RANDOX

PRODUCT INFORMATION

AU2353

1077UC

Please note that while Amylase is present in Assayed Urine Control Level 3 - lot 1077UC, no claims are made for the expected value or stability of this analyte.

CCS6189

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

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

CAT. NO.	AU 2353	**LOT NO.**	1077UC
SIZE:	12 x 10 ml	**EXPIRY:**	2023-10-28
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), Oxalate and 5-Hydroxyindole Acetic Acid (5-HIAA):

These analytes are unstable in urine samples and no claims are made on the stability. Samples should be prepared according to the standard procedures within each laboratory.

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.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Rev. 23 Jan '23 me

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

Cat. No. AU2353 Lot No. 1077UC Size: 12 x 10 ml Expiry: 2023-10-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
5-HIAA	µmol/l	288	230	346	HPLC
Calcium	mmol/l	3.59	3.23	3.95	Vitros
	mg/dl	14.4	12.9	15.9	
	mmol/l	4.82	4.34	5.30	Cresolphthalein complexone
	mg/dl	19.3	17.4	21.2	
	mmol/l	3.44	3.10	3.78	Ion selective electrode
	mg/dl	13.8	12.4	15.2	
	mmol/l	4.31	3.88	4.74	Arsenazo III
	mg/dl	17.3	15.6	19.0	
	mmol/l	4.67	4.20	5.14	NM-BAPTA
	mg/dl	18.7	16.8	20.6	
Chloride	mmol/l	253	215	291	Vitros
	mmol/l	263	224	302	ISE indirect
	mmol/l	261	222	300	ISE direct
Copper	µmol/l	3.81	3.05	4.57	Atomic absorption
	µg/dl	24.2	19.4	29.0	
Cortisol	nmol/l	383	287	479	Chemiluminescence (+ solvent extraction.)
	µg/dl	13.8	10.3	17.3	
	nmol/l	385	289	481	Chemiluminescence (direct)
	µg/dl	13.9	10.4	17.4	
Creatinine	mmol/l	15.7	12.6	18.8	Alkaline picrate no deproteinization
	mg/dl	177	142	212	
	mmol/l	16.4	13.1	19.7	Creatinine PAP method
	mg/dl	185	148	222	
	mmol/l	16.3	13.0	19.6	Enzymatic UV method
	mg/dl	184	147	221	
	mmol/l	16.3	13.0	19.6	Other enzymatic methods
	mg/dl	184	147	221	
	mmol/l	16.6	13.3	19.9	Roche Creatinine Plus
	mg/dl	188	150	226	
	mmol/l	16.1	12.9	19.3	Jaffe rate blanked
	mg/dl	182	146	218	
	mmol/l	15.9	12.7	19.1	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	180	144	216	
	mmol/l	15.9	12.7	19.1	Vitros IDMS Traceable
	mg/dl	180	144	216	
	mmol/l	16.4	13.1	19.7	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	185	148	222	
Dopamine	nmol/l	1681	1345	2017	HPLC
Epinephrine	nmol/l	275	220	330	HPLC
Glucose	mmol/l	15.5	12.4	18.6	Vitros
	mg/dl	279	223	335	

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Cat. No. AU2353 Lot No. 1077UC Size: 12 x 10 ml Expiry: 2023-10-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Glucose	mmol/l	14.9	11.9	17.9	Glucose oxidase
	mg/dl	268	214	322	
	mmol/l	15.1	12.1	18.1	Hexokinase
	mg/dl	272	218	326	
	mmol/l	14.6	11.7	17.5	Oxygen electrode
	mg/dl	263	211	315	
Magnesium	mmol/l	13.4	10.7	16.1	Vitros
	mg/dl	32.6	26.0	39.2	
	mmol/l	13.4	10.7	16.1	Calmagite
	mg/dl	32.6	26.0	39.2	
	mmol/l	13.5	10.8	16.2	Xylidyl Blue
	mg/dl	32.8	26.2	39.4	
	mmol/l	13.3	10.6	16.0	Arsenazo III
	mg/dl	32.3	25.8	38.8	
	mmol/l	13.7	11.0	16.4	Chlorphosphonazo III
	mg/dl	33.3	26.7	39.9	
	mmol/l	12.9	10.3	15.5	Methylthymol blue
	mg/dl	31.3	25.0	37.6	
	mmol/l	13.7	11.0	16.4	Enzymatic
	mg/dl	33.3	26.7	39.9	
Metanephrine	µmol/l	2.74	2.19	3.29	HPLC
Microalbumin	mg/l	179	143	215	Immunoturbidimetric
	mg/l	191	153	229	Nephelometric
Norepinephrine	nmol/l	1430	1144	1716	HPLC
Normetanephrine	µmol/l	4.05	3.24	4.86	HPLC
Osmolality	mOsm/kg	1143	914	1372	Freezing point depression
	mOsm/kg	1139	911	1367	Calculated
Oxalate	mmol/l	0.434	0.347	0.521	Oxalate oxidase
Phosphate Inorganic	mmol/l	28.7	23.0	34.4	Vitros
	mg/dl	89.0	71.3	107	
	mmol/l	27.0	21.6	32.4	Phosphomolybdate UV
	mg/dl	83.7	67.0	100	
	mmol/l	27.2	21.8	32.6	Phosphomolybdate enzymatic
	mg/dl	84.3	67.6	101	
Potassium	mmol/l	139	118	160	Vitros
	mmol/l	129	110	148	ISE direct
	mmol/l	127	108	146	ISE indirect
Protein Total	g/l	0.239	0.191	0.287	Biuret reaction with ppt
	mg/dl	23.9	19.1	28.7	
	mg/l	239	191	287	
	g/l	0.260	0.208	0.312	Biuret reaction - direct
	mg/dl	26.0	20.8	31.2	
	mg/l	260	208	312	
	g/l	0.231	0.185	0.277	Turbidimetry
	mg/dl	23.1	18.5	27.7	
	mg/l	231	185	277	

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Cat. No. AU2353 Lot No. 1077UC Size: 12 x 10 ml Expiry: 2023-10-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein Total	g/l	0.261	0.209	0.313	Pyrogallol Red
	mg/dl	26.1	20.9	31.3	
	mg/l	261	209	313	
	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	215	189	241	Vitros
	mmol/l	204	180	228	ISE direct
	mmol/l	205	180	230	ISE indirect
Urea	mmol/l	483	386	580	Vitros
	mg/dl	2903	2320	3486	
	mmol/l	474	379	569	Urease kinetic
	mg/dl	2849	2278	3420	
	mmol/l	475	380	570	Urease end point
	mg/dl	2855	2284	3426	
Uric Acid (Urate)	mmol/l	1.47	1.18	1.76	Ortho Vitros Microslide Systems
	mg/dl	24.7	19.8	29.6	
	mmol/l	1.41	1.13	1.69	Uricase catalase 340nm
	mg/dl	23.7	19.0	28.4	
	mmol/l	1.42	1.14	1.70	Uricase peroxidase no ascorbate oxidase
	mg/dl	23.9	19.2	28.6	
	mmol/l	1.43	1.14	1.72	Spectrophotometric at 280-290
	mg/dl	24.0	19.2	28.8	
	mmol/l	1.37	1.10	1.64	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	23.0	18.5	27.5	
	mmol/l	1.41	1.13	1.69	Uricase peroxidase with ascorbate oxidase
	mg/dl	23.7	19.0	28.4	
Vanillylmandelic Acid (VMA)	µmol/l	144	115	173	Column test
	µmol/l	147	118	176	HPLC