

## ASSAYED URINE CONTROL - LEVEL 2 (URN ASY CONTROL 2)

**CAT. NO.** AU 2352                      **LOT NO.** 1211UC  
**SIZE:** 12 x 10 ml                      **EXPIRY:** 2026-04-28  
**GTIN:** 05055273200539

### INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of urine on clinical chemistry systems. The Assayed Urine Controls are for the control of accuracy.

### DEVICE DESCRIPTION

The Urine Controls are supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for the following analytes at both levels; amylase, calcium, chloride, copper, cortisol, creatinine, dopamine, epinephrine, glucose, 5-Hydroxyindoleacetic acid, magnesium, metanephrine, microalbumin, norepinephrine (noradrenalin), normetanephrine, osmolality, oxalate, phosphorous inorganic, potassium, total protein, sodium, urea, uric acid and vanillylmandelic acid (VMA).

### SAFETY PRECAUTIONS AND WARNINGS

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 request.

### STORAGE AND STABILITY

**OPENED:** Store refrigerated (+2°C to +8°C). Reconstituted urine is stable for 8 hours at +15°C to +25°C and 5 days at +2°C to +8°C if kept capped in original container and free from contamination, or 14 days at -20°C. No stability claims are made for copper. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

### PREPARATION AND STABILITY OF SAMPLES FOR Catecholamines, Vanillylmandelic Acid (VMA), Oxalate and 5-Hydroxyindole Acetic Acid (5-HIAA):

These analytes are unstable in urine samples and no claims are made on the stability. Samples should be prepared according to the standard procedures within each laboratory.

**UNOPENED:** Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

### PREPARATION FOR USE

The Assayed Urine Control is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised urine with exactly 10 ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

### MATERIALS PROVIDED

Assayed Urine Control - Level 2 12 x 10 ml

### MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

**ASSIGNED VALUES**

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

Each batch of Assayed Urine Control is submitted to a number of external laboratories and values are assigned from a consensus of results obtained by these laboratories. With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean  $\pm$  2SD.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email [Technical.Services@randox.com](mailto:Technical.Services@randox.com).

| The presence of a vertical bar in the margin indicates a technical update from the previous revision. |

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

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## ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352 Lot. No. 1211UC Size 12 x 10ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
5-HIAA	µmol/l	31.4	25.1	37.7	HPLC
Amylase	U/l	130	104	156	Vitros
	U/l	232	186	278	Siemens - blocked pNPG7
	U/l	232	186	278	Other blocked pNPG7
	U/l	225	180	270	Randox Liquid Ethylidene pNPG7
	U/l	200	160	240	Roche liquid pNPG7
	U/l	208	166	250	Roche Integra 2-chloro-pNPG7
	U/l	211	169	253	Beckman Coulter - blocked pNPG7
	U/l	237	190	284	Other 2-chloro-pNPG3
	U/l	244	195	293	Abbott Architect Non-IFCC Cal.
	U/l	260	208	312	Abbott Architect IFCC Cal.
Calcium	mmol/l	1.57	1.41	1.73	Vitros
	mg/dl	6.29	5.65	6.93	
	mmol/l	1.55	1.40	1.71	Cresolphthalein complexone
	mg/dl	6.21	5.61	6.81	
	mmol/l	1.52	1.37	1.67	Arsenazo III
	mg/dl	6.09	5.49	6.69	
Chloride	mmol/l	1.55	1.40	1.71	NM-BAPTA
	mg/dl	6.21	5.61	6.81	
	mmol/l	84.9	72.2	97.6	Vitros
Copper	mmol/l	81.0	68.9	93.2	ISE indirect
	mmol/l	81.4	69.2	93.6	ISE direct
	µmol/l	1.36	1.09	1.63	Atomic absorption
Cortisol	µg/dl	8.65	6.93	10.4	
	nmol/l	95.1	71.3	119	Chemiluminescence (+ solvent extraction.)
Creatinine	µg/dl	3.42	2.57	4.27	
	mmol/l	6.78	5.42	8.14	Alkaline picrate no deproteinization
	mg/dl	76.6	61.2	92.0	
	mmol/l	7.16	5.73	8.59	Creatinine PAP method
	mg/dl	80.9	64.7	97.1	
	mmol/l	7.04	5.63	8.45	Enzymatic UV method
	mg/dl	79.6	63.6	95.6	
	mmol/l	7.03	5.62	8.44	Other enzymatic methods
	mg/dl	79.4	63.5	95.3	
	mmol/l	7.29	5.83	8.75	Roche Creatinine Plus
	mg/dl	82.4	65.9	98.9	
	mmol/l	6.95	5.56	8.34	Jaffe rate blanked
	mg/dl	78.5	62.8	94.2	
	mmol/l	6.92	5.54	8.30	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	78.2	62.6	93.8	
	mmol/l	7.19	5.75	8.63	Vitros IDMS Traceable
mg/dl	81.2	65.0	97.4		

