ABAXIS CHEMISTRY CONTROL LEVEL 1

Cat. No. 1100-9131E **Lot No.** 375310 – 1059UNCM / 6129MS-N
Size: 10 x 1 ml Control; 10 x 1 ml Diluent **Expiry:** 2019-10

INTENDED USE
This product is intended for *in vitro* diagnostic use in the quality control of serum on clinical chemistry systems.

DEVICE DESCRIPTION
The Abaxis Chemistry Controls are supplied at 2 levels, Level 1 and Level 2.

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). 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). Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

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

LIMITATIONS
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.
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.

PREPARATION
The Abaxis Chemistry Control is supplied lyophilised.

1. While holding the serum vial steady on the bench, carefully pipette 1000µL diluent into the serum vial.

2. Close the serum vial and invert gently several times. Allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.

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

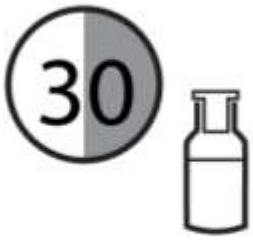
MATERIALS PROVIDED

Abaxis Chemistry Control	Level 1	10 x 1 ml
Abaxis Control Diluent	Level 1	10 x 1 ml

MATERIALS REQUIRED BUT NOT PROVIDED
General laboratory equipment.

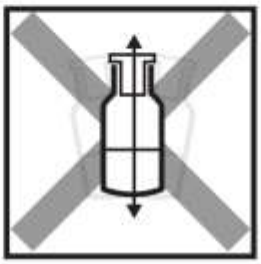
VALUE ASSIGNMENT
Target values and ranges are provided.

1. Carefully pipette 1000µL diluent into the serum vial



2. Allow to stand for 30 minutes before use

3. Ensure contents are completely dissolved by swirling gently



Do not shake

4. Refrigerate any unused material

THE VALUES BELOW ARE FOR USE WITH THE ABAXIS PICCOLO / PICCOLO XPRESS SYSTEM

METHOD	Abbreviation	Unit	1059UNCM Level 1		
			TARGET	LOW LIMIT	HIGH LIMIT
Albumin	ALB	g/dL	3.4	2.8	4.0
		g/L	34	28	40
Alkaline phosphatase	ALP	U/L	83	62	104
Alanine aminotransferase	ALT	U/L	33	25	41
Amylase	AMY	U/L	75	55	95
Aspartate aminotransferase	AST	U/L	27	20	34
Blood urea nitrogen	BUN	mg/dL	18	14	22
		mmol/L	6.4	5.0	7.9
Calcium	Ca	mg/dL	8.5	7.6	9.5
		mmol/L	2.13	1.90	2.37
Cholesterol	CHOL	mg/dL	99	85	112
		mmol/L	2.6	2.2	2.9
Creatine Kinase	CK	U/L	130	91	169
Chloride	CL^-	mmol/L	107	97	116
Creatinine	CRE	mg/dL	1.2	0.7	1.7
		µmol/L	106	62	150
Direct Bilirubin	DBIL	mg/dL	0.5	0.1	0.9
		µmol/L	8.6	1.7	15.4
Gamma GT	GGT	U/L	40	31	49
Glucose	GLU	mg/dL	108	90	125
		mmol/L	6.0	5.0	6.9
High-Density Lipoprotein	HDL	mg/dL	56	49	64
		mmol/L	1.45	1.27	1.66
Potassium	K^+	mmol/L	4.6	4.1	5.1
Lactate Dehydrogenase	LDH	U/L	118	97	140
Magnesium	Mg	mg/dL	2.1	1.8	2.4
		mmol/L	0.9	0.7	1.0
Sodium	Na^+	mmol/L	134	126	142
Phosphorus	PHOS	mg/dL	3.0	2.4	3.5
		mmol/L	0.97	0.77	1.13
Total Bilirubin	TBIL	mg/dL	1.2	0.8	1.6
		µmol/L	21	14	27
Bicarbonate	TCO_2	mmol/L	10	5	15
Total Protein	TP	g/dL	4.6	4.1	5.1
		g/L	46	41	51
Triglycerides	TRIG	mg/dL	96	79	114
		mmol/L	1.09	0.90	1.30
Uric Acid	UA	mg/dL	5.2	4.5	5.9
		µmol/L	309	268	351
Lactate	LAC	mmol/L	1.6	1.3	1.9
		mg/dL	14.4	9.0	17.1
C-Reactive Protein	CRP	mg/L	10.5	7.6	13.4
		mg/dL	1.1	0.8	1.3

Rev. 04 Feb 16 ml

THIS PAGE IS INTENTIONALLY BLANK

Randox Laboratories Ltd, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
T +44 (0) 28 9442 2413 **F** +44 (0) 28 9445 2912 **E** applications@randox.com **I** www.randox.com