

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

CAT. NO.	AU 2353	LOT NO.	I106UC
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 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 3 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 3 (URN ASY CONTROL 3)

货号. AU 2353 批号. I106UC

规格: 12 x 10 ml 效期: 2024-03-28

GTIN: 05055273200546

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 3 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。

EC	REP
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Dungloe, Donegal,
F94 TV06, Ireland

(S): 26 Jan 21 pl

ASSAYED URINE CONTROL LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot No. 1106UC Size: 12 x 10ml Expiry: 2024-03-28

Analyte	unit	Target	Range		methods
			low	high	
Amylase 淀粉酶	U/l	957	766	1148	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890 37°C
	U/l	966	772	1159	BS-2000,BS-2200,BS-2000M,BS-2200M 37°C
	U/l	943	755	1132	BS-430,BS-450,BS-460 37°C
	U/l	954	763	1145	BS-480,BS-490 37°C
	U/l	955	764	1145	BS-600,BS-620 37°C
Calcium 钙	mmol/l	4.01	3.60	4.42	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	16.1	14.5	17.7	
	mmol/l	4.36	3.92	4.80	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	17.5	15.7	19.2	
	mmol/l	4.12	3.70	4.54	BS-600,BS-620
Chloride 氯	mmol/l	262	223	301	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mmol/l	262	223	301	BS-2000,BS-2200,BS-2000M,BS-2200M
Creatinine 肌酐	mmol/l	15.5	12.3	18.6	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	175	139	211	
	mmol/l	16.8	13.3	20.2	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	190	151	228	
	mmol/l	15.0	11.9	18.1	BS-430,BS-450,BS-460
	mg/dl	170	135	204	
	mmol/l	15.7	12.5	18.9	BS-480,BS-490
	mg/dl	177	141	214	
Glucose - Oxidase 葡萄糖-葡萄糖氧化酶法	mmol/l	14.8	11.9	17.8	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	267	214	320	
	mmol/l	15.3	12.3	18.4	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	276	221	331	
	mmol/l	14.9	11.9	17.9	BS-430,BS-450,BS-460
	mg/dl	268	215	322	
	mmol/l	15.1	12.1	18.0	BS-480,BS-490
	mg/dl	271	217	325	
Glucose - Hexokinase 葡萄糖-己糖激酶法	mmol/l	14.9	11.9	17.8	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	268	214	321	
	mmol/l	15.1	12.1	18.2	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	273	219	327	
	mmol/l	14.8	11.8	17.7	BS-430,BS-450,BS-460
	mg/dl	266	213	319	
	mmol/l	15.0	12.0	17.9	BS-480,BS-490
	mg/dl	270	216	323	
Magnesium 镁	mmol/l	12.6	10.0	15.1	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/dl	30.5	24.4	36.7	
	mmol/l	13.5	10.8	16.2	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/dl	32.8	26.2	39.3	
	mmol/l	12.8	10.2	15.4	BS-600,BS-620
	mg/dl	31.2	24.9	37.4	
Microalbumin 微量白蛋白	mg/l	166	133	199	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
	mg/l	169	135	202	BS-2000,BS-2200,BS-2000M,BS-2200M
	mg/l	165	132	198	BS-430,BS-450,BS-460
	mg/l	164	131	197	BS-480,BS-490
	mg/l	163	131	196	BS-600,BS-620

ASSAYED URINE CONTROL LEVEL 3 (URN ASY CONTROL 3)

Cat. No. AU2353 Lot No. 1106UC Size: 12 x 10ml Expiry: 2024-03-28

Analyte	unit	Target	Range		methods	
			low	high		
Phosphate Inorganic 无机磷	mmol/l	25.5	20.4	30.6	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890	
	mg/dl	79.2	63.3	95.0		
	mmol/l	28.0	22.4	33.5	BS-2000,BS-2200,BS-2000M,BS-2200M	
	mg/dl	86.6	69.3	104.0		
	mmol/l	25.5	20.4	30.6	BS-430,BS-450,BS-460	
	mg/dl	79.1	63.3	94.9		
	mmol/l	26.3	21.0	31.5	BS-480,BS-490	
	mg/dl	81.4	65.1	97.7		
	mmol/l	26.2	20.9	31.4	BS-600,BS-620	
	mg/dl	81.1	64.9	97.3		
	Phosphate Inorganic-II 无机磷 - II	mmol/l	24.4	19.5	29.2	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
		mg/dl	75.5	60.4	90.6	
mmol/l		26.7	21.3	32.0	BS-2000,BS-2200,BS-2000M,BS-2200M	
mg/dl		82.6	66.1	99.2		
mmol/l		24.3	19.4	29.1	BS-430,BS-450,BS-460	
mg/dl		75.2	60.2	90.3		
mmol/l		25.8	20.6	31.0	BS-480,BS-490	
mg/dl		80.0	64.0	96.0		
mmol/l		25.0	20.0	30.0	BS-600,BS-620	
mg/dl		77.6	62.1	93.1		
Potassium 钾		mmol/l	134	114	154	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
		mmol/l	134	114	154	BS-2000,BS-2200,BS-2000M,BS-2200M
Protein Total 总蛋白	g/l	0.264	0.208	0.320	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890	
	mg/dl	26.4	20.8	32.0		
	mg/l	264	208	320		
	g/l	0.269	0.212	0.326	BS-2000,BS-2200,BS-2000M,BS-2200M	
	mg/dl	26.9	21.2	32.6		
	mg/l	269	212	326		
	g/l	0.267	0.211	0.324	BS-430,BS-450,BS-460	
	mg/dl	26.7	21.1	32.4		
	mg/l	267	211	324		
	g/l	0.265	0.209	0.322	BS-480,BS-490	
	mg/dl	26.5	20.9	32.2		
	mg/l	265	209	322		
Sodium 钠	mmol/l	202	178	226	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890	
	mmol/l	202	178	226	BS-2000,BS-2200,BS-2000M,BS-2200M	
Urea 尿素	mmol/l	410	328	492	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890	
	mg/dl	2460	1968	2952		
	mmol/l	436	349	523	BS-2000,BS-2200,BS-2000M,BS-2200M	
	mg/dl	2620	2096	3143		
	mmol/l	412	330	495	BS-430,BS-450,BS-460	
	mg/dl	2477	1982	2973		
	mmol/l	429	343	515	BS-480,BS-490	
	mg/dl	2575	2060	3091		
	mmol/l	418	334	501	BS-600,BS-620	
	mg/dl	2509	2008	3011		
	Uric Acid (Urate) 尿酸	mmol/l	1.23	0.986	1.47	BS-800,BS-820,BS-800M,BS-820M,BS-880,BS-890
		mg/dl	20.7	16.6	24.8	
mmol/l		1.30	1.04	1.56	BS-2000,BS-2200,BS-2000M,BS-2200M	
mg/dl		21.8	17.5	26.2		
mmol/l		1.21	0.970	1.45	BS-430,BS-450,BS-460	
mg/dl		20.3	16.3	24.4		
mmol/l		1.27	1.02	1.52	BS-480,BS-490	
mg/dl		21.3	17.1	25.6		
mmol/l		1.25	1.00	1.50	BS-600,BS-620	
mg/dl		21.0	16.8	25.2		