

PRODUCT INFORMATION

AU2353

1216UC

Please note that in Assayed Urine Control Level 3 lot 1216UC, no claim is made for the stability or level of Amylase in the control.

INC1213

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

CAT. NO.	AU 2353	LOT NO.	1216UC
SIZE	12 x 10 ml	EXPIRY:	2026-04-28
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.

- 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.
- Refer to the Control section of the individual analyser application.
- 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.

| 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

ASSAYED URINE CONTROL LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot. No. 1216UC Size 12 x 10ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods
			low	high	
5-HIAA	µmol/l	275	220	330	HPLC
Calcium	mmol/l	3.95	3.56	4.35	Vitros
	mg/dl	15.8	14.3	17.3	
	mmol/l	5.21	4.69	5.73	Cresolphthalein complexone
	mg/dl	20.9	18.8	23.0	
	mmol/l	4.60	4.14	5.06	Arsenazo III
	mg/dl	18.4	16.6	20.2	
Chloride	mmol/l	263	224	302	Vitros
	mmol/l	273	232	314	ISE indirect
	mmol/l	270	230	311	ISE direct
Copper	µmol/l	2.93	2.34	3.52	Atomic absorption
	µg/dl	18.6	14.9	22.3	
Cortisol	nmol/l	284	213	355	Chemiluminescence (+ solvent extraction.)
	µg/dl	10.2	7.67	12.7	
	nmol/l	274	206	343	Chemiluminescence (direct)
Creatinine	mmol/l	15.4	12.3	18.5	Alkaline picrate no deproteinization
	mg/dl	174	139	209	
	mmol/l	16.4	13.1	19.7	Creatinine PAP method
	mg/dl	185	148	222	
	mmol/l	16.1	12.9	19.3	Enzymatic UV method
	mg/dl	182	146	218	
	mmol/l	16.1	12.9	19.3	Other enzymatic methods
	mg/dl	182	146	218	
	mmol/l	16.5	13.2	19.8	Roche Creatinine Plus
	mg/dl	186	149	223	
	mmol/l	15.8	12.6	19.0	Jaffe rate blanked
	mg/dl	179	142	216	
	mmol/l	15.7	12.6	18.8	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	177	142	212	
	mmol/l	15.7	12.6	18.8	Vitros IDMS Traceable
	mg/dl	177	142	212	
	mmol/l	15.7	12.6	18.8	IDMS traceable
	mg/dl	177	142	212	
mmol/l	15.7	12.6	18.8	Jaffe rate blanked compensated (-18 µmol/l)	
mg/dl	177	142	212		
Dopamine	nmol/l	2247	1798	2696	HPLC
Epinephrine	nmol/l	351	281	421	HPLC
Glucose	mmol/l	15.0	12.0	18.0	Vitros
	mg/dl	270	216	324	

ASSAYED URINE CONTROL LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot. No. 1216UC Size 12 x 10ml Expiry 2026-04-28

