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

CAT. NO. AU 2352
LOT NO. 861UC
SIZE: 12 x 10 ml
EXPIRY: 2020-03-28
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 ± 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	29.6	23.7	35.5	HPLC
Amylase	U/l	112	89.6	134	Vitros
	U/l	191	153	229	Siemens - blocked pNPG7
	U/l	184	147	221	Randox Lyo. Ethylidene pNPG7
	U/l	193	154	232	Other blocked pNPG7
	U/l	210	168	252	Randox Liquid Ethylidene pNPG7
	U/l	176	141	211	Roche liquid pNPG7
	U/l	177	142	212	BM/Roche Colorimetric pNPG7
	U/l	207	166	248	Beckman Synchron CX4/CX5/CX7
	U/l	181	145	217	Roche Integra 2-chloro-pNPG7
	U/l	231	185	277	pNP Maltotrioside substrates
	U/l	191	153	229	Beckman Olympus - blocked pNPG7
	U/l	235	188	282	Siemens 2-chloro-pNPG3
	U/l	213	170	256	Other 2-chloro-pNPG3
	U/l	215	172	258	Abbott Architect Non-IFCC Cal.
	U/l	217	174	260	Abbott Architect IFCC Cal.
Calcium	mmol/l	1.60	1.44	1.76	Vitros
	mg/dl	6.41	5.77	7.05	
	mmol/l	1.56	1.40	1.72	Cresolphthalein complexone
	mg/dl	6.25	5.61	6.89	
	mmol/l	1.55	1.40	1.71	Ion selective electrode
	mg/dl	6.21	5.61	6.81	
	mmol/l	1.55	1.40	1.71	Arsenazo III
	mg/dl	6.21	5.61	6.81	
	mmol/l	1.55	1.40	1.71	NM-BAPTA
	mg/dl	6.21	5.61	6.81	
Chloride	mmol/l	84.3	71.7	96.9	Vitros
	mmol/l	83.3	70.8	95.8	ISE indirect
	mmol/l	87.7	74.5	101	ISE direct
Copper	µmol/l	1.30	1.04	1.56	Atomic absorption
	µg/dl	8.27	6.61	9.93	
Cortisol	nmol/l	103	77.3	129	Chemiluminescence (+ solvent extraction.)
	µg/dl	3.71	2.78	4.64	
	nmol/l	122	85.4	159	Chemiluminescence (direct)
	µg/dl	4.39	3.07	5.71	
Creatinine	mmol/l	6.93	5.54	8.32	Alkaline picrate no deproteinization
	mg/dl	78.3	62.6	94.0	
	mmol/l	7.16	5.73	8.59	Creatinine PAP method
	mg/dl	80.9	64.7	97.1	
	mmol/l	7.22	5.78	8.66	Enzymatic UV method (340nm)
	mg/dl	81.6	65.3	97.9	
	mmol/l	7.23	5.78	8.68	Other enzymatic methods
	mg/dl	81.7	65.3	98.1	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Creatinine	mmol/l	7.31	5.85	8.77	Roche Creatinine Plus
	mg/dl	82.6	66.1	99.1	
	mmol/l	6.92	5.54	8.30	Jaffe rate blanked
	mg/dl	78.2	62.6	93.8	
	mmol/l	6.93	5.54	8.32	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	78.3	62.6	94.0	
	mmol/l	6.89	5.51	8.27	Vitros IDMS Traceable
	mg/dl	77.9	62.3	93.5	
	mmol/l	7.06	5.65	8.47	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	79.8	63.8	95.8	
Dopamine	nmol/l	561	449	673	HPLC
Epinephrine	nmol/l	68.2	54.6	81.8	HPLC
Glucose	mmol/l	2.65	2.12	3.18	Vitros
	mg/dl	47.8	38.2	57.4	
	mmol/l	2.74	2.19	3.29	Glucose oxidase
	mg/dl	49.4	39.5	59.3	
	mmol/l	2.78	2.22	3.34	Hexokinase
