BEACON CONTROL NORM

(BIOCHEMISTRY)

Code	Product Name	Pack Size
LP011A	Beacon Control Norm	2x1 ml
LP011B	Beacon Control Norm	4x1 ml

BEACON

INTENDED USE

This product is intended for *in vitro* diagnostics use in the quality control of diagnostic assay. This Beacon Control Norm is for the control of accuracy.

DEVICE DESCRIPTION

The Beacon Control is supplied at 2 levels, Beacon Control Norm and Beacon Control Path. Target values and ranges are supplied for the analytes listed in value section at both levels.

SAFETY PRECAUTIONS AND WARNING

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory.

Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV I, 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 disease and disposed of accordingly.

Health and Safety Data Sheet are available on request.

STORAGE AND STABILITY

OPEN : 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 1 month when frozen once at -20°C (See limitations).

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

LIMITATIONS

For Total & Prostatic Acid Phosphatase, the materials should be stabilised adding 1 drop (25 - 30) of 0.7 M Acetic acid solution to 1 ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total and Prostatic Acid Phosphatase is stable for 2 hours at +15°C to +25°C, 2 days at +2°C to +8°C nd 1 month when frozen once at -20C.
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°Cbefore measurement.
The reconstituted stability for ALT is 5 days, when stored at +2°C to +8°C. The ALT is stable for 8 hours at +15°C to +25°C, and 28 days when frozen once at -18°C to 24°C.
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.
NEFA is stable for 1 day at +2°C to +8°C.
Total PSA is stable for 4 days at +2°C to +8°C, or 28 days in aliquots frozen at -18°C to -24°C.
Bacterial contamination of the reconstituted serum will cause reduction in the stability of many components.
Different lot number of this control should not be interchanged, as the assigned to the controls vary from lot to lot.
The control should not be used as a calibration materials.
The reconstituted stability for Beacon Control Norm for Iron, Alkaline Phosphatase (ALP) and Alanine Amino Transferase (ALT) is 3 days, when stored at +2°C to +8°C.
ALP, ALT and Iron are stable for 8 hours at +15°C to +25°C, and 28 days when frozen once at -18°C to -24°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.

PREPARATION FOR USE

The Beacon Control Norm is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 1 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 dissolve 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 use, mix contents thoroughly.

MATERIALS PROVIDED

Beacon Control Norm 2x1 ml / 4x1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette
Distilled Water

WASTE MANAGEMENT

Please refer to local legal requirements.

JAS-ANZ BSCIC ISO 9001 : 2015 BSCIC ISO 13485:2016

SYMBOLS USED ON LABELS

REF Catalogue Number | Manufacturer | See Instruction for Use

LOT Lot Number | CONT Content | Storage Temperature

Expiry Date | IVD In Vitro Diagnostics

BEA/24/BCN/LP/IFU-01 DATE: 10/08/2022

Lot No. : LP11-033

Beacon Control Norm

			Range				
Analytes	**Unit**	**Target**	**Low**	**High**	**1 SD**	**2 SD**	**Method**
Albumin	g/dl	4.18	3.55	4.81	0.32	0.63	Bromocresol Green Method
	g/l	41.8	35.5	48.1	3.15	6.30	
Alkaline Phosphatase	U/L	176	149	203	13.50	27.00	AMP Optimized IFCC 37°C
Amylase	U/L	86	73	99	6.50	13.00	Direct Substrate Method
Bilirubin (Direct)	mg/dl	0.761	0.603	0.91	0.08	0.15	DMSO Method
	µmol/l	12.99	10.31	15.71	1.40	2.80	
Bilirubin (Total)	mg/dl	1.48	1.15	1.77	0.14	0.28	DMSO Method
	µmol/l	25.30	19.66	30.26	2.65	5.30	
Calcium	mg/dl	8.62	7.74	9.50	0.44	0.88	Arsenazo III Method
	mmol/l	2.15	1.93	2.37	0.11	0.22	
Chloride	mmol/l	97.0	92.1	102	2.45	4.90	Colorimetric Method
Cholesterol	mg/dl	166	144	188	11.00	22.00	CHOD/POD Method
	mmol/l	4.29	3.74	4.84	0.28	0.55	
CK NAC	U/L	206	169	243	18.50	37.00	Optimized IFCC 37°C
Creatinine	mg/dl	1.51	1.22	1.80	0.15	0.29	Enzymatic Method
	µmol/l	134	108	160	13.00	26.00	
Gamma GT	U/L	49	42	56	3.50	7.00	SASZ Method
Glucose	mg/dl	113	96.2	130	8.40	16.80	GOD/POD Method
	mmol/l	6.28	5.34	7.22	0.47	0.94	
HDL Direct	mg/dl	53	45.2	60.8	3.90	7.80	PEGME Method
	mmol/l	1.37	1.17	1.57	0.10	0.20	
LDL Direct	mg/dl	70	60	80	5	10	Detergent Method
	mmol/l	1.81	1.55	2.07	0.12	0.25	
Lipase	U/L	32	26	38	3.0	6.0	Methyl Resorufin Method
LDH	U/L	209	178	240	15.5	31	L-P Kinetic Method
Magnesium	mg/dl	0.94	0.82	1.05	0.06	0.11	XB Method
	mmol/l	2.27	2.00	2.54	0.14	0.27	
Inorganic Phosphorous	mg/dl	4.59	3.91	5.27	0.34	0.68	Molybdate UV Method
	mmol/l	1.48	1.26	1.70	0.11	0.22	
Potassium	mmol/l	3.86	3.67	4.05	0.10	0.19	Colorimetric Method
SGOT	U/L	37	30	44	3.50	7.00	IFCC Method
SGPT	U/L	37	30	44	3.50	7.00	IFCC Method
Sodium	mmol/l	140	133	147	3.50	7.00	Colorimetric Method
Total Protein	g/dl	5.96	4.77	7.15	0.60	1.19	Biuret Method
	g/l	59.6	47.7	71.5	5.95	11.90	
Triglycerides	mg/dl	101	84.4	118	8.30	16.60	GPO/POD Method
	mmol/l	1.14	0.95	1.33	0.09	0.19	
Urea	mg/dl	44.7	37.9	51.5	3.40	6.80	UV GLDH Method
	mmol/l	7.43	6.31	8.55	0.56	1.12	
Uric Acid	mg/dl	6.08	5.29	6.87	0.40	0.79	Uricase / POD Method
	mmol/l	0.36	0.32	0.41	0.02	0.05	