

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

**CAT. NO.** AU 2352

**LOT NO.** 943UC

**SIZE:** 12 x 10 ml

**EXPIRY:** 2021-10-28

**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	27.9	22.3	33.5	HPLC
Amylase	U/l	124	99.0	149	Vitros
	U/l	227	182	272	Siemens - blocked pNPG7
	U/l	230	184	276	Other blocked pNPG7
	U/l	205	164	246	Roche liquid pNPG7
	U/l	208	166	250	BM/Roche Colorimetric pNPG7
	U/l	202	162	242	Roche Integra 2-chloro-pNPG7
	U/l	208	166	250	Other Roche 2-chloro-pNPG7
	U/l	229	183	275	Beckman Coulter - blocked pNPG7
	U/l	277	222	332	Siemens 2-chloro-pNPG3
	U/l	251	201	301	Other 2-chloro-pNPG3
	U/l	255	204	306	Abbott Architect Non-IFCC Cal.
	U/l	271	217	325	Abbott Architect IFCC Cal.
	U/l	242	194	290	Randox Liquid Ethylidene pNPG7
Calcium	mmol/l	1.74	1.57	1.91	Vitros
	mg/dl	6.97	6.29	7.65	
	mmol/l	1.67	1.50	1.84	Cresolphthalein complexone
	mg/dl	6.69	6.01	7.37	
	mmol/l	1.70	1.53	1.87	Ion selective electrode
	mg/dl	6.81	6.13	7.49	
	mmol/l	1.64	1.48	1.80	Arsenazo III
	mg/dl	6.57	5.93	7.21	
mmol/l	1.66	1.49	1.83	NM-BAPTA	
mg/dl	6.65	5.97	7.33		
Chloride	mmol/l	84.0	71.4	96.6	ISE indirect
	mmol/l	83.2	70.7	95.7	ISE direct
Copper	μmol/l	1.53	1.22	1.84	Atomic absorption
	μg/dl	9.73	7.76	11.7	
Cortisol	nmol/l	91.7	68.8	115	Chemiluminescence (+ solvent extraction.)
	μg/dl	3.30	2.48	4.12	
	nmol/l	117	87.8	146	Chemiluminescence (direct)
	μg/dl	4.21	3.16	5.26	
	nmol/l	135	101	169	Enzyme immunoassay (direct)
	μg/dl	4.86	3.64	6.08	
nmol/l	108	81.0	135	RIA methods (+ solvent extraction)	
μg/dl	3.89	2.92	4.86		
Creatinine	mmol/l	6.93	5.54	8.32	Alkaline picrate no deproteinization
	mg/dl	78.3	62.6	94.0	
	mmol/l	7.29	5.83	8.75	Creatinine PAP method
	mg/dl	82.4	65.9	98.9	
	mmol/l	7.30	5.84	8.76	Enzymatic UV method
	mg/dl	82.5	66.0	99.0	

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Size: 12 x 10 ml Expiry: 2021-10-28

