

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

CAT. NO. AU 2353 **LOT NO.** 797UC
SIZE: 12 x 10 ml **EXPIRY:** 2019-03

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 $\pm$ 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.

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

Cat. No. AU2353 Lot No. 797UC Size: 12 x 10 ml Expiry: 2019-03

Range					
Analyte	unit	Target	low	high	methods
5-HIAA	μmol/l	284	227	341	Colorimetric (nitrosonaphthol)
	μmol/l	299	239	359	HPLC
Amylase	U/l	446	357	535	Vitros
	U/l	877	702	1052	Siemens - blocked pNPG7
	U/l	858	686	1030	Randox - Ethylidene pNPG7
	U/l	884	707	1061	Other blocked pNPG7
	U/l	1058	846	1270	Randox liquid pNPG7
	U/l	797	638	956	Roche liquid pNPG7
	U/l	799	639	959	BM/Roche Colorimetric pNPG7
	U/l	819	655	983	Roche Integra 2-chloro-pNPG7
	U/l	969	775	1163	pNP Maltotrioxide substrates
	U/l	872	698	1046	Beckman Olympus - blocked pNPG7
	U/l	1080	864	1296	Siemens 2-chloro-pNPG3
	U/l	1001	801	1201	Other 2-chloro-pNPG3
Calcium	mmol/l	3.56	3.20	3.92	Vitros
	mg/dl	14.3	12.8	15.8	
	mmol/l	4.84	4.36	5.32	Cresolphthalein complexone
	mg/dl	19.4	17.5	21.3	
	mmol/l	3.41	3.07	3.75	Ion selective electrode
	mg/dl	13.7	12.3	15.1	
	mmol/l	4.44	4.00	4.88	Arsenazo III
	mg/dl	17.8	16.0	19.6	
	mmol/l	4.72	4.25	5.19	NM-BAPTA
	mg/dl	18.9	17.0	20.8	
Chloride	mmol/l	267	227	307	ISE indirect
	mmol/l	259	220	298	ISE direct
Copper	μmol/l	3.20	2.56	3.84	Atomic absorption
	μg/dl	20.4	16.3	24.5	
Cortisol	nmol/l	231	173	289	Chemiluminescence (+ solvent extraction.)
	μg/dl	8.32	6.23	10.4	
	nmol/l	255	191	319	Chemiluminescence (direct)
	μg/dl	9.18	6.88	11.5	
	nmol/l	253	190	316	Enzyme immunoassay (direct)
	μg/dl	9.11	6.84	11.4	
	nmol/l	281	211	351	RIA methods (+ solvent extraction)
	μg/dl	10.1	7.60	12.6	
Creatinine	mmol/l	16.4	13.1	19.7	Alkaline picrate no deproteinization
	mg/dl	185	148	222	
	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	

