

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

**CAT. NO.** AU 2352

**LOT NO.** 976UC

**SIZE:** 12 x 10 ml

**EXPIRY:** 2022-04-28

**GTIN:** 05055273200539

### 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-Hydroxyindoleacetic 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 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 2 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](mailto:Technical.Services@randox.com).

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Range					
Analyte	unit	Target	low	high	methods
5-HIAA	µmol/l	29.5	23.6	35.4	HPLC
Amylase	U/l	110	88.0	132	Vitros
	U/l	203	162	244	Siemens - blocked pNPG7
	U/l	211	169	253	Other blocked pNPG7
	U/l	196	157	235	Randox Liquid Ethylidene pNPG7
	U/l	186	149	223	Roche liquid pNPG7
	U/l	189	151	227	BM/Roche Colorimetric pNPG7
	U/l	202	162	242	Beckman Synchron CX4/CX5/CX7
	U/l	196	157	235	Roche Integra 2-chloro-pNPG7
	U/l	240	192	288	pNP Maltotrioxide substrates
	U/l	207	166	248	Beckman Coulter - blocked pNPG7
	U/l	259	207	311	Siemens 2-chloro-pNPG3
	U/l	227	182	272	Other 2-chloro-pNPG3
	U/l	230	184	276	Abbott Architect Non-IFCC Cal.
	U/l	247	198	296	Abbott Architect IFCC Cal.
Calcium	mmol/l	1.72	1.55	1.89	Vitros
	mg/dl	6.89	6.21	7.57	
	mmol/l	1.61	1.45	1.77	Cresolphthalein complexone
	mg/dl	6.45	5.81	7.09	
	mmol/l	1.62	1.46	1.78	Ion selective electrode
	mg/dl	6.49	5.85	7.13	
	mmol/l	1.59	1.43	1.75	Arsenazo III
	mg/dl	6.37	5.73	7.01	
mmol/l	1.60	1.44	1.76	NM-BAPTA	
mg/dl	6.41	5.77	7.05		
Chloride	mmol/l	86.6	73.6	100	Vitros
	mmol/l	82.4	70.0	94.8	ISE indirect
	mmol/l	81.8	69.5	94.1	ISE direct
Copper	µmol/l	1.36	1.09	1.63	Atomic absorption
	µg/dl	8.65	6.93	10.4	
Cortisol	nmol/l	110	82.5	138	Chemiluminescence (+ solvent extraction.)
	µg/dl	3.96	2.97	4.95	
	nmol/l	121	90.8	151	Chemiluminescence (direct)
	µg/dl	4.36	3.27	5.45	
Creatinine	mmol/l	6.85	5.48	8.22	Alkaline picrate no deproteinization
	mg/dl	77.4	61.9	92.9	
	mmol/l	6.97	5.58	8.36	Creatinine PAP method
	mg/dl	78.8	63.1	94.5	
	mmol/l	7.02	5.62	8.42	Enzymatic UV method
	mg/dl	79.3	63.5	95.1	
	mmol/l	7.05	5.64	8.46	Other enzymatic methods
	mg/dl	79.7	63.7	95.7	

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Size: 12 x 10 ml Expiry: 2022-04-28

