RANDOX CE

LIQUID CHEMISTRY PREMIUM PLUS - LEVEL 2 (LIQ CHEM PREMIUM PLUS 2)

CAT. NO. LUN 5094 **LOT NO.** 1112UN
SIZE: 12 x 10 ml **EXPIRY:** 2018-04-28
GTIN: 05055273207187

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 unassayed chemistry controls are supplied at 3 levels, level 1, 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). Thawed serum is stable for 7 days at +2°C to +8°C, with the following exceptions: Troponin T is stable for 3 days at +2°C to +8°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 frozen at –20°C to –70°C. Stable to expiration date printed on individual vials (see Limitations).

LIMITATIONS
For Total & Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25 µl - 30 µl) of 0.7M Acetic acid solution to 1 ml of the serum after thawing. After stabilisation, Total & Prostatic Acid Phosphatase is stable for 7 days at +2°C to +8°C.
Bilirubin in the serum is light sensitive and it is recommended that the serum is stored in the dark.
ALT, Total Acid Phosphatase, Alkaline Phosphatase, Total and Direct Bilirubin values may gradually decrease during the products shelf life.
Bacterial contamination of the thawed serum will cause reductions in the stability of many components.
The control should not be used as a calibration material.

PREPARATION
1. Allow the frozen control to thaw at room temperature (+15°C to +25°C) until completely thawed. Swirl the contents to ensure homogeneity.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED
Liquid Chemistry Premium Plus - Level 2 12 x 10 ml

MATERIALS REQUIRED BUT NOT PROVIDED
None

ANALYTES
α-1-Acid Glycoprotein; α-1-Antitrypsin; α-1-globulin (electrophoresis); α-2-globulin (electrophoresis); α-HBDH; β2 Microglobulin; β-globulin (electrophoresis); γ-globulin (electrophoresis); γ-GT; Acid Phosphatase (Prostatic); Acid Phosphatase (Total); Albumin; Albumin (electrophoresis); Alkaline Phosphatase; Amikacin; Alpha-fetoprotein; ALT (GPT); Amylase Pancreatic; Amylase Total; Apolipoprotein A-1; Apolipoprotein B; AST (GOT); Bicarbonate; Bile Acids; Bilirubin Direct; Bilirubin Total; C-Reactive Protein; Caeruloplasmin; Caffeine; Calcium; Carbamazepine; Carcinoembryonic Antigen (CEA); Chloride; Cholesterol; Cholinesterase; CK Total; Complement C3; Complement C4; Copper; Cortisol; Creatinine; D-3-Hydroxybutyrate; DHEA-S; Digoxin; Ethanol; Ferritin; Folate; Follicle Stimulating Hormone; Free T3; Free Thyroxine (FT4); Gentamicin; GLDH; Glucose; Haptoglobin; HDL-Cholesterol; Human Chorionic Gonadotrophin; Growth Hormone; Immunoglobulin A; Immunoglobulin E; Immunoglobulin G; Immunoglobulin M; Iron; Lactate; LAP; LD (LDH); LDL-Cholesterol; Lipase; Lipoprotein (a); Lithium; Luteinising Hormone; Magnesium; Myoglobin; Osmolality; Paracetamol; Phenobarbitone; Phenytoin; Phosphate Inorganic; Potassium; Prealbumin; Progesterone; Prolactin; Protein Total; Salicylate; Sodium; Testosterone; Theophylline; Thyroid Stimulating Hormone; Thyroxine (T4); TIBC; Transferrin; Triglycerides; Triiodothyronine (T3); Troponin T; T-uptake; UIBC; Urea-BUN; Uric Acid (Urate); Valproic Acid; Vancomycin; Vitamin B12; Zinc.

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

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