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Analyte	unit	Target	Range		methods
			low	high	
Creatinine	mmol/l	6.73	5.38	8.08	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	76.0	60.8	91.2	
	mmol/l	6.94	5.55	8.33	IDMS traceable
	mg/dl	78.4	62.7	94.1	
Dopamine	nmol/l	561	449	673	HPLC
Epinephrine	nmol/l	76.1	60.9	91.3	HPLC
Glucose	mmol/l	2.60	2.08	3.12	Vitros
	mg/dl	46.9	37.5	56.3	
	mmol/l	2.72	2.18	3.26	Glucose oxidase
	mg/dl	49.0	39.3	58.7	
	mmol/l	2.78	2.22	3.34	Hexokinase
	mg/dl	50.1	40.0	60.2	
	mmol/l	2.79	2.23	3.35	Glucose dehydrogenase
	mg/dl	50.3	40.2	60.4	
Magnesium	mmol/l	3.76	3.01	4.51	Vitros
	mg/dl	9.14	7.31	11.0	
	mmol/l	3.19	2.55	3.83	Xylidyl Blue
	mg/dl	7.75	6.20	9.30	
	mmol/l	3.13	2.50	3.76	Arsenazo III
	mg/dl	7.61	6.08	9.14	
	mmol/l	3.24	2.59	3.89	Chlorphosphonazo III
	mg/dl	7.87	6.29	9.45	
	mmol/l	3.22	2.58	3.86	Enzymatic
	mg/dl	7.82	6.27	9.37	
Metanephrine	µmol/l	0.270	0.216	0.324	HPLC
Microalbumin	mg/l	30.7	24.6	36.8	Immunoturbidimetric
Norepinephrine	nmol/l	243	194	292	HPLC
Normetanephrine	µmol/l	1.15	0.920	1.38	HPLC
Osmolality	mOsm/kg	390	312	468	Freezing point depression
	mOsm/kg	387	310	464	Calculated
Oxalate	mmol/l	0.108	0.086	0.130	Oxalate oxidase
Phosphate Inorganic	mmol/l	10.1	8.08	12.1	Vitros
	mg/dl	31.3	25.0	37.6	
	mmol/l	8.93	7.14	10.7	Phosphomolybdate UV
	mg/dl	27.7	22.1	33.3	
	mmol/l	8.98	7.18	10.8	Phosphomolybdate enzymatic
mg/dl	27.8	22.3	33.3		
Potassium	mmol/l	30.2	25.7	34.7	Vitros
	mmol/l	31.3	26.6	36.0	ISE direct
	mmol/l	29.9	25.4	34.4	ISE indirect
Protein Total	g/l	0.123	0.098	0.148	Biuret reaction - direct
	mg/dl	12.3	9.80	14.8	
	mg/l	123	98.0	148	
	g/l	0.111	0.089	0.133	Turbidimetry
	mg/dl	11.1	8.90	13.3	
	mg/l	111	89.0	133	

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Cat. No. AU2352 Lot. No. 1211UC Size 12 x 10ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods	
			low	high		
Protein Total	g/l	0.152	0.122	0.182	Pyrogallol Red	
	mg/dl	15.2	12.2	18.2		
	mg/l	152	122	182		
	g/l	0.191	0.153	0.229	Vitros	
	mg/dl	19.1	15.3	22.9		
	mg/l	191	153	229		
Sodium	mmol/l	63.6	56.0	71.2	Vitros	
	mmol/l	64.0	56.3	71.7	ISE direct	
	mmol/l	62.3	54.8	69.8	ISE indirect	
Urea	mmol/l	152	122	182	Vitros	
	mg/dl	914	733	1095		
	mmol/l	152	122	182	Urease kinetic	
	mg/dl	914	733	1095		
	mmol/l	153	122	184	Urease end point	
	mg/dl	920	733	1107		
	Uric Acid (Urate)	mmol/l	0.701	0.561	0.841	Ortho Vitros Microslide Systems
		mg/dl	11.8	9.42	14.2	
mmol/l		0.712	0.570	0.854	Uricase peroxidase no ascorbate oxidase	
mg/dl		12.0	9.58	14.4		
mmol/l		0.682	0.546	0.818	Uricase Peroxidase with ascorbate oxidase @ 546nm	
mg/dl		11.5	9.17	13.8		
mmol/l		0.691	0.553	0.829	Uricase peroxidase with ascorbate oxidase	
mg/dl		11.6	9.29	13.9		
Vanillylmandelic Acid (VMA)	µmol/l	34.4	27.5	41.3	Column test	
	µmol/l	28.2	22.6	33.8	HPLC	