NOVA-ONE® Diagnostics

Delivering Innovative Medical Diagnostics Everyday

NOD® Verification Samples Liquid Assayed (H)

ALL VALUE ASSIGNMENT RANGES CACULATED USING ABAXIS REAGENTS ON ABAXIS ANALYZERS

Product Number ALCV-G14033-050
Lot # 464020001
Containing Vial Lots S1 #464120001, S2 #464220001 & S3 #464320001
Expiration Date: **04 2022**
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 ≤ -20ºC. 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 CO_2 stability avoid prolonged exposure of the Verification Sample vials to ambient air / room temperature / light.

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 (18-25º 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.

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.

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 818-348-9696**

NOVA-ONE@nova-one.com 818-348-1543 Toll Free 800-810-7488 Fax 818-348-9696 (REV 08/01/2023)

NOVA-ONE Diagnostics, LLC 22287 Mulholland Hwy, Calabasas, CA 91364

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Assigned Values and Ranges (Representative Values)

Lot # 464020001 (Containing Vial Lots S1 # 464120001, S2 # 464220001 & S3 # 464320001)

Expiration Date: 04 – 2022

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	26	1072	1913
ALT/SGPT U/L	26	737	1506
Amylase, Pancreatic U/L	21	1316	2401
Aspartate Aminotransferase (AST/SGOT) U/L	20	793	1550
Bilirubin – Direct mg/dL	0.3	2.6	4.5
Bilirubin – Total mg/dL	0.4	3.0	5.6
BUN (Urea Nitrogen) mg/dL **(**Use with low recovery reagent rotors P/N 400-0023, 400-0028 & 400-0031)**	6	62	126
BUN (Urea Nitrogen) mg/dL	5	63	116
Calcium Total mg/dL	4.8	11.0	14.6
Carbon Dioxide (CO_2) mmol/L	37	24	8
Chloride mmol/L	85	110	132
HDL Cholesterol mg/dL	19	51	85
Total Cholesterol mg/dL	71	233	369
Creatine Kinase (CK) U/L	32	1776	3312
Creatinine mg/dL	0.6	8.2	16.3
GGT U/L	17	1312	2437
Glucose mg/dL	31	346	661
Lactate mmol/L	0.34	4.60	9.18
Lactate Dehydrogenase (LDH) U/L	66	413	806
Magnesium mg/dL	0.9	3.7	7.2
Phosphorus mg/dL	15.6	9.3	2.7
Potassium mmol/L	2.1	5.1	7.7
Protein, Total g/dL	3.1	6.5	10.0
Sodium mmol/L	121	143	169
Triglycerides mg/dL	40	209	378
Uric Acid mg/dL	0.8	7.1	14.4

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