



PRODUCT INFORMATION

AU2353

1272UC

Please note that while Copper is present in 1272UC – Assayed Urine Control Level 3, targets and ranges are not provided for this analyte.

CCS INC297

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

CAT. NO.	AU 2353	LOT NO.	I272UC
SIZE:	12 x 10 ml	EXPIRY:	2027-04-28
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.

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.

EC	REP
----	-----

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

Rev. 10 Aug '23 me

ASSAYED URINE CONTROL LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot. No. 1272UC Size 12 x 10 ml Expiry 2027-04-28

Range					
Analyte	unit	Target	low	high	methods
5-HIAA	μmol/l	264	211	317	HPLC
Amylase	U/l	446	357	535	Vitros
	U/l	984	787	1181	Siemens - blocked pNPG7
	U/l	982	786	1178	Randox Liquid Ethylidene pNPG7
	U/l	807	646	968	Roche liquid pNPG7
	U/l	840	672	1008	Roche Integra 2-chloro-pNPG7
	U/l	935	748	1122	Beckman Coulter - blocked pNPG7
	U/l	996	797	1195	Other 2-chloro-pNPG3
	U/l	1014	811	1217	Abbott Architect / Alinity cal factor 3431
	U/l	1040	832	1248	Abbott Architect / Alinity cal factor 3806
Calcium	mmol/l	3.39	3.05	3.73	Vitros
	mg/dl	13.6	12.2	15.0	
	mmol/l	4.66	4.19	5.13	Cresolphthalein complexone
	mg/dl	18.7	16.8	20.6	
	mmol/l	4.14	3.73	4.55	Arsenazo III
	mg/dl	16.6	14.9	18.3	
Chloride	mmol/l	4.48	4.03	4.93	NM-BAPTA
	mg/dl	18.0	16.2	19.8	
	mmol/l	246	209	283	Vitros
Cortisol	mmol/l	253	215	291	ISE indirect
	mmol/l	248	211	285	ISE direct
	nmol/l	260	195	325	Chemiluminescence (+ solvent extraction.)
Creatinine	μg/dl	9.36	7.02	11.7	
	nmol/l	239	179	299	Chemiluminescence (direct)
	μg/dl	8.60	6.44	10.8	
Creatinine	mmol/l	14.9	11.9	17.9	Alkaline picrate no deproteinization
	mg/dl	168	134	202	
	mmol/l	15.3	12.2	18.4	Creatinine PAP method
	mg/dl	173	138	208	
	mmol/l	15.4	12.3	18.5	Enzymatic UV method
	mg/dl	174	139	209	
	mmol/l	15.3	12.2	18.4	Other enzymatic methods
	mg/dl	173	138	208	
	mmol/l	15.8	12.6	19.0	Roche Creatinine Plus
	mg/dl	179	142	216	
	mmol/l	15.0	12.0	18.0	Jaffe rate blanked
	mg/dl	170	136	204	
	mmol/l	15.1	12.1	18.1	Jaffe rate blanked comp. (-26 μmol/l)
	mg/dl	171	137	205	
	mmol/l	15.1	12.1	18.1	Vitros IDMS Traceable
	mg/dl	171	137	205	
	mmol/l	15.3	12.2	18.4	Jaffe rate blanked compensated (-18 μmol/l)
	mg/dl	173	138	208	

ASSAYED URINE CONTROL LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot. No. 1272UC Size 12 x 10 ml Expiry 2027-04-28

Range					
Analyte	unit	Target	low	high	methods
Dopamine	nmol/l	1635	1308	1962	HPLC
Epinephrine	nmol/l	299	239	359	HPLC
Glucose	mmol/l	14.8	11.8	17.8	Vitros
	mg/dl	267	213	321	
	mmol/l	14.1	11.3	16.9	Glucose oxidase
	mg/dl	254	204	304	
	mmol/l	14.4	11.5	17.3	Hexokinase
	mg/dl	259	207	311	
Magnesium	mmol/l	12.9	10.3	15.5	Vitros
	mg/dl	31.3	25.0	37.6	
	mmol/l	12.9	10.3	15.5	Xylidyl Blue
	mg/dl	31.3	25.0	37.6	
	mmol/l	12.9	10.3	15.5	Arsenazo III
	mg/dl	31.3	25.0	37.6	
	mmol/l	13.3	10.6	16.0	Chlorphosphonazo III
	mg/dl	32.3	25.8	38.8	
Metanephrine	mmol/l	12.9	10.3	15.5	Enzymatic
	mg/dl	31.3	25.0	37.6	
Metanephrine	μmol/l	2.68	2.14	3.22	HPLC
Microalbumin	mg/l	187	150	224	Immunoturbidimetric
	mg/l	197	158	236	Nephelometric
Norepinephrine	nmol/l	1394	1115	1673	HPLC
Normetanephrine	μmol/l	4.19	3.35	5.03	HPLC
Osmolality	mOsm/kg	1124	899	1349	Freezing point depression
	mOsm/kg	1063	850	1276	Calculated
Oxalate	mmol/l	0.430	0.344	0.516	Oxalate oxidase
Phosphate Inorganic	mmol/l	28.4	22.7	34.1	Vitros
	mg/dl	88.0	70.4	106	
	mmol/l	26.7	21.4	32.0	Phosphomolybdate UV
	mg/dl	82.8	66.3	99.3	
	mmol/l	27.0	21.6	32.4	Phosphomolybdate enzymatic
	mg/dl	83.7	67.0	100	
Potassium	mmol/l	135	115	155	Vitros
	mmol/l	129	110	148	ISE direct
	mmol/l	123	105	141	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	
	g/l	0.241	0.193	0.289	Turbidimetry
	mg/dl	24.1	19.3	28.9	
	mg/l	241	193	289	
	g/l	0.278	0.222	0.334	Pyrogallol Red
	mg/dl	27.8	22.2	33.4	
	mg/l	278	222	334	
	g/l	0.101	0.081	0.121	Vitros
	mg/dl	10.1	8.10	12.1	
	mg/l	101	81.0	121	

ASSAYED URINE CONTROL LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot. No. 1272UC Size 12 x 10 ml Expiry 2027-04-28

Range					
Analyte	unit	Target	low	high	methods
Sodium	mmol/l	222	195	249	Vitros
	mmol/l	201	177	225	ISE direct
	mmol/l	202	178	226	ISE indirect
Urea	mmol/l	422	338	506	Vitros
	mg/dl	2536	2031	3041	
	mmol/l	426	341	511	Urease kinetic
	mg/dl	2560	2049	3071	
	mmol/l	429	343	515	Urease end point
	mg/dl	2578	2061	3095	
Uric Acid (Urate)	mmol/l	1.26	1.01	1.51	Ortho Vitros Microslide Systems
	mg/dl	21.2	17.0	25.4	
	mmol/l	1.25	1.00	1.50	Uricase peroxidase no ascorbate oxidase
	mg/dl	21.0	16.8	25.2	
	mmol/l	1.22	0.976	1.46	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	20.5	16.4	24.6	
	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	154	123	185	Column test
	µmol/l	147	118	176	HPLC