

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**

k032932

**B. Analyte:**

High Density Lipoprotein (HDL) Cholesterol

**C. Type of Test:**

Quantitative

**D. Applicant:**

Stanbio Laboratory

**E. Proprietary and Established Names:**

Stanbio Laboratory Direct HDL Cholesterol LiquiColor®

Stanbio Direct HDL/LDL Cholesterol Calibrator

**F. Regulatory Information:**

1. Regulation section:  
21 CFR § 862.1475, Lipoprotein Test System  
862.1150, Calibrator
2. Classification:  
Class I, Class II
3. Product Code:  
LBS,  
JIX,
4. Panel:  
Clinical Chemistry (75)

**G. Intended Use:**

1. Indication(s) for use:  
Direct HDL Cholesterol LiquiColor® and Direct HDL/LDL Cholesterol Calibrator system is a testing device for the quantitative determination of high-density lipoprotein cholesterol (HDL-C) in serum or plasma. HDL Cholesterol measurement aids the diagnosis and treatment of lipid and lipoprotein metabolism disorders.

2. Special condition for use statement(s):  
For In Vitro Diagnostic use only.  
Prescription use

3. Special instrument Requirements:  
Hitachi® 917 analyzer

**H. Device Description:**

The device is a system using the reagent and calibrator in combination to directly measure the HDL-Cholesterol. This is achieved by a homogenous method that directly measurement serum HDL-Cholesterol levels without the need for any off-line pretreatment or centrifugation steps. It employs a two-reagent system. The first reagent (R1) contains a combination of detergent, organic and inorganic phosphoric acid compounds, which specifically bind LDL, VLDL and chylomicrons leaving the HDL particles exposed. The second reagent (R2) contains enzymes, which then reacts with HDL cholesterol present in the sample. Consequently, only the HDL cholesterol is subject to cholesterol measurement.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):  
Roche HDL Cholesterol assay procedure
2. Predicate K number(s):  
k000568
3. Comparison with predicate:  
Both devices are for the quantitative determination of the same analyte in the same matrixes. Both devices employ enzymatic colorimetric reaction.

**J. Standard/Guidance Document Referenced (if applicable):**

National Cholesterol Education Program (NCEP) guidelines “Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). NIH Publication No. 01-3670: May 2001  
NCCLS EP5-A - Evaluation of Precision Performance of Clinical Chemistry Devices  
NCCLS EP6-P – Evaluation of the Linearity of Quantitative Analytical Methods  
NCCLS EP9-A – Method Comparison and Bias Estimation Using Patient Samples

**K. Test Principle:**

The tests employ enzymatic colorimetric reaction. The increase in absorbance due to color intensity generated during the reaction is measured photometrically, and is proportional to the HDL-Cholesterol concentration.

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:
  - a. Precision/Reproducibility:  
Within-Day and Day-to-Day precision for the Direct HDL Cholesterol LiquiColor method was determined following a modification of NCCLS EP5-A. Results are summarized below.

Within – Day; N =10

|             | Sample 1 | Sample 2 |
|-------------|----------|----------|
| Mean(mg/dL) | 37.7     | 74.5     |
| SD          | 0.24     | 0.42     |
| % CV        | 0.65     | 0.56     |

Day –to –Day (24 Days); N=18

|             | Sample 1 | Sample 2 | Sample 3 |
|-------------|----------|----------|----------|
| Mean(mg/dL) | 30.9     | 45.8     | 66.4     |
| SD          | 0.64     | 0.76     | 1.22     |
| % CV        | 2.0      | 1.6      | 1.8      |

*b. Linearity/assay reportable range:*

Performed according to NCCLS Guideline EP6-P, the results show this method is linear to 200 mg/dL.

*c. Traceability (controls, calibrators, or method):*

The value of this calibrator was assigned by procedures traceable to the National Reference System for Cholesterol (NRS/CHOL). This reagent system was not tested or certified by the CRMLN (Cholesterol Reference Method Laboratory Network)

*d. Sensitivity:*

Based on an instrument resolution of  $A=0.001$  absorbance units, this reagent has a sensitivity of 0.4 mg/dL of HDL cholesterol. This was demonstrated in a study assaying a sample of known concentration in 20 replicates.

*e. Analytical specificity:*

The test is not influenced by hemoglobin values up to 500 mg/dL, bilirubin levels up to 40 mg/dL, ascorbic acid up to 50 mg/dL, chylomicrons up to 3000 mg/dL. This was demonstrated in a study using two samples spiked with interferant.

*f. Assay cut-off:*

NA

2. Comparison studies:

*a. Method comparison with predicate device:*

Linear regression analysis of 50 serum samples with HDL cholesterol levels ranges from 18 to 123 mg/dL was performed, comparing the subject product (Y) to the predicate (X) with the following results:  
 $Y = 1.01 X - 0.4942$       $r = 0.9987$

*b. Matrix comparison: one sample was divided into aliquots as follows:*

| Samples | Type of blood tube | Assay |
|---------|--------------------|-------|
|         |                    |       |

|        |  |      |
|--------|--|------|
| Serum  | Reference (drawn by syringe)                       | 60.0 |
| Serum  | Plain Blood Tube                                   | 59.9 |
| Serum  | With additive for isolation                        | 60.9 |
| Serum  | Thrombin Blood Tube                                | 60.5 |
| Plasma | Heparin Lithium + polyester Gel Blood tube         | 59.7 |
| Plasma | Heparin Lithium + Acetic Iodide Lithium Blood Tube | 57.0 |
| Plasma | Heparin Sodium + Na F Blood Tube                   | 55.3 |

3. Clinical studies:

- a. *Clinical sensitivity:*  
Not applicable.
- b. *Clinical specificity:*  
Not applicable.
- c. *Other clinical supportive data (when a and b are not applicable):*  
Not applicable.

4. Clinical cut-off:

NA

5. Expected values/Reference range:

The expected values for serum HDL cholesterol are from Tietz N.W., Clinical Guide to Laboratory Tests, W. B. Saunders Co, Philadelphia 1986, P.256, as follows:

Males: 30 -70 mg/dL      Female: 30 -85 mg/dL

According to NCEP, HDL values greater than or equal to 40 mg/dL are considered desirable and value greater than or equal to 60 mg/dL are considered to offer some protection against coronary heart disease. Values below 40 mg/dL are considered to be a significant independent risk factor for coronary heart disease. It is recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories, and local populations.

**M. Conclusion:**

I recommend that the Stanbio Laboratory Direct HDL Cholesterol LiquiColor® and Stanbio Direct HDL/LDL Cholesterol Calibrator are substantially equivalent to the legally marketed predicate device.