BOVINE PRECISION MULTI SERA (BOV PREC CONTROL 1)

** TYPICAL VALUES **

Cat. No. SL1084 **Size:** 20 x 5 ml

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 30 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 30 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 be 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 be 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.
PSA is stable for 4 days at +2°C to +8°C, or 30 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 1 20 x 5 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Volumetric Pipette

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****TYPICAL VALUES****

Analyte	unit	target	methods
alpha-HBDH	U/l	78	DGKC 37°C
	U/l	59	DGKC 30°C
	U/l	44	DGKC 25°C
Acid Phosphatase (Prostatic)	U/l	3.34	1-Naphthyl Phosphate substrate Kinetic 37°C
Acid Phosphatase (Total)	U/l	9.91	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	28.9	Bromocresol Green
	g/dl	2.89	
Alkaline Phosphatase	U/l	160	Diethanolamine buffer DEA 37°C
	U/l	125	Diethanolamine buffer DEA 30°C
	U/l	102	Diethanolamine buffer DEA 25°C
	U/l	123	p-Nitrophenylphosphate AMP 37°C
	U/l	96	p-Nitrophenylphosphate AMP 30°C
	U/l	79	p-Nitrophenylphosphate AMP 25°C
ALT (GPT)	U/l	27	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	20	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	15	Tris buffer no P5P IFCC/SFBC 25°C
Amylase Total	U/l	91	Randox EPS Liquid and BM/Roche EPS Liquid 37°C
	U/l	115	Randox - Ethylidene pNPG7 37°C
AST (GOT)	U/l	23	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	16	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	11	Tris buffer no P5P IFCC/SFBC 25°C
Bicarbonate	mmol/l	13.6	Enzymatic
Bile Acids	µmol/l	10.4	4th Generation Colorimetric
	µmol/l	14.8	5th Generation Colorimetric
Bilirubin Direct	µmol/l	14.1	Diazo with Sulphanilic Acid
	mg/dl	0.82	
Bilirubin Total	µmol/l	20.3	Diazo with Sulphanilic Acid
	mg/dl	1.19	
Calcium	mmol/l	1.58	Cresolphthalein complexone
	mg/dl	6.33	
Chloride	mmol/l	88.7	ISE indirect
Cholesterol	mmol/l	3.52	Cholesterol Oxidase
	mg/dl	136	
CK Total	U/l	139	DGKC 37°C
	U/l	87	DGKC 30°C
	U/l	59	DGKC 25°C
Copper	µmol/l	11.0	Colorimetric
	µg/dl	70.0	
Cortisol	nmol/l	175	Radioimmunoassay
	µg/dl	6.30	

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Analyte	unit	target	methods
Creatinine	µmol/l	94.4	Alkaline picrate no deproteinization
	mg/dl	1.07	
	µmol/l	81.0	Randox Enzymatic UV method
	mg/dl	0.92	
D-3-Hydroxybutyrate	mmol/l	0.85	Enzymatic
Free Thyroxine (FT4)	pmol/l	18.2	Chemiluminescence
	pg/ml	14.2	
	ng/dl	1.42	
gamma-GT	U/l	33	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	26	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	20	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
GLDH	U/l	10	DGKC 37°C
	U/l	8	DGKC 30°C
	U/l	6	DGKC 25°C
Glucose	mmol/l	3.41	Glucose oxidase
	mg/dl	61.4	
Iron	µmol/l	20.0	Colorimetric without ppt.
	µg/dl	112	
Lactate	mmol/l	2.74	Enzymatic Colorimetric
	mg/dl	24.7	
LD (LDH)	U/l	146	Phosphate buffer DGKC 37°C
	U/l	105	Phosphate buffer DGKC 30°C
	U/l	74	Phosphate buffer DGKC 25°C
Lipase	U/l	168	Turbidimetric 37°C
	U/l	35	Randox Colorimetric 37°C
Lithium	mmol/l	0.63	Colorimetric
	mg/dl	0.44	
Magnesium	mmol/l	0.70	Xylidyl Blue
	mg/dl	1.70	
Osmolality	mmol/kg	284	Freezing point depression
Phosphate Inorganic	mmol/l	0.98	Phosphomolybdate UV
	mg/dl	3.04	
Potassium	mmol/l	3.15	ISE indirect
Protein Total	g/l	45.3	Biuret reaction end point
	g/dl	4.53	
PSA Total	ng/ml = µg/l	1.95	Chemiluminescence
Sodium	mmol/l	126	ISE indirect
Thyroxine (T4)	nmol/l	57.4	Chemiluminescence
	µg/dl	4.48	
	ng/ml	44.8	
TIBC	µmol/l	28.7	FE+UIBC(saturation with iron)
	µg/dl	160	
	µmol/l	29.0	Randox Direct
	µg/dl	162	

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Analyte	unit	target	methods
Triglycerides	mmol/l	0.71	Lipase/GPO-PAP no correction
	mg/dl	62.8	
Triiodothyronine (T3)	nmol/l	1.78	Chemiluminescence
	ng/ml	1.16	
	ng/dl	116	
Urea	mmol/l	3.01	Urease kinetic
	mg/dl	18.1	
	mmol/l	4.33	Urease Berthelot
	mg/dl	26.0	
	mmol/l	5.70	Urease hypochlorite
	mg/dl	34.3	
Uric Acid (Urate)	mmol/l	0.202	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	3.39	
Zinc	µmol/l	14.8	Colorimetric with deproteinisation
	µg/dl	96.6	