

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

CAT. NO. AU 2352 **LOT NO.** 792UC
SIZE: 12 x 10 ml **EXPIRY:** 2019-03

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. 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.

07 Sep '15 ne

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

Cat. No. AU2352 Lot No. 792UC Size: 12 x 10 ml Expiry: 2019-03

Range					
Analyte	unit	Target	low	high	methods
5-HIAA	μmol/l	34.8	27.8	41.8	Colorimetric (nitrosonaphthol)
	μmol/l	28.4	22.7	34.1	HPLC
Amylase	U/l	125	100	150	Vitros
	U/l	224	179	269	Siemens - blocked pNPG7
	U/l	229	183	275	Other blocked pNPG7
	U/l	259	207	311	Randox liquid pNPG7
	U/l	212	170	254	Roche liquid pNPG7
	U/l	211	169	253	BM/Roche Colorimetric pNPG7
	U/l	245	196	294	Beckman Synchron CX4/CX5/CX7
	U/l	213	170	256	Roche Integra 2-chloro-pNPG7
	U/l	228	182	274	Beckman Olympus - blocked pNPG7
	U/l	280	224	336	Siemens 2-chloro-pNPG3
	U/l	259	207	311	Other 2-chloro-pNPG3
Calcium	mmol/l	1.66	1.49	1.83	Vitros
	mg/dl	6.65	5.97	7.33	
	mmol/l	1.56	1.40	1.72	Cresolphthalein complexone
	mg/dl	6.25	5.61	6.89	
	mmol/l	1.57	1.41	1.73	Ion selective electrode
	mg/dl	6.29	5.65	6.93	
	mmol/l	1.57	1.41	1.73	Arsenazo III
	mg/dl	6.29	5.65	6.93	
Chloride	mmol/l	84.3	71.7	96.9	Vitros
	mmol/l	83.2	70.7	95.7	ISE indirect
	mmol/l	81.8	69.5	94.1	ISE direct
Copper	μmol/l	1.19	0.952	1.43	Atomic absorption
	μg/dl	7.57	6.05	9.09	
Cortisol	nmol/l	22.6	17.0	28.3	Chemiluminescence (+ solvent extraction.)
	μg/dl	0.814	0.612	1.02	
	nmol/l	40.0	30.0	50.0	Enzyme immunoassay (direct)
	μg/dl	1.44	1.08	1.80	
Creatinine	mmol/l	6.94	5.55	8.33	Alkaline picrate no deproteinization
	mg/dl	78.4	62.7	94.1	
	mmol/l	7.19	5.75	8.63	Creatinine PAP method
	mg/dl	81.2	65.0	97.4	
	mmol/l	7.12	5.70	8.54	Randox Enzymatic UV method
	mg/dl	80.5	64.4	96.6	
	mmol/l	7.03	5.62	8.44	Other enzymatic methods
	mg/dl	79.4	63.5	95.3	
	mmol/l	7.34	5.87	8.81	Roche Creatinine Plus
	mg/dl	82.9	66.3	100	

