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

CAT. NO.	AU 2352	**LOT NO.**	833UC
SIZE:	12 x 10 ml	**EXPIRY:**	2019-10
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. 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) and Oxalate:

These analytes are unstable in urine samples. Fifteen minutes after complete reconstitution of the urine, remove an aliquot and add 8 µl of HCl (6M) per ml urine. Sample is stable for 5 days at +2°C to +8°C. For Oxalate measurement, it is recommended that EDTA is added to the urine sample at a concentration of 5 mg/10 ml material. This is to prevent the precipitation of Calcium Oxalate.

5-Hydroxyindole Acetic Acid (5-HIAA):
This analyte is also unstable in reconstituted urine samples. Fifteen minutes after complete reconstitution of the urine, remove an aliquot and add 10 µl of Glacial Acetic Acid (17.4M) per ml of urine. Sample is stable for 7 days at +2°C to +8°C.

Please note that if Nitroso-Naphthol method is used for 5-HIAA, 12 µl of HCl (6M) per ml of urine should be added to an aliquot of reconstituted urine. Sample is stable for 7 days at +2°C to +8°C. The addition of HCl is also recommended where 5-HIAA is assayed using HPLC methods with prior extraction.

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

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 ± 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.

09 Jun 16 pl

RANDOX

ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352 Lot. No. 833UC Size 12 x 10ml Expiry 2019-10

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
5-HIAA	µmol/l	30.8	24.6	37.0	Colorimetric (nitrosonaphthol)
	µmol/l	28.9	23.1	34.7	HPLC
Amylase	U/l	118	94.4	142	Vitros
	U/l	201	161	241	Siemens - blocked pNPG7
	U/l	203	162	244	Other blocked pNPG7
	U/l	223	178	268	Randox liquid pNPG7
	U/l	186	149	223	Roche liquid pNPG7
	U/l	186	149	223	BM/Roche Colorimetric pNPG7
	U/l	250	200	300	Siemens 2-chloro-pNP linked substrate
	U/l	196	157	235	Roche Integra 2-chloro-pNPG7
	U/l	207	166	248	Beckman Olympus - blocked pNPG7
	U/l	253	202	304	Siemens 2-chloro-pNPG3
	U/l	225	180	270	Other 2-chloro-pNPG3
	U/l	235	188	282	I.L. 2-chloro-pNPG3
	U/l	227	182	272	Abbott Architect Non-IFCC Cal.
	U/l	253	202	304	Abbott Architect IFCC Cal.
Calcium	mmol/l	1.65	1.49	1.82	Vitros
	mg/dl	6.61	5.97	7.25	
	mmol/l	1.55	1.40	1.71	Cresolphthalein complexone
	mg/dl	6.21	5.61	6.81	
	mmol/l	1.53	1.38	1.68	Ion selective electrode
	mg/dl	6.13	5.53	6.73	
	mmol/l	1.53	1.38	1.68	Arsenazo III
	mg/dl	6.13	5.53	6.73	
	mmol/l	1.53	1.38	1.68	NM-BAPTA
	mg/dl	6.13	5.53	6.73	
Chloride	mmol/l	80.1	68.1	92.1	ISE indirect
	mmol/l	84.5	71.8	97.2	ISE direct
Copper	µmol/l	1.36	1.09	1.63	Atomic absorption
	µg/dl	8.65	6.93	10.4	
Cortisol	nmol/l	98.6	74.0	123	Chemiluminescence (+ solvent extraction.)
	µg/dl	3.55	2.66	4.44	
	nmol/l	128	96.0	160	Chemiluminescence (direct)
	µg/dl	4.61	3.46	5.76	
Creatinine	mmol/l	6.83	5.46	8.20	Alkaline picrate no deproteinization
	mg/dl	77.2	61.7	92.7	
	mmol/l	6.93	5.54	8.32	Creatinine PAP method
	mg/dl	78.3	62.6	94.0	
	mmol/l	7.12	5.70	8.54	Randox Enzymatic UV method
	mg/dl	80.5	64.4	96.6	
	mmol/l	7.10	5.68	8.52	Other enzymatic methods
	mg/dl	80.2	64.2	96.2	

RANDOX

ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352 Lot. No. 833UC Size 12 x 10ml Expiry 2019-10

