

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

A. 510(k) Number:

k042195

B. Purpose for Submission:

New device

C. Analyte:

HDL Cholesterol

D. Type of Test:

Quantitative

E. Applicant:

Beckman Coulter, Inc.

F. Proprietary and Established Names:

SYNCHRON® Systems HDL Cholesterol (HDL) Reagent

SYNCHRON® Systems Lipid Plus Calibrators 1 & 2

G. Regulatory Information:

1. Regulation section:

862.1475, Lipoprotein Test System

862.1150, Calibrator, Secondary

2. Classification:

Class I that meets the limitations of exemptions 862.9 (c) (9), Class II

3. Product Code:

LBS, JIT

4. Panel:

75

H. Intended Use:

1. Intended use(s):

See Indications for Use

2. Indication(s) for use:

HDL reagent, when used in conjunction with SYNCHRON LX® System(s) and SYNCHRON Systems Lipid Plus Calibrator, is intended for the

quantitative determination of HDL Cholesterol (HDL) in the high density lipoprotein (HDL) fraction of human serum or plasma.

HDL reagent, when used in conjunction with SYNCHRON CX® CE/DELTA/PRO System(s) and SYNCHRON Systems Lipid Plus Calibrator, is intended for the quantitative determination of HDL Cholesterol (HDL) in the high density lipoprotein (HDL) fraction of human serum or plasma.

The SYNCHRON® Systems Lipid Plus Calibrator 1 & 2, in conjunction with specified assays on the SYNCHRON® Systems, are intended to provide points of reference in the measurement of selected human lipids and proteins.

3. Special condition for use statement(s):
Prescription Use only
4. Special instrument Requirements:
SYNCHRON® CX CE/DELTA/PRO and LX Systems

I. Device Description:

The SYNCHRON® Systems HDL Reagent is supplied in a ready-to-use liquid format and filled into bar-coded cartridges, which are placed directly onto the appropriate SYNCHRON System. SYNCHRON Systems Lipid Plus Calibrators 1 & 2 are supplied as stabilized liquid calibrators prepared from human serum.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Beckman Coulter SYNCHRON® Systems HDLD Reagent
2. Predicate K number(s):
k040767
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Same	Same
Analytical range	5 – 135 mg/dL	Same
Reagents	Liquid, ready to use	Same
Sample type	Serum or plasma	Same
Differences		
Item	Device	Predicate
Sample size	4 µl	3 µl
Methodology	uses cholesterol oxidase acceleration and dissolving of HDL by use of a specific detergent	uses solubilization polyanion

K. Standard/Guidance Document Referenced (if applicable):

NCCLS EP5-A, NCCLS EP6-P, NCCLS EP7, NCCLS EP9-A, National Cholesterol Education Program Adult Treatment Panel III (ATP III)

L. Test Principle:

The SYNCHRON® Systems HDL method is a homogenous assay without the need for any off-line pretreatment or centrifugation steps. The method is based on accelerating the reaction of cholesterol oxidase to form non-reactive lipid complexes, and selectively dissolving HDL using a specific detergent. The HDL cholesterol is converted with cholesterol esterase and cholesterol oxidase to form hydrogen peroxide, which is then coupled with a chromogen to form a colored product. HDL reagent is used to measure the cholesterol concentration by a timed-endpoint method.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Within-run and total precision studies were designed from NCCLS EP5-A using multi-level control materials (number of data points = 80 for each level) based on the data from one system each for SYNCHRON CX and LX, run for 20 days, 2 runs per day, 2 observations per run. On the SYNCHRON CX Systems within-run % CV ranged from 1.5 % to 2.8 %; total imprecision, % CV ranged from 2.4 % to 5.1 %. On the SYNCHRON LX systems within run % CV ranged from 1.2 % to 2.3 %; total imprecision % CV ranged from 2.6 % to 6.1 %.

b. *Linearity/assay reportable range:*

The linear range of the assay was established as 5 – 135 mg/dL. Linearity studies were designed using NCCLS EP6-P. Serial dilutions of high serum samples were used. SYNCHRON systems values were plotted versus the sample dilution and an appropriate line fitted by standard linear regression. For the SYNCHRON CX Systems, $y = 1.0013x - 0.5601$, $r = 0.999$. For the SYNCHRON LX systems, $y = 1.0004x - 0.6862$, $r = 0.999$.