	mg/dl	50.1	40.0	60.2	
	mmol/l	2.85	2.28	3.42	GOD/02-Beckman method
	mg/dl	51.4	41.1	61.7	
Magnesium	mmol/l	3.41	2.73	4.09	Vitros
	mg/dl	8.29	6.63	9.95	
	mmol/l	2.94	2.35	3.53	Calmagite
	mg/dl	7.14	5.71	8.57	
	mmol/l	3.14	2.51	3.77	Xylidyl Blue
	mg/dl	7.63	6.10	9.16	
	mmol/l	3.20	2.56	3.84	Arsenazo III
	mg/dl	7.78	6.22	9.34	
	mmol/l	3.14	2.51	3.77	Chlorphosphonazo III
	mg/dl	7.63	6.10	9.16	
	mmol/l	3.19	2.55	3.83	Methylthymol blue
	mg/dl	7.75	6.20	9.30	
	mmol/l	3.24	2.59	3.89	Enzymatic
	mg/dl	7.87	6.29	9.45	
Metanephrine	µmol/l	0.245	0.196	0.294	HPLC
Microalbumin	mg/l	30.2	24.2	36.2	Immunoturbidimetric
	mg/l	32.5	26.0	39.0	Nephelometric
Norepinephrine	nmol/l	231	185	277	HPLC
Normetanephrine	µmol/l	1.23	0.984	1.48	HPLC
Osmolality	mOsm/kg	398	318	478	Freezing point depression
	mOsm/kg	401	321	481	Vapour pressure
	mOsm/kg	357	286	428	Calculated
Oxalate	mmol/l	0.105	0.084	0.126	Oxalate oxidase
Phosphate Inorganic	mmol/l	10.1	8.08	12.1	Vitros
	mg/dl	31.3	25.0	37.6	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Phosphate Inorganic	mmol/l	9.08	7.26	10.9	Phosphomolybdate UV
	mg/dl	28.1	22.5	33.7	
	mmol/l	9.10	7.28	10.9	Phosphomolybdate enzymatic
	mg/dl	28.2	22.6	33.8	
Potassium	mmol/l	30.9	26.3	35.5	Vitros
	mmol/l	30.4	25.8	35.0	ISE direct
	mmol/l	30.2	25.7	34.7	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	0.130	0.104	0.156	Biuret reaction - direct
	mg/dl	13.0	10.4	15.6	
	mg/l	130	104	156	
	g/l	0.116	0.093	0.139	Turbidimetry
	mg/dl	11.6	9.30	13.9	
	mg/l	116	93.0	139	
	g/l	0.127	0.089	0.165	Pyrogallol Red
	mg/dl	12.7	8.89	16.5	
	mg/l	127	88.9	165	
	g/l	0.187	0.150	0.224	Vitros
	mg/dl	18.7	15.0	22.4	
	mg/l	187	150	224	
Sodium	mmol/l	67.5	59.4	75.6	Vitros
	mmol/l	69.7	61.3	78.1	ISE direct
	mmol/l	63.6	56.0	71.2	ISE indirect
Urea	mmol/l	157	126	188	Vitros
	mg/dl	944	757	1131	
	mmol/l	159	127	191	Beckman-Conductivity
	mg/dl	956	763	1149	
	mmol/l	157	126	188	Urease kinetic
	mg/dl	944	757	1131	
	mmol/l	162	130	194	Urease end point
	mg/dl	974	781	1167	
Uric Acid (Urate)	mmol/l	0.757	0.606	0.908	Ortho Vitros Microslide Systems
	mg/dl	12.7	10.2	15.2	
	mmol/l	0.761	0.609	0.913	Uricase peroxidase no ascorbate oxidase
	mg/dl	12.8	10.2	15.4	
	mmol/l	0.822	0.658	0.986	Spectrophotometric at 280-290
	mg/dl	13.8	11.1	16.5	
	mmol/l	0.709	0.567	0.851	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	11.9	9.53	14.3	
	mmol/l	0.743	0.594	0.892	Uricase peroxidase with ascorbate oxidase
	mg/dl	12.5	9.98	15.0	
Vanillylmandelic Acid (VMA)	µmol/l	28.7	23.0	34.4	Column test
	µmol/l	28.1	22.5	33.7	HPLC