Synergent Biochem Inc.

LIQUID LIPID CONTROL

For ***in vitro*** diagnostic use
Cat. No. 915, Levels 1& 2

INTENDED USE

The Synergent Biochem, Inc. bi-level Lipid Control is a ready-to-use, assayed chemistry control material for use in monitoring the accuracy and precision of the quantitative lipid determinations.

SUMMARY AND PRINCIPLE

Synergent Liquid Lipid control is prepared from fresh human sera enriched with human lipid fractions. This assayed control includes assigned values for total cholesterol, direct HDL and LDL cholesterol and triglycerides. The use of assayed quality control materials in clinical chemistry procedures is necessary in maintaining good laboratory practices.

PRECAUTIONS

Human source material: Treat as potentially infectious. Each donor unit used in the preparation of this product has been tested by FDA accepted methods and found non-reactive for hepatitis B surface antigen (HBsAg), for antibody against human immune-deficiency virus (anti-HIV-1/2), and for antibody against hepatitis C virus (anti HCV). In spite of negative results at donor level, this control should be handled as potentially infectious material in accordance with good laboratory practices (GLP).

PROCEDURE

1. Remove control from refrigerator and allow warming to room temperature for 15 to 30 minutes.
2. Gently swirl the contents until homogenous. Do not shake vial to avoid the formation of foam.
3. Recap vial tightly after use. Store opened vial in refrigerator at 2° to 8° C

MATERIALS PROVIDED

Liquid Lipid Control - 6 vials, 3mL/vial.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Reagents and supplemental material required for the measurement of listed constituents.
2. General laboratory equipment
3. Suitable analyzer system.

PRODUCT STABILITY

The Synergent Liquid Lipid Control is stable until the expiration date when stored at +2 ℃ to +8 ℃. After opening the vial, the control is stable for 30 days when stored at +2 ℃ to +8 ℃.

LIMITATIONS OF PROCEDURE

Erroneous results may occur from:
1. Contamination of control. Discard vial if particulates or other signs of microbial contamination are observed.
2. Technique errors associated with reagent preparation and the assay procedure, using this product as a calibrator or using past the expiration date.

VALUE ASSIGNMENT

The mean values were derived from replicate analyses of vials representative of the entire lot. The expected range of the mean is provided as a reference for the laboratory until it has established its own mean and standard deviation. The indicated mean and its assigned range should serve as guidelines in assessing the performance of each test method. Measurements using other reagents and instrument systems may give different results.

ASSAY VALUES

Analyte / Instrument	Unit	Level 1 Lot: 1105702E Expiry: 02 / 2013		Level 2 Lot: 1105703E Expiry: 02 / 2013	
		Mean	Range	Mean	Range
Cholesterol, Total					
ChemWell	mg/dL	193	154-232	300	240-360
Roche Modular	mg/dL	215	172-258	303	242-364
Triglycerides					
ChemWell	mg/dL	145	116-174	394	315-473
Roche Modular	mg/dL	134	107-161	372	298-446
Cholesterol, HDL					
ChemWell	mg/dL	66	53-79	41	33-49
Roche Modular	mg/dL	73	58-88	40	32-48
Cholesterol, LDL					
ChemWell	mg/dL	107	86-128	191	153-229
Roche Modular	mg/dL	122	98-146	204	163-245
Apolipoprotein A1					
Beckman Immage	mg/dL	§		§	
Roche Modular	mg/dL	143	114-172	90	72-108
Apolipoprotein B					
Beckman Immage	mg/dL	§		§	
Roche Modular	mg/dL	98	78-118	168	134-202

§ The data required to establish the means and acceptable ranges for this assay were not obtained due to limited assignment participation.

TECHNICAL ASSISTANCE

For technical assistance and ordering information contact Synergent Biochem Inc. at 562-809-3389.

CATALOG NUMBERS:

915 6 X 3mL BI-LEVEL
915-1 6 X 3mL LEVEL 1
915-2 6 X 3mL LEVEL 2

Rev10/07

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