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

CAT. NO. AU 2352 **LOT NO.** 1013UC
SIZE: 12 x 10 ml **EXPIRY:** 2022-10-28

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 ± 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	28.1	22.5	33.7	HPLC
Amylase	U/l	88.8	71.0	107	Vitros
	U/l	165	132	198	Siemens - blocked pNPG7
	U/l	163	130	196	Other blocked pNPG7
	U/l	173	138	208	Randox Liquid Ethylidene pNPG7
	U/l	149	119	179	Roche liquid pNPG7
	U/l	168	134	202	Beckman Synchron CX4/CX5/CX7
	U/l	157	126	188	Roche Integra 2-chloro-pNPG7
	U/l	165	132	198	Beckman Coulter - blocked pNPG7
	U/l	203	162	244	Siemens 2-chloro-pNPG3
	U/l	183	146	220	Other 2-chloro-pNPG3
	U/l	186	149	223	Abbott Architect Non-IFCC Cal.
	U/l	196	157	235	Abbott Architect IFCC Cal.
Calcium	mmol/l	1.63	1.47	1.79	Vitros
	mg/dl	6.53	5.89	7.17	
	mmol/l	1.55	1.40	1.71	Cresolphthalein complexone
	mg/dl	6.21	5.61	6.81	
	mmol/l	1.56	1.40	1.72	Ion selective electrode
	mg/dl	6.25	5.61	6.89	
	mmol/l	1.54	1.39	1.69	Arsenazo III
	mg/dl	6.17	5.57	6.77	
	mmol/l	1.55	1.40	1.71	NM-BAPTA
	mg/dl	6.21	5.61	6.81	
Chloride	mmol/l	83.2	70.7	95.7	ISE indirect
	mmol/l	85.3	72.5	98.1	ISE direct
Copper	µmol/l	1.45	0.725	2.18	Atomic absorption
	µg/dl	9.22	4.61	13.9	
Cortisol	nmol/l	102	76.5	128	Chemiluminescence (+ solvent extraction.)
	µg/dl	3.67	2.75	4.59	
	nmol/l	117	87.8	146	Chemiluminescence (direct)
	µg/dl	4.21	3.16	5.26	
Creatinine	mmol/l	6.75	5.40	8.10	Alkaline picrate no deproteinization
	mg/dl	76.3	61.0	91.6	
	mmol/l	6.91	5.53	8.29	Creatinine PAP method
	mg/dl	78.1	62.5	93.7	
	mmol/l	6.98	5.58	8.38	Enzymatic UV method
	mg/dl	78.9	63.1	94.7	
	mmol/l	7.03	5.62	8.44	Other enzymatic methods
	mg/dl	79.4	63.5	95.3	
	mmol/l	7.28	5.82	8.74	Roche Creatinine Plus
	mg/dl	82.3	65.8	98.8	
	mmol/l	6.98	5.58	8.38	Jaffe rate blanked
	mg/dl	78.9	63.1	94.7	

