

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

A. 510(k) Number: K040767

B. Purpose for Submission: New Device

C. Analyte: Direct High Density Lipoprotein Cholesterol (HDL)

D. Type of Test: Two point calibration colorimetric end point

E. Applicant: Beckman Coulter, Inc

F. Proprietary and Established Names: Proprietary – Synchron Systems HDL Cholesterol (HDL) Reagent Established Name lipoprotein test system.

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1475
2. Classification: I
3. Product Code: LBS
4. Panel: 75

H. Intended Use:

1. Intended use(s): SYNCHRON Systems HDL Cholesterol (HDL) Reagent, when used in conjunction with Synchron Systems Lipid Calibrator. Is intended for the quantitative determination of HDL cholesterol in the high-density lipoprotein (HDL) fraction of serum or plasma on Synchron Systems.
2. Indication(s) for use: SYNCHRON Systems HDL Cholesterol (HDL) Reagent, when used in conjunction with SYNCHRON Systems Lipid calibrator, is intended for the quantitative determination of HDL cholesterol in the high-density lipoprotein (HDL) fraction of serum or plasma on SYNCHRON systems.
3. Special condition for use statement(s): Prescription Use
4. Special instrument Requirements: For use on Beckman Coulter SYNCHRON systems.

I. Device Description: SYNCHRON Systems HDL Cholesterol (HDLD) Reagent, when used in conjunction with Synchron Systems Lipid Calibrator, is intended for the quantitative determination of HDL cholesterol in the high-density lipoprotein (HDL) fraction of serum or plasma on Synchron Systems.

J. Substantial Equivalence Information:

1. Predicate device name(s): Synchron Systems HDLC Reagent
2. Predicate K number(s): K934045
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	HDLD Reagent	HDLC Reagent
Liquid stable reagent	HDLD Reagent	HDLC Reagent
Differences		
Item	Device	Predicate
Methodology	HDLD is a direct method	HDLC is an indirect method
Analytic Range	HDLD = 5 – 135 mg/dl	HDLC = 5 – 90 mg/dl

K. Standard/Guidance Document Referenced (if applicable): NCCLS EP9 – User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples, NCCLS EP5 – User Evaluation of Precision Performance of Clinical Chemistry Devices, NCCLS EP6 – Evaluation of Linearity of Quantitative Methods, NCCLE EP7 – Interference Testing in Clinical Chemistry, NCCLS C28 – How to Define and Determine Reference Intervals in the Clinical Laboratory

L. Test Principle: Timed endpoint colorimetric

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:* Precision studies were performed based upon the NCCLS EP5 – “User Evaluation of Precision Performance of Clinical Chemistry Devices”. Controls and various serum pools were used for the precision studies. The HDLD precision was established as - Within run S.D. (mg/dl) 3.0, %CV 3.0 Total SD (mg/dl) 4.5, %CV 4.5

b. Linearity/assay reportable range: Linearity was determined based on the NCCLS EP6 – “Evaluation of the Linearity of Quantitative Methods”. Linearity was established as - Slope 1.0 +/- 0.1, Intercept = 0.5 mg/dl, $r = 0.97$. Linear range was established as 5 – 135 mg/dl, N=66.

c. Traceability (controls, calibrators, or method): Beckman Coulter has documented traceability to the National Cholesterol Education Program’s recommended accuracy base for HDL Cholesterol by performing a direct comparison with a Cholesterol Reference Method Laboratory Network laboratory using fresh human specimens which cover the NCEP medical decision points.

d. Detection limit: Detection limit for the SYNCHRON Systems is 5.0 mg/dl. The analytical sensitivity of the Synchron Systems HDLD was evaluated by comparing the recovery of saline to the recovery of a low control.

e. Analytical specificity: Studies were performed to assess common or known substances that could interfere with the method. A summary of the data appears for the common interferents: Hemoglobin @ 500 mg/dl, Bilirubin 30 mg/dl, Lipemia 4+, Ascorbic Acid 50 mg/dl, Immunoglobulin 3000 mg/dl.

f. Assay cut-off: Sensitivity for HDLD determination is 5.0 mg/dL. The analytical sensitivity of the Synchron Systems HDLD was evaluated by comparing the recovery of saline to the recovery of a low control. Reference Interval data was obtained from NIH publications assigning risk as Low for <40 mg/dl and High as > or = to 60 mg/dl

2. Comparison studies:

a. Method comparison with predicate device: Method comparison was demonstrated on the Synchron CX and LX systems in a direct comparison of the predicate with the SYNTRON HDL cholesterol reagent.

b. Matrix comparison: Comparisons were made on surplus fresh, refrigerated and frozen samples. Controls and pools were used for precision studies. Serum versus plasma studies were performed to substantiate the use of heparin and EDTA anticoagulants for HDL Cholesterol testing.

3. Clinical studies:

a. Clinical sensitivity: N/A

b. Clinical specificity: N/A

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off: N/A
5. Expected values/Reference range: Reference Interval data was obtained from NIH publications assigning risk as Low for <40 mg/dl and High as > or = to 60 mg/dl

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

Other Supportive Information: