

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

CAT. NO. AU 2353 **LOT NO.** 748UC
SIZE: 12 x 10 ml **EXPIRY:** 2018-04

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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Cat. No. AU2353 Lot No. 748UC Size: 12 x 10 ml Expiry: 2018-04

Range					
Analyte	unit	target	low	high	methods
5-HIAA	μmol/l	300	240	360	Colorimetric (nitrosonaphthol)
	μmol/l	307	246	368	HPLC
Amylase	U/l	416	333	499	Vitros
	U/l	841	673	1009	Siemens - blocked pNPG7
	U/l	599	479	719	Randox - Ethylidene pNPG7
	U/l	897	718	1076	Other blocked pNPG7
	U/l	883	706	1060	Randox liquid pNPG7
	U/l	766	613	919	Roche liquid pNPG7
	U/l	774	619	929	BM/Roche Colorimetric pNPG7
	U/l	867	694	1040	Beckman maltotetraose
	U/l	794	635	953	Roche Integra 2-chloro-pNPG7
	U/l	768	614	922	Other Roche 2-chloro-pNPG7
	U/l	848	678	1018	Beckman Coulter - blocked pNPG7
	U/l	1009	807	1211	Siemens 2-chloro-pNPG3
	U/l	943	754	1132	Other 2-chloro-pNPG3
Calcium	mmol/l	3.51	3.16	3.86	Vitros
	mg/dl	14.1	12.7	15.5	
	mmol/l	4.79	4.31	5.27	Cresolphthalein complexone
	mg/dl	19.2	17.3	21.1	
	mmol/l	3.46	3.11	3.81	Ion selective electrode
	mg/dl	13.9	12.5	15.3	
	mmol/l	4.49	4.04	4.94	Arsenazo III
	mg/dl	18.0	16.2	19.8	
	mmol/l	4.72	4.25	5.19	NM-BAPTA
	mg/dl	18.9	17.0	20.8	
Chloride	mmol/l	255	217	293	ISE indirect
	mmol/l	252	214	290	ISE direct
Copper	μmol/l	3.99	3.19	4.79	Atomic absorption
	μg/dl	25.4	20.3	30.5	
Cortisol	nmol/l	369	277	461	Chemiluminescence (direct)
	μg/dl	13.3	9.97	16.6	
	nmol/l	358	269	448	Enzyme immunoassay (direct)
	μg/dl	12.9	9.68	16.1	
	nmol/l	302	227	378	RIA methods (+ solvent extraction)
	μg/dl	10.9	8.17	13.6	
Creatinine	mmol/l	16.0	12.8	19.2	Vitros
	mg/dl	181	145	217	
	mmol/l	16.2	13.0	19.4	Alkaline picrate no deproteinization
	mg/dl	183	147	219	
	mmol/l	16.9	13.5	20.3	Creatinine PAP method
	mg/dl	191	153	229	
	mmol/l	16.7	13.4	20.0	Randox Enzymatic UV method
	mg/dl	189	151	227	

