

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

CAT. NO. AU 2353 **LOT NO.** 981UC
SIZE: 12 x 10 ml **EXPIRY:** 2022-04-28
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. 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 be 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 3 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.

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Cat. No. AU2353 Lot No. 981UC Size: 12 x 10 ml Expiry: 2022-04-28

Range					
Analyte	unit	Target	low	high	methods
5-HIAA	µmol/l	301	241	361	HPLC
Amylase	U/l	438	350	526	Vitros
	U/l	834	667	1001	Siemens - blocked pNPG7
	U/l	858	686	1030	Other blocked pNPG7
	U/l	928	742	1114	Randox Liquid Ethylidene pNPG7
	U/l	757	606	908	Roche liquid pNPG7
	U/l	781	625	937	BM/Roche Colorimetric pNPG7
	U/l	850	680	1020	Beckman Synchron CX4/CX5/CX7
	U/l	788	630	946	Roche Integra 2-chloro-pNPG7
	U/l	877	702	1052	Beckman Coulter - blocked pNPG7
	U/l	1065	852	1278	Siemens 2-chloro-pNPG3
	U/l	966	773	1159	Other 2-chloro-pNPG3
	U/l	970	776	1164	Abbott Architect Non-IFCC Cal.
	U/l	1078	862	1294	Abbott Architect IFCC Cal.
Calcium	mmol/l	3.89	3.50	4.28	Vitros
	mg/dl	15.6	14.0	17.2	
	mmol/l	5.11	4.60	5.62	Cresolphthalein complexone
	mg/dl	20.5	18.4	22.6	
	mmol/l	3.60	3.24	3.96	Ion selective electrode
	mg/dl	14.4	13.0	15.8	
	mmol/l	4.65	4.19	5.12	Arsenazo III
	mg/dl	18.6	16.8	20.4	
mmol/l	4.95	4.46	5.45	NM-BAPTA	
mg/dl	19.8	17.9	21.7		
Chloride	mmol/l	271	230	312	ISE indirect
	mmol/l	267	227	307	ISE direct
Copper	µmol/l	3.73	2.98	4.48	Atomic absorption
	µg/dl	23.7	19.0	28.4	
Cortisol	nmol/l	271	203	339	Chemiluminescence (+ solvent extraction.)
	µg/dl	9.76	7.31	12.2	
	nmol/l	291	218	364	Chemiluminescence (direct)
	µg/dl	10.5	7.85	13.2	
Creatinine	mmol/l	16.1	12.9	19.3	Alkaline picrate no deproteinization
	mg/dl	182	146	218	
	mmol/l	16.0	12.8	19.2	Creatinine PAP method
	mg/dl	181	145	217	
	mmol/l	16.6	13.3	19.9	Enzymatic UV method
	mg/dl	188	150	226	
	mmol/l	16.4	13.1	19.7	Other enzymatic methods
	mg/dl	185	148	222	
	mmol/l	16.8	13.4	20.2	Roche Creatinine Plus
	mg/dl	190	151	229	

