

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

CAT. NO.	AU 2352	LOT NO.	1101UC
SIZE:	12 x 10 ml	EXPIRY:	2024-03-28
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 analytes listed in the table below.

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.

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.

- 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.
- Refer to the Control section of the individual analyser application.
- 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 reference laboratories for assignment.

定值尿液质控-水平 2 (URN ASY CONTROL 2)

货号. AU 2352 批号. I101UC

规格: 12 x 10 ml 效期: 2024-03-28

GTIN: 05055273200539

预期用途

本产品适用于临床生化尿液体外诊断的质量控制，作为定值质控监测靶值表中所列项目的准确性和重复性。

产品描述

定值尿液质控血清供应两种浓度，水平2和水平3，均提供各项的靶值和范围。

安全预防措施和警告

本产品仅用于体外诊断。禁止用口吸取。参照实验室对试剂的常规预防措施进行处理。

本产品采用人源基质，对所有人源均进行了 HIV (HIV1、HIV2) 抗体、肝炎 B 表面抗原 (HbsAg) 和肝炎 C 病毒 (HCV) 抗体的测试，结果均呈阴性。检测这些项目所采用的方法均经 FDA 认证。

但是无法完全保证避免传染物质，因此该产品和所有的病人样品均应当按照能够传播疾病的样品小心处理。

本产品可提供 Health and Safety Data Sheets。

保存和稳定性

开瓶: 冷藏 2~8°C 保存。复溶后的尿液质控在 15°C~25°C 稳定 8 小时，或可在 2~8°C 保存 5 天，或在 -20°C 保存 14 天。取用适当的样本量，用后请勿回收。

未开瓶: 冷藏 2~8 °C 可保存至效期末。

预处理

定值尿液质控为冻干粉。

1. 小心往瓶中准确加入 10 ml 蒸馏水，在 15~25 °C 的条件下复溶，盖上瓶盖，使用前放置 30 分钟。轻轻翻转瓶子，确保内容物完全溶解；不要振荡，避免气泡的产生。

2. 参照分析仪的质控说明部分。

3. 未使用的产品请冷藏或冷冻，再次使用前，确保样品充分混合均匀。

产品提供

定值尿液质控- 水平 2 12 x 10 ml

需要但未提供物质

定量移液管

赋值

各批次定值尿液质控均送至参考实验室测试。



Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

(S): 26 Jan 21 pl

ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352		Lot No. 1101UC		Size: 12 x 10ml		Expiry: 2024-03-28	
Analyte	unit	Target	Range		methods		
			low	high			
Amylase 淀粉酶	U/l	231	185	277	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C		
	U/l	233	186	279	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C		
	U/l	233	186	280	BS-430,BS-450,BS-460 37°C		
	U/l	231	185	277	BS-480,BS-490 37°C		
	U/l	234	187	281	BS-600,BS-620 37°C		
Calcium 钙	mmol/l	1.54	1.38	1.70	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890		
	mg/dl	6.18	5.55	6.80			
	mmol/l	1.68	1.51	1.85	BS-2000,BS-2200,BS-2000M,BS-2200M		
	mg/dl	6.74	6.06	7.42			
	mmol/l	1.60	1.44	1.76	BS-600,BS-620		
mg/dl	6.42	5.77	7.06				
Chloride 氯	mmol/l	85.9	73.0	98.8	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890		
	mmol/l	85.9	73.0	98.8	BS-2000,BS-2200,BS-2000M,BS-2200M		
Creatinine 肌酐	mmol/l	6.75	5.37	8.13	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890		
	mg/dl	76.4	60.8	91.9			
	mmol/l	7.22	5.75	8.69	BS-2000,BS-2200,BS-2000M,BS-2200M		
	mg/dl	81.7	65.0	98.3			
	mmol/l	6.39	5.09	7.69	BS-430,BS-450,BS-460		
	mg/dl	72.3	57.5	87.0			
	mmol/l	6.75	5.37	8.13	BS-480,BS-490		
	mg/dl	76.4	60.8	91.9			
Glucose - Oxidase 葡萄糖-葡萄糖氧化酶法	mmol/l	2.76	2.21	3.31	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890		
	mg/dl	49.7	39.8	59.6			
	mmol/l	2.84	2.27	3.41	BS-2000,BS-2200,BS-2000M,BS-2200M		
	mg/dl	51.2	41.0	61.4			
	mmol/l	2.74	2.19	3.29	BS-430,BS-450,BS-460		
	mg/dl	49.4	39.5	59.2			
	mmol/l	2.79	2.23	3.35	BS-480,BS-490		
	mg/dl	50.3	40.3	60.3			
Glucose - Hexokinase 葡萄糖-己糖激酶法	mmol/l	2.75	2.20	3.30	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890		
	mg/dl	49.5	39.7	59.4			
	mmol/l	2.80	2.24	3.36	BS-2000,BS-2200,BS-2000M,BS-2200M		
	mg/dl	50.5	40.4	60.5			
	mmol/l	2.68	2.15	3.21	BS-430,BS-450,BS-460		
	mg/dl	48.3	38.7	57.9			
	mmol/l	2.78	2.23	3.33	BS-480,BS-490		
	mg/dl	50.1	40.1	60.1			
Magnesium 镁	mmol/l	2.78	2.23	3.33	BS-600,BS-620		
	mg/dl	50.1	40.1	60.1			
	mmol/l	2.90	2.32	3.48	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890		
	mg/dl	7.05	5.63	8.46			
	mmol/l	3.08	2.46	3.70	BS-2000,BS-2200,BS-2000M,BS-2200M		
	mg/dl	7.48	5.98	8.99			
Microalbumin 微量白蛋白	mmol/l	2.90	2.32	3.48	BS-600,BS-620		
	mg/dl	7.05	5.63	8.46			
	mg/l	35.2	28.1	42.2	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890		
	mg/l	35.7	28.6	42.9	BS-2000,BS-2200,BS-2000M,BS-2200M		
	mg/l	34.2	27.3	41.0	BS-430,BS-450,BS-460		
mg/l	35.6	28.5	42.7	BS-480,BS-490			
mg/l	34.7	27.8	41.6	BS-600,BS-620			

