ASSAYED URINE CONTROL - LEVEL 3 (URN ASY CONTROL 3)

CAT. NO. AU 2353 **LOT NO.** 1018UC
SIZE: 12 x 10 ml **EXPIRY:** 2022-10-28

GTIN: 05055273200546

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 hydroxy indole acetic 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 be 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 3 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.

07 May '19 ne

RANDOX

ASSAYED URINE CONTROL - LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot No. 1018UC Size: 12 x 10 ml Expiry: 2022-10-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
5-HIAA	µmol/l	275	220	330	HPLC
Amylase	U/l	461	369	553	Vitros
	U/l	875	700	1050	Siemens - blocked pNPG7
	U/l	831	665	997	Randox Lyo. Ethylidene pNPG7
	U/l	859	687	1031	Other blocked pNPG7
	U/l	823	658	988	Randox Liquid Ethylidene pNPG7
	U/l	769	615	923	Roche liquid pNPG7
	U/l	930	744	1116	Beckman Synchron CX4/CX5/CX7
	U/l	807	646	968	Roche Integra 2-chloro-pNPG7
	U/l	879	703	1055	Beckman Coulter - blocked pNPG7
	U/l	1060	848	1272	Siemens 2-chloro-pNPG3
	U/l	967	774	1160	Other 2-chloro-pNPG3
	U/l	993	794	1192	Abbott Architect Non-IFCC Cal.
	U/l	1084	867	1301	Abbott Architect IFCC Cal.
Calcium	mmol/l	3.59	3.23	3.95	Vitros
	mg/dl	14.4	12.9	15.9	
	mmol/l	4.78	4.30	5.26	Cresolphthalein complexone
	mg/dl	19.2	17.2	21.2	
	mmol/l	3.30	2.97	3.63	Ion selective electrode
	mg/dl	13.2	11.9	14.5	
	mmol/l	4.23	3.81	4.65	Arsenazo III
	mg/dl	17.0	15.3	18.7	
	mmol/l	4.55	4.10	5.01	NM-BAPTA
	mg/dl	18.2	16.4	20.0	
Chloride	mmol/l	252	214	290	Vitros
	mmol/l	255	217	293	ISE indirect
	mmol/l	251	213	289	ISE direct
Copper	µmol/l	3.64	1.66	5.62	Atomic absorption
	µg/dl	23.2	10.6	35.8	
Cortisol	nmol/l	255	191	319	Chemiluminescence (+ solvent extraction.)
	µg/dl	9.18	6.88	11.5	
	nmol/l	271	203	339	Chemiluminescence (direct)
	µg/dl	9.76	7.31	12.2	
Creatinine	mmol/l	15.6	12.5	18.7	Alkaline picrate no deproteinization
	mg/dl	176	141	211	
	mmol/l	16.1	12.9	19.3	Creatinine PAP method
	mg/dl	182	146	218	
	mmol/l	16.0	12.8	19.2	Enzymatic UV method
	mg/dl	181	145	217	
	mmol/l	16.2	13.0	19.4	Other enzymatic methods
	mg/dl	183	147	219	
	mmol/l	16.5	13.2	19.8	Roche Creatinine Plus
	mg/dl	186	149	223	