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Creatinine	mmol/l	7.24	5.79	8.69	Roche Creatinine Plus
	mg/dl	81.8	65.4	98.2	
	mmol/l	6.79	5.43	8.15	Jaffe rate blanked
	mg/dl	76.7	61.4	92.0	
	mmol/l	6.88	5.50	8.26	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	77.7	62.2	93.2	
	mmol/l	6.81	5.45	8.17	Vitros IDMS Traceable
	mg/dl	77.0	61.6	92.4	
	mmol/l	6.70	5.36	8.04	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	75.7	60.6	90.8	
Dopamine	nmol/l	514	411	617	HPLC
Epinephrine	nmol/l	61.3	49.0	73.6	HPLC
Glucose	mmol/l	2.75	2.20	3.30	Vitros
	mg/dl	49.6	39.6	59.6	
	mmol/l	2.74	2.19	3.29	Glucose oxidase
	mg/dl	49.4	39.5	59.3	
	mmol/l	2.77	2.22	3.32	Hexokinase
	mg/dl	49.9	40.0	59.8	
	mmol/l	2.67	2.14	3.20	GOD/02-Beckman method
	mg/dl	48.1	38.6	57.6	
Magnesium	mmol/l	3.37	2.70	4.04	Vitros
	mg/dl	8.19	6.56	9.82	
	mmol/l	3.00	2.40	3.60	Calmagite
	mg/dl	7.29	5.83	8.75	
	mmol/l	3.10	2.48	3.72	Xylidyl Blue
	mg/dl	7.53	6.03	9.03	
	mmol/l	3.11	2.49	3.73	Arsenazo III
	mg/dl	7.56	6.05	9.07	
	mmol/l	3.08	2.46	3.70	Chlorphosphonazo III
	mg/dl	7.48	5.98	8.98	
	mmol/l	3.19	2.55	3.83	Methylthymol blue
	mg/dl	7.75	6.20	9.30	
	mmol/l	3.15	2.52	3.78	Enzymatic
	mg/dl	7.65	6.12	9.18	
Metanephrine	µmol/l	0.218	0.174	0.262	HPLC
Microalbumin	mg/l	32.0	25.6	38.4	Immunoturbidimetric
	mg/l	34.0	27.2	40.8	Nephelometric
Norepinephrine	nmol/l	232	186	278	HPLC
Normetanephrine	µmol/l	1.21	0.968	1.45	HPLC
Osmolality	mOsm/kg	388	310	466	Freezing point depression
	mOsm/kg	341	273	409	Calculated
Oxalate	mmol/l	0.103	0.082	0.124	Oxalate oxidase
Phosphate Inorganic	mmol/l	9.79	7.83	11.7	Vitros
	mg/dl	30.3	24.3	36.3	
	mmol/l	8.56	6.85	10.3	Phosphomolybdate UV
	mg/dl	26.5	21.2	31.8	

RANDOX

ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352 Lot. No. 833UC Size 12 x 10ml Expiry 2019-10

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Phosphate Inorganic	mmol/l	8.60	6.88	10.3	Phosphomolybdate enzymatic
	mg/dl	26.7	21.3	32.1	
Potassium	mmol/l	30.4	25.8	35.0	Vitros
	mmol/l	30.0	25.5	34.5	ISE direct
	mmol/l	29.7	25.2	34.2	ISE indirect
Protein Total	g/l	0.135	0.108	0.162	Biuret reaction - direct
	mg/dl	13.5	10.8	16.2	
	mg/l	135	108	162	
	g/l	0.115	0.092	0.138	Turbidimetry
	mg/dl	11.5	9.20	13.8	
	mg/l	115	92.0	138	
	g/l	0.150	0.105	0.195	Pyrogallol Red
	mg/dl	15.0	10.5	19.5	
	mg/l	150	105	195	
	g/l	0.165	0.132	0.198	Vitros
	mg/dl	16.5	13.2	19.8	
	mg/l	165	132	198	
Sodium	mmol/l	65.2	57.4	73.0	Vitros
	mmol/l	64.4	56.7	72.1	ISE direct
	mmol/l	61.2	53.9	68.5	ISE indirect
Urea	mmol/l	153	122	184	Vitros
	mg/dl	920	733	1107	
	mmol/l	159	127	191	Beckman-Conductivity
	mg/dl	956	763	1149	
	mmol/l	153	122	184	Urease kinetic
	mg/dl	920	733	1107	
	mmol/l	163	130	196	Urease end point
	mg/dl	980	781	1179	
Uric Acid (Urate)	mmol/l	0.659	0.527	0.791	Ortho Vitros Microslide Systems
	mg/dl	11.1	8.85	13.4	
	mmol/l	0.705	0.564	0.846	Uricase peroxidase no ascorbate oxidase
	mg/dl	11.8	9.48	14.1	
	mmol/l	0.736	0.589	0.883	Spectrophotometric at 280-290
	mg/dl	12.4	9.90	14.9	
	mmol/l	0.656	0.525	0.787	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	11.0	8.82	13.2	
	mmol/l	0.692	0.554	0.830	Uricase peroxidase with ascorbate oxidase
	mg/dl	11.6	9.31	13.9	
Vanillylmandelic Acid (VMA)	µmol/l	27.2	21.8	32.6	Column test
	µmol/l	28.5	22.8	34.2	HPLC

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com