

**ALL VALUE ASSIGNMENT RANGES CALCULATED  
USING ABAXIS REAGENTS ON ABAXIS ANALYZERS**

Lot # **528016002** Expiration Date: **02-2017**  
Containing Vial Lots L1 # 528116001 & L2 # 528216002

2 Levels x 3 vials x 1 mL **ALPC-G14123-100 (3 Mo supply)**  
2 Levels x 6 vials x 1 mL **ALPC-G14126-100 (6 Mo supply)**

**Intended Use**

**NOD<sup>®</sup>** 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. Both control levels must be successfully run with the Abaxis Piccolo<sup>®</sup> Classic and Xpress at least once per month or with every reagent rotor lot change whichever comes first for waived labs. Labs using one of the 5 non-waved reagent rotor discs are considered "Moderately Complex" should run the controls once a month and Verification Samples must be run at least every six months.

**CLIA Waived Testing**

- At least every 30 days or with each new lot number of disc panels (whichever comes first).
- Whenever laboratory conditions have changed significantly.
- When training or retraining of personnel is indicated.
- When test results do not match patient symptoms or clinical findings.

**CLIA Moderately Complex Testing**

- At least every 30 days.
- Whenever laboratory conditions have changed significantly.
- When training or retraining of personnel is indicated.
- When test results do not match patient symptoms or clinical findings

**Verification kits are also available from NOVA-ONE as are the Data Reduction analysis services for the control and verification results.**

**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 Control kit store unopened at  $\leq -15^{\circ}\text{C}$ . Store vials away from the light. The Chemistry Control can be used for up to **14 days** when stored **unopened** at 2-8 $^{\circ}\text{C}$ . For optimum Bilirubin and CO<sub>2</sub> 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<sup>®</sup>** 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 a 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 and found to be non-reactive for HbsAg, Anti-HIV I/II, Anti-HCV, HIV-1 RNA, and HCV RNA. Donors of human plasma units used in making this product were tested and found negative for syphilis. 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 infectious and be treated in the same manner as a patient specimen.

**NOVA-ONE Tech Support will assist you by providing Data Reduction analysis for control and verification results.**

**[NOVA-ONE@sbcglobal.net](mailto:NOVA-ONE@sbcglobal.net) 818-348-1543 Toll Free 800-810-7488 Fax 818-348-9696**

**NOVA-ONE Diagnostics, LLC 22287 Mulholland Hwy, Calabasas CA 91302**

**(REV 08/22/2016)**

**Assigned Values and Ranges (Representative Values)**

**Lot # 528016002** (Containing Vial Lots L1 # 528116001 & L2 # 528216002)

**ALL VALUE ASSIGNMENT RANGES CALCULATED USING ABAXIS REAGENTS ON ABAXIS ANALYZERS**

Expiration Date: **02-2017**

METHOD: Abaxis Piccolo Analyte, Units	Level 1		Level 2	
	Mean	Range	Mean	Range
Albumin g/dL	3.0	2.3 - 3.7	4.1	3.2 - 5.1
Alkaline Phosphatase (ALP) U/L	99	74 - 124	394	296 - 493
ALT/SGPT U/L	54	42 - 67	189	145 - 232
Amylase, Pancreatic U/L	69	49 - 89	292	252 - 332
Aspartate Aminotransferase (AST/SGOT) U/L	83	64 - 102	312	240 - 384
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	4.8	3.5 - 6.0
BUN (Urea Nitrogen) mg/dL	20	16 - 25	51	46 - 56
Calcium Total mg/dL	7.6	6.6 - 8.6	11.8	10.5 - 13.1
Carbon Dioxide (CO <sub>2</sub> ) mmole/L	20	15 - 25	25	19 - 31
Chloride mmole/L	94	86 - 103	115	104 - 125
HDL Cholesterol mg/dL	29	23 - 35	56	45 - 67
Total Cholesterol mg/dL	154	132 - 175	266	228 - 303
Creatine Kinase (CK) U/L	226	181 - 271	748	598 - 898
Creatinine mg/dL	1.5	0.9 - 2.1	5.2	4.1 - 6.4
GGT U/L	48	37 - 58	199	155 - 242
Glucose mg/dL	68	57 - 79	279	234 - 324
Lactate mmol/L	1.56	1.31 - 1.81	4.01	3.37 - 4.65
Lactate Dehydrogenase (LDH) U/L	104	86 - 123	463	380 - 546
Magnesium mg/dL	1.6	1.3 - 1.8	4.7	3.9 - 5.4
Phosphorus mg/dL	2.9	2.4 - 3.4	5.4	4.4 - 6.4
Potassium mmole/L	3.5	3.0 - 4.0	6.7	6.1 - 7.3
Protein, Total g/dL	4.9	4.4 - 5.4	7.4	6.6 - 8.1
Sodium mmole/L	123	116 - 131	151	142 - 160
Triglycerides mg/dL	150	123 - 177	276	226 - 325
Uric Acid mg/dL	3.0	2.6 - 3.5	10.3	8.8 - 11.7
CRP mg/L	40	29 - 51	134	98 - 170

**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

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