

## ABAXIS CHEMISTRY CONTROL LEVEL 2

**Cat. No.** I100-9132E

**Lot No.** 282460 - 611UECM / 5218MS

**Size:** 10 x 1 ml Control; 10 x 1 ml Diluent

**Expiry:** 2016-12

### 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 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 pour all the diluent into the serum vial. Do not shake excess diluent out of the diluent 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 2	10 x 1 ml
Abaxis Control Diluent	Level 2	10 x 1 ml

### MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory equipment.

### VALUE ASSIGNMENT

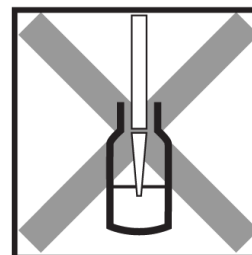
Target values and ranges are provided.



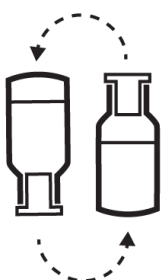
1. Carefully pour all the diluent into the serum vial



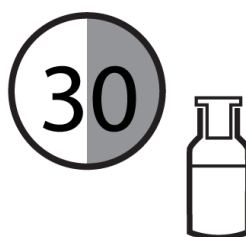
Do not shake excess diluent out of the diluent vial



Do not pipette



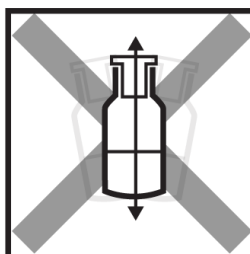
2. Gently invert serum vial several times



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

PARAMETER	Unit	611UECM Level 2		
		TARGET	LOW LIMIT	HIGH LIMIT
Albumin	g/dl	4.8	3.7	6.0
Alkaline Phosphatase	U/l	293	220	366
Alanine Transaminase	U/l	90	69	111
Amylase	U/l	188	148	228
Aspartate Transaminase	U/l	95	73	117
BUN	mg/dl	50	44	55
Calcium	mg/dl	11.4	10.2	12.7
Cholesterol	mg/dl	171	147	195
Creatine Kinase	U/l	551	441	661
Chloride	mmol/L	114	104	124
Creatinine	mg/dl	3.7	2.9	4.6
C-Reactive Protein	mg/L	10.3	7.5	13.1
Direct Bilirubin	mg/dl	4.0	2.9	5.0
Gamma GT	U/l	127	99	155
Glucose	mg/dl	246	206	285
HDL	mg/dl	61	51	70
Potassium	mmol/L	6.1	5.5	6.7
Lactate	mmol/L	3.8	3.1	4.5
Lactate Dehydrogenase	U/l	664	545	784
Magnesium	mg/dl	3.8	3.2	4.4
Sodium	mmol/L	164	154	174
Phosphorus	mg/dl	7.3	5.9	8.6
Total Bilirubin	mg/dl	4.2	3.1	5.2
Bicarbonate	mmol/L	21	15	27
Total Protein	g/dl	6.7	6.0	7.5
Triglycerides	mg/dl	244	200	288
Uric Acid	mg/dl	9.5	8.2	10.9

PARAMETER	Unit	611UECM Level 2		
		TARGET	LOW LIMIT	HIGH LIMIT
Albumin	g/L	48	37	60
Alkaline Phosphatase	µkat/L	4.88	3.67	6.10
Alanine Transaminase	µkat/L	1.50	1.15	1.85
Amylase	µkat/L	3.13	2.47	3.80
Aspartate Transaminase	µkat/L	1.58	1.22	1.95
BUN	mmol/L	17.9	15.7	19.6
Calcium	mmol/L	2.84	2.55	3.17
Cholesterol	mmol/L	4.43	3.81	5.05
Creatine Kinase	µkat/L	9.18	7.35	11.0
Chloride	mmol/L	114	104	124
Creatinine	µmol/L	327	257	407
C-Reactive Protein	mg/L	10.3	7.5	13.1
Direct Bilirubin	µmol/L	68.4	49.6	85.5
Gamma GT	µkat/L	2.12	1.65	2.58
Glucose	mmol/L	13.7	11.4	15.8
HDL	mmol/L	1.58	1.32	1.81
Potassium	mmol/L	6.1	5.5	6.7
Lactate	mg/dL	34.2	27.9	40.5
Lactate Dehydrogenase	µkat/L	11.1	9.08	13.1
Magnesium	mmol/L	1.56	1.32	1.81
Sodium	mmol/L	164	154	174
Phosphorus	mmol/L	2.35	1.90	2.77
Total Bilirubin	µmol/L	71.8	53.0	88.9
Bicarbonate	mEq/L	21	15	27
Total Protein	g/L	67	60	75
Triglycerides	mmol/L	2.76	2.26	3.25
Uric Acid	mmol/L	0.565	0.488	0.649

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