

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

CAT. NO. AU 2353

LOT NO. 704UC

SIZE: 12 x 10ml

EXPIRY: 2017-03

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 is 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 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 Support, Northern Ireland, tel: +44 (0) 28 9442 2413 or email Technical.Support@randox.com

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Range					
Analyte	unit	target	low	high	methods
5-HIAA	μmol/l	278	222	334	HPLC
Amylase	U/l	423	338	508	Vitros
	U/l	817	654	980	Siemens - blocked pNPG7
	U/l	932	746	1118	Other blocked pNPG7
	U/l	853	682	1024	Randox liquid pNPG7
	U/l	785	628	942	Roche liquid pNPG7
	U/l	797	638	956	BM/Roche Colorimetric pNPG7
	U/l	810	648	972	Roche Integra 2-chloro-pNPG7
	U/l	805	644	966	Other Roche 2-chloro-pNPG7
	U/l	867	694	1040	Beckman Coulter - blocked pNPG7
	U/l	1054	843	1265	Siemens 2-chloro-pNPG3
	U/l	941	753	1129	Other 2-chloro-pNPG3
Calcium	mmol/l	3.62	3.26	3.98	Vitros
	mg/dl	14.5	13.1	15.9	
	mmol/l	5.06	4.55	5.57	Cresolphthalein complexone
	mg/dl	20.3	18.2	22.4	
	mmol/l	3.58	3.22	3.94	Ion selective electrode
	mg/dl	14.3	12.9	15.7	
	mmol/l	4.64	4.18	5.10	Arsenazo III
	mg/dl	18.6	16.8	20.4	
Chloride	mmol/l	260	221	299	Vitros
	mmol/l	261	222	300	ISE indirect
	mmol/l	261	222	300	ISE direct
Copper	μmol/l	3.90	3.12	4.68	Atomic absorption
	μg/dl	24.8	19.8	29.8	
Cortisol	nmol/l	284	213	355	Chemiluminescence (+ solvent extraction.)
	μg/dl	10.2	7.67	12.7	
	nmol/l	314	220	408	Chemiluminescence (direct)
	μg/dl	11.3	7.92	14.7	
	nmol/l	288	216	360	RIA methods (+ solvent extraction)
	μg/dl	10.4	7.78	13.0	
Creatinine	mmol/l	16.7	13.4	20.0	Vitros
	mg/dl	189	151	227	Alkaline picrate no deproteinization
	mmol/l	16.7	13.4	20.0	
	mg/dl	189	151	227	
	mmol/l	17.1	13.7	20.5	Creatinine PAP method
	mg/dl	193	155	231	
	mmol/l	16.9	13.5	20.3	Randox Enzymatic UV method
	mg/dl	191	153	229	
	mmol/l	16.9	13.5	20.3	Other enzymatic methods
	mg/dl	191	153	229	