Analyte	unit	Target	Range		methods	
			low	high		
Glucose	mmol/l	14.5	11.6	17.4	Glucose oxidase	
	mg/dl	261	209	313		
	mmol/l	14.7	11.8	17.6	Hexokinase	
	mg/dl	265	213	317		
	mmol/l	15.0	12.0	18.0	Glucose dehydrogenase	
	mg/dl	270	216	324		
	Magnesium	mmol/l	14.1	11.3	16.9	Vitros
		mg/dl	34.3	27.5	41.1	
mmol/l		14.2	11.4	17.0	Xylidyl Blue	
mg/dl		34.5	27.7	41.3		
mmol/l		14.3	11.4	17.2	Arsenazo III	
mg/dl		34.7	27.7	41.7		
mmol/l		14.8	11.8	17.8	Chlorphosphonazo III	
mg/dl		36.0	28.7	43.3		
mmol/l		14.1	11.3	16.9	Methylthymol blue	
mg/dl		34.3	27.5	41.1		
mmol/l		14.4	11.5	17.3	Enzymatic	
mg/dl		35.0	27.9	42.1		
Metanephrine	µmol/l	2.54	2.03	3.05	HPLC	
Microalbumin	mg/l	174	139	209	Immunoturbidimetric	
	mg/l	184	147	221	Nephelometric	
Norepinephrine	nmol/l	1538	1230	1846	HPLC	
Normetanephrine	µmol/l	4.00	3.20	4.80	HPLC	
Osmolality	mOsm/kg	1112	890	1334	Freezing point depression	
	mOsm/kg	1109	887	1331	Vapour pressure	
	mOsm/kg	1106	885	1327	Calculated	
Oxalate	mmol/l	0.415	0.332	0.498	Oxalate oxidase	
Phosphate Inorganic	mmol/l	26.3	21.0	31.6	Vitros	
	mg/dl	81.5	65.1	97.9		
	mmol/l	24.1	19.3	28.9	Phosphomolybdate UV	
	mg/dl	74.7	59.8	89.6		
mmol/l	24.3	19.4	29.2	Phosphomolybdate enzymatic		
mg/dl	75.3	60.1	90.5			
Potassium	mmol/l	145	123	167	Vitros	
	mmol/l	136	116	156	ISE direct	
	mmol/l	130	111	150	ISE indirect	
Protein Total	g/l	0.265	0.212	0.318	Biuret reaction - direct	
	mg/dl	26.5	21.2	31.8		
	mg/l	265	212	318		
	g/l	0.239	0.191	0.287	Turbidimetry	
	mg/dl	23.9	19.1	28.7		
	mg/l	239	191	287		
	g/l	0.227	0.182	0.272	Sulphosalicylic acid	
	mg/dl	22.7	18.2	27.2		
	mg/l	227	182	272		
	g/l	0.253	0.202	0.304	Pyrogallol Red	
	mg/dl	25.3	20.2	30.4		
	mg/l	253	202	304		

ASSAYED URINE CONTROL LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot. No. 1216UC Size 12 x 10ml Expiry 2026-04-28

Range					
Analyte	unit	Target	low	high	methods
Protein Total	g/l	0.096	0.077	0.115	Vitros
	mg/dl	9.60	7.70	11.5	
	mg/l	96.0	77.0	115	
Sodium	mmol/l	220	194	246	Vitros
	mmol/l	203	179	227	ISE direct
	mmol/l	204	180	228	ISE indirect
Urea	mmol/l	437	350	524	Vitros
	mg/dl	2626	2104	3148	
	mmol/l	432	346	518	Urease kinetic
	mg/dl	2596	2079	3113	
	mmol/l	434	347	521	
Uric Acid (Urate)	mmol/l	1.21	0.968	1.45	Ortho Vitros Microslide Systems
	mg/dl	20.3	16.3	24.3	
	mmol/l	1.26	1.01	1.51	Uricase peroxidase no ascorbate oxidase
	mg/dl	21.2	17.0	25.4	
	mmol/l	1.32	1.06	1.58	Spectrophotometric at 280-290
	mg/dl	22.2	17.8	26.6	
	mmol/l	1.23	0.984	1.48	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	20.7	16.5	24.9	
	mmol/l	1.23	0.984	1.48	Uricase peroxidase with ascorbate oxidase
	mg/dl	20.7	16.5	24.9	
Vanillylmandelic Acid (VMA)	µmol/l	163	130	196	Column test
	µmol/l	143	114	172	HPLC

**ADDITIONAL VALUES FOR
ASSAYED URINE CONTROL - LEVEL 3
(URN ASY CONTROL 3)
Cat No. AU2353
Lot No. 1216UC
GTIN: 05055273200546**

COMPONENTS	UNITS	TARGET	RANGE	METHOD
Microalbumin	mg/l	190	152 - 228	Vitros 5.1 FS/5600/ XT 7600 Microtip

EC REP Radox Teoranta, Meenmore,
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