PRODUCT INFORMATION

AU2352

1248UC

Please note that while Copper is present in 1248UC – Assayed Urine Control Level 2, targets and ranges are not provided for this analyte.

INC1995

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

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

CAT. NO. AU 2352 **LOT NO.** 1248UC

SIZE: 12 x 10 ml **EXPIRY:** 2026-11-28

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 ± 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. 05 May '23 me

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ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU 2352 Lot. No. 1248UC Size 12 x 10ml Expiry 2026-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
5-HIAA	µmol/l	30.8	24.6	37.0	HPLC
Amylase	U/l	121	96.8	145	Vitros
	U/l	236	189	283	Siemens - blocked pNPG7
	U/l	226	181	271	Randox Liquid Ethylidene pNPG7
	U/l	198	158	238	Roche liquid pNPG7
	U/l	202	162	242	Roche Integra 2-chloro-pNPG7
	U/l	219	175	263	Beckman Coulter - blocked pNPG7
	U/l	261	209	313	Siemens 2-chloro-pNPG3
	U/l	243	194	292	Other 2-chloro-pNPG3
	U/l	244	195	293	Abbott Architect / Alinity cal factor 3431
	U/l	249	199	299	Abbott Architect / Alinity cal factor 3806
Calcium	mmol/l	1.65	1.49	1.82	Vitros
	mg/dl	6.61	5.97	7.25	
	mmol/l	1.59	1.43	1.75	Cresolphthalein complexone
	mg/dl	6.37	5.73	7.01	
	mmol/l	1.56	1.40	1.72	Arsenazo III
	mg/dl	6.25	5.61	6.89	
	mmol/l	1.59	1.43	1.75	NM-BAPTA
	mg/dl	6.37	5.73	7.01	
Chloride	mmol/l	81.6	69.4	93.8	Vitros
	mmol/l	79.5	67.6	91.4	ISE indirect
	mmol/l	77.2	65.6	88.8	ISE direct
Cortisol	nmol/l	108	81.0	135	Chemiluminescence (+ solvent extraction.)
	µg/dl	3.89	2.92	4.86	
	nmol/l	104	78.0	130	Chemiluminescence (direct)
	µg/dl	3.74	2.81	4.67	
Creatinine	mmol/l	6.74	5.39	8.09	Alkaline picrate no deproteinization
	mg/dl	76.2	60.9	91.5	
	mmol/l	7.13	5.70	8.56	Creatinine PAP method
	mg/dl	80.6	64.4	96.8	
	mmol/l	7.05	5.64	8.46	Enzymatic UV method
	mg/dl	79.7	63.7	95.7	
	mmol/l	7.03	5.62	8.44	Other enzymatic methods
	mg/dl	79.4	63.5	95.3	
	mmol/l	7.30	5.84	8.76	Roche Creatinine Plus
	mg/dl	82.5	66.0	99.0	
	mmol/l	6.70	5.36	8.04	Jaffe rate blanked
	mg/dl	75.7	60.6	90.8	
	mmol/l	6.87	5.50	8.24	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	77.6	62.2	93.0	
	mmol/l	6.93	5.54	8.32	Vitros IDMS Traceable
	mg/dl	78.3	62.6	94.0	

