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

CAT. NO. AU 2352 **LOT NO.** 1122UC
SIZE: 12 x 10 ml **EXPIRY:** 2024-09-28
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.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
5-HIAA	µmol/l	29.3	23.4	35.2	HPLC
Amylase	U/l	116	92.8	139	Vitros
	U/l	207	166	248	Siemens - blocked pNPG7
	U/l	211	169	253	Other blocked pNPG7
	U/l	216	173	259	Randox Liquid Ethylidene pNPG7
	U/l	188	150	226	Roche liquid pNPG7
	U/l	193	154	232	Roche Integra 2-chloro-pNPG7
	U/l	205	164	246	Beckman Coulter - blocked pNPG7
	U/l	252	202	302	Siemens 2-chloro-pNPG3
	U/l	221	177	265	Other 2-chloro-pNPG3
	U/l	227	182	272	Abbott Architect Non-IFCC Cal.
	U/l	245	196	294	Abbott Architect IFCC Cal.
Calcium	mmol/l	1.69	1.52	1.86	Vitros
	mg/dl	6.77	6.09	7.45	
	mmol/l	1.56	1.40	1.72	Cresolphthalein complexone
	mg/dl	6.25	5.61	6.89	
	mmol/l	1.53	1.38	1.68	Arsenazo III
	mg/dl	6.13	5.53	6.73	
	mmol/l	1.55	1.40	1.71	NM-BAPTA
	mg/dl	6.21	5.61	6.81	
Chloride	mmol/l	86.6	73.6	100	Vitros
	mmol/l	82.0	69.7	94.3	ISE indirect
	mmol/l	83.4	70.9	95.9	ISE direct
Copper	µmol/l	1.23	0.984	1.48	Atomic absorption
	µg/dl	7.82	6.26	9.38	
Cortisol	nmol/l	110	82.5	138	Chemiluminescence (+ solvent extraction.)
	µg/dl	3.96	2.97	4.95	
	nmol/l	113	84.8	141	Chemiluminescence (direct)
	µg/dl	4.07	3.05	5.09	
Creatinine	mmol/l	6.85	5.48	8.22	Alkaline picrate no deproteinization
	mg/dl	77.4	61.9	92.9	
	mmol/l	7.19	5.75	8.63	Creatinine PAP method
	mg/dl	81.2	65.0	97.4	
	mmol/l	7.04	5.63	8.45	Enzymatic UV method
	mg/dl	79.6	63.6	95.6	
	mmol/l	7.02	5.62	8.42	Other enzymatic methods
	mg/dl	79.3	63.5	95.1	
	mmol/l	7.37	5.90	8.84	Roche Creatinine Plus
	mg/dl	83.3	66.7	100	
	mmol/l	6.96	5.57	8.35	Jaffe rate blanked
	mg/dl	78.6	62.9	94.3	
	mmol/l	6.93	5.54	8.32	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	78.3	62.6	94.0	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Creatinine	mmol/l	7.16	5.73	8.59	Vitros IDMS Traceable
	mg/dl	80.9	64.7	97.1	
	mmol/l	6.99	5.59	8.39	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	79.0	63.2	94.8	
Dopamine	nmol/l	510	408	612	HPLC
Epinephrine	nmol/l	63.0	50.4	75.6	HPLC
Glucose	mmol/l	2.58	2.06	3.10	Vitros
	mg/dl	46.5	37.1	55.9	
	mmol/l	2.80	2.24	3.36	Glucose oxidase
	mg/dl	50.5	40.4	60.6	
	mmol/l	2.76	2.21	3.31	Hexokinase
	mg/dl	49.7	39.8	59.6	
Magnesium	mmol/l	3.33	2.66	4.00	Vitros
	mg/dl	8.09	6.46	9.72	
	mmol/l	3.04	2.43	3.65	Xylidyl Blue
	mg/dl	7.39	5.90	8.88	
	mmol/l	3.07	2.46	3.68	Arsenazo III
	mg/dl	7.46	5.98	8.94	
	mmol/l	3.08	2.46	3.70	Chlorphosphonazo III
	mg/dl	7.48	5.98	8.98	
	mmol/l	3.06	2.45	3.67	Methylthymol blue
	mg/dl	7.44	5.95	8.93	
	mmol/l	3.09	2.47	3.71	Enzymatic
	mg/dl	7.51	6.00	9.02	
Metanephrine	µmol/l	0.269	0.215	0.323	HPLC
Microalbumin	mg/l	30.2	24.2	36.2	Immunoturbidimetric
	mg/l	33.7	27.0	40.4	Nephelometric
Norepinephrine	nmol/l	228	182	274	HPLC
Normetanephrine	µmol/l	1.23	0.984	1.48	HPLC
Osmolality	mOsm/kg	393	314	472	Freezing point depression
	mOsm/kg	357	286	428	Calculated
Oxalate	mmol/l	0.120	0.096	0.144	Oxalate oxidase
Phosphate Inorganic	mmol/l	10.4	8.32	12.5	Vitros
	mg/dl	32.2	25.8	38.6	
	mmol/l	9.00	7.20	10.8	Phosphomolybdate UV
	mg/dl	27.9	22.3	33.5	
	mmol/l	8.97	7.18	10.8	Phosphomolybdate enzymatic
	mg/dl	27.8	22.3	33.3	
Potassium	mmol/l	30.9	26.3	35.5	Vitros
	mmol/l	31.2	26.5	35.9	ISE direct
	mmol/l	29.9	25.4	34.4	ISE indirect
Protein Total	g/l	0.120	0.096	0.144	Biuret reaction - direct
	mg/dl	12.0	9.60	14.4	
	mg/l	120	96.0	144	
	g/l	0.102	0.082	0.122	Turbidimetry
	mg/dl	10.2	8.20	12.2	
	mg/l	102	82.0	122	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein Total	g/l	0.130	0.104	0.156	Pyrogallol Red
	mg/dl	13.0	10.4	15.6	
	mg/l	130	104	156	
	g/l	0.181	0.145	0.217	Vitros
	mg/dl	18.1	14.5	21.7	
	mg/l	181	145	217	
Sodium	mmol/l	67.9	59.8	76.0	Vitros
	mmol/l	66.4	58.4	74.4	ISE direct
	mmol/l	63.3	55.7	70.9	ISE indirect
Urea	mmol/l	160	128	192	Vitros
	mg/dl	962	769	1155	
	mmol/l	154	123	185	Urease kinetic
	mg/dl	926	739	1113	
	mmol/l	153	122	184	Urease end point
	mg/dl	920	733	1107	
Uric Acid (Urate)	mmol/l	0.735	0.588	0.882	Ortho Vitros Microslide Systems
	mg/dl	12.3	9.88	14.7	
	mmol/l	0.724	0.579	0.869	Uricase peroxidase no ascorbate oxidase
	mg/dl	12.2	9.73	14.7	
	mmol/l	0.702	0.562	0.842	Spectrophotometric at 280-290
	mg/dl	11.8	9.44	14.2	
	mmol/l	0.692	0.554	0.830	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	11.6	9.31	13.9	
	mmol/l	0.702	0.562	0.842	Uricase peroxidase with ascorbate oxidase
	mg/dl	11.8	9.44	14.2	
Vanillylmandelic Acid (VMA)	µmol/l	29.3	23.4	35.2	Column test
	µmol/l	27.6	22.1	33.1	HPLC