ASSAYED URINE CONTROL LEVEL 2 (URN ASY CONTROL 2)

Cat. No. AU2352 Lot No. 1101UC Size: 12 x 10ml Expiry: 2024-03-28

Analyte	unit	Target	Range		methods	
			low	high		
Phosphate Inorganic 无机磷	mmol/l	8.43	6.74	10.1	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890	
	mg/dl	26.1	20.9	31.4		
	mmol/l	8.96	7.17	10.8	BS-2000,BS-2200,BS-2000M,BS-2200M	
	mg/dl	27.8	22.2	33.3		
	mmol/l	8.71	6.97	10.5	BS-430,BS-450,BS-460	
	mg/dl	27.0	21.6	32.4		
	mmol/l	8.47	6.78	10.2	BS-480,BS-490	
	mg/dl	26.3	21.0	31.5		
	mmol/l	8.43	6.74	10.1	BS-600,BS-620	
	mg/dl	26.1	20.9	31.4		
	Phosphate Inorganic-II 无机磷 - II	mmol/l	7.96	6.37	9.55	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
		mg/dl	24.7	19.7	29.6	
mmol/l		8.55	6.84	10.3	BS-2000,BS-2200,BS-2000M,BS-2200M	
mg/dl		26.5	21.2	31.8		
mmol/l		8.29	6.63	9.95	BS-430,BS-450,BS-460	
mg/dl		25.7	20.6	30.8		
mmol/l		8.32	6.66	10.0	BS-480,BS-490	
mg/dl		25.8	20.6	31.0		
mmol/l		8.10	6.48	9.72	BS-600,BS-620	
mg/dl		25.1	20.1	30.1		
Potassium 钾		mmol/l	29.6	25.1	34.0	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
		mmol/l	29.6	25.1	34.0	BS-2000,BS-2200,BS-2000M,BS-2200M
Protein Total 总蛋白	g/l	0.111	0.087	0.134	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890	
	mg/dl	11.1	8.73	13.4		
	mg/l	111	87.3	134		
	g/l	0.118	0.093	0.143	BS-2000,BS-2200,BS-2000M,BS-2200M	
	mg/dl	11.8	9.28	14.3		
	mg/l	118	92.8	143		
	g/l	0.110	0.087	0.134	BS-430,BS-450,BS-460	
	mg/dl	11.0	8.71	13.4		
	mg/l	110	87.1	134		
	g/l	0.111	0.088	0.135	BS-480,BS-490	
	mg/dl	11.1	8.78	13.5		
	mg/l	111	87.8	135		
	g/l	0.110	0.086	0.133	BS-600,BS-620	
	mg/dl	11.0	8.64	13.3		
mg/l	110	86.4	133			
Sodium 钠	mmol/l	61.7	54.4	69.0	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890	
	mmol/l	61.7	54.4	69.0	BS-2000,BS-2200,BS-2000M,BS-2200M	
Urea 尿素	mmol/l	145	116	174	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890	
	mg/dl	869	695	1043		
	mmol/l	155	124	186	BS-2000,BS-2200,BS-2000M,BS-2200M	
	mg/dl	932	746	1119		
	mmol/l	145	116	174	BS-430,BS-450,BS-460	
	mg/dl	870	696	1044		
	mmol/l	151	121	182	BS-480,BS-490	
	mg/dl	910	728	1092		
	mmol/l	148	119	178	BS-600,BS-620	
	mg/dl	890	712	1068		
	Uric Acid (Urate) 尿酸	mmol/l	0.647	0.519	0.775	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
		mg/dl	10.9	8.72	13.0	
mmol/l		0.691	0.554	0.828	BS-2000,BS-2200,BS-2000M,BS-2200M	
mg/dl		11.6	9.31	13.9		
mmol/l		0.624	0.500	0.748	BS-430,BS-450,BS-460	
mg/dl		10.5	8.41	12.6		
mmol/l		0.666	0.534	0.798	BS-480,BS-490	
mg/dl		11.2	8.98	13.4		
mmol/l		0.656	0.526	0.786	BS-600,BS-620	
mg/dl		11.0	8.84	13.2		