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Analyte	unit	Target	low	high	methods
Creatinine	mmol/l	16.7	13.4	20.0	Other enzymatic methods
	mg/dl	189	151	227	
	mmol/l	17.1	13.7	20.5	Roche Creatinine Plus
	mg/dl	193	155	231	
	mmol/l	16.1	12.9	19.3	Jaffe rate blanked
	mg/dl	182	146	218	
	mmol/l	16.1	12.9	19.3	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	182	146	218	
	mmol/l	16.0	12.8	19.2	Vitros IDMS Traceable
	mg/dl	181	145	217	
	mmol/l	16.3	13.0	19.6	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	184	147	221	
Dopamine	nmol/l	1871	1497	2245	HPLC
Epinephrine	nmol/l	327	262	392	HPLC
Glucose	mmol/l	15.2	12.2	18.2	Vitros
	mg/dl	274	220	328	
	mmol/l	14.8	11.8	17.8	Glucose oxidase
	mg/dl	267	213	321	
	mmol/l	15.1	12.1	18.1	Hexokinase
	mg/dl	272	218	326	
	mmol/l	15.3	12.2	18.4	Oxygen electrode
	mg/dl	276	220	332	
Magnesium	mmol/l	13.7	11.0	16.4	Vitros
	mg/dl	33.3	26.7	39.9	
	mmol/l	13.5	10.8	16.2	Calmagite
	mg/dl	32.8	26.2	39.4	
	mmol/l	13.8	11.0	16.6	Xylidyl Blue
	mg/dl	33.5	26.7	40.3	
	mmol/l	13.6	10.9	16.3	Arsenazo III
	mg/dl	33.0	26.5	39.5	
	mmol/l	14.0	11.2	16.8	Chlorphosphonazo III
	mg/dl	34.0	27.2	40.8	
	mmol/l	13.1	10.5	15.7	Methylthymol blue
	mg/dl	31.8	25.5	38.1	
	mmol/l	13.8	11.0	16.6	Enzymatic
	mg/dl	33.5	26.7	40.3	
Metanephrine	µmol/l	2.67	2.14	3.20	HPLC
Microalbumin	mg/l	182	146	218	Vitros
	mg/l	170	136	204	Immunoturbidimetric
	mg/l	180	144	216	Nephelometric
Norepinephrine	nmol/l	1489	1191	1787	HPLC
Normetanephrine	µmol/l	4.20	3.36	5.04	HPLC
Osmolality	mOsm/kg	1148	918	1378	Freezing point depression
	mOsm/kg	1155	924	1386	Vapour pressure
	mOsm/kg	1134	907	1361	Calculated
Oxalate	mmol/l	0.459	0.367	0.551	Oxalate oxidase

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Analyte	unit	Target	low	high	methods
Phosphate Inorganic	mmol/l	29.8	23.8	35.8	Vitros
	mg/dl	92.4	73.8	111	
	mmol/l	27.6	22.1	33.1	Phosphomolybdate UV
	mg/dl	85.6	68.5	103	
	mmol/l	27.8	22.2	33.4	Phosphomolybdate enzymatic
	mg/dl	86.2	68.8	104	
Potassium	mmol/l	142	121	163	Vitros
	mmol/l	130	111	150	ISE direct
	mmol/l	128	109	147	ISE indirect
Protein Total	g/l	0.224	0.179	0.269	Biuret reaction with ppt
	mg/dl	22.4	17.9	26.9	
	mg/l	224	179	269	
	g/l	0.242	0.194	0.290	Biuret reaction - direct
	mg/dl	24.2	19.4	29.0	
	mg/l	242	194	290	
	g/l	0.224	0.179	0.269	Turbidimetry
	mg/dl	22.4	17.9	26.9	
	mg/l	224	179	269	
	g/l	0.235	0.188	0.282	Pyrogallol Red
	mg/dl	23.5	18.8	28.2	
	mg/l	235	188	282	
Sodium	mmol/l	222	195	249	Vitros
	mmol/l	206	181	231	ISE direct
	mmol/l	207	182	232	ISE indirect
Urea	mmol/l	489	391	587	Vitros
	mg/dl	2939	2350	3528	
	mmol/l	491	393	589	Beckman-Conductivity
	mg/dl	2951	2362	3540	
	mmol/l	481	385	577	Urease kinetic
	mg/dl	2891	2314	3468	
Uric Acid (Urate)	mmol/l	507	406	608	Urease end point
	mg/dl	3047	2440	3654	
	mmol/l	1.30	1.04	1.56	Ortho Vitros Microslide Systems
	mg/dl	21.8	17.5	26.1	
	mmol/l	1.28	1.02	1.54	Uricase catalase 340nm
	mg/dl	21.5	17.1	25.9	
	mmol/l	1.32	1.06	1.58	Uricase peroxidase no ascorbate oxidase
	mg/dl	22.2	17.8	26.6	
	mmol/l	1.38	1.10	1.66	Spectrophotometric at 280-290
	mg/dl	23.2	18.5	27.9	
	mmol/l	1.27	1.02	1.52	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	21.3	17.1	25.5	
	mmol/l	1.30	1.04	1.56	Uricase peroxidase with ascorbate oxidase
	mg/dl	21.8	17.5	26.1	

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Analyte	unit	Target	low	high	methods
Vanillylmandelic Acid (VMA)	µmol/l	146	117	175	Column test
	µmol/l	146	117	175	HPLC