Range						
Analyte	unit	Target	low	high	methods	
Creatinine	mmol/l	7.26	5.81	8.71	Roche Creatinine Plus	
	mg/dl	82.0	65.7	98.3		
	mmol/l	6.97	5.58	8.36	Jaffe rate blanked	
	mg/dl	78.8	63.1	94.5		
	mmol/l	6.89	5.51	8.27	Jaffe rate blanked comp. (-26 µmol/l)	
	mg/dl	77.9	62.3	93.5		
	mmol/l	6.83	5.46	8.20	Vitros IDMS Traceable	
	mg/dl	77.2	61.7	92.7		
	mmol/l	6.84	5.47	8.21	Jaffe rate blanked compensated (-18 µmol/l)	
	mg/dl	77.3	61.8	92.8		
Dopamine	nmol/l	588	470	706	HPLC	
Epinephrine	nmol/l	74.5	59.6	89.4	HPLC	
Glucose	mmol/l	2.66	2.13	3.19	Vitros	
	mg/dl	47.9	38.4	57.4		
	mmol/l	2.72	2.18	3.26	Glucose oxidase	
	mg/dl	49.0	39.3	58.7		
	mmol/l	2.75	2.20	3.30	Hexokinase	
	mg/dl	49.6	39.6	59.6		
	mmol/l	2.78	2.22	3.34	Glucose dehydrogenase	
	mg/dl	50.1	40.0	60.2		
	Magnesium	mmol/l	3.54	2.83	4.25	Vitros
		mg/dl	8.60	6.88	10.3	
		mmol/l	2.89	2.31	3.47	Calmagite
		mg/dl	7.02	5.61	8.43	
	mmol/l	3.13	2.50	3.76	Xylidyl Blue	
	mg/dl	7.61	6.08	9.14		
	mmol/l	3.06	2.45	3.67	Arsenazo III	
	mg/dl	7.44	5.95	8.93		
	mmol/l	3.09	2.47	3.71	Chlorphosphonazo III	
	mg/dl	7.51	6.00	9.02		
	mmol/l	3.23	2.58	3.88	Methylthymol blue	
	mg/dl	7.85	6.27	9.43		
	mmol/l	3.12	2.50	3.74	Enzymatic	
	mg/dl	7.58	6.08	9.08		
Metanephrine	µmol/l	0.279	0.223	0.335	HPLC	
Microalbumin	mg/l	31.6	25.3	37.9	Immunoturbidimetric	
	mg/l	31.3	25.0	37.6	Nephelometric	
Norepinephrine	nmol/l	243	194	292	HPLC	
Normetanephrine	µmol/l	1.18	0.944	1.42	HPLC	
Osmolality	mOsm/kg	393	314	472	Freezing point depression	
	mOsm/kg	326	261	391	Calculated	
Oxalate	mmol/l	0.113	0.090	0.136	Oxalate oxidase	
Phosphate Inorganic	mmol/l	9.69	7.75	11.6	Vitros	
	mg/dl	30.0	24.0	36.0		
	mmol/l	8.87	7.10	10.6	Phosphomolybdate UV	
	mg/dl	27.5	22.0	33.0		

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		Range			
Analyte	unit	Target	low	high	methods
Phosphate Inorganic	mmol/l	8.73	6.98	10.5	Phosphomolybdate enzymatic
	mg/dl	27.1	21.6	32.6	
Potassium	mmol/l	31.5	26.8	36.2	Vitros
	mmol/l	30.3	25.8	34.8	ISE direct
	mmol/l	29.8	25.3	34.3	ISE indirect
Protein Total	g/l	0.122	0.098	0.146	Biuret reaction with ppt
	mg/dl	12.2	9.80	14.6	
	mg/l	122	98.0	146	
	g/l	0.133	0.106	0.160	Biuret reaction - direct
	mg/dl	13.3	10.6	16.0	
	mg/l	133	106	160	
	g/l	0.121	0.097	0.145	Turbidimetry
	mg/dl	12.1	9.70	14.5	
	mg/l	121	97.0	145	
	g/l	0.151	0.121	0.181	Pyrogallol Red
	mg/dl	15.1	12.1	18.1	
	mg/l	151	121	181	
	g/l	0.202	0.162	0.242	Vitros
	mg/dl	20.2	16.2	24.2	
mg/l	202	162	242		
Sodium	mmol/l	70.3	61.9	78.7	Vitros
	mmol/l	64.6	56.8	72.4	ISE direct
	mmol/l	62.1	54.6	69.6	ISE indirect
Urea	mmol/l	161	129	193	Vitros
	mg/dl	968	775	1161	
	mmol/l	159	127	191	Beckman-Conductivity
	mg/dl	956	763	1149	
	mmol/l	153	122	184	Urease kinetic
	mg/dl	920	733	1107	
mmol/l	157	126	188	Urease end point	
mg/dl	944	757	1131		
Uric Acid (Urate)	mmol/l	0.781	0.625	0.937	Ortho Vitros Microslide Systems
	mg/dl	13.1	10.5	15.7	
	mmol/l	0.724	0.579	0.869	Uricase peroxidase no ascorbate oxidase
	mg/dl	12.2	9.73	14.7	
	mmol/l	0.746	0.597	0.895	Spectrophotometric at 280-290
	mg/dl	12.5	10.0	15.0	
	mmol/l	0.682	0.546	0.818	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	11.5	9.17	13.8	
mmol/l	0.711	0.569	0.853	Uricase peroxidase with ascorbate oxidase	
mg/dl	11.9	9.56	14.2		
Vanillylmandelic Acid (VMA)	µmol/l	29.6	23.7	35.5	Column test
	µmol/l	28.7	23.0	34.4	HPLC