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

CAT. NO.	AU 2353	**LOT NO.**	838UC
SIZE:	12 x 10 ml	**EXPIRY:**	2019-10
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.

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ASSAYED URINE CONTROL LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot. No. 838UC Size 12 x 10ml Expiry 2019-10

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
5-HIAA	µmol/l	293	234	352	HPLC
Amylase	U/l	427	342	512	Vitros
	U/l	831	665	997	Siemens - blocked pNPG7
	U/l	833	666	1000	Other blocked pNPG7
	U/l	877	702	1052	Randox liquid pNPG7
	U/l	758	606	910	Roche liquid pNPG7
	U/l	754	603	905	BM/Roche Colorimetric pNPG7
	U/l	788	630	946	Roche Integra 2-chloro-pNPG7
	U/l	936	749	1123	pNP Maltotrioside substrates
	U/l	855	684	1026	Beckman Olympus - blocked pNPG7
	U/l	1044	835	1253	Siemens 2-chloro-pNPG3
	U/l	945	756	1134	Other 2-chloro-pNPG3
	U/l	970	776	1164	Abbott Architect Non-IFCC Cal.
	U/l	1008	806	1210	Abbott Architect IFCC Cal.
Calcium	mmol/l	3.49	3.14	3.84	Vitros
	mg/dl	14.0	12.6	15.4	
	mmol/l	4.73	4.26	5.20	Cresolphthalein complexone
	mg/dl	19.0	17.1	20.9	
	mmol/l	3.32	2.99	3.65	Ion selective electrode
	mg/dl	13.3	12.0	14.6	
	mmol/l	4.32	3.89	4.75	Arsenazo III
	mg/dl	17.3	15.6	19.0	
	mmol/l	4.61	4.15	5.07	NM-BAPTA
	mg/dl	18.5	16.6	20.4	
Chloride	mmol/l	264	224	304	ISE indirect
	mmol/l	265	225	305	ISE direct
Copper	µmol/l	3.22	2.58	3.86	Atomic absorption
	µg/dl	20.5	16.4	24.6	
Cortisol	nmol/l	264	198	330	Chemiluminescence (+ solvent extraction.)
	µg/dl	9.50	7.13	11.9	
	nmol/l	297	223	371	Chemiluminescence (direct)
	µg/dl	10.7	8.03	13.4	
Creatinine	mmol/l	16.0	12.8	19.2	Alkaline picrate no deproteinization
	mg/dl	181	145	217	
	mmol/l	16.9	13.5	20.3	Creatinine PAP method
	mg/dl	191	153	229	
	mmol/l	16.6	13.3	19.9	Randox Enzymatic UV method
	mg/dl	188	150	226	
	mmol/l	16.8	13.4	20.2	Other enzymatic methods
	mg/dl	190	151	229	
	mmol/l	16.7	13.4	20.0	Roche Creatinine Plus
	mg/dl	189	151	227	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Creatinine	mmol/l	15.8	12.6	19.0	Jaffe rate blanked
	mg/dl	179	142	216	
	mmol/l	15.9	12.7	19.1	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	180	144	216	
	mmol/l	15.7	12.6	18.8	Vitros IDMS Traceable
	mg/dl	177	142	212	
	mmol/l	16.3	13.0	19.6	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	184	147	221	
Dopamine	nmol/l	1623	1298	1948	HPLC
Epinephrine	nmol/l	268	214	322	HPLC
Glucose	mmol/l	15.7	12.6	18.8	Vitros
	mg/dl	283	227	339	
	mmol/l	15.1	12.1	18.1	Glucose oxidase
