RANDOX 0843 CE

HUMAN PRECISION CONTROL - LEVEL 2 (HUM PREC CONTROL 2)

Cat. No. UN1557 **Lot No.** 843UN
Size: 20 x 5ml **Expiry:** 2017-04

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

DEVICE DESCRIPTION
The Precision Human Controls are supplied at 2 levels, level 2 and 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 (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 serum is stable for 8 hours at +15°C to +25°C or 7 days at +2°C to +8°C, and 28 days when frozen once at -20°C (see Limitations). 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.

LIMITATIONS
For Total & Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25µl - 30µl) of 0.7M Acetic acid solution to 1ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total & Prostatic Acid Phosphatase is stable for 2 hours at +15°C to +25°C, 2 days at +2°C to +8°C and 28 days when frozen once at -20°C.
Alkaline Phosphatase levels in the reconstituted serum will rise over the stability period. It is recommended that the reconstituted serum is allowed to stand for 1 hour at +15°C to +25°C before measurement.
Bilirubin in the serum is light sensitive and it is recommended that the serum is stored in the dark. Stored in the dark, it is stable for 4 days at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.
NEFA is stable for 1 day at +2°C to +8°C.
PSA is stable for 4 days at +2°C to +8°C, or 28 days in aliquots frozen at -20°C.
Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components.
Different lot numbers of this control should not be interchanged, as the values vary from lot to lot. The control should not be used as a calibration material.

PREPARATION
The Precision Human Control is supplied lyophilised.
1. Carefully reconstitute each vial of lyophilised serum with exactly 5ml 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
Precision Human Control - Level 2 20 x 5ml

MATERIALS REQUIRED BUT NOT PROVIDED
Volumetric pipette

ANALYTES
Alpha-HBDH; Acid Phosphatase (Prostatic); Acid Phosphatase (Total); Albumin; Alkaline Phosphatase; Alpha-1-Acid Glycoprotein; Alpha-1-Antitrypsin; Alphafoetoprotein; ALT (GPT); Amylase Pancreatic; Amylase Total; Apolipoprotein A-1; Apolipoprotein B; AST (GOT); Bicarbonate; Bile Acids; Bilirubin Direct; Bilirubin Total; C-Reactive Protein; Caeruloplasmin; Calcium; Carbamazepine; Carcinoembryonic Antigen (CEA); Chloride; Cholesterol; Cholinesterase; CK Total; Complement C3; Complement C4; Copper; Cortisol; Creatinine; D-3-Hydroxybutyrate; Digoxin; Ferritin; Folate; Free T3; Free Thyroxine (FT4); Gentamicin; Gamma-GT; GLDH; Glucose; Haptoglobin; HDL Cholesterol; Human Chorionic Gonadotrophin; Immunoglobulin A; Immunoglobulin E; Immunoglobulin G; Immunoglobulin M; Iron; Lactate; LAP; LD (LDH); Lipase; Lithium; Magnesium; Myoglobin; NEFA; Osmolality; Paracetamol; Phenobarbitone; Phenytoin; Phosphate Inorganic; Potassium; Prealbumin; Prolactin; Protein Total; PSA Total; Salicylate; Sodium; Theophylline; Thyroid Stimulating Hormone; Thyroxine (T4); TIBC; Tobramycin; Transferrin; Triglycerides; Triiodothyronine (T3); Troponin I; UIBC; Urea; Uric Acid (Urate); Valproic Acid; Vancomycin; Vitamin B12; Zinc.

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

27 Jan '14 ne

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