

# ABAXIS CHEMISTRY CONTROL LEVEL I

**Cat. No.** I100-9131E

**Lot No.** 282447 - 824UNCM / 5217MS

**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 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 I | 10 x 1 ml |
| Abaxis Control Diluent   | Level I | 10 x 1 ml |

## MATERIALS REQUIRED BUT NOT PROVIDED

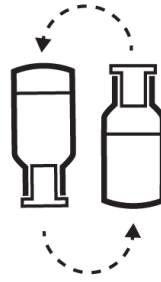
General laboratory equipment.

## VALUE ASSIGNMENT

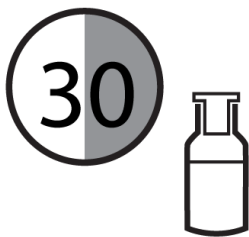
Target values and ranges are provided.



1. Carefully pipette 1000 $\mu$ L diluent into the serum vial



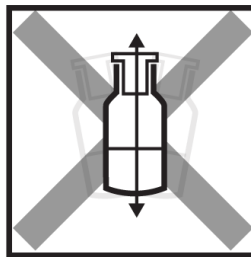
Gently invert serum vial several times



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   | 824UNCM Level I |           |            |
|----------------------------|------------------|--------|-----------------|-----------|------------|
|                            |                  |        | TARGET          | LOW LIMIT | HIGH LIMIT |
| Albumin                    | ALB              | g/dL   | 3,4             | 2,6       | 4,2        |
|                            |                  | g/L    | 34,0            | 26,0      | 42,0       |
| Alkaline phosphatase       | ALP              | U/L    | 80              | 60        | 101        |
| Alanine aminotransferase   | ALT              | U/L    | 33              | 23        | 43         |
| Amylase                    | AMY              | U/L    | 56              | 36        | 76         |
| Aspartate aminotransferase | AST              | U/L    | 34              | 26        | 42         |
| Blood urea nitrogen        | BUN              | mg/dL  | 18              | 14        | 22         |
|                            |                  | mmol/L | 6,4             | 5,0       | 7,9        |
| Calcium                    | Ca               | mg/dL  | 8,9             | 7,9       | 9,9        |
|                            |                  | mmol/L | 2,2             | 1,9       | 2,5        |
| Cholesterol                | CHOL             | mg/dL  | 98              | 84        | 112        |
|                            |                  | mmol/L | 2,5             | 2,1       | 2,9        |
| Creatine Kinase            | CK               | U/L    | 111             | 88        | 133        |
| Chloride                   | CL <sup>-</sup>  | mmol/L | 94              | 86        | 103        |
| Creatinine                 | CRE              | mg/dL  | 0,7             | 0,2       | 1,2        |
|                            |                  | µmol/L | 61,9            | 17,6      | 106        |
| Direct Bilirubin           | DBIL             | mg/dL  | 0,5             | 0,1       | 0,9        |
|                            |                  | µmol/L | 8,6             | 1,7       | 15,4       |
| Gamma GT                   | GGT              | U/L    | 38              | 30        | 47         |
| Glucose                    | GLU              | mg/dL  | 110             | 92        | 127        |
|                            |                  | mmol/L | 6,1             | 5,1       | 7,1        |
| High-Density Lipoprotein   | HDL              | mg/dL  | 49              | 43        | 55         |
|                            |                  | mmol/L | 1,3             | 1,1       | 1,5        |
| Potassium                  | K <sup>+</sup>   | mmol/L | 4,0             | 3,5       | 4,5        |
| Lactate Dehydrogenase      | LDH              | U/L    | 163             | 133       | 192        |
| Magnesium                  | Mg               | mg/dL  | 2,0             | 1,7       | 2,3        |
|                            |                  | mmol/L | 0,82            | 0,7       | 0,94       |
| Sodium                     | Na <sup>+</sup>  | mmol/L | 132             | 124       | 141        |
| Phosphorus                 | PHOS             | mg/dL  | 3,7             | 3,1       | 4,4        |
|                            |                  | mmol/L | 1,2             | 1,0       | 1,4        |
| Total Bilirubin            | TBIL             | mg/dL  | 1,2             | 0,8       | 1,6        |
|                            |                  | µmol/L | 20,5            | 13,6      | 27,4       |
| Bicarbonate                | TCO <sub>2</sub> | mmol/L | 11              | 6         | 16         |
| Total Protein              | TP               | g/dL   | 4,7             | 4,2       | 5,2        |
|                            |                  | g/L    | 47              | 42        | 52         |
| Triglycerides              | TRIG             | mg/dL  | 98              | 80        | 115        |
|                            |                  | mmol/L | 1,1             | 0,9       | 1,3        |
| Uric Acid                  | UA               | mg/dL  | 4,3             | 3,3       | 5,3        |
|                            |                  | µmol/L | 255,8           | 196,3     | 315,2      |
| Lactate                    | LAC              | mg/dL  | 13,5            | 9         | 18         |
|                            |                  | mmol/L | 1,5             | 1,0       | 2,0        |
| C-Reactive Protein         | CRP              | mg/dL  | <0,5            | <0,5      | <0,5       |
|                            |                  | mg/L   | <5              | <5        | <5         |

