

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

CAT. NO. UC5075 **LOT NO.** 1242UC
SIZE 10 x 10 ml **EXPIRY:** 2025-06-28
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.

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 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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 Dungloe, Donegal,
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METHOD

LIQ URN CONTROL 3

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Amylase	U/l	120	96.0	144	12.00	24.00	Randox Liquid Ethylidene pNPG7
	U/l	125	100	150	12.50	25.00	Roche liquid stable pNPG7
	U/l	103	82.4	124	10.30	20.60	Siemens 2-chloro-pNPG3
	U/l	114	91.2	137	11.40	22.80	Other 2-chloro-pNPG3
Calcium	mmol/l	2.90	2.61	3.19	0.15	0.29	Cresolphthalein complexone
	mg/dl	11.6	10.5	12.7	0.55	1.10	
	mmol/l	2.60	2.34	2.86	0.13	0.26	Arsenazo III
	mg/dl	10.4	9.38	11.4	0.51	1.02	
Chloride	mmol/l	2.83	2.55	3.11	0.14	0.28	NM-BAPTA
	mg/dl	11.3	10.2	12.4	0.55	1.10	
Chloride	mmol/l	169	144	194	12.50	25.00	ISE indirect
	mmol/l	162	138	186	12.00	24.00	ISE direct
Cortisol	nmol/l	827	620	1034	103.50	207.00	Roche Cobas e series
	µg/dl	29.8	22.3	37.3	3.75	7.50	
	nmol/l	756	567	945	94.50	189.00	Abbott Architect (5P02)/ Alinity (8P45)
	µg/dl	27.2	20.4	34.0	3.40	6.80	
Creatinine	mmol/l	15.0	12.0	18.0	1.50	3.00	Alkaline picrate no deproteinization
	mg/dl	170	136	204	17.00	34.00	
	mmol/l	14.8	11.8	17.8	1.50	3.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	167	133	201	17.00	34.00	
	mmol/l	15.6	12.5	18.7	1.55	3.10	Roche Creatinine Plus
	mg/dl	176	141	211	17.50	35.00	

METHOD

LIQ URN CONTROL 3

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Glucose	mmol/l	15.0	12.0	18.0	1.50	3.00	Hexokinase
	mg/dl	270	216	324	27.00	54.00	
	mmol/l	15.2	12.2	18.2	1.50	3.00	Glucose oxidase
	mg/dl	274	220	328	27.00	54.00	
hCG pregnancy	N/A	POS	-	-	-	-	Alere hCG Test 37°C
Magnesium	mmol/l	4.90	3.92	5.88	0.49	0.98	Xylidyl Blue
	mg/dl	11.9	9.53	14.3	1.19	2.37	
	mmol/l	5.06	4.05	6.07	0.51	1.01	Methylthymol blue
	mg/dl	12.3	9.84	14.8	1.23	2.46	
	mmol/l	4.90	3.92	5.88	0.49	0.98	Enzymatic
	mg/dl	11.9	9.53	14.3	1.19	2.37	
Microalbumin	mg/l	66.6	53.3	79.9	6.65	13.30	Immunoturbidimetric
Osmolality	mOsm/kg	842	674	1010	84.00	168.00	Freezing point depression
pH	pH units	6.18	5.56	6.80	0.31	0.62	pH meter
Phosphate Inorganic	mmol/l	14.5	11.6	17.4	1.45	2.90	Phosphomolybdate UV
	mg/dl	45.0	36.0	54.0	4.50	9.00	
Potassium	mmol/l	66.1	56.2	76.0	4.95	9.90	ISE direct
	mmol/l	72.3	61.5	83.1	5.40	10.80	ISE indirect
Protein Total	g/l	0.75	0.60	0.90	0.08	0.15	Turbidimetric
	mg/dl	75.3	60.2	90.4	7.55	15.10	Turbidimetric
	mg/l	753	602	904	75.50	151.00	Turbidimetric
	g/l	0.88	0.70	1.05	0.09	0.18	Pyrogallol Red
	mg/dl	87.6	70.1	105	8.75	17.50	Pyrogallol Red
	mg/l	876	701	1051	87.50	175.00	Pyrogallol Red



