

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

Cat. No. UC1503 **Lot No.** 860UC **Size:** 10 x 10 ml **Expiry:** 2020-02

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 (HIVI, 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 (\pm 2°C to \pm 8°C). Reconstituted urine is stable for 5 days at \pm 2°C to \pm 8°C if kept capped in original container and free from contamination, or 14 days at \pm 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 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

Urine Precision Control - Level 3 10 x 10 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ANALYTES

Calcium; Chloride; Creatinine; Glucose; Magnesium; Osmolality; Phosphate Inorganic; Potassium; Protein Total; Sodium; Urea; Uric Acid (Urate).

TYPICAL VALUES FOR THIS UNASSAYED CONTROL CAN BE OBTAINED AT: www.Randox.com.

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