

ALL VALUE ASSIGNMENT RANGES CALCULATED USING ABAXIS REAGENTS ON ABAXIS ANALYZERS

Product Number ALCV-G14133-050
Lot # 521024001
Containing Vial Lots S1 #521124001, S2 #521224001,
& S3 #521324001
Expiration Date: **2025-06-30**
3 Levels x 3 vials x 0.5mL

Intended Use

NOD[®] Verification Samples are human Liquid assayed serum samples used to validate analyzer performance according to CLIA guidelines. The laboratory testing procedures are listed in the following text. Verification Samples must be run at least every six months in Labs using non-waived Reagent discs 400-0026 Hepatic Panel; 400-0031 Basic Metabolic Panel Plus; and 400-0034 MetLyte Plus CRP.

Summary and Principles

The use of independent quality verification sample 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. Three levels of verification samples 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 verification samples are 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 Verification kit store unopened at $\leq -20^{\circ}\text{C}$. Store vials away from the light. Bilirubin may decrease over the product shelf life.

Thawed and Unopened: The Verification Samples can be used for up to **14 days** when stored unopened 2-8°C. For optimum Bilirubin and CO₂ stability avoid prolonged exposure of the Verification Sample vials to ambient air / room temperature / light.

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.

Re-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 818-348-969**

Procedure

The verification samples should be handled with the same safety precautions as a patient sample. Samples should be run as a quality control, **Not** as a patient sample, according to the instructions accompanying the instrument, kit, or reagent being used. Before sampling, the verification samples should be mixed thoroughly but gently.



Thaw **NOD[®]** Verification Samples at room temperature (18-25° C) for 30 minutes or until completely thawed. Mix the vial thoroughly by inverting several times, before sampling gently swirls until homogeneous with no visible signs of precipitate. Avoid vigorous shaking. After sampling the Verification samples 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 verification samples 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 printed on the circular were derived from replicate analyses on the Piccolo Clinical Chemistry Analyzer and are specific for this lot of Liquid Assayed Chemistry Verification Samples. **NOVA-ONE Tech Support will provide Data Reduction analysis assistance for control and verification results.**

Specific Performance Characteristics

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

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Assigned Values and Ranges (Representative Values)

Lot # 521024001 (Containing Vial Lots S1 # 521124001, S2 # 521224001, & S3 # 521324001)

Expiration Date: 2025-06-30



METHOD: Abaxis Piccolo	Sample 1	Sample 2	Sample 3
Analyte, Units	Mean	Mean	Mean
Albumin g/dL	1.9	3.9	5.5
Alkaline Phosphatase (ALP) U/L	30	942	1751
ALT/SGPT U/L	21	600	1215
Amylase, Pancreatic U/L	21	1124	2230
Aspartate Aminotransferase (AST/SGOT) U/L	19	688	1354
Bilirubin – Direct mg/dL	0.1	1.8	3.8
Bilirubin – Total mg/dL	0.3	2.4	4.2
BUN (Urea Nitrogen) mg/dL (**Use with low recovery reagent rotors P/N 400-0023, 400-0028 & 400-0031)	3.3	62	120
BUN (Urea Nitrogen) mg/dL	5.7	61	129
Calcium Total mg/dL	4.3	10.2	14.5
Carbon Dioxide (CO ₂) mmol/L	30	16.3	6.0
Chloride mmol/L	84	106	127
HDL Cholesterol mg/dL	24	52	71
Total Cholesterol mg/dL	67	207	322
Creatine Kinase (CK) U/L	28	1626	3000
Creatinine mg/dL	0.5	7.1	13.2
GGT U/L	14.3	1196	2175
Glucose mg/dL	28	306	578
Lactate mmol/L	0.35	4.89	9.11
Lactate Dehydrogenase (LDH) U/L	64	390	778
Magnesium mg/dL	0.9	3.8	7.1
Phosphorus mg/dL	15.4	11.5	7.4
Potassium mmol/L	2.4	4.6	6.8
Protein, Total g/dL	2.9	6.1	9.3
Sodium mmol/L	116	138	159
Triglycerides mg/dL	32	230	420
Uric Acid mg/dL	0.7	5.2	10.4
CRP mg/L	14.2	86	166

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