	mg/dl	272	218	326	
	mmol/l	15.5	12.4	18.6	Hexokinase
	mg/dl	279	223	335	
	mmol/l	15.4	12.3	18.5	GOD/02-Beckman method
	mg/dl	278	222	334	
Magnesium	mmol/l	13.6	10.9	16.3	Vitros
	mg/dl	33.0	26.5	39.5	
	mmol/l	13.3	10.6	16.0	Calmagite
	mg/dl	32.3	25.8	38.8	
	mmol/l	13.4	10.7	16.1	Xylidyl Blue
	mg/dl	32.6	26.0	39.2	
	mmol/l	13.5	10.8	16.2	Arsenazo III
	mg/dl	32.8	26.2	39.4	
	mmol/l	13.8	11.0	16.6	Chlorphosphonazo III
	mg/dl	33.5	26.7	40.3	
	mmol/l	13.4	10.7	16.1	Methylthymol blue
	mg/dl	32.6	26.0	39.2	
	mmol/l	13.7	11.0	16.4	Enzymatic
	mg/dl	33.3	26.7	39.9	
Metanephrine	µmol/l	2.20	1.76	2.64	HPLC
Microalbumin	mg/l	176	141	211	Immunoturbidimetric
	mg/l	187	150	224	Nephelometric
Norepinephrine	nmol/l	1358	1086	1630	HPLC
Normetanephrine	µmol/l	4.03	3.22	4.84	HPLC
Osmolality	mOsm/kg	1107	886	1328	Freezing point depression
	mOsm/kg	1126	901	1351	Calculated
Oxalate	mmol/l	0.433	0.346	0.520	Oxalate oxidase
Phosphate Inorganic	mmol/l	29.8	23.8	35.8	Vitros
	mg/dl	92.4	73.8	111	
	mmol/l	27.5	22.0	33.0	Phosphomolybdate UV
	mg/dl	85.3	68.2	102	
	mmol/l	27.5	22.0	33.0	Phosphomolybdate enzymatic
	mg/dl	85.3	68.2	102	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Potassium	mmol/l	137	116	158	Vitros
	mmol/l	128	109	147	ISE direct
	mmol/l	127	108	146	ISE indirect
Protein Total	g/l	0.259	0.207	0.311	Biuret reaction - direct
	mg/dl	25.9	20.7	31.1	
	mg/l	259	207	311	
	g/l	0.241	0.193	0.289	Turbidimetry
	mg/dl	24.1	19.3	28.9	
	mg/l	241	193	289	
	g/l	0.245	0.196	0.294	Pyrogallol Red
	mg/dl	24.5	19.6	29.4	
	mg/l	245	196	294	
	g/l	0.080	0.064	0.096	Vitros
	mg/dl	8.00	6.40	9.60	
	mg/l	80.0	64.0	96.0	
Sodium	mmol/l	212	187	237	Vitros
	mmol/l	202	178	226	ISE direct
	mmol/l	205	180	230	ISE indirect
Urea	mmol/l	456	365	547	Vitros
	mg/dl	2741	2194	3288	
	mmol/l	476	381	571	Beckman-Conductivity
	mg/dl	2861	2290	3432	
	mmol/l	448	358	538	Urease kinetic
	mg/dl	2692	2152	3232	
	mmol/l	471	377	565	Urease end point
	mg/dl	2831	2266	3396	
Uric Acid (Urate)	mmol/l	1.25	1.00	1.50	Ortho Vitros Microslide Systems
	mg/dl	21.0	16.8	25.2	
	mmol/l	1.29	1.03	1.55	Uricase peroxidase no ascorbate oxidase
	mg/dl	21.7	17.3	26.1	
	mmol/l	1.35	1.08	1.62	Spectrophotometric at 280-290
	mg/dl	22.7	18.1	27.3	
	mmol/l	1.24	0.992	1.49	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	20.8	16.7	24.9	
	mmol/l	1.26	1.01	1.51	Uricase peroxidase with ascorbate oxidase
	mg/dl	21.2	17.0	25.4	
Vanillylmandelic Acid (VMA)	µmol/l	156	125	187	Column test
	µmol/l	142	114	170	HPLC

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