METHOD

LIQ URN CONTROL 3

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Sodium	mmol/l	153	135	171	9.00	18.00	ISE direct
	mmol/l	164	144	184	10.00	20.00	ISE indirect
Specific Gravity	N/A	1.02	1.01	1.03	-	-	Roche Urisys 1100 / 1800 / 2400
Uric Acid (Urate)	mmol/l	0.93	0.74	1.12	0.09	0.19	Uricase peroxidase no ascorbate oxidase
	mg/dl	15.6	12.5	18.7	1.55	3.10	
	mmol/l	0.87	0.70	1.04	0.09	0.17	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	14.6	11.7	17.5	1.45	2.90	
	mmol/l	0.90	0.72	1.08	0.09	0.18	Uricase peroxidase with ascorbate oxidase
	mg/dl	15.1	12.1	18.1	1.50	3.00	
Urea	mmol/l	284	227	341	28.50	57.00	Urease kinetic
	mg/dl	1707	1364	2050	171.50	343.00	


Abbott Alinity/ Architect c/ci Systems®
LIQ URN CONTROL 3

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Amylase	U/l	119	95.2	143	11.90	23.80	Other 2-chloro-pNPG3
Calcium	mmol/l	2.64	2.38	2.90	0.13	0.26	Arsenazo III
	mg/dl	10.6	9.54	11.7	0.53	1.06	
Chloride	mmol/l	173	147	199	13.00	26.00	ISE indirect
Creatinine	mmol/l	14.8	11.8	17.8	1.50	3.00	Alkaline picrate no deproteinization
	mg/dl	167	133	201	17.00	34.00	
Glucose	mmol/l	15.2	12.2	18.2	1.50	3.00	Hexokinase
	mg/dl	274	220	328	27.00	54.00	
Magnesium	mmol/l	4.90	3.92	5.88	0.49	0.98	Enzymatic
	mg/dl	11.9	9.53	14.3	1.19	2.37	
Phosphate Inorganic	mmol/l	14.8	11.8	17.8	1.50	3.00	Phosphomolybdate UV
	mg/dl	45.9	36.6	55.2	4.65	9.30	
Potassium	mmol/l	72.3	61.5	83.1	5.40	10.80	ISE indirect
Protein Total	g/l	0.74	0.59	0.89	0.07	0.15	Turbidimetric
	mg/dl	74.2	59.4	89.0	7.40	14.80	Turbidimetric
	mg/l	742	594	890	74.00	148.00	Turbidimetric
Sodium	mmol/l	160	141	179	9.50	19.00	ISE indirect
Uric Acid (Urate)	mmol/l	0.87	0.70	1.05	0.09	0.18	Uricase peroxidase with ascorbate oxidase
	mg/dl	14.7	11.7	17.7	1.50	3.00	
Urea	mmol/l	266	213	320	26.73	53.46	Urease kinetic
	mg/dl	1601	1280	1922	160.50	321.00	



Beckman Coulter AU Series®

LIQ URN CONTROL 3

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Amylase	U/l	109	87.2	131	10.90	21.80	Other 2-chloro-pNPG3
Calcium	mmol/l	2.65	2.39	2.91	0.13	0.26	Arsenazo III
	mg/dl	10.6	9.58	11.6	0.51	1.02	
	mmol/l	2.84	2.56	3.12	0.14	0.28	Cresolphthalein complexone
	mg/dl	11.4	10.3	12.5	0.55	1.10	
Chloride	mmol/l	165	140	190	12.50	25.00	ISE indirect
Creatinine	mmol/l	15.0	12.0	18.0	1.50	3.00	Alkaline picrate no deproteinization
	mg/dl	170	136	204	17.00	34.00	
Glucose	mmol/l	15.1	12.1	18.1	1.50	3.00	Hexokinase
	mg/dl	272	218	326	27.00	54.00	
Magnesium	mmol/l	5.19	4.15	6.23	0.52	1.04	Xylidyl Blue
	mg/dl	12.6	10.1	15.1	1.25	2.50	
Microalbumin	mg/l	70.0	56.0	84.0	7.00	14.00	Immunoturbidimetric
Phosphate Inorganic	mmol/l	14.3	11.4	17.2	1.45	2.90	Phosphomolybdate UV
	mg/dl	44.3	35.3	53.3	4.50	9.00	
Potassium	mmol/l	73.7	62.6	84.8	5.55	11.10	ISE indirect
Protein Total	g/l	0.97	0.77	1.16	0.10	0.19	Pyrogallol Red
	mg/dl	96.5	77.2	116	9.65	19.30	Pyrogallol Red
	mg/l	965	772	1158	96.50	193.00	Pyrogallol Red
Sodium	mmol/l	165	145	185	10.00	20.00	ISE indirect
Uric Acid (Urate)	mmol/l	0.93	0.74	1.11	0.09	0.19	Uricase peroxidase with ascorbate oxidase
	mg/dl	15.6	12.5	18.7	1.55	3.10	

