

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

CAT. NO. AU 2353 **LOT NO.** 1106UC
SIZE: 12 x 10 ml **EXPIRY:** 2024-03-28
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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Range					
Analyte	unit	Target	low	high	methods
5-HIAA	µmol/l	275	220	330	HPLC
Amylase	U/l	543	434	652	Vitros
	U/l	951	761	1141	Siemens - blocked pNPG7
	U/l	993	794	1192	Other blocked pNPG7
	U/l	1028	822	1234	Randox Liquid Ethylidene pNPG7
	U/l	849	679	1019	Roche liquid pNPG7
	U/l	975	780	1170	Beckman Synchron CX4/CX5/CX7
	U/l	1051	841	1261	Siemens - maltopenta/hexaoside
	U/l	881	705	1057	Roche Integra 2-chloro-pNPG7
	U/l	942	754	1130	Beckman Coulter - blocked pNPG7
	U/l	1131	905	1357	Siemens 2-chloro-pNPG3
	U/l	1028	822	1234	Other 2-chloro-pNPG3
	U/l	1047	838	1256	Abbott Architect Non-IFCC Cal.
	U/l	1149	919	1379	Abbott Architect IFCC Cal.
Calcium	mmol/l	3.55	3.20	3.91	Vitros
	mg/dl	14.2	12.8	15.6	
	mmol/l	4.73	4.26	5.20	Cresolphthalein complexone
	mg/dl	19.0	17.1	20.9	
	mmol/l	3.36	3.02	3.70	Ion selective electrode
	mg/dl	13.5	12.1	14.9	
	mmol/l	4.21	3.79	4.63	Arsenazo III
	mg/dl	16.9	15.2	18.6	
mmol/l	4.56	4.10	5.02	NM-BAPTA	
mg/dl	18.3	16.4	20.2		
Chloride	mmol/l	261	222	300	Vitros
	mmol/l	268	228	308	ISE indirect
	mmol/l	269	229	309	ISE direct
Copper	µmol/l	3.62	2.90	4.34	Atomic absorption
	µg/dl	23.0	18.4	27.6	
Cortisol	nmol/l	246	185	308	Chemiluminescence (+ solvent extraction.)
	µg/dl	8.86	6.66	11.1	
	nmol/l	272	204	340	Chemiluminescence (direct)
	µg/dl	9.79	7.34	12.2	
	nmol/l	328	246	410	
µg/dl	11.8	8.86	14.7	Enzyme immunoassay (direct)	
Creatinine	mmol/l	15.3	12.2	18.4	Alkaline picrate no deproteinization
	mg/dl	173	138	208	
	mmol/l	16.1	12.9	19.3	Creatinine PAP method
	mg/dl	182	146	218	
	mmol/l	15.7	12.6	18.8	Enzymatic UV method
	mg/dl	177	142	212	
	mmol/l	15.9	12.7	19.1	Other enzymatic methods
	mg/dl	180	144	216	

