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

A. 510(k) Number:
k032936

B. Analyte:
Low Density Lipoprotein (LDL) Cholesterol

C. Type of Test:
Quantitative

D. Applicant:
Stanbio Laboratory

E. Proprietary and Established Names:
Stanbio Laboratory Direct LDL Cholesterol LiquiColor®
Stanbio Direct HDL/LDL Cholesterol Calibrator

F. Regulatory Information:
  1. <u>Regulation section</u>:
     21 CFR § 862.1475, Lipoprotein Test System
              862.1150, Calibrator

  2. <u>Classification</u>:
     Class I, Class II

  3. <u>Product Code</u>:
     MRR,
     JIX

  4. <u>Panel</u>:
     Clinical Chemistry (75)

G. Intended Use:
  1. <u>Indication(s) for use:</u>

     Direct LDL Cholesterol LiquiColor® and Direct HDL/LDL Cholesterol
     Calibrator system is a testing device for the quantitative determination of
     low-density lipoprotein cholesterol (LDL-C) in serum or plasma. LDL
     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 LDL-Cholesterol. This is achieved by a homogenous method that directly measures serum LDL-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 HDL, VLDL and chylomicrons leaving the LDL particles exposed. The second reagent (R2) contains enzymes, which then reacts with LDL cholesterol present in the sample. Consequently, only the LDL cholesterol is subject to cholesterol measurement.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   LDL Cholesterol Plus

2. Predicate K number(s):
   k012287

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 LDL-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)	50	99
SD	0.28	0.49
% CV	0.56	0.44

Day –to –Day (24 days; N=17)

	Sample 1	Sample 2	Sample 3
Mean(mg/dL)	97	138	204
SD	1.29	1.92	2.90
% CV	1.33	1.40	1.43

b. *Linearity/assay reportable range:*
Performed according to NCCLS Guideline EP6-P, the results show this method is linear to 520 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 LDL 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, and chylomicrons up to 3000 mg/dL. This was demonstrated in a study using two samples spiked with interferant.

f. *Assay cut-off:*
NA

2. <u>Comparison studies:</u>

   a. *Method comparison with predicate device:*

   Linear regression analysis of 62 serum samples with LDL cholesterol levels ranges from 22 to 178 mg/dL was performed, comparing the subject product (Y) to the predicate (X) with the following results:
   $Y = 1.025 X - 4.0289$ $r = 0.9969$

   b. *Matrix comparison study in which one sample was split as follows:*

Samples	Type of blood tube	Assay
Serum	Reference (drawn by syringe)	110.7
Serum	Plain Blood Tube	111.1
Serum	With additive for isolation	109.7
Serum	Thrombin Blood Tube	110.5
Plasma	Heparin Lithium + polyester Gel Blood tube	108.0
Plasma	Heparin Lithium + Acetic Iodide Lithium Blood Tube	105.6
Plasma	Heparin Sodium + Na F Blood Tube	98.0

3. <u>Clinical studies:</u>

   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. <u>Clinical cut-off:</u>
   NA

5. <u>Expected values/Reference range:</u>
   According to NCEP recommendations for patients classifications are suggested for the prevention and management of coronary heart disease,
   Optimal: <100 mg/dL (2.58 mmol/L)
   Near Optimal: 100-129 mg/dL (2.59-3.34 mmol/L)
   Borderline High: 130-159 mg/dL (3.36-4.11 mmol/L)
   High: 160-189mg/dL (4.14-4.88 mmol/L)
   Very High: ≥190 mg/dL (≥4.90 mmol/L)

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