

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.	I072UC
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, 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. 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 is 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):

This analyte is also unstable in reconstituted 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 2 12 x 10 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

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.

29 Apr 20 pl

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	
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

Analyte	unit	Target	Range		methods
			low	high	
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	
Magnesium	mmol/l	3.37	2.70	4.04	Vitros
	mg/dl	8.19	6.56	9.82	
	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	

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

Analyte	unit	Target	Range		methods		
			low	high			
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			
	Sodium	g/l	0.139	0.111	0.167	Pyrogallol Red	
		mg/dl	13.9	11.1	16.7		
		mg/l	139	111	167		
		Urea	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			
	Uric Acid (Urate)	mmol/l	149	119	179	Urease kinetic	
		mg/dl	895	715	1075		
	Uric Acid (Urate)	mmol/l	149	119	179	Urease end point	
		mg/dl	895	715	1075		
		Uric Acid (Urate)	mmol/l	0.852	0.682	1.02	Ortho Vitros Microslide Systems
			mg/dl	14.3	11.5	17.1	
Uric Acid (Urate)		mmol/l	0.777	0.622	0.932	Uricase catalase 340nm	
		mg/dl	13.1	10.4	15.8		
Uric Acid (Urate)		mmol/l	0.770	0.616	0.924	Uricase peroxidase no ascorbate oxidase	
		mg/dl	12.9	10.3	15.5		
Uric Acid (Urate)	mmol/l	0.772	0.618	0.926	Spectrophotometric at 280-290		
	mg/dl	13.0	10.4	15.6			
Uric Acid (Urate)	mmol/l	0.724	0.579	0.869	Uricase Peroxidase with ascorbate oxidase @ 546nm		
	mg/dl	12.2	9.73	14.7			
Uric Acid (Urate)	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		