

Product Number ALPC-G14026-100 &amp; G14021-100

Lot # 1103018

Containing Vial Lots L1 #1103018-1 &amp; L2 #1103018-2

**Expiration Date:** 03-2012

2 Levels x 6 vials x 1 mL ALPC-G14026-100

2 Levels x 1 vial x 1 mL ALPC-G14021-100

**Intended Use**

**NOD®** Chemistry Control is a human Liquid assayed or un-assayed control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert. Controls must be run with the Abaxis Piccolo® Classic and Xpress at least once per month for non-waived labs and for waived labs once per month or every reagent rotor lot change whichever comes first. Verification Samples must be run at least every six months for non-waived labs.

**Summary and Principles**

The use of independent quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control are available to allow performance monitoring within the clinical range.

**Reagent Composition**

This product is prepared from purified human serum to which biochemical material (human and animal tissue extracts); drugs, chemicals, stabilizers and preservatives have been added. The control is in a prepackaged liquid form to avoid potential error or contaminate being introduced during reconstitution.

**Storage and Stability**

To achieve maximum shelf life for the kit store unopened at  $\leq -20^{\circ}\text{C}$ . Store vials away from the light. **Thawed and Unopened:** The Chemistry Control can be used for up to **14 days** when stored **unopened** at  $2-8^{\circ}\text{C}$ . For optimum Bilirubin and  $\text{CO}_2$  stability avoid prolonged exposure of the Control vials

to ambient air / room temperatures / light. NOTE; Bilirubin may decrease over the product shelf life

**Procedure**

The control should be treated the same as a patient sample and run according to the instructions accompanying the instrument, kit, or reagent being used. Before sampling the control should be mixed thoroughly but gently.

Thaw **NOD®** Chemistry Control at room temperature ( $18-25^{\circ}\text{C}$ ) for 1 hour or until completely thawed. Mix the vial thoroughly by inverting several times, before sampling gently swirl until homogeneous with no visible signs of precipitate. Avoid vigorous shaking. After sampling, the Control should be promptly re-capped and stored at  $2-8^{\circ}\text{C}$ . Dispose of at the end of day or upon completion of data collection.

**Limitation of Procedure**

(a) This product should not be used past the expiration date (b) if there is evidence of microbial contamination in the control or excessive turbidity discard the vial (c) This product is not intended for use as a standard.

The assay values recovered in the laboratory are method dependent and reflect reagent, method and technique and instrument variations. If methods and / or reagents are changed or modified the resulting assay value may be different.

**Assignment of Values**

The mean values and acceptable ranges printed on the circular were derived from replicate analyses on the Piccolo Blood Clinical Chemistry Analyzer and are specific for this lot of Liquid Assayed Chemistry Controls. Individual laboratory values should fall within the corresponding acceptable ranges.

**Specific Performance Characteristics**

To ensure the reliability and usefulness of the control, the product must be properly handled and stored as described.

Individual donor units used in the preparation of this product have been tested by FDA approved methods for anti-HIV 1 & 2, HBsAg, anti-HCV, HIV-1 antigens and Syphilis and found non-reactive. No test method can offer complete assurance that products derived from human source material will not transmit infectious diseases. Therefore, this product should be considered potentially infective and be treated in the same manner as a patient specimen.

**Ordering Information:** Verification P/N ALCV-G14033-050 or Control P/N ALPC-G14026-100  
By Ordering On Line at **NOVA-ONE.NET**; or Fax to 818-348-9696



**Assigned Values and Ranges (Representative Values)**  
**Lot #1103018 (Containing Vial Lots L1 #1103018-1 & L2 #1103018-2)**

**Sodium Values need to be matched to Reagent disc Lot number used; See notes \* and \*\* below.**

Expiration Date: 03-2012

METHOD: Abaxis Piccolo Analyte, Units	Level 1		Level 2	
	Mean	Range	Mean	Range
ALT/SGPT U/L	45	35 - 55	187	144 - 230
Albumin g/dL	2.7	2.1 - 3.3	4.5	3.5 - 5.6
Alkaline Phosphatase (ALP) U/L	95	71 - 119	399	299 - 499
Amylase, Pancreatic U/L	70	50 - 90	299	259 - 339
Aspartate Aminotransferase (AST/SGOT) U/L	73	56 - 89	293	225 - 360
Bilirubin – Direct mg/dL	0.6	0.2 - 1.0	2.2	1.6 - 2.8
Bilirubin – Total mg/dL	1.4	1.0 - 1.8	4.1	3.0 - 5.2
BUN (Urea Nitrogen) mg/dL	22	17 - 26	51	46 - 57
Calcium Total mg/dL	7.4	6.4 - 8.4	11.7	10.4 - 13.0
Carbon Dioxide (CO <sub>2</sub> ) mmole/L	15	10 - 20	25	19 - 31
Chloride mmole/L	95	86 - 103	115	105 - 125
HDL Cholesterol mg/dL	33	29 - 38	63	55 - 71
Total Cholesterol mg/dL	129	111 - 148	271	233 - 309
Creatine Kinase (CK) U/L	212	169 - 254	783	627 - 940
Creatinine mg/dL	1.2	0.6 - 1.8	5.3	4.1 - 6.4
GGT U/L	49	39 - 60	193	150 - 235
Glucose mg/dL	71	59 - 82	274	231 - 318
Lactate Dehydrogenase (LDH) U/L	121	99 - 143	509	418 - 601
Magnesium mg/dL	1.5	1.3 - 1.7	4.5	3.8 - 5.2
Phosphorus mg/dL	2.3	1.9 - 2.7	5.4	4.5 - 6.4
Potassium mmole/L	3.0	2.5 - 3.5	6.3	5.7 - 6.9
Protein, Total g/dL	4.7	4.2 - 5.2	7.6	6.8 - 8.4
Sodium* mmole/L Use with Lots between 0445XXX & 1155XX	123	116 - 131	151	141 - 160
Sodium** mmole/L Use with Lots before 0445XXX & after 1155XX	128	120 - 136	152	143 - 161
Triglycerides mg/dL	137	112 - 162	242	199 - 286
Uric Acid mg/dL	3.8	3.3 - 4.4	10.0	8.6 - 11.4

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[NOVA-ONE@sbglobal.net](mailto:NOVA-ONE@sbglobal.net) 818-348-1543 Fax 818-348-9696  
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NOVA-ONE Diagnostics, LLC 22287 Mulholland Hwy, Calabasas CA 91302

