



PRODUCT INFORMATION

AU2352

1072UC

Please note that while Copper is present in 1072UC – Assayed Urine Control Level 2, targets and ranges are not provided for this analyte.

CCS6424

ASSAYED URINE CONTROL - LEVEL 2 (URN ASY CONTROL 2)

CAT. NO. AU 2352 **LOT NO.** 1072UC
SIZE: 12 x 10 ml **EXPIRY:** 2023-10-28
GTIN: 05055273200539

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-Hydroxyindoleacetic 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 2 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. 07 Feb '23 me

ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352 Lot. No. 1072UC Size 12 x 10 ml Expiry 2023-10-28

Range					
Analyte	unit	Target	low	high	methods
5-HIAA	μmol/l	29.3	23.4	35.2	HPLC
Amylase	U/l	124	99.0	149	Vitros
	U/l	227	182	272	Siemens - blocked pNPG7
	U/l	234	187	281	Other blocked pNPG7
	U/l	250	200	300	Randox Liquid Ethylidene pNPG7
	U/l	210	168	252	Roche liquid pNPG7
	U/l	242	194	290	Beckman Synchron CX4/CX5/CX7
	U/l	216	173	259	Roche Integra 2-chloro-pNPG7
	U/l	232	186	278	Beckman Coulter - blocked pNPG7
	U/l	264	211	317	Siemens 2-chloro-pNPG3
	U/l	250	200	300	Other 2-chloro-pNPG3
	U/l	254	203	305	Abbott Architect Non-IFCC Cal.
	U/l	273	218	328	Abbott Architect IFCC Cal.
Calcium	mmol/l	1.64	1.48	1.80	Vitros
	mg/dl	6.57	5.93	7.21	
	mmol/l	1.55	1.40	1.71	Cresolphthalein complexone
	mg/dl	6.21	5.61	6.81	
	mmol/l	1.47	1.32	1.62	Ion selective electrode
	mg/dl	5.89	5.29	6.49	
	mmol/l	1.52	1.37	1.67	Arsenazo III
	mg/dl	6.09	5.49	6.69	
	mmol/l	1.53	1.38	1.68	NM-BAPTA
	mg/dl	6.13	5.53	6.73	
Chloride	mmol/l	84.3	71.7	96.9	Vitros
	mmol/l	80.8	68.7	92.9	ISE indirect
	mmol/l	81.5	69.3	93.7	ISE direct
Cortisol	nmol/l	163	122	204	Chemiluminescence (+ solvent extraction.)
	μg/dl	5.87	4.39	7.35	
	nmol/l	169	127	211	Chemiluminescence (direct)
	μg/dl	6.08	4.57	7.59	
Creatinine	mmol/l	6.65	5.32	7.98	Alkaline picrate no deproteinization
	mg/dl	75.1	60.1	90.1	
	mmol/l	6.97	5.58	8.36	Creatinine PAP method
	mg/dl	78.8	63.1	94.5	
	mmol/l	6.86	5.49	8.23	Enzymatic UV method
	mg/dl	77.5	62.0	93.0	
	mmol/l	6.91	5.53	8.29	Other enzymatic methods
	mg/dl	78.1	62.5	93.7	
	mmol/l	7.16	5.73	8.59	Roche Creatinine Plus
	mg/dl	80.9	64.7	97.1	
	mmol/l	6.76	5.41	8.11	Jaffe rate blanked
	mg/dl	76.4	61.1	91.7	

ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352 Lot. No. 1072UC Size 12 x 10 ml Expiry 2023-10-28

