510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
K034000

B. Analyte:
Total triglycerides

C. Type of Test:
Quantitative colorimetric and Calibrator

D. Applicant:
Clinical Data, Inc.

E. Proprietary and Established Names:
Vitalab Triglycerides Reagent and Vitalab Triglyceride Calibrator

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.1705 and 21 CFR 862.1150
2. Classification:
   Class 1 and Class 2
3. Product Code:
   CDT and JIX
4. Panel:
   Chemistry (75)

G. Intended Use:

1. Intended use(s):
   Vitalab Triglycerides Reagent is for the quantitative determination of triglycerides in serum and plasma using the Vitalab Selectra Analyzer.
2. Indication(s) for use:
   Triglycerides results may be used for the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction and other diseases involving lipid metabolism, various endocrine disorders, or for assessing of the risk of developing cardiovascular diseases.
3. Special condition for use statement(s):
   Not applicable
4. Special instrument Requirements:
   The Vitalab Triglycerides Reagent and Calibrator are intended to be used with the Vitalab Selectra Chemistry Analyzers.

H. Device Description:
The Vitalab Triglycerides Reagent, the Vitalab Calibrator and the Vitalab Selectra Analyzer are used as a system for the quantitative analysis of total triglycerides in serum and plasma. The Vitalab

Triglycerides Reagent is an *in vitro* diagnostic reagent and is a component of this system. The reagent is supplied as a two liquid-stable components which can be combined either prior to, or as an integral part of, the assay in the approximate ratio of four parts Triglycerides Reagent and one part Triglycerides Activator.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Beckman Synchron Triglycerides Reagent Kit (product #445850) and the Synchron Multi-Calibrator (product #442600)
2. Predicate K number(s):
   K915084 and K883181
3. Comparison with predicate (**Triglyceride Reagent**):

Similarities		
Item	**Device**	**Predicate**
Product type	Calibrated endpoint reagent	same
Intended Use	Quantitative determination of total triglycerides in serum and plasma	same
Chemical Reaction	Enzymatic GPO methodology with Trinder indicator system	same
Measurement method	Enzymatic endpoint at approximately 500 nm (505 nm)	same (520 nm)
Reagent components	lipase ATP glycerol kinase glycerol phosphate oxidase peroxidase 4-aminoantipyrine p-chlorophenol other ingredients	lipase ATP glycerol kinase glycerol phosphate oxidase peroxidase DHBS p-chlorophenol other ingredients
Analytical Range	5 to 900 mg/dL	10 to 1,000 mg/dL
Calibration	Single point	same

J. Standard/Guidance Document Referenced (if applicable):
None

K. Test Principle:
The Vitalab Triglycerides Reagent determines triglycerides using the lipase/GPO enzymatic assay procedure coupled to a Trinder indicator reaction. The resulting increase in absorbance at 505 nm is proportional to the triglycerides concentration of the sample.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*

      Precision is demonstrated by the replicate assay of commercially available control serum. Each sample is assayed in triplicate twice per day over 10 days using the

Vitalab Triglycerides Reagent on a Selectra E Analyzer. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of Triglycerides Recoveries in mg/dL

		Within Run			Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	74	0.4	0.5%	0.7	1.0%
Serum 2	60	121	0.6	0.5%	1.2	1.0%
Serum 3	60	168	0.8	0.5%	1.8	1.1%

b. Linearity/assay reportable range:

Ten aqueous standards ranging from 0 to approximately 930 mg/dL triglycerides are prepared by diluting a stock solution of a bovine source triglycerides concentrate with a buffered aqueous solution. These standards and the matrix solution are assayed in ascending order over four independently calibrated analytical runs. Standard recoveries are compared to dilution factors by least squares linear regression through the origin. A residual statistic is calculated for each standard as the difference between the mean recovery and its predicted value from the linear regression statistics.

The maximum residual is 5 mg/dL triglycerides indicating linearity throughout the linear range.

c. Traceability (controls, calibrators, or method):
Calibrator set points are traceable to laboratory prepared, analytical glycerol standards.

d. Detection limit:
Normal saline is assayed thirty times in a single analytical run. The detection limit is calculated as the mean plus two standard deviations of the results. The observed mean and standard deviation are both 0.0 mg/dL. The detection limit of the assay is 1 mg/dL triglycerides, which is the round-off error of the assay. The claimed detection limit is 5 mg/dL.

e. Analytical specificity:
Potential interference by ascorbic acid, bilirubin and hemoglobin is determined in three separate studies. In each study, a serum pool with approximately normal triglycerides levels is prepared from individual patient specimens and is divided into two aliquots. One aliquot is spiked with the potential interfering substance. The other aliquot is diluted with normal saline, if necessary, to mimic the dilution the spiked pool. These aliquots are then blended to prepare test pools with the interferant concentrations listed below. The red blood cell (RBC) hemolysate, which is used to spike the high pool for the hemolysis test, is prepared from at least five patient specimens according to the Osmotic Shock Procedure described in

NCCLS Document EP7-P, Volume 6 No.13.

Interfering Substance	Levels tested
Ascorbic acid	0.6, 1.2, 1.8, 2.4, 3.0 mg/dL
Ditaurobilirubin	8, 16, 24, 32, 40 mg/dL (as bilirubin)
RBC hemolysate	40, 80, 120, 160, 200 mg/dL (as hemoglobin)

Each set of original and spiked pools are then assayed in an alternating order 9 and 6 times respectively in a single analytical run. Differences in recoveries between the original and spiked pools are reported with t-statistics. Statistically significant differences greater than 5% are reported on the package insert.

The addition of 1.8 and 3.0 mg/dL ascorbic acid suppresses triglycerides results by 10.5 and 17.7 mg/dL respectively. Bilirubin at 16 and 40 mg/dL suppresses recoveries by 8.5 and 20 mg/dL respectively. Hemoglobin at 200 mg/dL elevates recoveries by 8 mg/dL.

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Random, unaltered specimens from individual anonymous adult patients are collected from local clinical labs. These samples are supplemented with additional specimens with elevated triglycerides levels to yield a total of 60 serum and 60 heparinized plasma specimens. These specimens are randomly assorted into groups of 15 serum and 15 plasma specimens each. One group of serum and plasma specimens are assayed using a Vitalab Selectra and the Beckman Synchron CX5 triglycerides applications, each calibrated with its required calibrator.

One specimen exceeded the usable range of the Selectra method and was excluded from the following comparisons. The remaining results were grouped by specimen type and compared by Deming regression assuming equal variances between methods. Regression statistics are given below.

Serum Correlation

	Value	95% Confidence Interval
Intercept	-4.0 mg/dL	-6.9 to 1.16 mg/dL
Slope	1.071	1.059 to 1.083
sy.x	3.6 mg/dL	
n	59	
range	56 to 519 mg/dL	

Plasma Correlation

	Value	95% Confidence Interval
Intercept	-0.2 mg/dL	-2.4 to 2.1 mg/dL

Slope	1.068	1.057 to 1.079
sy.x	3.8 mg/dL	
n	60	
range	28 to 701 mg/dL	

Where x = Competitive Reagent Results
y = Selectra Results

b. Matrix comparison:
Serum and plasma specimens are individually compared to the predicate method by Deming regression. Except for a clinically insignificant shift in the y-intercept, regression statistics for both specimen types are substantially equivalent, indicating equivalency between the two matrices.

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:
   Reference ranges are established in the literature and quoted from NCEP (Adult Treatment Panel III). NIH Publication No. 02-5215, September 2002.

M. Conclusion:

I recommend that the Vitalab Triglyceride Reagent be found substantially equivalent to the listed predicate.