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

RANDOX

ASSAYED URINE CONTROL - LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot No. 1018UC Size: 12 x 10 ml Expiry: 2022-10-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Creatinine	mmol/l	16.0	12.8	19.2	Jaffe rate blanked
	mg/dl	181	145	217	
	mmol/l	15.6	12.5	18.7	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	176	141	211	
	mmol/l	16.1	12.9	19.3	Vitros IDMS Traceable
	mg/dl	182	146	218	
	mmol/l	16.1	12.9	19.3	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	182	146	218	
Dopamine	nmol/l	1918	1534	2302	HPLC
Epinephrine	nmol/l	334	196	472	HPLC
Glucose	mmol/l	15.0	12.0	18.0	Vitros
	mg/dl	270	216	324	
	mmol/l	14.4	11.5	17.3	Glucose oxidase
	mg/dl	259	207	311	
	mmol/l	14.6	11.7	17.5	Hexokinase
	mg/dl	263	211	315	
	mmol/l	14.4	11.5	17.3	Oxygen electrode
	mg/dl	259	207	311	
Magnesium	mmol/l	13.4	10.7	16.1	Vitros
	mg/dl	32.6	26.0	39.2	
	mmol/l	13.1	10.5	15.7	Calmagite
	mg/dl	31.8	25.5	38.1	
	mmol/l	13.4	10.7	16.1	Xylidyl Blue
	mg/dl	32.6	26.0	39.2	
	mmol/l	13.2	10.6	15.8	Arsenazo III
	mg/dl	32.1	25.8	38.4	
	mmol/l	13.8	11.0	16.6	Chlorphosphonazo III
	mg/dl	33.5	26.7	40.3	
	mmol/l	13.1	10.5	15.7	Methylthymol blue
	mg/dl	31.8	25.5	38.1	
	mmol/l	13.3	10.6	16.0	Enzymatic
	mg/dl	32.3	25.8	38.8	
Metanephrine	µmol/l	2.58	2.06	3.10	HPLC
Microalbumin	mg/l	177	142	212	Immunoturbidimetric
	mg/l	181	145	217	Nephelometric
Norepinephrine	nmol/l	1477	1182	1772	HPLC
Normetanephrine	µmol/l	3.98	3.18	4.78	HPLC
Osmolality	mOsm/kg	1080	864	1296	Freezing point depression
	mOsm/kg	1077	862	1292	Calculated
Oxalate	mmol/l	0.439	0.351	0.527	Oxalate oxidase
Phosphate Inorganic	mmol/l	28.2	22.6	33.8	Vitros
	mg/dl	87.4	70.1	105	
	mmol/l	26.7	21.4	32.0	Phosphomolybdate UV
	mg/dl	82.8	66.3	99.3	
	mmol/l	26.3	21.0	31.6	Phosphomolybdate enzymatic
	mg/dl	81.5	65.1	97.9	

RANDOX

ASSAYED URINE CONTROL - LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot No. 1018UC Size: 12 x 10 ml Expiry: 2022-10-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Potassium	mmol/l	136	116	156	Vitros
	mmol/l	122	104	140	ISE direct
	mmol/l	124	105	143	ISE indirect
Protein Total	g/l	0.221	0.177	0.265	Biuret reaction with ppt
	mg/dl	22.1	17.7	26.5	
	mg/l	221	177	265	
	g/l	0.267	0.214	0.320	Biuret reaction - direct
	mg/dl	26.7	21.4	32.0	
	mg/l	267	214	320	
	g/l	0.248	0.198	0.298	Turbidimetry
	mg/dl	24.8	19.8	29.8	
	mg/l	248	198	298	
	g/l	0.259	0.207	0.311	Pyrogallol Red
	mg/dl	25.9	20.7	31.1	
	mg/l	259	207	311	
	g/l	0.108	0.086	0.130	Vitros
	mg/dl	10.8	8.60	13.0	
	mg/l	108	86.0	130	
Sodium	mmol/l	210	185	235	Vitros
	mmol/l	195	172	218	ISE direct
	mmol/l	197	173	221	ISE indirect
Urea	mmol/l	443	354	532	Vitros
	mg/dl	2662	2128	3196	
	mmol/l	456	365	547	Beckman-Conductivity
	mg/dl	2741	2194	3288	
	mmol/l	436	349	523	Urease kinetic
	mg/dl	2620	2097	3143	
	mmol/l	435	348	522	Urease end point
	mg/dl	2614	2091	3137	
Uric Acid (Urate)	mmol/l	1.29	1.03	1.55	Ortho Vitros Microslide Systems
	mg/dl	21.7	17.3	26.1	
	mmol/l	1.29	1.03	1.55	Uricase catalase 340nm
	mg/dl	21.7	17.3	26.1	
	mmol/l	1.27	1.02	1.52	Uricase peroxidase no ascorbate oxidase
	mg/dl	21.3	17.1	25.5	
	mmol/l	1.31	1.05	1.57	Spectrophotometric at 280-290
	mg/dl	22.0	17.6	26.4	
	mmol/l	1.23	0.984	1.48	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	20.7	16.5	24.9	
	mmol/l	1.24	0.992	1.49	Uricase peroxidase with ascorbate oxidase
	mg/dl	20.8	16.7	24.9	
Vanillylmandelic Acid (VMA)	µmol/l	139	111	167	Column test
	µmol/l	141	113	169	HPLC