	5.49	6.70	0.30	0.61	pH meter
Phosphate Inorganic	mmol/l	8.65	6.92	10.4	0.87	1.73	Phosphomolybdate UV
	mg/dl	26.8	21.5	32.1	2.65	5.30	
Potassium	mmol/l	29.7	25.3	34.1	2.21	4.41	ISE direct
	mmol/l	29.9	25.4	34.4	2.25	4.50	ISE indirect
Protein Total	g/l	0.17	0.13	0.20	0.02	0.03	Turbidimetric
	mg/dl	16.8	13.4	20.2	1.70	3.40	Turbidimetric
	mg/l	168	134	202	17.00	34.00	Turbidimetric
	g/l	0.18	0.14	0.22	0.02	0.04	Pyrogallol Red
	mg/dl	18.0	14.4	21.6	1.80	3.60	Pyrogallol Red
	mg/l	180	144	216	18.00	36.00	Pyrogallol Red
Sodium	mmol/l	82.1	72.2	92.0	4.95	9.89	ISE direct
	mmol/l	83.6	73.6	93.6	5.00	10.00	ISE indirect
Specific Gravity	N/A	1.02	1.01	1.03	-----	-----	Roche Urisys 1100 / 1800 / 2400
Urea	mmol/l	151	121	181	14.96	29.91	Urease kinetic
	mg/dl	907	727	1087	90.00	180.00	



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Uric Acid (Urate)	mmol/l	0.56	0.45	0.67	0.06	0.11	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.41	7.53	11.3	0.94	1.88	
	mmol/l	0.61	0.49	0.73	0.06	0.12	Uricase 293nm UV
	mg/dl	10.2	8.16	12.2	1.02	2.04	
	mmol/l	0.61	0.49	0.73	0.06	0.12	Uricase peroxidase with ascorbate oxidase
	mg/dl	10.2	8.18	12.2	1.01	2.02	