BEACON CONTROL PATH

(BIOCHEMISTRY)

Code	Product Name	Pack Size
LP012A	Beacon Control Path	2x1 ml
LP012B	Beacon Control Path	4x1 ml

BEACON

INTENDED USE

This product is intended for *in vitro* diagnostics use in the quality control of diagnostic assay. This Beacon Control Path 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 stabilized adding 1 drop (25 - 30) of 0.7 M Acetic acid solution to 1 ml of the serum exactly 30 minutes after reconstitution. After stabilization 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 path for Alanine Amino Transferase (ALT) and Alkaline Phosphatase (ALP) is 3 days, when stored at +2°C to +8°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.
Alkaline Phosphatase and ALT are stable for 8 hours at +15°C to +25°C, and 28 days when frozen once at –18°C to –24°C

PREPARATION FOR USE

The Beacon Control Path is supplied lyophilized.

1. Carefully reconstitute each vial of lyophilized 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 analyzer application.

3. Refrigerate any unused material. Prior to use, mix contents thoroughly.

MATERIALS PROVIDED

Beacon Control Path 2x1 ml / 4x1 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette
Distilled Water

WASTE MANAGEMENT

Please refer to local legal requirements.

BSCIC ISO 9001 : 2015 JAS-ANZ 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/BCP/LP/IFU-01 DATE: 10/08/2022

Lot No. : LP12- 037

Beacon Control Path

			Range				
Analytes	**Unit**	**Target**	**Low**	**High**	**1 SD**	**2 SD**	**Method**
Albumin	g/dl	2.95	2.51	3.39	0.22	0.44	Bromocresol Green Method
	g/l	29.5	25.1	33.9	2.20	4.40	
Alkaline Phosphatase	U/L	379	322	436	28.50	57.00	AMP Optimized IFCC 37°C
Amylase	U/L	259	220	298	19.50	39.00	Direct Substrate Method
Bilirubin (Direct)	mg/dl	2.42	1.90	2.94	0.26	0.52	DMSO Method
	µmol/l	41.4	32.5	50.3	4.45	8.90	
Bilirubin (Total)	mg/dl	4.95	3.92	5.98	0.52	1.03	DMSO Method
	µmol/l	84.66	67.04	102.28	8.81	17.62	
Calcium	mg/dl	12.4	11.2	13.6	0.60	1.20	Arsenazo III Method
	mmol/l	3.10	2.79	3.41	0.16	0.31	
Chloride	mmol/l	110	105	115	2.50	5.00	Colorimetric Method
Cholesterol	mg/dl	290	252	328	19.0	38.00	CHOD/POD Method
	mmol/l	7.51	6.53	8.49	0.49	0.98	
CK NAC	U/L	547	449	645	49.0	98.00	Optimized IFCC 37°C
Creatinine	mg/dl	5.49	4.40	6.58	0.55	1.09	Enzymatic Method
	µmol/l	486	389	583	48.50	97.00	
Gamma GT	U/L	141	120	162	10.50	21.00	SASZ Method
Glucose	mg/dl	287	243	331	22.00	44.00	GOD/POD Method
	mmol/l	15.9	13.5	18.3	1.20	2.40	
HDL Direct	mg/dl	111	94.2	128	8.40	16.80	PEGME Method
	mmol/l	2.87	2.44	3.30	0.22	0.43	
LDL Direct	mg/dl	118	100	136	9.00	18.00	Detergent Method
	mmol/l	3.05	2.59	3.52	0.23	0.46	
Lipase	U/L	66	53	79	6.50	13.00	Methyl Resorufin Method
LDH	U/L	360	306	414	27.00	54.00	L-P Kinetic Method
Magnesium	mmol/l	1.76	1.55	1.97	0.11	0.21	XB Method
	mg/dl	4.28	3.77	4.79	0.26	0.51	
Inorganic Phosphorous	mg/dl	6.88	5.86	7.90	0.51	1.02	Molybdate UV Method
	mmol/l	2.22	1.89	2.55	0.17	0.33	
Potassium	mmol/l	5.95	5.65	6.25	0.15	0.30	Colorimetric Method
SGOT	U/L	132	105	159	13.50	27.00	IFCC Method
SGPT	U/L	137	110	164	13.50	27.00	IFCC Method
Sodium	mmol/l	156	148	164	4.00	8.00	Colorimetric Method
Total Protein	g/dl	4.57	3.66	5.48	0.46	0.91	Biuret Method
	g/l	45.7	36.6	54.8	4.55	9.10	
Triglycerides	mg/dl	255	214	296	20.50	41.00	GPO/POD Method
	mmol/l	2.88	2.42	3.34	0.23	0.46	
Urea	mg/dl	120	102	138	9.00	18.00	UV GLDH Method
	mmol/l	20	17	23	1.50	3.00	
Uric Acid	mg/dl	9.31	8.10	10.5	0.61	1.21	Uricase / POD Method
	mmol/l	0.55	0.48	0.63	0.04	0.07	