

URINE PRECISION CONTROL - LEVEL 3 (URN PREC CONTROL 3)

** TYPICAL VALUES **

Cat. No. UCI503 **Size:** 10 x 10 ml

INTENDED USE

This product is intended for *in vitro* diagnostic use as an unassayed urine control to monitor laboratory precision on clinical chemistry systems.

DEVICE DESCRIPTION

The Urine Precision Controls are supplied at 2 levels, Level 2 and Level 3.

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 (HIV1, 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 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 Urine Precision Controls are supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised urine with exactly 10 ml of distilled water at +15°C to +25°C. Close 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

Urine Precision Control Level 3 10 x 10 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette

Revised 22 Jan 13 rw

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Cat. No. UC1503 Size: 10 x 10ml

TYPICAL VALUES

Analyte	unit	target	methods
Calcium	mmol/l	3.49	Cresolphthalein complexone
	mg/dl	14.0	
Chloride	mmol/l	248	ISE indirect
Creatinine	mmol/l	17.5	Alkaline picrate no deproteinization
	mg/dl	198	
Glucose	mmol/l	16.4	Glucose oxidase
	mg/dl	296	
Magnesium	mmol/l	6.00	Xylidyl Blue
	mg/dl	14.6	
Osmolality	mmol/kg	767	Freezing point depression
Phosphate Inorganic	mmol/l	27.4	Phosphomolybdate UV
	mg/dl	84.9	
Potassium	mmol/l	101	ISE indirect
Protein Total	g/l	0.670	Pyrogallol Red
	mg/dl	67.0	
	mg/l	670	
Sodium	mmol/l	166	ISE indirect
Urea	mmol/l	246	Urease kinetic
	mg/dl	1478	
Uric Acid (Urate)	mmol/l	1.258	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	21.1	