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ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU 2352 Lot. No. 1248UC Size 12 x 10ml Expiry 2026-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Creatinine	mmol/l	7.12	5.70	8.54	IDMS traceable
	mg/dl	80.5	64.4	96.6	
	mmol/l	6.83	5.46	8.20	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	77.2	61.7	92.7	
Dopamine	nmol/l	570	456	684	HPLC
Epinephrine	nmol/l	71.8	57.4	86.2	HPLC
Glucose	mmol/l	2.55	2.17	2.93	Vitros
	mg/dl	46.0	39.1	52.9	
	mmol/l	2.76	2.35	3.17	Glucose oxidase
	mg/dl	49.7	42.3	57.1	
	mmol/l	2.72	2.31	3.13	Hexokinase
	mg/dl	49.0	41.6	56.4	
Magnesium	mmol/l	3.75	3.30	4.20	Vitros
	mg/dl	9.11	8.02	10.2	
	mmol/l	3.06	2.69	3.43	Xylidyl Blue
	mg/dl	7.44	6.54	8.34	
	mmol/l	3.11	2.74	3.48	Arsenazo III
	mg/dl	7.56	6.66	8.46	
	mmol/l	3.11	2.74	3.48	Chlorphosphonazo III
	mg/dl	7.56	6.66	8.46	
	mmol/l	3.16	2.78	3.54	Methylthymol blue
	mg/dl	7.68	6.76	8.60	
	mmol/l	3.16	2.78	3.54	Enzymatic
	mg/dl	7.68	6.76	8.60	
Metanephrine	µmol/l	0.234	0.187	0.281	HPLC
Microalbumin	mg/l	32.4	25.9	38.9	Immunoturbidimetric
Norepinephrine	nmol/l	240	192	288	HPLC
Normetanephrine	µmol/l	1.16	0.928	1.39	HPLC
Osmolality	mOsm/kg	439	351	527	Freezing point depression
	mOsm/kg	343	274	412	Calculated
Oxalate	mmol/l	0.090	0.072	0.108	Oxalate oxidase
Phosphate Inorganic	mmol/l	10.4	8.84	12.0	Vitros
	mg/dl	32.2	27.4	37.0	
	mmol/l	9.11	7.74	10.5	Phosphomolybdate UV
	mg/dl	28.2	24.0	32.4	
	mmol/l	9.41	8.00	10.8	Phosphomolybdate enzymatic
	mg/dl	29.2	24.8	33.6	
Potassium	mmol/l	30.9	26.3	35.5	Vitros
	mmol/l	31.7	26.9	36.5	ISE direct
	mmol/l	30.1	25.6	34.6	ISE indirect
Protein Total	g/l	0.130	0.104	0.156	Biuret reaction - direct
	mg/dl	13.0	10.4	15.6	
	mg/l	130	104	156	
	g/l	0.110	0.088	0.132	Turbidimetry
	mg/dl	11.0	8.80	13.2	
	mg/l	110	88.0	132	

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Cat. No. AU 2352 Lot. No. 1248UC Size 12 x 10ml Expiry 2026-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Protein Total	g/l	0.170	0.136	0.204	Pyrogallol Red
	mg/dl	17.0	13.6	20.4	
	mg/l	170	136	204	
	g/l	0.200	0.160	0.240	Vitros
	mg/dl	20.0	16.0	24.0	
	mg/l	200	160	240	
	g/l	0.230	0.184	0.276	Siemens UCFP Reagent
	mg/dl	23.0	18.4	27.6	
	mg/l	230	184	276	
Sodium	mmol/l	66.0	58.1	73.9	Vitros
	mmol/l	63.4	55.8	71.0	ISE direct
	mmol/l	62.7	55.2	70.2	ISE indirect
Urea	mmol/l	152	129	175	Vitros
	mg/dl	914	775	1053	
	mmol/l	156	133	179	Urease kinetic
	mg/dl	938	799	1077	
	mmol/l	156	133	179	Urease end point
	mg/dl	938	799	1077	
Uric Acid (Urate)	mmol/l	0.750	0.653	0.848	Ortho Vitros Microslide Systems
	mg/dl	12.6	11.0	14.2	
	mmol/l	0.740	0.644	0.836	Uricase peroxidase no ascorbate oxidase
	mg/dl	12.4	10.8	14.0	
	mmol/l	0.780	0.679	0.881	Spectrophotometric at 280-290
	mg/dl	13.1	11.4	14.8	
	mmol/l	0.710	0.618	0.802	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	11.9	10.4	13.4	
	mmol/l	0.720	0.626	0.814	Uricase peroxidase with ascorbate oxidase
	mg/dl	12.1	10.5	13.7	
Vanillylmandelic Acid (VMA)	µmol/l	31.1	24.9	37.3	Column test
	µmol/l	28.1	22.5	33.7	HPLC

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