ASSAYED URINE CONTROL - LEVEL 2 (URN ASY CONTROL 2)

CAT. NO. AU 2352 **LOT NO.** 718UC
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 STABILITIY 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 2 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 ± 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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			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
5-HIAA	µmol/l	36.4	29.1	43.7	Colorimetric (nitrosonaphthol)
	µmol/l	28.8	23.0	34.6	HPLC
Amylase	U/l	110	88.0	132	Vitros
	U/l	195	156	234	Siemens - blocked pNPG7
	U/l	215	172	258	Other blocked pNPG7
	U/l	205	164	246	Randox liquid pNPG7
	U/l	188	150	226	Roche liquid pNPG7
	U/l	182	146	218	BM/Roche Colorimetric pNPG7
	U/l	193	154	232	Roche Integra 2-chloro-pNPG7
	U/l	185	148	222	Other Roche 2-chloro-pNPG7
	U/l	204	163	245	Beckman Coulter - blocked pNPG7
	U/l	240	192	288	Siemens 2-chloro-pNPG3
	U/l	217	174	260	Other 2-chloro-pNPG3
Calcium	mmol/l	1.66	1.49	1.83	Vitros
	mg/dl	6.65	5.97	7.33	
	mmol/l	1.60	1.44	1.76	Cresolphthalein complexone
	mg/dl	6.41	5.77	7.05	
	mmol/l	1.60	1.44	1.76	Ion selective electrode
	mg/dl	6.41	5.77	7.05	
	mmol/l	1.59	1.43	1.75	Arsenazo III
	mg/dl	6.37	5.73	7.01	
	mmol/l	1.57	1.41	1.73	NM-BAPTA
	mg/dl	6.29	5.65	6.93	
Chloride	mmol/l	81.7	69.4	94.0	ISE indirect
	mmol/l	81.0	68.9	93.2	ISE direct
Copper	µmol/l	1.09	0.872	1.31	Atomic absorption
	µg/dl	6.93	5.55	8.31	
Cortisol	nmol/l	96.6	72.5	121	Chemiluminescence (+ solvent extraction.)
	µg/dl	3.48	2.61	4.35	
	nmol/l	139	104	174	Chemiluminescence (direct)
	µg/dl	5.00	3.74	6.26	
	nmol/l	97.9	73.4	122	RIA methods (+ solvent extraction)
	µg/dl	3.52	2.64	4.40	
Creatinine	mmol/l	6.89	5.51	8.27	Vitros
	mg/dl	77.9	62.3	93.5	
	mmol/l	6.96	5.57	8.35	Alkaline picrate no deproteinization
	mg/dl	78.6	62.9	94.3	
	mmol/l	7.25	5.80	8.70	Creatinine PAP method
	mg/dl	81.9	65.5	98.3	
	mmol/l	7.14	5.71	8.57	Randox Enzymatic UV method
	mg/dl	80.7	64.5	96.9	
	mmol/l	7.17	5.74	8.60	Other enzymatic methods
	mg/dl	81.0	64.9	97.1	

