Synergent Biochem Inc. Calibration Verification Kit¹

Synergent Biochem, Inc. www.synergentbiochem.com Cat. No. 815

This product is for use on CardioChek® PA or CardioChek® Plus professional analyzers using PTS Panels® lipid panel and CHOL+HDL+GLU test strips²

This kit contains solutions that are used to perform calibration verification (cal-ver) for the following analytes: total cholesterol, HDL cholesterol, triglycerides, and glucose in three levels. There are 2 sets (3 levels each) for a total of 6 vials of solutions. One set of 3 levels is used for total cholesterol, triglycerides, and glucose, and the second set of 3 levels is used for HDL cholesterol only. For calibration verification, please use the same test strips that you will use for your patients.

- 1. Read the calibration verification kit package insert before using.
- 2. Follow manufacturer recommendations for storage and testing temperature.
- 3. Follow PTS Panels package inserts and the analyzer User Guide to run the test strips on the analyzer.
- 4. Gently swirl or invert each vial to thoroughly mix solution (do not shake).
- 5. Remove the lid and carefully remove the tip from each vial.
- 6. After inserting the test strip into the analyzer, use a precision pipet to apply 50 μL of the Level 1 calibration verification solution to the test strip. Repeat for Level 2 and Level 3 with a new test strip each time.

NOTE: There are 6 vials of cal-ver solutions. The first set of 3 vials contains total cholesterol, triglycerides, and glucose. The second set of 3 vials contains HDL cholesterol only.

- 7. Test at least two replicates for each level.
- 8. Record the values for each analyte and enter results into a spreadsheet software program, such as Microsoft Excel.
- 9. Plot the values obtained for the test strips (y-axis) against the target concentrations for the analyte listed in the Calibration Verification Value Card (x-axis).
- 10. Use the spreadsheet software program to calculate the linear regression parameters.³

Note: If R^2 is displayed, make sure you calculate r (square root of R^2). If r is < 0.88, troubleshoot and retest as necessary.

- 1. See Package Insert for instructions.
- 2. This procedure is for use with PTS Panels lipid panel and CHOL+HDL+GLU test strips only.
- 3. Each lab should establish their own acceptance criteria.

The following table provides a guideline of strips used, assuming duplicate testing of each level:

Synergent Calibration Verification	Number of Test Strips Needed	Analytes Tested (reflectance chemistry)
Level 1 Total Cholesterol (Chol) Triglycerides (Trig) Glucose (Glu)	2	Total Cholesterol, Triglycerides, and/or Glucose
Level 2 Total Cholesterol (Chol) Triglycerides (Trig) Glucose (Glu)	2	Total Cholesterol, Triglycerides, and/or Glucose
Level 3 Total Cholesterol (Chol) Triglycerides (Trig) Glucose (Glu)	2	Total Cholesterol, Triglycerides, and/or Glucose
Level 1 HDL Cholesterol (HDL-C)	2	HDL Cholesterol
Level 2 HDL Cholesterol (HDL-C)	2	HDL Cholesterol
Level 3 HDL Cholesterol (HDL-C)	2	HDL Cholesterol
Total Number of Test Strips Used	12	

Please call Customer Service at +1-317-870-5610 (direct) or 1-877-870-5610 (toll-free US only) if you have any questions or comments.

IMPORTANT NOTE: The glucose in this product is intended for use with the PTS reflectance (colorimetric) CHOL+HDL+GLU test strips. This product is not intended to be used with the amperometric eGLU test strips.