

## **PRODUCT INFORMATION**

UC5075

1161UC

Certain analyser / analyte combinations are yet to be assigned for this control and will be added in due course.

Where this is the case, "TBD" (to be determined) has been entered into the value tables which will be updated as soon as possible.

INC170

## LIQUID URINE CONTROL - LEVEL 3 (LIQ URN CONTROL 3)

**CAT. NO.** UC5075                      **LOT NO.** 1161UC  
**SIZE:** 10 x 10ml                      **EXPIRY:** 2023-04-28  
**GTIN:** 05055273207576

### INTENDED USE

The Randox Liquid Urine Control - Level 3 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 and immunoassay 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](http://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 3    10 x 10ml

### 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.



Randox Teoranta, Meenmore,  
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Rev. 29 July '21 ne

## MEAN OF ALL INSTRUMENTS

LIQ URN CONTROL 3

Lot No. 1161UC Cat. No. UC5075

Size 10 x 10ml Expiry 2023-04-28

Analyte	unit	Target	Range		1SD	2SD	methods
			low	high			
Amylase	U/l	163	130	196	16.50	33.00	Randox Liquid Ethylidene pNPG7
	U/l	155	124	186	15.50	31.00	Roche liquid stable pNPG7
	U/l	131	105	157	13.00	26.00	Siemens 2-chloro-pNPG3
	U/l	136	109	163	13.50	27.00	Other 2-chloro-pNPG3
Calcium	mmol/l	2.94	2.65	3.23	0.15	0.29	Cresolphthalein complexone
	mg/dl	11.8	10.6	13.0	0.60	1.20	
	mmol/l	2.61	2.35	2.87	0.13	0.26	Arsenazo III
	mg/dl	10.5	9.42	11.6	0.54	1.08	
	mmol/l	2.88	2.59	3.17	0.15	0.29	NM-BAPTA
mg/dl	11.5	10.4	12.6	0.55	1.10		
Chloride	mmol/l	165	140	190	12.50	25.00	ISE indirect
	mmol/l	133	113	153	10.00	20.00	ISE direct
Cortisol	nmol/l	570	428	712	71.00	142.00	Roche Cobas e series
	µg/dl	20.5	15.4	25.6	2.55	5.10	
	nmol/l	TBD	-----	-----	-----	-----	Abbott Architect (5P02)/ Alinity (8P45)
	µg/dl	TBD	-----	-----	-----	-----	
Creatinine	mmol/l	14.5	11.6	17.4	1.45	2.90	Alkaline picrate no deproteinization
	mg/dl	164	131	197	16.50	33.00	
	mmol/l	14.2	11.4	17.0	1.40	2.80	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	160	129	191	15.50	31.00	
	mmol/l	14.8	11.8	17.8	1.50	3.00	Roche Creatinine Plus
	mg/dl	167	133	201	17.00	34.00	

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### LIQ URN CONTROL 3

Lot No. 1161UC Cat. No. UC5075

Size 10 x 10ml Expiry 2023-04-28

#### Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Glucose	mmol/l	14.5	11.6	17.4	1.45	2.90	Hexokinase
	mg/dl	261	209	313	26.00	52.00	
	mmol/l	14.9	11.9	17.9	1.50	3.00	Glucose oxidase
	mg/dl	268	214	322	27.00	54.00	
hCG pregnancy	N/A	POS	-----	-----	-----	-----	Alere hCG Test 37°C
Magnesium	mmol/l	4.75	3.80	5.70	0.48	0.95	Xylidyl Blue
	mg/dl	11.5	9.23	13.8	1.14	2.27	
	mmol/l	4.70	3.76	5.64	0.47	0.94	Methylthymol blue
	mg/dl	11.4	9.14	13.7	1.13	2.26	
	mmol/l	4.57	3.66	5.48	0.46	0.91	Enzymatic
	mg/dl	11.1	8.89	13.3	1.11	2.21	
Microalbumin	mg/l	60.7	48.6	72.8	6.05	12.10	Immunoturbidimetric
Osmolality	mOsm/kg	910	728	1092	91.0	182	Freezing point depression
pH	pH units	6.12	5.51	6.73	0.31	0.61	pH meter
Phosphate Inorganic	mmol/l	14.1	11.3	16.9	1.40	2.80	Phosphomolybdate UV
	mg/dl	43.7	35.0	52.4	4.35	8.70	
Potassium	mmol/l	66.3	56.4	76.2	4.95	9.90	ISE direct
	mmol/l	69.5	59.1	79.9	5.20	10.40	ISE indirect
Sodium	mmol/l	157	138	176	9.50	19.00	ISE direct
	mmol/l	163	143	183	10.00	20.00	ISE indirect
Specific Gravity	N/A	1.02	1.01	1.03	-----	-----	Roche Urisys 1100 / 1800 / 2400
Total Protein	g/l	0.94	0.76	1.13	0.09	0.19	Pyrogallol Red
	mg/dl	94.4	75.5	113	9.45	18.90	Pyrogallol Red
	mg/l	944	755	1133	94.50	189.00	Pyrogallol Red

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LIQ URN CONTROL 3

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Size 10 x 10ml Expiry 2023-04-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Total Protein	g/l	0.82	0.66	0.99	0.08	0.16	Turbidimetric
	mg/dl	82.2	65.8	98.6	8.20	16.40	Turbidimetric
	mg/l	822	658	986	82.00	164.00	Turbidimetric
Urea	mmol/l	280	224	336	28.00	56.00	Urease kinetic
	mg/dl	1683	1346	2020	168.50	337.00	
Uric Acid (Urate)	mmol/l	0.86	0.69	1.04	0.09	0.17	Uricase peroxidase no ascorbate oxidase
	mg/dl	14.5	11.6	17.4	1.45	2.90	
	mmol/l	0.86	0.69	1.03	0.09	0.17	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	14.4	11.5	17.3	1.45	2.90	
	mmol/l	0.89	0.71	1.06	0.09	0.18	Uricase peroxidase with ascorbate oxidase
	mg/dl	14.9	11.9	17.9	1.50	3.00	
	mmol/l	0.94	0.75	1.13	0.09	0.19	Uricase 293nm UV
	mg/dl	15.8	12.6	19.0	1.60	3.20	