RANDOX 0086 CE

BOVINE PRECISION MULTI SERA - LEVEL 2 (BOV PREC CONTROL 2)

CAT. NO.	SN1085	**LOT NO.**	461SN
SIZE:	20 x 5 ml	**EXPIRY:**	2019-09
GTIN:	05055273206272		

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 Bovine 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.

This control is manufactured from bovine serum. Human source material, which has been added, 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.

LIMITATIONS
For Total & Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25 - 30 µl) of 0.7M Acetic acid solution to 1 ml of the serum. 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 2 days at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.
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.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

PREPARATION FOR USE
The Precision Bovine Multi-sera is supplied lyophilised.
1. Carefully reconstitute each vial of lyophilised serum with exactly 5 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
Precision Bovine Multi-sera - Level 2 20 x 5 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Volumetric pipette

ANALYTES
Alpha-HBDH; Acid Phosphatase (Prostatic); Acid Phosphatase (Total); Albumin; Alkaline Phosphatase; ALT (GPT); Amylase Total; AST (GOT); Bicarbonate; Bile Acids; Bilirubin Direct; Bilirubin Total; Calcium; Chloride; Cholesterol; CK Total; Copper; Cortisol; Creatinine; D-3-Hydroxybutyrate; Free Thyroxine (FT4); Gamma-GT; GLDH; Glucose; Iron; Lactate; LD (LDH); Lipase; Lithium; Magnesium; Osmolality; Phosphate Inorganic; Potassium; Protein Total; PSA Total; Sodium; Thyroxine (T4); TIBC; Triglycerides; Triiodothyronine (T3); Urea; Uric Acid (Urate); Zinc.

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

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