Analyte	unit	Target	Range		methods
			low	high	
Creatinine	mmol/l	7.20	5.76	8.64	Other enzymatic methods
	mg/dl	81.4	65.1	97.7	
	mmol/l	7.39	5.91	8.87	Roche Creatinine Plus
	mg/dl	83.5	66.8	100	
	mmol/l	7.06	5.65	8.47	Jaffe rate blanked
	mg/dl	79.8	63.8	95.8	
	mmol/l	6.87	5.50	8.24	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	77.6	62.2	93.0	
mmol/l	6.84	5.47	8.21	Vitros IDMS Traceable	
mg/dl	77.3	61.8	92.8		
mmol/l	7.02	5.62	8.42	Jaffe rate blanked compensated (-18 µmol/l)	
mg/dl	79.3	63.5	95.1		
Dopamine	nmol/l	538	430	646	HPLC
Epinephrine	nmol/l	77.2	61.8	92.6	HPLC
Glucose	mmol/l	2.60	2.08	3.12	Vitros
	mg/dl	46.9	37.5	56.3	
	mmol/l	2.79	2.23	3.35	Glucose oxidase
	mg/dl	50.3	40.2	60.4	
	mmol/l	2.78	2.22	3.34	Hexokinase
	mg/dl	50.1	40.0	60.2	
	mmol/l	2.86	2.29	3.43	Glucose dehydrogenase
	mg/dl	51.5	41.3	61.7	
Magnesium	mmol/l	3.88	3.10	4.66	Vitros
	mg/dl	9.43	7.53	11.3	
	mmol/l	3.18	2.54	3.82	Calmagite
	mg/dl	7.73	6.17	9.29	
	mmol/l	3.42	2.74	4.10	Xylidyl Blue
	mg/dl	8.31	6.66	9.96	
	mmol/l	3.46	2.77	4.15	Arsenazo III
	mg/dl	8.41	6.73	10.1	
	mmol/l	3.38	2.70	4.06	Chlorphosphonazo III
	mg/dl	8.21	6.56	9.86	
	mmol/l	3.50	2.80	4.20	Methylthymol blue
	mg/dl	8.51	6.80	10.2	
mmol/l	3.45	2.76	4.14	Enzymatic	
mg/dl	8.38	6.71	10.1		
Metanephrine	µmol/l	0.218	0.174	0.262	HPLC
Microalbumin	mg/l	31.5	25.2	37.8	Immunoturbidimetric
	mg/l	33.7	27.0	40.4	Nephelometric
Norepinephrine	nmol/l	247	198	296	HPLC
Normetanephrine	µmol/l	1.25	1.00	1.50	HPLC
Osmolality	mOsm/kg	403	322	484	Freezing point depression
	mOsm/kg	345	276	414	Calculated
Oxalate	mmol/l	0.109	0.076	0.142	Oxalate oxidase
Phosphate Inorganic	mmol/l	9.64	7.71	11.6	Vitros
	mg/dl	29.9	23.9	35.9	

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Analyte	unit	Target	Range		methods	
			low	high		
Phosphate Inorganic	mmol/l	8.94	7.15	10.7	Phosphomolybdate UV	
	mg/dl	27.7	22.2	33.2		
	mmol/l	9.03	7.22	10.8	Phosphomolybdate enzymatic	
	mg/dl	28.0	22.4	33.6		
Potassium	mmol/l	31.7	26.9	36.5	Vitros	
	mmol/l	31.1	26.4	35.8	ISE direct	
	mmol/l	30.6	26.0	35.2	ISE indirect	
Protein Total	g/l	0.118	0.094	0.142	Biuret reaction with ppt	
	mg/dl	11.8	9.40	14.2		
	mg/l	118	94.0	142		
	g/l	0.129	0.103	0.155	Biuret reaction - direct	
	mg/dl	12.9	10.3	15.5		
	mg/l	129	103	155		
	g/l	0.115	0.092	0.138	Turbidimetry	
	mg/dl	11.5	9.20	13.8		
	mg/l	115	92.0	138		
	g/l	0.135	0.108	0.162	Pyrogallol Red	
	mg/dl	13.5	10.8	16.2		
	mg/l	135	108	162		
g/l	0.191	0.153	0.229	Vitros		
mg/dl	19.1	15.3	22.9			
mg/l	191	153	229			
Sodium	mmol/l	70.2	61.8	78.6	Vitros	
	mmol/l	66.2	58.3	74.1	ISE direct	
	mmol/l	63.5	55.9	71.1	ISE indirect	
Urea	mmol/l	163	130	196	Vitros	
	mg/dl	980	781	1179		
	mmol/l	160	128	192	Beckman-Conductivity	
	mg/dl	962	769	1155		
	mmol/l	157	126	188	Urease kinetic	
	mg/dl	944	757	1131		
	mmol/l	161	129	193	Urease end point	
	mg/dl	968	775	1161		
Uric Acid (Urate)	mmol/l	0.825	0.660	0.990	Ortho Vitros Microslide Systems	
	mg/dl	13.9	11.1	16.7		
	mmol/l	0.738	0.590	0.886	Uricase peroxidase no ascorbate oxidase	
	mg/dl	12.4	9.91	14.9		
	mmol/l	0.783	0.626	0.940	Spectrophotometric at 280-290	
	mg/dl	13.2	10.5	15.9		
	mmol/l	0.706	0.565	0.847	Uricase Peroxidase with ascorbate oxidase @ 546nm	
	mg/dl	11.9	9.49	14.3		
	mmol/l	0.730	0.584	0.876	Uricase peroxidase with ascorbate oxidase	
	mg/dl	12.3	9.81	14.8		
	Vanillylmandelic Acid (VMA)	µmol/l	28.9	23.1	34.7	Column test
		µmol/l	29.3	23.4	35.2	HPLC