

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

CAT. NO. AU 2352 **LOT NO.** 1148UC
SIZE 12 x 10 ml **EXPIRY:** 2025-05-28
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.

- 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.
- Refer to the Control section of the individual analyser application.
- 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.

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

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Randox Teoranta, Meenmore,
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Rev. 23 Jan '23 me

ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352 Lot. No. 1148UC Size 12 x 10ml Expiry 2025-05-28

Range					
Analyte	unit	Target	low	high	methods
5-HIAA	µmol/l	31.2	25.0	37.4	HPLC
Amylase	U/l	117	93.6	140	Vitros
	U/l	208	166	250	Siemens - blocked pNPG7
	U/l	215	172	258	Other blocked pNPG7
	U/l	211	169	253	Randox Liquid Ethylidene pNPG7
	U/l	191	153	229	Roche liquid pNPG7
	U/l	216	173	259	Beckman Synchron CX4/CX5/CX7
	U/l	235	188	282	Siemens - maltopenta/hexaoside
	U/l	192	154	230	Roche Integra 2-chloro-pNPG7
	U/l	212	170	254	Beckman Coulter - blocked pNPG7
	U/l	251	201	301	Siemens 2-chloro-pNPG3
	U/l	226	181	271	Other 2-chloro-pNPG3
	U/l	227	182	272	Abbott Architect Non-IFCC Cal.
	U/l	251	201	301	Abbott Architect IFCC Cal.
Calcium	mmol/l	1.80	1.62	1.98	Vitros
	mg/dl	7.21	6.49	7.93	
	mmol/l	1.58	1.42	1.74	Cresolphthalein complexone
	mg/dl	6.33	5.69	6.97	
	mmol/l	1.52	1.37	1.67	Ion selective electrode
	mg/dl	6.09	5.49	6.69	
	mmol/l	1.56	1.40	1.72	Arsenazo III
	mg/dl	6.25	5.61	6.89	
mmol/l	1.59	1.43	1.75	NM-BAPTA	
mg/dl	6.37	5.73	7.01		
Chloride	mmol/l	86.5	73.5	99.0	Vitros
	mmol/l	82.4	70.0	94.8	ISE indirect
	mmol/l	84.4	71.7	97.1	ISE direct
Copper	µmol/l	1.35	1.08	1.62	Atomic absorption
	µg/dl	8.59	6.87	10.3	
Cortisol	nmol/l	104	78.0	130	Chemiluminescence (+ solvent extraction.)
	µg/dl	3.74	2.81	4.67	
	nmol/l	124	93.0	155	Chemiluminescence (direct)
	µg/dl	4.46	3.35	5.57	
Creatinine	mmol/l	6.86	5.49	8.23	Alkaline picrate no deproteinization
	mg/dl	77.5	62.0	93.0	
	mmol/l	7.19	5.75	8.63	Creatinine PAP method
	mg/dl	81.2	65.0	97.4	
	mmol/l	7.01	5.61	8.41	Enzymatic UV method
	mg/dl	79.2	63.4	95.0	
	mmol/l	7.05	5.64	8.46	Other enzymatic methods
	mg/dl	79.7	63.7	95.7	
	mmol/l	7.36	5.89	8.83	Roche Creatinine Plus
	mg/dl	83.2	66.6	100	

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Cat. No. AU2352 Lot. No. 1148UC Size 12 x 10ml Expiry 2025-05-28