**Beckman Coulter AU Series®**

LIQ URN CONTROL 3

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Urea	mmol/l	282	226	338	28.00	56.00	Urease kinetic
	mg/dl	1695	1358	2032	168.50	337.00	

**ROCHE COBAS SERIES®****LIQ URN CONTROL 3**

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Amylase	U/l	125	100	150	12.50	25.00	Roche liquid stable pNPG7
Calcium	mmol/l	2.83	2.55	3.11	0.14	0.28	NM-BAPTA
	mg/dl	11.3	10.2	12.4	0.55	1.10	
Chloride	mmol/l	170	145	195	12.50	25.00	ISE indirect
Creatinine	mmol/l	15.5	12.4	18.6	1.55	3.10	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	175	140	210	17.50	35.00	
	mmol/l	15.6	12.5	18.7	1.55	3.10	Roche Creatinine Plus
	mg/dl	176	141	211	17.50	35.00	
Glucose	mmol/l	15.0	12.0	18.0	1.50	3.00	Hexokinase
	mg/dl	270	216	324	27.00	54.00	
Magnesium	mmol/l	5.13	4.10	6.16	0.52	1.03	Xylidyl Blue
	mg/dl	12.5	9.96	15.0	1.27	2.54	
Microalbumin	mg/l	64.1	51.3	76.9	6.40	12.80	Immunoturbidimetric
Phosphate Inorganic	mmol/l	13.9	11.1	16.7	1.40	2.80	Phosphomolybdate UV
	mg/dl	43.1	34.4	51.8	4.35	8.70	
Potassium	mmol/l	71.0	60.4	81.6	5.30	10.60	ISE indirect
Protein Total	g/l	0.76	0.61	0.92	0.08	0.15	Turbidimetric
	mg/dl	76.4	61.1	91.7	7.65	15.30	Turbidimetric
	mg/l	764	611	917	76.50	153.00	Turbidimetric
Sodium	mmol/l	167	147	187	10.00	20.00	ISE indirect
Uric Acid (Urate)	mmol/l	0.87	0.69	1.04	0.09	0.17	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	14.5	11.6	17.4	1.45	2.90	

**ROCHE COBAS SERIES®**

LIQ URN CONTROL 3

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Urea	mmol/l	274	219	329	27.50	55.00	Urease kinetic
	mg/dl	1647	1316	1978	165.50	331.00	


RX SERIES®
LIQ URN CONTROL 3

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Amylase	U/l	120	96.0	144	12.00	24.00	Randox Liquid Ethylidene pNPG7
Calcium	mmol/l	2.51	2.26	2.76	0.13	0.25	Arsenazo III
	mg/dl	10.1	9.06	11.1	0.52	1.04	
Chloride	mmol/l	162	138	186	12.00	24.00	ISE direct
Creatinine	mmol/l	15.1	12.1	18.1	1.50	3.00	Alkaline picrate no deproteinization
	mg/dl	171	137	205	17.00	34.00	
Glucose	mmol/l	15.7	12.6	18.8	1.55	3.10	Glucose oxidase
	mg/dl	283	227	339	28.00	56.00	
Magnesium	mmol/l	4.39	3.51	5.27	0.44	0.88	Xylidyl Blue
	mg/dl	10.7	8.53	12.9	1.09	2.17	
Microalbumin	mg/l	62.1	49.7	74.5	6.20	12.40	Immunoturbidimetric
Phosphate Inorganic	mmol/l	14.2	11.4	17.0	1.40	2.80	Phosphomolybdate UV
	mg/dl	44.0	35.3	52.7	4.35	8.70	
Potassium	mmol/l	66.1	56.2	76.0	4.95	9.90	ISE direct
Protein Total	g/l	0.89	0.71	1.07	0.09	0.18	Pyrogallol Red
	mg/dl	88.8	71.0	107	8.90	17.80	Pyrogallol Red
	mg/l	888	710	1066	89.00	178.00	Pyrogallol Red
Sodium	mmol/l	153	135	171	9.00	18.00	ISE direct
Uric Acid (Urate)	mmol/l	0.87	0.70	1.05	0.09	0.18	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	14.7	11.7	17.7	1.50	3.00	
Urea	mmol/l	291	233	349	29.00	58.00	Urease kinetic
	mg/dl	1749	1400	2098	174.50	349.00	

