

Product Number ALPC-G14021-100
Lot # 0908009
Containing Vial Lots L1 #0908009-1 & L2 #0908009-2
Expiration Date: 9-2010
2 Levels x 1 vials x 1 mL

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 Control 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°C. For optimum Bilirubin and CO₂ stability avoid prolonged exposure of the Control vials to ambient air / room temperatures / light. NOTE: Bilirubin may decrease over the product shelf life

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

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° 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. 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.

Assigned Values and Ranges (Representative Values)
Lot #0908009 (Containing Vial Lots L1 #0908009-1 & L2 #0908009-2)

Expiration Date: 09-2010

METHOD: Abaxis Piccolo Analyte, Units	Level 1		Level 2	
	Mean	Range	Mean	Range
ALT/SGPT U/L	50	38 - 60	181	139 - 223
Albumin g/dL	2.7	2.1 - 3.3	4.5	3.5 - 5.5
Alkaline Phosphatase (ALP) U/L	107	85 - 129	425	336 - 514
Amylase, Pancreatic U/L	73	53 - 93	291	251 - 331
Aspartate Aminotransferase (AST/SGOT) U/L	75	58 - 92	300	230 - 370
Bilirubin - Direct mg/dL	0.7	0.5 - 0.9	2.1	1.7 - 2.5
Bilirubin - Total mg/dL	1.4	1.0 - 1.8	4.0	3.0 - 5.0
BUN (Urea Nitrogen) mg/dL	20	15 - 25	49	42 - 56
Calcium Total mg/dL	7.3	6.3 - 8.3	11.6	10.3 - 12.9
Carbon Dioxide (CO ₂) mEq/L	14	9 - 19	22	16 - 28
Chloride mEq/L	94	87 - 101	115	106 - 124
HDL Cholesterol mg/dL	34	29 - 39	58	50 - 66
Total Cholesterol mg/dL	144	125 - 163	292	254 - 330
Creatine Kinase (CK) U/L	216	173 - 259	819	655 - 983
Creatinine mg/dL	1.3	0.6 - 2.0	5.1	4.1 - 6.1
GGT U/L	52	40 - 64	188	145 - 231
Glucose mg/dL	70	60 - 80	270	243 - 297
Lactate Dehydrogenase (LDH) U/L	135	108 - 162	521	417 - 625
Magnesium mg/dL	1.6	1.3 - 1.9	4.9	4.2 - 5.6
Phosphorus mg/dL	3.2	2.6 - 3.8	6.2	5.1 - 7.3
Potassium mEq/L	2.9	2.4 - 3.4	5.8	5.2 - 6.4
Protein, Total g/dL	4.8	4.3 - 5.3	7.5	6.7 - 8.3
Sodium mEq/L	125	119 - 131	150	142 - 158
Triglycerides mg/dL	138	113 - 163	309	254 - 364
Uric Acid mg/dL	3.4	2.7 - 4.1	10.1	8.4 - 11.8

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