Range					
Analyte	unit	Target	low	high	methods
Creatinine	mmol/l	6.77	5.42	8.12	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	76.5	61.2	91.8	
	mmol/l	6.82	5.46	8.18	Vitros IDMS Traceable
	mg/dl	77.1	61.7	92.5	
	mmol/l	6.84	5.47	8.21	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	77.3	61.8	92.8	
Dopamine	nmol/l	493	394	592	HPLC
Epinephrine	nmol/l	60.5	48.4	72.6	HPLC
Glucose	mmol/l	2.61	2.09	3.13	Vitros
	mg/dl	47.0	37.7	56.3	
	mmol/l	2.73	2.18	3.28	Glucose oxidase
	mg/dl	49.2	39.3	59.1	
	mmol/l	2.77	2.22	3.32	Hexokinase
	mg/dl	49.9	40.0	59.8	
	mmol/l	2.78	2.22	3.34	Glucose dehydrogenase
	mg/dl	50.1	40.0	60.2	
	mmol/l	3.37	2.70	4.04	Vitros
	mg/dl	8.19	6.56	9.82	
Magnesium	mmol/l	3.04	2.43	3.65	Xylidyl Blue
	mg/dl	7.39	5.90	8.88	
	mmol/l	3.07	2.46	3.68	Arsenazo III
	mg/dl	7.46	5.98	8.94	
	mmol/l	2.97	2.38	3.56	Chlorphosphonazo III
	mg/dl	7.22	5.78	8.66	
	mmol/l	3.11	2.49	3.73	Methylthymol blue
	mg/dl	7.56	6.05	9.07	
	mmol/l	3.08	2.46	3.70	Enzymatic
	mg/dl	7.48	5.98	8.98	
Metanephrine	µmol/l	0.213	0.170	0.256	HPLC
Microalbumin	mg/l	32.4	25.9	38.9	Immunoturbidimetric
	mg/l	35.0	28.0	42.0	Nephelometric
Norepinephrine	nmol/l	221	177	265	HPLC
Normetanephrine	µmol/l	1.08	0.864	1.30	HPLC
Osmolality	mOsm/kg	387	310	464	Freezing point depression
	mOsm/kg	334	267	401	Calculated
Oxalate	mmol/l	0.115	0.092	0.138	Oxalate oxidase
Phosphate Inorganic	mmol/l	9.79	7.83	11.7	Vitros
	mg/dl	30.3	24.3	36.3	
	mmol/l	8.70	6.96	10.4	Phosphomolybdate UV
	mg/dl	27.0	21.6	32.4	
	mmol/l	8.72	6.98	10.5	Phosphomolybdate enzymatic
	mg/dl	27.0	21.6	32.4	
Potassium	mmol/l	31.0	26.4	35.7	Vitros
	mmol/l	31.3	26.6	36.0	ISE direct
	mmol/l	30.1	25.6	34.6	ISE indirect
Protein Total	g/l	0.124	0.099	0.149	Biuret reaction - direct
	mg/dl	12.4	9.90	14.9	
	mg/l	124	99.0	149	

ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352 Lot. No. 1072UC Size 12 x 10 ml Expiry 2023-10-28

Range					
Analyte	unit	Target	low	high	methods
Protein Total	g/l	0.107	0.086	0.128	Turbidimetry
	mg/dl	10.7	8.60	12.8	
	mg/l	107	86.0	128	
	g/l	0.139	0.111	0.167	Pyrogallol Red
	mg/dl	13.9	11.1	16.7	
	mg/l	139	111	167	
	g/l	0.197	0.158	0.236	Vitros
	mg/dl	19.7	15.8	23.6	
	mg/l	197	158	236	
Sodium	mmol/l	65.0	57.2	72.8	Vitros
	mmol/l	65.0	57.2	72.8	ISE direct
	mmol/l	61.3	53.9	68.7	ISE indirect
Urea	mmol/l	154	123	185	Vitros
	mg/dl	926	739	1113	
	mmol/l	149	119	179	Urease kinetic
	mg/dl	895	715	1075	
	mmol/l	149	119	179	Urease end point
Uric Acid (Urate)	mmol/l	0.852	0.682	1.02	Ortho Vitros Microslide Systems
	mg/dl	14.3	11.5	17.1	
	mmol/l	0.777	0.622	0.932	Uricase catalase 340nm
	mg/dl	13.1	10.4	15.8	
	mmol/l	0.770	0.616	0.924	Uricase peroxidase no ascorbate oxidase
	mg/dl	12.9	10.3	15.5	
	mmol/l	0.772	0.618	0.926	Spectrophotometric at 280-290
	mg/dl	13.0	10.4	15.6	
	mmol/l	0.724	0.579	0.869	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	12.2	9.73	14.7	
	mmol/l	0.754	0.603	0.905	Uricase peroxidase with ascorbate oxidase
	mg/dl	12.7	10.1	15.3	
Vanillylmandelic Acid (VMA)	µmol/l	27.9	22.3	33.5	Column test
	µmol/l	31.1	24.9	37.3	HPLC