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

Cat. No. AU2352 Lot No. 792UC Size: 12 x 10 ml Expiry: 2019-03

Range					
Analyte	unit	Target	low	high	methods
Creatinine	mmol/l	6.93	5.54	8.32	Jaffe rate blanked
	mg/dl	78.3	62.6	94.0	
	mmol/l	6.91	5.53	8.29	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	78.1	62.5	93.7	
	mmol/l	7.03	5.62	8.44	Vitros IDMS Traceable
	mg/dl	79.4	63.5	95.3	
	mmol/l	6.78	5.42	8.14	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	76.6	61.2	92.0	
Dopamine	nmol/l	563	450	676	HPLC
Epinephrine	nmol/l	70.8	56.6	85.0	HPLC
Glucose	mmol/l	2.57	2.06	3.08	Vitros
	mg/dl	46.3	37.1	55.5	
	mmol/l	2.69	2.15	3.23	Glucose oxidase
	mg/dl	48.5	38.7	58.3	
	mmol/l	2.77	2.22	3.32	Hexokinase
	mg/dl	49.9	40.0	59.8	
	mmol/l	2.75	2.20	3.30	Oxygen electrode
	mg/dl	49.6	39.6	59.6	
Magnesium	mmol/l	3.24	2.59	3.89	Vitros
	mg/dl	7.87	6.29	9.45	
	mmol/l	3.02	2.42	3.62	Calmagite
	mg/dl	7.34	5.88	8.80	
	mmol/l	3.15	2.52	3.78	Xylidyl Blue
	mg/dl	7.65	6.12	9.18	
	mmol/l	3.21	2.57	3.85	Arsenazo III
	mg/dl	7.80	6.25	9.35	
	mmol/l	3.08	2.46	3.70	Chlorphosphonazo III
	mg/dl	7.48	5.98	8.98	
	mmol/l	3.22	2.58	3.86	Methylthymol blue
	mg/dl	7.82	6.27	9.37	
	mmol/l	3.12	2.50	3.74	Enzymatic
	mg/dl	7.58	6.08	9.08	
Metanephrine	µmol/l	0.298	0.238	0.358	HPLC
Microalbumin	mg/l	28.6	22.9	34.3	Immunoturbidimetric
	mg/l	30.0	24.0	36.0	Nephelometric
Norepinephrine	nmol/l	235	188	282	HPLC
Normetanephrine	µmol/l	1.15	0.920	1.38	HPLC
Osmolality	mOsm/kg	396	317	475	Freezing point depression
	mOsm/kg	382	306	458	Vapour pressure
	mOsm/kg	350	280	420	Calculated
Oxalate	mmol/l	0.101	0.081	0.121	Oxalate oxidase
Phosphate Inorganic	mmol/l	9.99	7.99	12.0	Vitros
	mg/dl	31.0	24.8	37.2	
	mmol/l	8.68	6.94	10.4	Phosphomolybdate UV
	mg/dl	26.9	21.5	32.3	
	mmol/l	8.70	6.96	10.4	Phosphomolybdate enzymatic
	mg/dl	27.0	21.6	32.4	

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

Cat. No. AU2352 Lot No. 792UC Size: 12 x 10 ml Expiry: 2019-03

Range					
Analyte	unit	Target	low	high	methods
Potassium	mmol/l	31.2	26.5	35.9	Vitros
	mmol/l	30.3	25.8	34.8	ISE direct
	mmol/l	30.0	25.5	34.5	ISE indirect
Protein Total	g/l	0.116	0.093	0.139	Biuret reaction - direct
	mg/dl	11.6	9.30	13.9	
	mg/l	116	93.0	139	
	g/l	0.102	0.082	0.122	Turbidimetry
	mg/dl	10.2	8.20	12.2	
	mg/l	102	82.0	122	
	g/l	0.122	0.085	0.159	Pyrogallol Red
	mg/dl	12.2	8.54	15.9	
	mg/l	122	85.4	159	
	g/l	0.130	0.104	0.156	Vitros
	mg/dl	13.0	10.4	15.6	
	mg/l	130	104	156	
Sodium	mmol/l	72.0	63.4	80.6	Vitros
	mmol/l	67.8	59.7	75.9	ISE direct
	mmol/l	64.3	56.6	72.0	ISE indirect
Urea	mmol/l	154	123	185	Vitros
	mg/dl	926	739	1113	
	mmol/l	159	127	191	Beckman-Conductivity
	mg/dl	956	763	1149	
	mmol/l	156	125	187	Urease kinetic
	mg/dl	938	751	1125	
	mmol/l	159	127	191	Urease end point
	mg/dl	956	763	1149	
	mmol/l	0.705	0.564	0.846	Ortho Vitros Microslide Systems
	mg/dl	11.8	9.48	14.1	
Uric Acid (Urate)	mmol/l	0.723	0.578	0.868	Uricase peroxidase no ascorbate oxidase
	mg/dl	12.1	9.71	14.5	
	mmol/l	0.747	0.598	0.896	Spectrophotometric at 280-290
	mg/dl	12.5	10.0	15.0	
	mmol/l	0.678	0.542	0.814	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	11.4	9.11	13.7	
	mmol/l	0.702	0.562	0.842	Uricase peroxidase with ascorbate oxidase
	mg/dl	11.8	9.44	14.2	
Vanillylmandelic Acid (VMA)	µmol/l	26.7	21.4	32.0	Column test
	µmol/l	28.3	22.6	34.0	HPLC