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

CAT. NO.	AU 2353	**LOT NO.**	1253UC
SIZE:	12 x 10 ml	**EXPIRY:**	2026-11-28
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. No stability claims are made for copper. 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):
These analytes are unstable in 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

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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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Cat. No. AU2353 Lot. No. 1253UC Size 12 x 10ml Expiry 2026-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
5-HIAA	µmol/l	287	230	344	HPLC
Amylase	U/l	983	786	1180	Siemens - blocked pNPG7
	U/l	931	745	1117	Randox Liquid Ethylidene pNPG7
	U/l	777	622	932	Roche liquid pNPG7
	U/l	880	704	1056	Beckman Coulter - blocked pNPG7
	U/l	808	646	970	Roche Integra 2-chloro-pNPG7
	U/l	1086	869	1303	Siemens 2-chloro-pNPG3
	U/l	983	786	1180	Other 2-chloro-pNPG3
	U/l	1015	812	1218	Abbott Architect IFCC Cal.
	U/l	997	798	1196	Abbott Architect Non-IFCC Cal.
	U/l	458	366	550	Vitros
Calcium	mmol/l	4.51	4.06	4.96	NM-BAPTA
	mg/dl	18.1	16.3	19.9	
	mmol/l	4.71	4.24	5.18	Cresolphthalein complexone
	mg/dl	18.9	17.0	20.8	
	mmol/l	4.19	3.77	4.61	Arsenazo III
	mg/dl	16.8	15.1	18.5	
	mmol/l	3.50	3.15	3.85	Vitros
	mg/dl	14.0	12.6	15.4	
Chloride	mmol/l	245	208	282	Vitros
	mmol/l	254	216	292	ISE indirect
	mmol/l	251	213	289	ISE direct
Cortisol	nmol/l	237	178	296	Chemiluminescence (direct)
	µg/dl	8.53	6.41	10.7	
	nmol/l	236	177	295	Chemiluminescence (+ solvent extraction.)
	µg/dl	8.50	6.37	10.6	
Creatinine	mmol/l	15.7	12.6	18.8	Other enzymatic methods
	mg/dl	177	142	212	
	mmol/l	16.1	12.9	19.3	Roche Creatinine Plus
	mg/dl	182	146	218	
	mmol/l	15.2	12.2	18.2	Vitros IDMS Traceable
	mg/dl	172	138	206	
	mmol/l	15.7	12.6	18.8	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	177	142	212	
	mmol/l	15.4	12.3	18.5	Jaffe rate blanked
	mg/dl	174	139	209	
	mmol/l	15.4	12.3	18.5	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	174	139	209	
	mmol/l	15.1	12.1	18.1	Alkaline picrate no deproteinization
	mg/dl	171	137	205	
	mmol/l	15.8	12.6	19.0	Enzymatic UV method
	mg/dl	179	142	216	

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Cat. No. AU2353 Lot. No. 1253UC Size 12 x 10ml Expiry 2026-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Creatinine	mmol/l	15.6	12.5	18.7	IDMS traceable
	mg/dl	176	141	211	
	mmol/l	15.9	12.7	19.1	Creatinine PAP method
	mg/dl	180	144	216	
Dopamine	nmol/l	1897	1518	2276	HPLC
Epinephrine	nmol/l	366	293	439	HPLC
Glucose	mmol/l	14.3	11.4	17.2	Hexokinase
	mg/dl	258	205	311	
	mmol/l	13.9	11.1	16.7	Glucose oxidase
	mg/dl	250	200	300	
	mmol/l	14.5	11.6	17.4	Vitros
	mg/dl	261	209	313	
Magnesium	mmol/l	13.5	10.8	16.2	Chlorphosphonazo III
	mg/dl	32.8	26.2	39.4	
	mmol/l	13.5	10.8	16.2	Vitros
	mg/dl	32.8	26.2	39.4	
	mmol/l	13.5	10.8	16.2	Enzymatic
	mg/dl	32.8	26.2	39.4	
	mmol/l	13.4	10.7	16.1	Methylthymol blue
	mg/dl	32.6	26.0	39.2	
	mmol/l	13.2	10.6	15.8	Xylidyl Blue
	mg/dl	32.1	25.8	38.4	
	mmol/l	13.5	10.8	16.2	Arsenazo III
	mg/dl	32.8	26.2	39.4	
Metanephrine	µmol/l	2.56	2.05	3.07	HPLC
Microalbumin	mg/l	183	146	220	Nephelometric
	mg/l	173	138	208	Immunoturbidimetric
Norepinephrine	nmol/l	1485	1188	1782	HPLC
Normetanephrine	µmol/l	4.07	3.26	4.88	HPLC
Osmolality	mOsm/kg	1076	861	1291	Calculated
	mOsm/kg	1124	899	1349	Freezing point depression
Oxalate	mmol/l	0.440	0.352	0.528	Oxalate oxidase
Phosphate Inorganic	mmol/l	27.2	21.8	32.6	Beckman PHOSm (365nm)
	mg/dl	84.3	67.6	101	
	mmol/l	28.1	22.5	33.7	Vitros
	mg/dl	87.1	69.8	104	
	mmol/l	26.8	21.4	32.2	Phosphomolybdate enzymatic
	mg/dl	83.1	66.3	100	
	mmol/l	26.7	21.4	32.0	Phosphomolybdate UV
	mg/dl	82.8	66.3	99.3	
Potassium	mmol/l	134	114	154	Vitros
	mmol/l	123	105	141	ISE direct
	mmol/l	122	104	140	ISE indirect
Protein Total	g/l	0.260	0.208	0.312	Biuret reaction - direct
	mg/dl	26.0	20.8	31.2	
	mg/l	260	208	312	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein Total	g/l	0.230	0.184	0.276	Turbidimetry
	mg/dl	23.0	18.4	27.6	
	mg/l	230	184	276	
	g/l	0.090	0.072	0.108	Vitros
	mg/dl	9.00	7.20	10.8	
	mg/l	90.0	72.0	108	
	g/l	0.160	0.128	0.192	Siemens UCFP Reagent
	mg/dl	16.0	12.8	19.2	
	mg/l	160	128	192	
Sodium	mmol/l	200	176	224	ISE direct
	mmol/l	217	191	243	Vitros
	mmol/l	202	178	226	ISE indirect
Urea	mmol/l	418	334	502	Vitros
	mg/dl	2512	2007	3017	
	mmol/l	430	344	516	Urease end point
	mg/dl	2584	2067	3101	
	mmol/l	428	342	514	Urease kinetic
	mg/dl	2572	2055	3089	
Uric Acid (Urate)	mmol/l	1.39	1.11	1.67	Ortho Vitros Microslide Systems
	mg/dl	23.4	18.6	28.2	
	mmol/l	1.36	1.09	1.63	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	22.8	18.3	27.3	
	mmol/l	1.38	1.10	1.66	Uricase peroxidase with ascorbate oxidase
	mg/dl	23.2	18.5	27.9	
	mmol/l	1.39	1.11	1.67	Uricase peroxidase no ascorbate oxidase
	mg/dl	23.4	18.6	28.2	
	mmol/l	1.48	1.18	1.78	Spectrophotometric at 280-290
	mg/dl	24.9	19.8	30.0	
Vanillylmandelic Acid (VMA)	µmol/l	153	122	184	HPLC
	µmol/l	141	113	169	Column test

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