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Analyte	unit	Target	Range		methods
			low	high	
Creatinine	mmol/l	16.5	13.2	19.8	Jaffe rate blanked
	mg/dl	186	149	223	
	mmol/l	16.0	12.8	19.2	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	181	145	217	
	mmol/l	16.2	13.0	19.4	Vitros IDMS Traceable
	mg/dl	183	147	219	
	mmol/l	16.7	13.4	20.0	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	189	151	227	
Dopamine	nmol/l	2081	1665	2497	HPLC
Epinephrine	nmol/l	329	263	395	HPLC
Glucose	mmol/l	15.7	12.6	18.8	Vitros
	mg/dl	283	227	339	
	mmol/l	15.1	12.1	18.1	Glucose oxidase
	mg/dl	272	218	326	
	mmol/l	15.3	12.2	18.4	Hexokinase
	mg/dl	276	220	332	
	mmol/l	15.7	12.6	18.8	Glucose dehydrogenase
	mg/dl	283	227	339	
Magnesium	mmol/l	13.5	10.8	16.2	Vitros
	mg/dl	32.8	26.2	39.4	
	mmol/l	13.3	10.6	16.0	Calmagite
	mg/dl	32.3	25.8	38.8	
	mmol/l	13.8	11.0	16.6	Xylidyl Blue
	mg/dl	33.5	26.7	40.3	
	mmol/l	13.3	10.6	16.0	Arsenazo III
	mg/dl	32.3	25.8	38.8	
	mmol/l	14.1	11.3	16.9	Chlorphosphonazo III
	mg/dl	34.3	27.5	41.1	
	mmol/l	13.1	10.5	15.7	Methylthymol blue
	mg/dl	31.8	25.5	38.1	
	mmol/l	13.5	10.8	16.2	Enzymatic
	mg/dl	32.8	26.2	39.4	
Metanephrine	µmol/l	2.71	2.17	3.25	HPLC
Microalbumin	mg/l	191	153	229	Immunoturbidimetric
	mg/l	203	162	244	Nephelometric
Norepinephrine	nmol/l	1479	1183	1775	HPLC
Normetanephrine	µmol/l	4.03	3.22	4.84	HPLC
Osmolality	mOsm/kg	1124	899	1349	Freezing point depression
	mOsm/kg	1063	850	1276	Calculated
Oxalate	mmol/l	0.485	0.388	0.582	Oxalate oxidase
Phosphate Inorganic	mmol/l	29.4	23.5	35.3	Vitros
	mg/dl	91.1	72.9	109	
	mmol/l	27.6	22.1	33.1	Phosphomolybdate UV
	mg/dl	85.6	68.5	103	
	mmol/l	27.4	21.9	32.9	Phosphomolybdate enzymatic
	mg/dl	84.9	67.9	102	

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Range					
Analyte	unit	Target	low	high	methods
Potassium	mmol/l	138	117	159	Vitros
	mmol/l	130	111	150	ISE direct
	mmol/l	128	109	147	ISE indirect
Protein Total	g/l	0.244	0.195	0.293	Biuret reaction with ppt
	mg/dl	24.4	19.5	29.3	
	mg/l	244	195	293	
	g/l	0.275	0.220	0.330	Biuret reaction - direct
	mg/dl	27.5	22.0	33.0	
	mg/l	275	220	330	
	g/l	0.264	0.211	0.317	Turbidimetry
	mg/dl	26.4	21.1	31.7	
	mg/l	264	211	317	
	g/l	0.274	0.219	0.329	Pyrogallol Red
	mg/dl	27.4	21.9	32.9	
	mg/l	274	219	329	
g/l	0.111	0.089	0.133	Vitros	
mg/dl	11.1	8.90	13.3		
mg/l	111	89.0	133		
Sodium	mmol/l	219	193	245	Vitros
	mmol/l	207	182	232	ISE direct
	mmol/l	209	184	234	ISE indirect
Urea	mmol/l	448	358	538	Vitros
	mg/dl	2692	2152	3232	
	mmol/l	467	374	560	Beckman-Conductivity
	mg/dl	2807	2248	3366	
	mmol/l	448	358	538	Urease kinetic
	mg/dl	2692	2152	3232	
mmol/l	460	368	552	Urease end point	
mg/dl	2765	2212	3318		
Uric Acid (Urate)	mmol/l	1.34	1.07	1.61	Ortho Vitros Microslide Systems
	mg/dl	22.5	18.0	27.0	
	mmol/l	1.21	0.968	1.45	Uricase catalase 340nm
	mg/dl	20.3	16.3	24.3	
	mmol/l	1.30	1.04	1.56	Uricase peroxidase no ascorbate oxidase
	mg/dl	21.8	17.5	26.1	
	mmol/l	1.35	1.08	1.62	Spectrophotometric at 280-290
	mg/dl	22.7	18.1	27.3	
	mmol/l	1.26	1.01	1.51	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	21.2	17.0	25.4	
mmol/l	1.29	1.03	1.55	Uricase peroxidase with ascorbate oxidase	
mg/dl	21.7	17.3	26.1		
Vanillylmandelic Acid (VMA)	µmol/l	163	130	196	Column test
	µmol/l	151	121	181	HPLC