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Analyte	unit	Target	Range		methods
			low	high	
Creatinine	mmol/l	16.3	13.0	19.6	Roche Creatinine Plus
	mg/dl	184	147	221	
	mmol/l	15.8	12.6	19.0	Jaffe rate blanked
	mg/dl	179	142	216	
	mmol/l	15.3	12.2	18.4	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	173	138	208	
	mmol/l	15.9	12.7	19.1	Vitros IDMS Traceable
	mg/dl	180	144	216	
	mmol/l	16.0	12.8	19.2	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	181	145	217	
Dopamine	nmol/l	1652	1322	1982	HPLC
Epinephrine	nmol/l	271	217	325	HPLC
Glucose	mmol/l	15.5	12.4	18.6	Vitros
	mg/dl	279	223	335	
	mmol/l	14.9	11.9	17.9	Glucose oxidase
	mg/dl	268	214	322	
	mmol/l	15.0	12.0	18.0	Hexokinase
	mg/dl	270	216	324	
Magnesium	mmol/l	12.8	10.2	15.4	Vitros
	mg/dl	31.1	24.8	37.4	
	mmol/l	12.6	10.1	15.1	Calmagite
	mg/dl	30.6	24.5	36.7	
	mmol/l	12.7	10.2	15.2	Xylidyl Blue
	mg/dl	30.9	24.8	37.0	
	mmol/l	12.4	9.92	14.9	Arsenazo III
	mg/dl	30.1	24.1	36.1	
	mmol/l	13.2	10.6	15.8	Chlorphosphonazo III
	mg/dl	32.1	25.8	38.4	
	mmol/l	12.1	9.68	14.5	Methylthymol blue
	mg/dl	29.4	23.5	35.3	
	mmol/l	12.7	10.2	15.2	Enzymatic
	mg/dl	30.9	24.8	37.0	
Metanephrine	µmol/l	2.53	2.02	3.04	HPLC
	µmol/l	1.32	1.06	1.58	ELISA
Microalbumin	mg/l	176	141	211	Immunoturbidimetric
	mg/l	175	140	210	Nephelometric
Norepinephrine	nmol/l	1396	1117	1675	HPLC
Normetanephrine	µmol/l	4.21	3.37	5.05	HPLC
Osmolality	mOsm/kg	1107	886	1328	Freezing point depression
	mOsm/kg	1083	866	1300	Calculated
Oxalate	mmol/l	0.474	0.379	0.569	Oxalate oxidase
Phosphate Inorganic	mmol/l	29.2	23.4	35.0	Vitros
	mg/dl	90.5	72.5	109	
	mmol/l	26.6	21.3	31.9	Phosphomolybdate UV
	mg/dl	82.5	66.0	99.0	

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		Range			
Analyte	unit	Target	low	high	methods
Phosphate Inorganic	mmol/l	26.6	21.3	31.9	Phosphomolybdate enzymatic
	mg/dl	82.5	66.0	99.0	
Potassium	mmol/l	148	126	170	Vitros
	mmol/l	138	117	159	ISE direct
	mmol/l	133	113	153	ISE indirect
Protein Total	g/l	0.264	0.211	0.317	Biuret reaction - direct
	mg/dl	26.4	21.1	31.7	
	mg/l	264	211	317	
	g/l	0.230	0.184	0.276	Turbidimetry
	mg/dl	23.0	18.4	27.6	
	mg/l	230	184	276	
	g/l	0.262	0.210	0.314	Pyrogallol Red
	mg/dl	26.2	21.0	31.4	
	mg/l	262	210	314	
	g/l	0.115	0.092	0.138	Vitros
mg/dl	11.5	9.20	13.8		
mg/l	115	92.0	138		
Sodium	mmol/l	218	192	244	Vitros
	mmol/l	203	179	227	ISE direct
	mmol/l	203	179	227	ISE indirect
Urea	mmol/l	449	359	539	Vitros
	mg/dl	2698	2158	3238	Beckman-Conductivity
	mmol/l	446	357	535	
	mg/dl	2680	2146	3214	
	mmol/l	434	347	521	Urease kinetic
	mg/dl	2608	2085	3131	
Uric Acid (Urate)	mmol/l	1.37	1.10	1.64	Ortho Vitros Microslide Systems
	mg/dl	23.0	18.5	27.5	
	mmol/l	1.39	1.11	1.67	Uricase catalase 340nm
	mg/dl	23.4	18.6	28.2	
	mmol/l	1.36	1.09	1.63	Uricase peroxidase no ascorbate oxidase
	mg/dl	22.8	18.3	27.3	
	mmol/l	1.41	1.13	1.69	Spectrophotometric at 280-290
	mg/dl	23.7	19.0	28.4	
	mmol/l	1.33	1.06	1.60	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	22.3	17.8	26.8	
	mmol/l	1.35	1.08	1.62	Uricase peroxidase with ascorbate oxidase
	mg/dl	22.7	18.1	27.3	
Vanillylmandelic Acid (VMA)	µmol/l	144	115	173	Column test
	µmol/l	144	115	173	HPLC