ASSAYED URINE CONTROL - LEVEL 3 (URN ASY CONTROL 3)

CAT. NO. AU 2353 **LOT NO.** 1127UC
SIZE: 12 x 10 ml **EXPIRY:** 2024-09-28
GTIN: 05055273200546

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 hydroxy indole acetic 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 be 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 3 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,
F94 TV06, Ireland

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
5-HIAA	µmol/l	279	223	335	HPLC
Amylase	U/l	497	398	596	Vitros
	U/l	904	723	1085	Siemens - blocked pNPG7
	U/l	874	699	1049	Other blocked pNPG7
	U/l	950	760	1140	Randox Liquid Ethylidene pNPG7
	U/l	797	638	956	Roche liquid pNPG7
	U/l	949	759	1139	Beckman Synchron CX4/CX5/CX7
	U/l	834	667	1001	Roche Integra 2-chloro-pNPG7
	U/l	893	714	1072	Beckman Coulter - blocked pNPG7
	U/l	1144	915	1373	Siemens 2-chloro-pNPG3
	U/l	978	782	1174	Other 2-chloro-pNPG3
	U/l	1000	800	1200	Abbott Architect Non-IFCC Cal.
	U/l	1082	866	1298	Abbott Architect IFCC Cal.
Calcium	mmol/l	3.58	3.22	3.94	Vitros
	mg/dl	14.3	12.9	15.7	
	mmol/l	4.75	4.28	5.23	Cresolphthalein complexone
	mg/dl	19.0	17.2	20.8	
	mmol/l	4.21	3.79	4.63	Arsenazo III
	mg/dl	16.9	15.2	18.6	
	mmol/l	4.56	4.10	5.02	NM-BAPTA
	mg/dl	18.3	16.4	20.2	
Chloride	mmol/l	265	225	305	Vitros
	mmol/l	272	231	313	ISE indirect
	mmol/l	267	227	307	ISE direct
Copper	µmol/l	3.61	2.89	4.33	Atomic absorption
	µg/dl	23.0	18.4	27.6	
Cortisol	nmol/l	260	195	325	Chemiluminescence (+ solvent extraction.)
	µg/dl	9.36	7.02	11.7	
	nmol/l	282	212	353	Chemiluminescence (direct)
	µg/dl	10.2	7.63	12.8	
Creatinine	mmol/l	15.5	12.4	18.6	Alkaline picrate no deproteinization
	mg/dl	175	140	210	
	mmol/l	16.2	13.0	19.4	Creatinine PAP method
	mg/dl	183	147	219	
	mmol/l	15.8	12.6	19.0	Enzymatic UV method
	mg/dl	179	142	216	
	mmol/l	16.0	12.8	19.2	Other enzymatic methods
	mg/dl	181	145	217	
	mmol/l	16.4	13.1	19.7	Roche Creatinine Plus
	mg/dl	185	148	222	
	mmol/l	16.0	12.8	19.2	Jaffe rate blanked
	mg/dl	181	145	217	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Creatinine	mmol/l	15.6	12.5	18.7	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	176	141	211	
	mmol/l	15.5	12.4	18.6	Vitros IDMS Traceable
	mg/dl	175	140	210	
	mmol/l	16.0	12.8	19.2	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	181	145	217	
Dopamine	nmol/l	1967	1574	2360	HPLC
Epinephrine	nmol/l	334	267	401	HPLC
Glucose	mmol/l	15.7	12.6	18.8	Vitros
	mg/dl	283	227	339	
	mmol/l	15.5	12.4	18.6	Glucose oxidase
	mg/dl	279	223	335	
	mmol/l	15.3	12.2	18.4	Hexokinase
	mg/dl	276	220	332	
Magnesium	mmol/l	13.0	10.4	15.6	Vitros
	mg/dl	31.6	25.3	37.9	
	mmol/l	13.2	10.6	15.8	Xylidyl Blue
	mg/dl	32.1	25.8	38.4	
	mmol/l	13.2	10.6	15.8	Arsenazo III
	mg/dl	32.1	25.8	38.4	
	mmol/l	13.7	11.0	16.4	Chlorphosphonazo III
	mg/dl	33.3	26.7	39.9	
	mmol/l	13.1	10.5	15.7	Methylthymol blue
	mg/dl	31.8	25.5	38.1	
	mmol/l	13.1	10.5	15.7	Enzymatic
	mg/dl	31.8	25.5	38.1	
Metanephrine	µmol/l	2.58	2.06	3.10	HPLC
Microalbumin	mg/l	176	141	211	Immunoturbidimetric
	mg/l	188	150	226	Nephelometric
Norepinephrine	nmol/l	1560	1248	1872	HPLC
Normetanephrine	µmol/l	4.43	3.54	5.32	HPLC
Osmolality	mOsm/kg	1112	890	1334	Freezing point depression
	mOsm/kg	1068	854	1282	Calculated
Oxalate	mmol/l	0.484	0.387	0.581	Oxalate oxidase
Phosphate Inorganic	mmol/l	29.2	23.4	35.0	Vitros
	mg/dl	90.5	72.5	109	
	mmol/l	26.8	21.4	32.2	Phosphomolybdate UV
	mg/dl	83.1	66.3	100	
	mmol/l	26.5	21.2	31.8	Phosphomolybdate enzymatic
	mg/dl	82.2	65.7	98.7	
Potassium	mmol/l	148	126	170	Vitros
	mmol/l	137	116	158	ISE direct
	mmol/l	133	113	153	ISE indirect
Protein Total	g/l	0.238	0.190	0.286	Biuret reaction with ppt
	mg/dl	23.8	19.0	28.6	
	mg/l	238	190	286	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein Total	g/l	0.247	0.198	0.296	Biuret reaction - direct
	mg/dl	24.7	19.8	29.6	
	mg/l	247	198	296	
	g/l	0.229	0.183	0.275	Turbidimetry
	mg/dl	22.9	18.3	27.5	
	mg/l	229	183	275	
	g/l	0.264	0.211	0.317	Pyrogallol Red
	mg/dl	26.4	21.1	31.7	
	mg/l	264	211	317	
	g/l	0.117	0.094	0.140	Vitros
	mg/dl	11.7	9.40	14.0	
	mg/l	117	94.0	140	
Sodium	mmol/l	220	194	246	Vitros
	mmol/l	206	181	231	ISE direct
	mmol/l	207	182	232	ISE indirect
Urea	mmol/l	440	352	528	Vitros
	mg/dl	2644	2116	3172	
	mmol/l	433	346	520	Urease kinetic
	mg/dl	2602	2079	3125	
	mmol/l	432	346	518	Urease end point
	mg/dl	2596	2079	3113	
Uric Acid (Urate)	mmol/l	1.27	1.02	1.52	Ortho Vitros Microslide Systems
	mg/dl	21.3	17.1	25.5	
	mmol/l	1.31	1.05	1.57	Uricase catalase 340nm
	mg/dl	22.0	17.6	26.4	
	mmol/l	1.28	1.02	1.54	Uricase peroxidase no ascorbate oxidase
	mg/dl	21.5	17.1	25.9	
	mmol/l	1.26	1.01	1.51	Spectrophotometric at 280-290
	mg/dl	21.2	17.0	25.4	
	mmol/l	1.25	1.00	1.50	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	21.0	16.8	25.2	
	mmol/l	1.24	0.992	1.49	Uricase peroxidase with ascorbate oxidase
	mg/dl	20.8	16.7	24.9	
Vanillylmandelic Acid (VMA)	µmol/l	147	118	176	Column test
	µmol/l	145	116	174	HPLC