NOVA-ONE® Diagnostics

Delivering Innovative Medical Diagnostics Everyday

NOD® CHEMISTRY CONTROL +CRP Liquid Assayed (H)

ALL VALUE ASSIGNMENT RANGES CALCULATED USING ABAXIS REAGENTS ON ABAXIS ANALYZERS

Lot # **528023002** Expiration Date: **02-2024**
Containing Vial Lots L1 # 528123001 & L2 # 528223002

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

CLIA Moderately Complex Testing
a. At least every 30 days.
b. Whenever laboratory conditions have changed significantly.
c. When training or retraining of personnel is indicated.
d. 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 ≤-15ºC. Store vials away from the light. Once thawed and opened, the Chemistry Control can be used for up to **14 days** when tightly capped and stored at 2-8°C. For optimum Bilirubin and 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 (18-25º 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°C for later use. Note thaw date of the control vials and dispose of 14 days after thawed, sampled, and stored refrigerated.

Control vials may be removed from refrigerated storage, gently inverted several times, and used immediately for all panels except the Lipid and Lipid Panel Plus. Return controls to refrigerated storage within 10 minutes for later use. For the Lipid Panel and Lipid Panel Plus, allow the control vials to sit at room temperature for 30 minutes and gently invert several times before testing. Return the vials to refrigerated storage after use.

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@nova-one.com **818-348-1543 Fax 818-348-9696**
NOVA-ONE Diagnostics®, LLC 22287 Mulholland Hwy, Calabasas CA 91302
(REV 08/15/2023)

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Assigned Values and Ranges (Representative Values)

Lot # 528023002 (Containing Vial Lots L1 # 528123001 & L2 # 528223002)

ALL VALUE ASSIGNMENT RANGES CALCULATED USING ABAXIS REAGENTS ON ABAXIS ANALYZERS

Expiration Date: **02-2024**

METHOD: Abaxis Piccolo	Level 1		Level 2	
Analyte, Units	**Mean**	**Range**	**Mean**	**Range**
Albumin g/dL	3.0	2.3 - 3.6	4.4	3.4 - 5.4
Alkaline Phosphatase (ALP) U/L	96	72 - 120	411	317 - 506
ALT/SGPT U/L	51	40 - 63	166	128 - 204
Amylase, Pancreatic U/L	84	64 - 104	299	230 - 367
Aspartate Aminotransferase (AST/SGOT) U/L	84	65 - 104	295	227 - 363
Bilirubin – Direct mg/dL	0.9	0.5 - 1.3	2.0	1.6 - 2.5
Bilirubin – Total mg/dL	1.5	1.1 - 1.9	4.6	3.6 - 5.7
BUN (Urea Nitrogen) mg/dL	18	14 - 22	53	41 - 65
C Reactive Protein mg/L	42	36 - 48	136	105 - 168
Calcium Total mg/dL	7.9	6.9 - 8.9	12.7	9.8 - 15.7
Carbon Dioxide (CO_2) mmole/L	17	12 - 22	27	21 - 33
Chloride mmole/L	94	85 - 102	123	95 - 152
HDL Cholesterol mg/dL	36	29 - 44	63	48 - 77
Total Cholesterol mg/dL	149	128 - 170	306	235 - 376
Creatine Kinase (CK) U/L	219	175 - 263	714	550 - 878
Creatinine mg/dL	1.6	1.0 - 2.2	5.5	4.3 - 6.8
GGT U/L	67	53 - 82	236	181 - 290
Glucose mg/dL	76	64 - 88	265	204 - 326
Lactate mmol/L	2.27	1.90 - 2.63	5.28	4.06 - 6.49
Lactate Dehydrogenase (LDH) U/L	121	99 - 143	434	334 - 534
Magnesium mg/dL	1.3	1.1 - 1.5	6.2	4.7 - 7.6
Phosphorus mg/dL	2.5	2.1 - 3.0	5.9	4.5 - 7.2
Potassium mmole/L	2.5	2.0 - 3.0	7.0	5.4 - 8.6
Protein, Total g/dL	4.9	4.4 - 5.4	7.5	5.8 - 9.2
Sodium mmole/L	123	116 - 131	164	126 - 201
Triglycerides mg/dL	141	116 - 166	285	219 - 350
Uric Acid mg/dL	3.6	3.1 - 4.1	10.4	8.0 - 12.8

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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