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Creatinine	mmol/l	7.18	5.74	8.62	Roche Creatinine Plus
	mg/dl	81.1	64.9	97.3	
	mmol/l	6.99	5.59	8.39	Jaffe rate blanked
	mg/dl	79.0	63.2	94.8	
	mmol/l	6.92	5.54	8.30	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	78.2	62.6	93.8	
	mmol/l	6.81	5.45	8.17	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	77.0	61.6	92.4	
Dopamine	nmol/l	512	410	614	HPLC
Epinephrine	nmol/l	58.3	46.6	70.0	HPLC
Glucose	mmol/l	2.54	2.03	3.05	Vitros
	mg/dl	45.8	36.6	55.0	
	mmol/l	2.70	2.16	3.24	Glucose oxidase
	mg/dl	48.7	38.9	58.5	
	mmol/l	2.76	2.21	3.31	Hexokinase
	mg/dl	49.7	39.8	59.6	
	mmol/l	2.73	2.18	3.28	GOD/02-Beckman method
	mg/dl	49.2	39.3	59.1	
Magnesium	mmol/l	3.28	2.62	3.94	Vitros
	mg/dl	7.97	6.37	9.57	
	mmol/l	3.02	2.42	3.62	Calmagite
	mg/dl	7.34	5.88	8.80	
	mmol/l	3.02	2.42	3.62	Xylidyl Blue
	mg/dl	7.34	5.88	8.80	
	mmol/l	3.06	2.45	3.67	Arsenazo III
	mg/dl	7.44	5.95	8.93	
	mmol/l	2.92	2.34	3.50	Chlorphosphonazo III
	mg/dl	7.10	5.69	8.51	
	mmol/l	3.09	2.47	3.71	Methylthymol blue
	mg/dl	7.51	6.00	9.02	
	mmol/l	3.01	2.41	3.61	Enzymatic
	mg/dl	7.31	5.86	8.76	
Metanephrine	µmol/l	0.281	0.225	0.337	HPLC
Microalbumin	mg/l	30.6	24.5	36.7	Immunoturbidimetric
	mg/l	34.2	27.4	41.0	Nephelometric
Norepinephrine	nmol/l	234	187	281	HPLC
Normetanephrine	µmol/l	1.17	0.936	1.40	HPLC
Osmolality	mOsm/kg	391	313	469	Freezing point depression
Oxalate	mmol/l	0.102	0.082	0.122	Oxalate oxidase
Phosphate Inorganic	mmol/l	9.84	7.87	11.8	Vitros
	mg/dl	30.5	24.4	36.6	
	mmol/l	8.77	7.02	10.5	Phosphomolybdate UV
	mg/dl	27.2	21.8	32.6	
	mmol/l	8.76	7.01	10.5	Phosphomolybdate enzymatic
	mg/dl	27.2	21.7	32.7	

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Potassium	mmol/l	30.8	26.2	35.4	Vitros
	mmol/l	30.0	25.5	34.5	ISE direct
	mmol/l	29.8	25.3	34.3	ISE indirect
Protein Total	g/l	0.128	0.102	0.154	Biuret reaction with ppt
	mg/dl	12.8	10.2	15.4	
	mg/l	128	102	154	
	g/l	0.124	0.099	0.149	Biuret reaction - direct
	mg/dl	12.4	9.90	14.9	
	mg/l	124	99.0	149	
	g/l	0.103	0.082	0.124	Turbidimetry
	mg/dl	10.3	8.20	12.4	
	mg/l	103	82.0	124	
	g/l	0.132	0.106	0.158	Pyrogallol Red
	mg/dl	13.2	10.6	15.8	
	mg/l	132	106	158	
	g/l	0.135	0.108	0.162	Vitros
	mg/dl	13.5	10.8	16.2	
	mg/l	135	108	162	
Sodium	mmol/l	62.8	55.3	70.3	Vitros
	mmol/l	62.9	55.4	70.4	ISE direct
	mmol/l	61.5	54.1	68.9	ISE indirect
Urea	mmol/l	158	126	190	Vitros
	mg/dl	950	757	1143	
	mmol/l	159	127	191	Beckman-Conductivity
	mg/dl	956	763	1149	
	mmol/l	155	124	186	Urease kinetic
	mg/dl	932	745	1119	
	mmol/l	166	133	199	Urease end point
	mg/dl	998	799	1197	
Uric Acid (Urate)	mmol/l	0.875	0.700	1.05	Ortho Vitros Microslide Systems
	mg/dl	14.7	11.8	17.6	
	mmol/l	0.878	0.702	1.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	14.8	11.8	17.8	
	mmol/l	0.910	0.728	1.09	Spectrophotometric at 280-290
	mg/dl	15.3	12.2	18.4	
	mmol/l	0.823	0.658	0.988	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	13.8	11.1	16.5	
	mmol/l	0.845	0.676	1.01	Uricase peroxidase with ascorbate oxidase
	mg/dl	14.2	11.4	17.0	
Vanillylmandelic Acid	µmol/l	26.9	21.5	32.3	HPLC