



Synergent Biochem Inc.

CALIBRATION VERIFICATION KIT

For Total Cholesterol, HDL-Cholesterol, Triglycerides and Glucose

For **in vitro** diagnostic use

Cat. No. 815

INTENDED USE

The Synergent Biochem, Inc. Calibration Verification Kit is a ready-to-use, assayed chemistry material for use in the calibration verification of total cholesterol, HDL cholesterol, triglycerides and glucose analytes.

SUMMARY AND PRINCIPLE

Synergent Calibration Verification Kit is prepared from fresh human sera enriched with human lipid fractions. This kit includes total cholesterol, HDL cholesterol, triglycerides and glucose analytes.

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 kit or vial(s) from refrigerator and allow warming to room temperature for 15 to 30 minutes.
2. Gently swirl the contents until homogenous. Do not shake vial. Avoid the formation of foam.
3. Recap vial tightly after use. Store opened vial in refrigerator at 2° to 8° C
4. Follow manufacturer's instruction for each specific test system.

MATERIALS PROVIDED

Calibration Verification Kit For Total Cholesterol, HDL Cholesterol, Triglycerides and glucose - 6 vials, 3mL/vial.

1. Total Cholesterol (Chol), Triglycerides (Trig) and Glucose (Glu) Level 1, 2 & 3
2. HDL-Cholesterol (HDL-C) Level 1, 2 & 3

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 Calibration Verification Kit is stable until the expiration date when stored at +2 °C to +8 °C. After opening the vial, the product is stable for 30 days when stored at +2 °C to +8 °C.

LIMITATIONS OF PROCEDURE

Erroneous results may occur from:

1. Contamination of product. 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 indicated mean should serve as guidelines in assessing the performance of each test method. Measurements using other reagents and instrument systems may give different results.

EXPECTED VALUES

See value card insert for specific test system in use.

TECHNICAL ASSISTANCE

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

CATALOG NUMBERS:

815 6 X 3mL TRI-LEVEL

Rev 0 4/2017



Synergent Biochem Inc.

Calibration Verification Value Card

pts panels® Lipid Panel and pts panels® CHOL+HDL+GLU Test Strips
for use with CardioChek® professional analyzers

Kit Lot: 1712101
PN: 815
Expiry: 10/2018

Analytes	Level 1	Level 2	Level 3	Unit
Total Cholesterol	183	258	338	mg/dL
	4.7	6.7	8.7	mmol/L
HDL Cholesterol	29	51	81	mg/dL
	0.7	1.3	2.1	mmol/L
Triglycerides	192	306	451	mg/dL
	2.2	3.5	5.1	mmol/L
Glucose	74	221	512	mg/dL
	4.1	12.3	28.4	mmol/L

NOTE: Sample volume = 50 µL for test strips