Analyte	unit	Target	Range		methods
			low	high	
Creatinine	mmol/l	6.82	5.46	8.18	Jaffe rate blanked
	mg/dl	77.1	61.7	92.5	
	mmol/l	6.90	5.52	8.28	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	78.0	62.4	93.6	
	mmol/l	7.17	5.74	8.60	Vitros IDMS Traceable
	mg/dl	81.0	64.9	97.1	
	mmol/l	6.83	5.46	8.20	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	77.2	61.7	92.7	
Dopamine	nmol/l	620	496	744	HPLC
Epinephrine	nmol/l	72.9	58.3	87.5	HPLC
Glucose	mmol/l	2.57	2.06	3.08	Vitros
	mg/dl	46.3	37.1	55.5	
	mmol/l	2.79	2.23	3.35	Glucose oxidase
	mg/dl	50.3	40.2	60.4	
	mmol/l	2.77	2.22	3.32	Hexokinase
	mg/dl	49.9	40.0	59.8	
Magnesium	mmol/l	3.12	2.50	3.74	Vitros
	mg/dl	7.58	6.08	9.08	
	mmol/l	2.92	2.34	3.50	Xylidyl Blue
	mg/dl	7.10	5.69	8.51	
	mmol/l	2.90	2.32	3.48	Arsenazo III
	mg/dl	7.05	5.64	8.46	
	mmol/l	2.90	2.32	3.48	Chlorphosphonazo III
	mg/dl	7.05	5.64	8.46	
	mmol/l	2.98	2.38	3.58	Methylthymol blue
	mg/dl	7.24	5.78	8.70	
	mmol/l	2.94	2.35	3.53	Enzymatic
	mg/dl	7.14	5.71	8.57	
Metanephrine	µmol/l	0.295	0.236	0.354	HPLC
Microalbumin	mg/l	26.9	21.5	32.3	Immunoturbidimetric
	mg/l	28.9	23.1	34.7	Nephelometric
Norepinephrine	nmol/l	249	199	299	HPLC
Normetanephrine	µmol/l	1.26	1.01	1.51	HPLC
Osmolality	mOsm/kg	396	317	475	Freezing point depression
	mOsm/kg	349	279	419	Calculated
Oxalate	mmol/l	0.099	0.079	0.119	Oxalate oxidase
Phosphate Inorganic	mmol/l	9.61	7.69	11.5	Vitros
	mg/dl	29.8	23.8	35.8	
	mmol/l	8.38	6.70	10.1	Phosphomolybdate UV
	mg/dl	26.0	20.8	31.2	
	mmol/l	8.40	6.72	10.1	Phosphomolybdate enzymatic
	mg/dl	26.0	20.8	31.2	
Potassium	mmol/l	31.4	26.7	36.1	Vitros

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Analyte	unit	Target	Range		methods
			low	high	
Potassium	mmol/l	31.2	26.5	35.9	ISE direct
	mmol/l	30.1	25.6	34.6	ISE indirect
Protein Total	g/l	0.141	0.113	0.169	Biuret reaction - direct
	mg/dl	14.1	11.3	16.9	
	mg/l	141	113	169	
	g/l	0.124	0.099	0.149	Turbidimetry
	mg/dl	12.4	9.90	14.9	
	mg/l	124	99.0	149	
	g/l	0.160	0.128	0.192	Pyrogallol Red
	mg/dl	16.0	12.8	19.2	
	mg/l	160	128	192	
	Sodium	g/l	0.193	0.154	0.232
mg/dl		19.3	15.4	23.2	
mg/l		193	154	232	
Sodium	mmol/l	66.4	58.4	74.4	Vitros
	mmol/l	70.1	61.7	78.5	ISE direct
	mmol/l	63.7	56.1	71.3	ISE indirect
Urea	mmol/l	163	130	196	Vitros
	mg/dl	980	781	1179	
	mmol/l	155	124	186	Urease kinetic
	mg/dl	932	745	1119	
	mmol/l	158	126	190	Urease end point
mg/dl	950	757	1143		
Uric Acid (Urate)	mmol/l	0.754	0.603	0.905	Ortho Vitros Microslide Systems
	mg/dl	12.7	10.1	15.3	
	mmol/l	0.745	0.596	0.894	Uricase peroxidase no ascorbate oxidase
	mg/dl	12.5	10.0	15.0	
	mmol/l	0.794	0.635	0.953	Spectrophotometric at 280-290
	mg/dl	13.3	10.7	15.9	
	mmol/l	0.715	0.572	0.858	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	12.0	9.61	14.4	
mmol/l	0.734	0.587	0.881	Uricase peroxidase with ascorbate oxidase	
mg/dl	12.3	9.86	14.7		
Vanillylmandelic Acid	µmol/l	27.8	22.2	33.4	HPLC