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

The SYNCHRON® Systems Lipid Plus Calibrators 1 & 2 is traceable to NIST SRM 19516. The traceability process is based on prEN ISO 17511. Labeling for the SYNCHRON® Systems HDL Cholesterol (HDL) Reagent contains the statement that the assay has not been certified per NCEP guidelines.

d. *Detection limit:*

Analytical sensitivity is defined as the concentration that can be distinguished from zero with 95 % confidence. The sensitivity for the method was established as 5 mg/dL.

e. *Analytical specificity:*

Studies were performed to assess common or known substances that could interfere with the method. The following substances were tested for interference:

Substance	Source	Maximum Level Tested	Observed Effect on Analyte
Hemoglobin	RBC hemolysate	500 mg/dL	NSI
Bilirubin	Porcine	30 mg/dL	NSI
Lipemia	Intralipid	4+ (1800 mg/dL)	NSI
Ascorbic Acid	n/a	100 mg/dL	NSI
Immunoglobulin IgG	Human	5000 mg/dL	NSI

NSI = No significant interference (within ± 6 mg/dL or 6 %)

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Method comparison experiments were designed using NCCLS EP9-A and employed Deming regression to assess the data. The correlation test results were obtained using the predicate SYNCHRON Systems HDLD Reagents (k040767) and the candidate SYNCHRON systems HDL reagents. Additional comparison studies were conducted versus the SYNCHRON Systems HDLC method.

Instrument	Slope	Intercept	r	n	Range of Values	Comparison Method
SYNCHRON CX	0.992	-2.8	0.994	79	11-134 mg/dL	SYNCHRON HDLD
SYNCHRON LX	1.000	-2.8	0.993	79	9-135 mg/dL	SYNCHRON HDLD
SYNCHRON CX	1.037	-5.1	0.979	79	11-130 mg/dL	SYNCHRON HDLC
SYNCHRON LX	1.047	-4.0	0.980	79	10-131 mg/dL	SYNCHRON HDLC

b. *Matrix comparison:*

Serum versus plasma studies were performed to substantiate the use of heparin and EDTA anticoagulants. For each anticoagulant, a minimum of 50 healthy volunteers were drawn with values ranging from 14 mg/dL to 120 mg/dL.

Summary Data for SYNCHRON CX Systems

Anticoagulant	Level of Anticoagulant Tested	Deming Regression Analysis
Sodium Heparin	14 units/mL	$Y = 0.985x + 0.5$; $r = 0.995$
Lithium Heparin	14 units/mL	$Y = 0.959x + 0.6$; $r = 0.993$
EDTA	1.5 units/mL	$Y = 0.946x - 1.1$; $r = 0.996$

Summary Data for SYNCHRON LX Systems

Anticoagulant	Level of Anticoagulant Tested	Deming Regression Analysis
Sodium Heparin	14 units/mL	$Y = 1.030x - 3.2$; $r = 0.992$
Lithium Heparin	14 units/mL	$Y = 0.958x + 0.5$; $r = 0.991$
EDTA	1.5 units/mL	$Y = 0.952x - 1.4$; $r = 0.993$

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)*

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The reference Interval for HDL is based on the 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); Executive Summary. NIH Publication No. 01-3670, National Institutes of Health. Bethesda. Maryland: May 2001.

Cardiovascular Risk	Units
High	< 40 mg/dL
Low	≥ 60 mg/dL

N. Conclusion:

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