

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

CAT. NO. AU 2353 **LOT NO.** 723UC
SIZE: 12 x 10ml **EXPIRY:** 2017-10

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 8µl 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 5mg / 10ml 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 10µl 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, 12µl 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 10ml 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 10ml

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. 723UC Size: 12 x 10ml Expiry: 2017-10

Range					
Analyte	unit	target	low	high	methods
5-HIAA	μmol/l	313	250	376	HPLC
Amylase	U/l	426	341	511	Vitros
	U/l	830	664	996	Siemens - blocked pNPG7
	U/l	931	745	1117	Other blocked pNPG7
	U/l	867	694	1040	Randox liquid pNPG7
	U/l	789	631	947	Roche liquid pNPG7
	U/l	771	617	925	BM/Roche Colorimetric pNPG7
	U/l	894	715	1073	Beckman maltotetraose
	U/l	791	633	949	Other Roche 2-chloro-pNPG7
	U/l	865	692	1038	Beckman Coulter - blocked pNPG7
	U/l	1034	827	1241	Siemens 2-chloro-pNPG3
	U/l	949	759	1139	Other 2-chloro-pNPG3
Calcium	mmol/l	3.68	3.31	4.05	Vitros
	mg/dl	14.7	13.3	16.1	
	mmol/l	5.00	4.50	5.50	Cresolphthalein complexone
	mg/dl	20.0	18.0	22.0	
	mmol/l	3.62	3.26	3.98	Ion selective electrode
	mg/dl	14.5	13.1	15.9	
	mmol/l	4.64	4.18	5.10	Arsenazo III
	mg/dl	18.6	16.8	20.4	
	mmol/l	4.80	4.32	5.28	NM-BAPTA
	mg/dl	19.2	17.3	21.1	
Chloride	mmol/l	260	221	299	ISE indirect
	mmol/l	262	223	301	ISE direct
Copper	μmol/l	3.42	2.74	4.10	Atomic absorption
	μg/dl	21.8	17.4	26.2	
Cortisol	nmol/l	304	228	380	Chemiluminescence (+ solvent extraction.)
	μg/dl	10.9	8.21	13.6	
	nmol/l	340	255	425	Chemiluminescence (direct)
	μg/dl	12.2	9.18	15.2	
	nmol/l	293	220	366	RIA methods (+ solvent extraction)
	μg/dl	10.5	7.92	13.1	
Creatinine	mmol/l	17.4	13.9	20.9	Vitros
	mg/dl	197	157	237	
	mmol/l	17.4	13.9	20.9	Alkaline picrate no deproteinization
	mg/dl	197	157	237	
	mmol/l	18.4	14.7	22.1	Creatinine PAP method
	mg/dl	208	166	250	
	mmol/l	17.9	14.3	21.5	Randox Enzymatic UV method
	mg/dl	202	162	242	
	mmol/l	18.1	14.5	21.7	Other enzymatic methods
	mg/dl	205	164	246	

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Analyte	unit	target	low	high	methods
Creatinine	mmol/l	17.9	14.3	21.5	Roche Creatinine Plus
	mg/dl	202	162	242	
	mmol/l	17.7	14.2	21.2	Jaffe rate blanked
	mg/dl	200	160	240	
	mmol/l	17.3	13.8	20.8	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	195	156	234	
	mmol/l	16.7	13.4	20.0	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	189	151	227	
Dopamine	nmol/l	1843	1474	2212	HPLC
Epinephrine	nmol/l	322	258	386	HPLC
Glucose	mmol/l	16.2	13.0	19.4	Vitros
	mg/dl	292	234	350	
	mmol/l	15.6	12.5	18.7	Glucose oxidase
	mg/dl	281	225	337	
	mmol/l	15.8	12.6	19.0	Hexokinase
	mg/dl	285	227	343	
	mmol/l	15.5	12.4	18.6	GOD/02-Beckman method
	mg/dl	279	223	335	
Magnesium	mmol/l	13.5	10.8	16.2	Vitros
	mg/dl	32.8	26.2	39.4	
	mmol/l	13.8	11.0	16.6	Calmagite
	mg/dl	33.5	26.7	40.3	
	mmol/l	13.7	11.0	16.4	Xylidyl Blue
	mg/dl	33.3	26.7	39.9	
	mmol/l	13.5	10.8	16.2	Arsenazo III
	mg/dl	32.8	26.2	39.4	
	mmol/l	13.1	10.5	15.7	Chlorphosphonazo III
	mg/dl	31.8	25.5	38.1	
	mmol/l	13.3	10.6	16.0	Methylthymol blue
	mg/dl	32.3	25.8	38.8	
	mmol/l	14.1	11.3	16.9	Enzymatic
	mg/dl	34.3	27.5	41.1	
Metanephrine	µmol/l	2.71	2.17	3.25	HPLC
Microalbumin	mg/l	178	142	214	Immunoturbidimetric
	mg/l	195	156	234	Nephelometric
Norepinephrine	nmol/l	1573	1258	1888	HPLC
Normetanephrine	µmol/l	4.32	3.46	5.18	HPLC
Osmolality	mOsm/kg	1108	886	1330	Freezing point depression
Oxalate	mmol/l	0.480	0.384	0.576	Oxalate oxidase
Phosphate Inorganic	mmol/l	28.8	23.0	34.6	Vitros
	mg/dl	89.3	71.3	107	
	mmol/l	26.4	21.1	31.7	Phosphomolybdate UV
	mg/dl	81.8	65.4	98.2	
	mmol/l	26.6	21.3	31.9	Phosphomolybdate enzymatic
	mg/dl	82.5	66.0	99.0	
Potassium	mmol/l	140	119	161	Vitros

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Analyte	unit	target	low	high	methods
Potassium	mmol/l	128	109	147	ISE direct
	mmol/l	125	106	144	ISE indirect
Protein Total	g/l	0.254	0.203	0.305	Biuret reaction - direct
	mg/dl	25.4	20.3	30.5	
	mg/l	254	203	305	
	g/l	0.234	0.187	0.281	Turbidimetry
	mg/dl	23.4	18.7	28.1	
	mg/l	234	187	281	
	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	0.081	0.065	0.097	Vitros
	mg/dl	8.10	6.50	9.70	
	mg/l	81.0	65.0	97.0	
Sodium	mmol/l	195	172	218	Vitros
	mmol/l	195	172	218	ISE direct
	mmol/l	194	171	217	ISE indirect
Urea	mmol/l	463	370	556	Vitros
	mg/dl	2783	2224	3342	
	mmol/l	473	378	568	Beckman-Conductivity
	mg/dl	2843	2272	3414	
	mmol/l	460	368	552	Urease kinetic
	mg/dl	2765	2212	3318	
	mmol/l	465	372	558	Urease end point
	mg/dl	2795	2236	3354	
Uric Acid (Urate)	mmol/l	1.53	1.22	1.84	Ortho Vitros Microslide Systems
	mg/dl	25.7	20.5	30.9	
	mmol/l	1.55	1.24	1.86	Uricase peroxidase no ascorbate oxidase
	mg/dl	26.0	20.8	31.2	
	mmol/l	1.58	1.26	1.90	Spectrophotometric at 280-290
	mg/dl	26.5	21.2	31.8	
	mmol/l	1.47	1.18	1.76	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	24.7	19.8	29.6	
	mmol/l	1.50	1.20	1.80	Uricase peroxidase with ascorbate oxidase
	mg/dl	25.2	20.2	30.2	
Vanillylmandelic Acid (VMA)	µmol/l	147	118	176	Column test
	µmol/l	155	124	186	HPLC