

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

A. 510(k) Number:

k061377

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Apolipoprotein A1

Apolipoprotein B

D. Type of Test:

Quantitative

E. Applicant:

Pointe Scientific, Inc.

F. Proprietary and Established Names:

Apolipoprotein A1 Reagent Set

Apolipoprotein B Reagent Set

Apolipoprotein A1 Calibrator Set

Apolipoprotein B Calibrator Set

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1475

21 CFR § 862.1150

2. Classification:

Class I, meets the limitations to exemption [21 CFR 862.9(c)(4)] (Assay)

Class II (Calibrators)

3. Product code:

MSJ, Apolipoproteins

JIT, Calibrator, Secondary

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See the Indications for use below.

2. Indication(s) for use:

These products are to be used for the quantitative determination of apolipoprotein A1 and Apolipoprotein B in human serum by immunoturbidimetric analysis. The determination of apolipoprotein A1 and apolipoprotein B are commonly performed as an aid in the assessment of individuals who are at risk for developing coronary artery disease.

3. Special conditions for use statement(s):

For professional prescription use only

4. Special instrument requirements:

Hitachi 717

I. Device Description:

This device is two different reagents sets for the detection of either apolipoprotein A1 or apolipoprotein B , each of which use immunoturbidimetric analysis to determine their concentrations in human serum. In order to calibrate instruments to be used with this test, a calibrator is available that uses a six point calibration curve. This device has been tested on the Hitachi 717, however use on other instruments is possible.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Kamiya Biomedical Co. Apolipoprotein A1 Reagent, Apolipoprotein B Reagent, Calibrators
2. Predicate 510(k) number(s):
k993345, k993354, k993606
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Quantitative determination apolipoprotein A1 or apolipoprotein B	Quantitative determination apolipoprotein A1 or apolipoprotein B
Detection	Measurement at 340 nm	Measurement at 340 nm
Sample Type	serum	serum
Assay Methodology	immunoturbidimetric	immunoturbidimetric
Calibration	Six point calibration curve	Six point calibration curve

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

None identified.

L. Test Principle:

An insoluble turbid immunoprecipitate is formed by the reaction between the apo A1 or apo B antigen in human serum and the specific antibody in the R2 reagent. Maximum exposure of antigenic sites to which the antibody will bind is achieved by using the R1 reagent. The resulting turbidity is measured spectrophotometrically at 340nm and the apo A1 or apo B in the serum is determined from a calibration curve obtained by using the four level calibrator set used to calibrate the chemistry analyzer.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Precision studies were performed on 3 different concentrations of apolipoprotein A1 and apolipoprotein B. The within day results were obtained by running two samples in replicas of 20 on the same day. Day to day results were obtained by

performing one run per day of each of these same materials in duplicate over a span of 20 days. The precision studies were performed on a Roche Diagnostics, Hitachi 717 chemistry analyzer. Results are summarized below.

Run to Run				
Analyte	N	Mean	SD	%CV
Apo A1	20	54.3	2.8	5.1
Apo A1	20	118.3	2.7	2.3
Apo A1	20	221.3	2.9	1.3
Apo B	20	24.3	0.4	1.8
Apo B	20	119.0	2.8	2.3
Apo B	20	179.5	4.7	2.6

With Run				
Analyte	N	Mean	SD	%CV
Apo A1	20	53.1	1.4	2.7
Apo A1	20	118.2	2.5	2.1
Apo A1	20	219.5	2.6	1.2
Apo B	20	24.3	1.0	4.2
Apo B	20	119.2	1.6	1.3
Apo B	20	180.2	7.6	4.2

b. Linearity/assay reportable range:

Linearity was assessed by analyzing 10 dilutions of a human serum sample spiked with Apolipoprotein A1 to the approximate level of 340 mg/dL and Apolipoprotein B to the approximate level of 330 mg/dL. Results are summarized below.

Apolipoprotein A1		
Sample	Expected Value, mg/dL	Observed Value, mg/dL
1	6.3	2.0
2	39.6	42.0
3	72.9	75.0
4	106.3	108.0
5	139.6	141.0
6	172.9	176.0
7	206.2	203.0
8	239.6	235.0
9	272.9	269.0
10	306.2	309.0
11	339.5	342.0

Linear regression analysis gave the following: Observed = 0.974(Expected) + 1.9; r = 0.9996. The claimed assay measuring range is 2 – 300 mg/dL Apolipoprotein A1.

Apolipoprotein B		
Sample	Expected Value, mg/dL	Observed Value, mg/dL
1	2.6	1.0
2	35.1	39.0
3	67.6	70.0
4	100.1	96.0
5	132.7	127.0
6	165.2	165.0
7	197.7	205.0
8	230.2	229.0
9	262.7	262.0
10	295.3	297.0
11	327.8	326.0

Least squares regression analysis gave the following: Observed = 0.997 (Expected) + 2.6; $r = 0.9994$. The claimed assay measuring range is 3 – 300 mg/dL Apolipoprotein B.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Calibrators are traceable to IFCC-traceable APO B calibration material from Bacton, product code 8802AE and IFCC-traceable APO A1 calibration material from Bacton, product code 8801AE. Stability studies supports the claimed shelf-life of the calibrators is 18 months and the claimed open vial stability is 28 days.

d. Detection limit:

The lowest limit of detection for the apolipoprotein A1 and apolipoprotein B was determined by testing various dilutions of a low concentration sample and running the dilutions in replicates of 20. The lowest sample where the CV was determined to be less than 25% was selected as the lowest limit of detection. For Apolipoprotein A1, a sample of 2 mg/dL was found to show a CV below 25%. For Apolipoprotein B, a sample of 3 mg/dL was found to show a CV below 25%.

e. Analytical specificity:

For apolipoprotein A1, no interference was observed in samples containing bilirubin up to 20.0 mg/dL, hemoglobin up to 500 mg/dL and lipemia (intralipid) up to 1000 mg/dL. Potential cross reactivity of the anti-apo A1 antibody with Apolipoprotein A2 was not evaluated. This was stated in the labeling.

For apolipoprotein B, no interference was observed in samples containing bilirubin up to 20.0 mg/dL, hemoglobin up to 500 mg/dL and lipemia (intralipid) up to 1000 mg/dL. Potential cross reactivity of the anti-apo B antibody with Apolipoprotein A2, or Apolipoprotein B48 was not evaluated. This was stated in the labeling.

f. Assay cut-off:
Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A total of 104 patient samples were run using apolipoprotein A1 and apolipoprotein B methods against the predicate on the Hitachi 717 chemistry analyzer.

Linear regression analysis gave the following relationship for the apolipoprotein A1 reagent with samples ranging from 27-243 mg/dL: Device = 0.984(Predicate) + 2.6; $r = 0.994$

Linear regression analysis gave the following relationship for the apolipoprotein B reagent with samples ranging from 24-231 mg/dL: Device = 0.996(Predicate) + 0.9; $r = 0.994$

b. Matrix comparison:
Not applicable.

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:
Not applicable.

5. Expected values/Reference range:

The reference range for apolipoprotein A1 and apolipoprotein B are identified in the labeling as:

apolipoprotein A1

Males: 94-178 mg/dL

Females: 101-199 mg/dL

apolipoprotein B

Males: 63-133 mg/dL

Females: 60-126 mg/dL

These values were quoted from the following reference:

Burtis, C.A., E.R. Ashwood, Tietz Textbook of Clinical Chemistry; W.B. Saunders Company, Philadelphia 3rd Ed. (1999) p.1802.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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