**SIEMENS ADVIA 1200/1650/1800/2400®****LIQ URN CONTROL 3**

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Calcium	mmol/l	2.99	2.69	3.29	0.15	0.30	Cresolphthalein complexone
	mg/dl	12.0	10.8	13.2	0.60	1.20	
Creatinine	mmol/l	14.7	11.8	17.6	1.45	2.90	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	166	133	199	16.50	33.00	
Glucose	mmol/l	15.3	12.2	18.4	1.55	3.10	Glucose oxidase
	mg/dl	276	220	332	28.00	56.00	
	mmol/l	15.2	12.2	18.2	1.50	3.00	Hexokinase
	mg/dl	274	220	328	27.00	54.00	
Microalbumin	mg/l	62.7	50.2	75.2	6.25	12.50	Immunoturbidimetric
Phosphate Inorganic	mmol/l	15.0	12.0	18.0	1.50	3.00	Phosphomolybdate UV
	mg/dl	46.5	37.2	55.8	4.65	9.30	
Protein Total	g/l	0.86	0.69	1.03	0.09	0.17	Pyrogallol Red
	mg/dl	86.1	68.9	103	8.60	17.20	Pyrogallol Red
	mg/l	861	689	1033	86.00	172.00	Pyrogallol Red
Uric Acid (Urate)	mmol/l	0.94	0.75	1.12	0.09	0.19	Uricase peroxidase no ascorbate oxidase
	mg/dl	15.7	12.6	18.8	1.55	3.10	
Urea	mmol/l	306	245	367	30.50	61.00	Urease kinetic
	mg/dl	1839	1472	2206	183.50	367.00	

**Siemens Atellica Solution****LIQ URN CONTROL 3**

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Calcium	mmol/l	2.90	2.61	3.19	0.15	0.29	Cresolphthalein complexone
	mg/dl	11.6	10.5	12.7	0.55	1.10	
Creatinine	mmol/l	14.3	11.4	17.2	1.45	2.90	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	162	129	195	16.50	33.00	
Glucose	mmol/l	14.6	11.7	17.5	1.45	2.90	Glucose oxidase
	mg/dl	263	211	315	26.00	52.00	
	mmol/l	14.6	11.7	17.5	1.45	2.90	Hexokinase
	mg/dl	263	211	315	26.00	52.00	
Microalbumin	mg/l	61.7	49.4	74.0	6.15	12.30	Immunoturbidimetric
Phosphate Inorganic	mmol/l	14.8	11.8	17.8	1.50	3.00	Phosphomolybdate UV
	mg/dl	45.9	36.6	55.2	4.65	9.30	
Uric Acid (Urate)	mmol/l	0.92	0.74	1.11	0.09	0.18	Uricase peroxidase no ascorbate oxidase
	mg/dl	15.5	12.4	18.6	1.55	3.10	
Urea	mmol/l	275	220	330	27.50	55.00	Urease kinetic
	mg/dl	1653	1322	1984	165.50	331.00	

**SIEMENS DIMENSION SERIES®****LIQ URN CONTROL 3**

Lot. No. 1242UC Cat. No. UC5075

Size 10 x 10ml Expiry 2025-06-28

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Amylase	U/l	103	82.4	124	10.30	20.60	Siemens 2-chloro-pNPG3
Calcium	mmol/l	2.86	2.57	3.15	0.15	0.29	Cresolphthalein complexone (CPC)
	mg/dl	11.5	10.3	12.7	0.60	1.20	
Creatinine	mmol/l	15.2	12.2	18.2	1.50	3.00	Alkaline picrate no deproteinization
	mg/dl	172	138	206	17.00	34.00	
Glucose	mmol/l	15.1	12.1	18.1	1.50	3.00	Hexokinase
	mg/dl	272	218	326	27.00	54.00	
Magnesium	mmol/l	5.06	4.05	6.07	0.51	1.01	Methylthymol blue
	mg/dl	12.3	9.84	14.8	1.23	2.46	
Microalbumin	mg/l	71.7	57.4	86.0	7.15	14.30	Immunoturbidimetric
Phosphate Inorganic	mmol/l	14.7	11.8	17.6	1.45	2.90	Phosphomolybdate UV
	mg/dl	45.6	36.6	54.6	4.50	9.00	
Protein Total	g/l	0.79	0.63	0.95	0.08	0.16	Pyrogallol Red
	mg/dl	79.0	63.2	94.8	7.90	15.80	Pyrogallol Red
	mg/l	790	632	948	79.00	158.00	Pyrogallol Red
Uric Acid (Urate)	mmol/l	0.94	0.75	1.12	0.09	0.19	Uricase 293nm UV
	mg/dl	15.7	12.6	18.8	1.55	3.10	
Urea	mmol/l	291	233	349	29.00	58.00	Urease kinetic
	mg/dl	1749	1400	2098	174.50	349.00	