



## PRODUCT INFORMATION

AU2353

1253UC

Please note that while Copper is present in 1253UC – Assayed Urine Control Level 3, targets and ranges are not provided for this analyte.

INC1862

## 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  $\pm$  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](mailto:Technical.Services@randox.com).

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

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.
Calcium	U/l	458	366	550	Vitros
	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		
Chloride	mmol/l	3.50	3.15	3.85	Vitros
	mg/dl	14.0	12.6	15.4	
	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.)
Creatinine	µg/dl	8.50	6.37	10.6	
	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		

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

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

Analyte	unit	Target	Range		methods
			low	high	
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	
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	
Metanephrine	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	
Potassium	mmol/l	26.7	21.4	32.0	Phosphomolybdate UV
	mg/dl	82.8	66.3	99.3	
	mmol/l	134	114	154	Vitros
Protein Total	mmol/l	123	105	141	ISE direct
	mmol/l	122	104	140	ISE indirect
	g/l	0.260	0.208	0.312	Biuret reaction - direct
Protein Total	mg/dl	26.0	20.8	31.2	
	mg/l	260	208	312	

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

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

Analyte	unit	Target	Range		methods	
			low	high		
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	