

PRODUCT INFORMATION

UC5074

1160UC

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.

Guidance values for certain "Mean of All Instruments" analyte methods may be available upon request until values are available.

INC170

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

CAT NO. UC5074	LOT NO. 1160UC
SIZE: 10 x 10 ml	EXPIRY: 2023-04-28
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 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 (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
----	-----

Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

' \$July '21 me

MEAN OF ALL INSTRUMENTS

LIQ URN CONTROL 2

Lot. No. 1160UC Cat. No. UC5074

Size 10 x 10ml Expiry 2023-04-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Amylase	U/l	29.8	23.8	35.8	3.00	6.00	Roche liquid pNPG7
	U/l	24.0	19.2	28.8	2.40	4.80	Siemens 2-chloro-pNPG3
	U/l	26.2	21.0	31.4	2.60	5.20	Other 2-chloro-pNPG3
	U/l	31.0	24.8	37.2	3.10	6.20	Randox Liquid Ethylidene pNPG7
Calcium	mmol/l	1.82	1.64	2.00	0.09	0.18	Cresolphthalein complexone
	mg/dl	7.29	6.57	8.01	0.36	0.72	
	mmol/l	1.77	1.59	1.95	0.09	0.18	Arsenazo III
	mg/dl	7.09	6.37	7.81	0.36	0.72	
	mmol/l	1.84	1.66	2.02	0.09	0.18	NM-BAPTA
mg/dl	7.37	6.65	8.09	0.36	0.72		
Chloride	mmol/l	77.5	65.9	89.1	5.80	11.60	ISE indirect
	mmol/l	64.1	54.5	73.7	4.80	9.60	ISE direct
Cortisol	nmol/l	85.3	64.0	107	10.65	21.30	Roche Cobas e series
	µg/dl	3.07	2.30	3.84	0.39	0.77	
	nmol/l	TBD	-	-	-	-	Abbott Architect (5P02)/ Alinity (8P45)
	µg/dl	TBD	-	-	-	-	
Creatinine	mmol/l	6.24	4.99	7.49	0.63	1.25	Alkaline picrate no deproteinization
	mg/dl	70.5	56.4	84.6	7.05	14.10	
	mmol/l	6.51	5.21	7.81	0.65	1.30	Roche Creatinine Plus
	mg/dl	73.6	58.9	88.3	7.35	14.70	
	mmol/l	6.33	5.06	7.60	0.64	1.27	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	71.5	57.2	85.8	7.15	14.30	

MEAN OF ALL INSTRUMENTS

LIQ URN CONTROL 2

Lot. No. 1160UC Cat. No. UC5074

Size 10 x 10ml Expiry 2023-04-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Glucose	mmol/l	1.27	1.02	1.52	0.13	0.25	Glucose oxidase
	mg/dl	22.9	18.4	27.4	2.25	4.50	
	mmol/l	1.27	1.02	1.52	0.13	0.25	Hexokinase
	mg/dl	22.9	18.4	27.4	2.25	4.50	
hCG pregnancy	N/A	NEG	-	-	-	-	Alere hCG Test 37°C
Magnesium	mmol/l	2.32	1.86	2.78	0.23	0.46	Xylidyl Blue
	mg/dl	5.46	4.52	6.76	0.56	1.12	
	mmol/l	2.26	1.81	2.71	0.23	0.45	Methylthymol blue
	mg/dl	5.49	4.40	6.58	0.55	1.09	
	mmol/l	2.12	1.70	2.54	0.21	0.45	Enzymatic
	mg/dl	5.15	4.13	6.17	0.51	1.02	
Microalbumin	mg/l	23.3	18.6	28.0	2.35	4.70	Immunoturbidimetric
Osmolality	mOsm/kg	505	404	606	50.5	101	Freezing point depression
pH	pH units	5.91	5.32	6.50	0.30	0.59	pH meter
Phosphate Inorganic	mmol/l	7.71	6.17	9.25	0.77	1.54	Phosphomolybdate UV
	mg/dl	23.9	19.1	28.7	2.40	4.80	
Potassium	mmol/l	28.9	24.6	33.2	2.15	4.30	ISE direct
	mmol/l	28.4	24.1	32.7	2.15	4.30	ISE indirect
Sodium	mmol/l	87.3	76.8	97.8	5.25	10.50	ISE direct
	mmol/l	78.8	69.3	88.3	4.75	9.50	ISE indirect
Specific Gravity	N/A	1.02	1.01	1.03	-	-	Roche Urisys 1100 / 1800 / 2400
Total Protein	g/l	0.15	0.12	0.18	0.02	0.03	Turbidimetric
	mg/dl	14.8	11.8	17.8	1.50	3.00	Turbidimetric
	mg/l	148	118	178	15.00	30.00	Turbidimetric



MEAN OF ALL INSTRUMENTS

LIQ URN CONTROL 2

Lot. No. 1160UC Cat. No. UC5074

Size 10 x 10ml Expiry 2023-04-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Total Protein	g/l	0.17	0.14	0.21	0.02	0.03	Pyrogallol Red
	mg/dl	17.2	13.8	20.6	1.70	3.40	Pyrogallol Red
	mg/l	172	138	206	17.00	34.00	Pyrogallol Red
Uric Acid (Urate)	mmol/l	0.56	0.45	0.67	0.06	0.11	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.41	7.53	11.3	0.94	1.88	
	mmol/l	0.55	0.44	0.66	0.06	0.11	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.26	7.41	11.1	0.93	1.85	
	mmol/l	0.58	0.47	0.70	0.06	0.12	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.81	7.85	11.8	0.98	1.96	
Urea	mmol/l	149	119	179	15.00	30.00	Urease kinetic
	mg/dl	895	715	1075	90.00	180.00	