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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	16.9	13.5	20.3	Roche Creatinine Plus
	mg/dl	191	153	229	
	mmol/l	16.3	13.0	19.6	Jaffe rate blanked
	mg/dl	184	147	221	
	mmol/l	16.1	12.9	19.3	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	182	146	218	
Dopamine	mmol/l	16.0	12.8	19.2	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	181	145	217	
Dopamine	nmol/l	1949	1559	2339	HPLC
Epinephrine	nmol/l	321	257	385	HPLC
Glucose	mmol/l	15.7	12.6	18.8	Vitros
	mg/dl	283	227	339	
	mmol/l	15.2	12.2	18.2	Glucose oxidase
	mg/dl	274	220	328	
	mmol/l	15.5	12.4	18.6	Hexokinase
	mg/dl	279	223	335	
	mmol/l	15.3	12.2	18.4	GOD/02-Beckman method
	mg/dl	276	220	332	
	mmol/l	15.2	12.2	18.2	Glucose dehydrogenase
	mg/dl	274	220	328	
Magnesium	mmol/l	16.1	12.9	19.3	Oxygen electrode
	mg/dl	290	232	348	
	mmol/l	13.4	10.7	16.1	Vitros
	mg/dl	32.6	26.0	39.2	
	mmol/l	13.2	10.6	15.8	Calmagite
	mg/dl	32.1	25.8	38.4	
	mmol/l	13.3	10.6	16.0	Xylidyl Blue
	mg/dl	32.3	25.8	38.8	
	mmol/l	12.6	10.1	15.1	Arsenazo III
	mg/dl	30.6	24.5	36.7	
Metanephthine	mmol/l	13.4	10.7	16.1	Chlorphosphonazo III
	mg/dl	32.6	26.0	39.2	
	mmol/l	12.6	10.1	15.1	Methylthymol blue
	mg/dl	30.6	24.5	36.7	
	mmol/l	13.6	10.9	16.3	Enzymatic
	mg/dl	33.0	26.5	39.5	
Metanephthine	µmol/l	2.60	2.08	3.12	HPLC
Microalbumin	mg/l	171	137	205	Immunoturbidimetric
	mg/l	205	164	246	Nephelometric
Norepinephrine	nmol/l	1502	1202	1802	HPLC
Normetanephthine	µmol/l	4.23	3.38	5.08	HPLC
Osmolality	mOsm/kg	1096	877	1315	Freezing point depression
	mOsm/kg	1076	861	1291	Calculated

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Analyte	unit	target	low	high	methods
Oxalate	mmol/l	0.460	0.368	0.552	Oxalate oxidase
Phosphate Inorganic	mmol/l	29.5	23.6	35.4	Vitros
	mg/dl	91.5	73.2	110	
	mmol/l	27.6	22.1	33.1	Phosphomolybdate UV
	mg/dl	85.6	68.5	103	
	mmol/l	27.4	21.9	32.9	Phosphomolybdate enzymatic
	mg/dl	84.9	67.9	102	
Potassium	mmol/l	138	117	159	Vitros
	mmol/l	128	109	147	ISE direct
	mmol/l	127	108	146	ISE indirect
Protein Total	g/l	0.242	0.194	0.290	Biuret reaction with ppt
	mg/dl	24.2	19.4	29.0	
	mg/l	242	194	290	
	g/l	0.234	0.187	0.281	Biuret reaction - direct
	mg/dl	23.4	18.7	28.1	
	mg/l	234	187	281	
	g/l	0.223	0.178	0.268	Turbidimetry
	mg/dl	22.3	17.8	26.8	
	mg/l	223	178	268	
	g/l	0.239	0.191	0.287	Pyrogallol Red
	mg/dl	23.9	19.1	28.7	
	mg/l	239	191	287	
	g/l	0.064	0.051	0.077	Vitros
	mg/dl	6.40	5.10	7.70	
	mg/l	64.0	51.0	77.0	
Sodium	mmol/l	204	180	228	Vitros
	mmol/l	195	172	218	ISE direct
	mmol/l	197	173	221	ISE indirect
Urea	mmol/l	457	366	548	Vitros
	mg/dl	2747	2200	3294	
	mmol/l	467	374	560	Beckman-Conductivity
	mg/dl	2807	2248	3366	
	mmol/l	447	358	536	Urease kinetic
	mg/dl	2686	2152	3220	
	mmol/l	452	362	542	Urease end point
	mg/dl	2717	2176	3258	
Uric Acid (Urate)	mmol/l	1.27	1.02	1.52	Ortho Vitros Microslide Systems
	mg/dl	21.3	17.1	25.5	
	mmol/l	1.25	1.00	1.50	Uricase catalase 340nm
	mg/dl	21.0	16.8	25.2	
	mmol/l	1.30	1.04	1.56	Uricase peroxidase no ascorbate oxidase
	mg/dl	21.8	17.5	26.1	
	mmol/l	1.32	1.06	1.58	Spectrophotometric at 280-290
	mg/dl	22.2	17.8	26.6	
	mmol/l	1.25	1.00	1.50	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	21.0	16.8	25.2	

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Uric Acid (Urate)	mmol/l	1.28	1.02	1.54	Uricase peroxidase with ascorbate oxidase
	mg/dl	21.5	17.1	25.9	
Vanillylmandelic Acid (VMA)	μmol/l	144	115	173	Column test
	μmol/l	148	118	178	HPLC