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Analyte	unit	target	low	high	methods
Creatinine	mmol/l	17.3	13.8	20.8	Roche Creatinine Plus
	mg/dl	195	156	234	
	mmol/l	16.7	13.4	20.0	Jaffe rate blanked
	mg/dl	189	151	227	
	mmol/l	16.5	13.2	19.8	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	186	149	223	
	mmol/l	16.5	13.2	19.8	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	186	149	223	
Dopamine	nmol/l	1407	1126	1688	HPLC
Epinephrine	nmol/l	308	221	395	HPLC
Glucose	mmol/l	15.5	12.4	18.6	Vitros
	mg/dl	279	223	335	
	mmol/l	15.3	12.2	18.4	Glucose oxidase
	mg/dl	276	220	332	
	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	
	mmol/l	16.0	12.8	19.2	Glucose dehydrogenase
	mg/dl	288	231	345	
	mmol/l	15.7	12.6	18.8	Oxygen electrode
	mg/dl	283	227	339	
Magnesium	mmol/l	13.8	11.0	16.6	Vitros
	mg/dl	33.5	26.7	40.3	
	mmol/l	13.8	11.0	16.6	Calmagite
	mg/dl	33.5	26.7	40.3	
	mmol/l	13.8	11.0	16.6	Xylidyl Blue
	mg/dl	33.5	26.7	40.3	
	mmol/l	12.2	9.46	14.9	Arsenazo III
	mg/dl	29.6	23.0	36.2	
	mmol/l	13.0	10.4	15.6	Chlorphosphonazo III
	mg/dl	31.6	25.3	37.9	
	mmol/l	13.1	10.5	15.7	Methylthymol blue
	mg/dl	31.8	25.5	38.1	
	mmol/l	14.0	11.2	16.8	Enzymatic
	mg/dl	34.0	27.2	40.8	
Metanephrine	µmol/l	2.65	1.93	3.37	HPLC
Microalbumin	mg/l	376	301	451	Immunoturbidimetric
	mg/l	395	316	474	Nephelometric
Norepinephrine	nmol/l	1516	1213	1819	HPLC
Normetanephrine	µmol/l	4.27	3.42	5.12	HPLC
Osmolality	mOsm/kg	1145	916	1374	Freezing point depression
	mOsm/kg	1111	889	1333	Calculated
Oxalate	mmol/l	0.460	0.368	0.552	Oxalate oxidase
Phosphate Inorganic	mmol/l	29.6	23.7	35.5	Vitros
	mg/dl	91.8	73.5	110	

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Analyte	unit	target	low	high	methods
Phosphate Inorganic	mmol/l	28.1	22.5	33.7	Phosphomolybdate UV
	mg/dl	87.1	69.8	104	
	mmol/l	28.0	22.4	33.6	Phosphomolybdate enzymatic
	mg/dl	86.8	69.4	104	
Potassium	mmol/l	141	120	162	Vitros
	mmol/l	132	112	152	ISE direct
	mmol/l	129	110	148	ISE indirect
Protein Total	g/l	0.490	0.392	0.588	Biuret reaction with ppt
	mg/dl	49.0	39.2	58.8	
	mg/l	490	392	588	
	g/l	0.470	0.376	0.564	Biuret reaction - direct
	mg/dl	47.0	37.6	56.4	
	mg/l	470	376	564	
	g/l	0.430	0.344	0.516	Turbidimetry
	mg/dl	43.0	34.4	51.6	
	mg/l	430	344	516	
	g/l	0.470	0.376	0.564	Pyrogallol Red
	mg/dl	47.0	37.6	56.4	
	mg/l	470	376	564	
	g/l	0.250	0.200	0.300	Vitros
	mg/dl	25.0	20.0	30.0	
	mg/l	250	200	300	
Sodium	mmol/l	204	180	228	Vitros
	mmol/l	193	170	216	ISE direct
	mmol/l	194	171	217	ISE indirect
Urea	mmol/l	504	403	605	Vitros
	mg/dl	3029	2422	3636	
	mmol/l	504	403	605	Beckman-Conductivity
	mg/dl	3029	2422	3636	
	mmol/l	491	393	589	Urease kinetic
	mg/dl	2951	2362	3540	
	mmol/l	509	407	611	Urease end point
	mg/dl	3059	2446	3672	
Uric Acid (Urate)	mmol/l	1.37	1.10	1.64	Ortho Vitros Microslide Systems
	mg/dl	23.0	18.5	27.5	
	mmol/l	1.29	1.03	1.55	Uricase catalase 340nm
	mg/dl	21.7	17.3	26.1	
	mmol/l	1.34	1.07	1.61	Uricase peroxidase no ascorbate oxidase
	mg/dl	22.5	18.0	27.0	
	mmol/l	1.39	1.11	1.67	Spectrophotometric at 280-290
	mg/dl	23.4	18.6	28.2	
	mmol/l	1.28	1.02	1.54	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	21.5	17.1	25.9	
	mmol/l	1.32	1.06	1.58	Uricase peroxidase with ascorbate oxidase
	mg/dl	22.2	17.8	26.6	

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Analyte	unit	target	low	high	methods
Vanillylmandelic Acid (VMA)	µmol/l	147	118	176	Column test
	µmol/l	153	119	187	HPLC