%

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Creatinine	mmol/l	6.83	5.46	8.20	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	77.2	61.7	92.7	
	mmol/l	6.91	5.53	8.29	Vitros IDMS Traceable
	mg/dl	78.1	62.5	93.7	
	mmol/l	6.82	5.46	8.18	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	77.1	61.7	92.5	
Dopamine	nmol/l	530	312	749	HPLC
Epinephrine	nmol/l	68.3	54.6	82.0	HPLC
Glucose	mmol/l	2.54	2.03	3.05	Vitros
	mg/dl	45.8	36.6	55.0	
	mmol/l	2.76	2.21	3.31	Glucose oxidase
	mg/dl	49.7	39.8	59.6	
	mmol/l	2.75	2.20	3.30	Hexokinase
	mg/dl	49.6	39.6	59.6	
Magnesium	mmol/l	3.58	2.86	4.30	Vitros
	mg/dl	8.70	6.95	10.5	
	mmol/l	2.92	2.34	3.50	Calmagite
	mg/dl	7.10	5.69	8.51	
	mmol/l	3.06	2.45	3.67	Xylidyl Blue
	mg/dl	7.44	5.95	8.93	
	mmol/l	3.13	2.50	3.76	Arsenazo III
	mg/dl	7.61	6.08	9.14	
	mmol/l	3.07	2.46	3.68	Chlorphosphonazo III
	mg/dl	7.46	5.98	8.94	
	mmol/l	3.19	2.55	3.83	Methylthymol blue
	mg/dl	7.75	6.20	9.30	
	mmol/l	3.13	2.50	3.76	Enzymatic
	mg/dl	7.61	6.08	9.14	
Metanephrine	µmol/l	0.287	0.230	0.344	HPLC
Microalbumin	mg/l	28.6	22.9	34.3	Immunoturbidimetric
	mg/l	28.1	22.5	33.7	Nephelometric
Norepinephrine	nmol/l	235	188	282	HPLC
Normetanephrine	µmol/l	1.19	0.952	1.43	HPLC
Osmolality	mOsm/kg	392	314	470	Freezing point depression
	mOsm/kg	331	265	397	Calculated
Oxalate	mmol/l	0.113	0.090	0.136	Oxalate oxidase
Phosphate Inorganic	mmol/l	9.71	7.77	11.7	Vitros
	mg/dl	30.1	24.1	36.1	
	mmol/l	8.75	7.00	10.5	Phosphomolybdate UV
	mg/dl	27.1	21.7	32.5	
	mmol/l	8.78	7.02	10.5	Phosphomolybdate enzymatic
	mg/dl	27.2	21.8	32.6	
Potassium	mmol/l	31.1	26.4	35.8	Vitros
	mmol/l	30.6	26.0	35.2	ISE direct
	mmol/l	29.7	25.2	34.2	ISE indirect

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein Total	g/l	0.127	0.102	0.152	Biuret reaction - direct
	mg/dl	12.7	10.2	15.2	
	mg/l	127	102	152	
	g/l	0.114	0.091	0.137	Turbidimetry
	mg/dl	11.4	9.10	13.7	
	mg/l	114	91.0	137	
	g/l	0.142	0.114	0.170	Pyrogallol Red
	mg/dl	14.2	11.4	17.0	
	mg/l	142	114	170	
	g/l	0.189	0.151	0.227	Vitros
	mg/dl	18.9	15.1	22.7	
	mg/l	189	151	227	
Sodium	mmol/l	62.9	55.4	70.4	Vitros
	mmol/l	65.8	57.9	73.7	ISE direct
	mmol/l	62.6	55.1	70.1	ISE indirect
Urea	mmol/l	159	127	191	Vitros
	mg/dl	956	763	1149	
	mmol/l	157	126	188	Beckman-Conductivity
	mg/dl	944	757	1131	
	mmol/l	151	121	181	Urease kinetic
	mg/dl	908	727	1089	
	mmol/l	157	126	188	Urease end point
	mg/dl	944	757	1131	
Uric Acid (Urate)	mmol/l	0.813	0.650	0.976	Ortho Vitros Microslide Systems
	mg/dl	13.7	10.9	16.5	
	mmol/l	0.708	0.566	0.850	Uricase catalase 340nm
	mg/dl	11.9	9.51	14.3	
	mmol/l	0.698	0.558	0.838	Uricase peroxidase no ascorbate oxidase
	mg/dl	11.7	9.37	14.0	
	mmol/l	0.750	0.600	0.900	Spectrophotometric at 280-290
	mg/dl	12.6	10.1	15.1	
	mmol/l	0.663	0.530	0.796	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	11.1	8.90	13.3	
	mmol/l	0.677	0.542	0.812	Uricase peroxidase with ascorbate oxidase
	mg/dl	11.4	9.11	13.7	
Vanillylmandelic Acid (VMA)	µmol/l	30.0	24.0	36.0	Column test
	µmol/l	27.8	22.2	33.4	HPLC

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