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

A. 510(k) Number:
k110394

B. Purpose for Submission:
New device for adding four new analytes, direct bilirubin, triglycerides, iron, and uric acid to a previously cleared calibrator material (k030621)

C. Measurand:
Analytes: Albumin, Calcium, Cholesterol, Creatinine, Direct Bilirubin, Iron, Glucose, Magnesium, Phosphorus, Total Bilirubin, Total Protein, Triglycerides, Urea, and Uric Acid

D. Type of Test:
Calibrator material

E. Applicant:
Vital Diagnostics

F. Proprietary and Established Names:
ATAC Serum Calibrator (Direct Bilirubin and Iron)

G. Regulatory Information:
1. Regulation section:
   21 CFR § 862.1150 - Calibrator
2. Classification:
   Class II
3. Product code:
   JIX - Calibrator, Multi-Analyte Mixture
4. Panel:
   Clinical Chemistry - 75

H. Intended Use:
1. Intended use(s):
   Refer to indications for use below.
2. Indication(s) for use:
   The ATAC Serum Calibrator is intended for use with the ATAC Clinical Systems to establish points of reference that are used in the determination of albumin, calcium, cholesterol, creatinine, direct bilirubin, glucose, iron, magnesium, phosphorus, total bilirubin, total protein, triglycerides, urea and uric acid in human specimens..

3. Special conditions for use statement(s):
   For *in vitro* diagnostic use only. For prescription use.
4. Special instrument requirements:
   ATAC 8000 Random Access Chemistry Analyzer

I. Device Description:

The ATAC Serum Calibrator is a lyophilized human serum with biological materials added as required to obtain desired component levels. The final product contains the following components: albumin, calcium, cholesterol, creatinine, direct bilirubin, glucose, iron, magnesium, phosphorus, total bilirubin, total protein, triglycerides, urea and uric acid in human specimens. The kit consists of 4 vials of the multi calibrators and 4 vials of the ATAC Calibrator Diluents. The volume per vial of the ATAC Calibrator Diluent is 10.0 ml. ATAC Calibrators are manufactured from human serum. The source material in this product have been tested for human immunodeficiency virus (HIV1, HIV2) antibody, hepatitis B surface antigen (HBsAg), and hepatitis C (HCV) antibody and found to be non-reactive.

J. Substantial Equivalence Information:

1. Predicate device name:
   k990460
2. Predicate 510(k) number:
   Roche Calibrator for Automated Systems (C.f.a.s.)
3. Comparison with predicate:

Comparison Table		
Item	New Device (k110394)	Predicate (k990460)
Intended Use	Intended for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.	Same
Format	Lyophilized	Same
Analytes	Albumin, calcium, cholesterol, creatinine, direct bilirubin, iron, glucose, magnesium, phosphorus, total bilirubin, total protein, urea nitrogen, uric acid	Albumin, calcium, cholesterol, creatinine, direct bilirubin, iron, glucose, magnesium, phosphorus, total bilirubin, total protein, urea (BUN), uric acid, acid phosphatase, alkaline phosphatase, alanine aminotransferase, α-amylase, aspartate aminotransferase, cholinesterase, creatine kinase, γ-glutamyltransferase,, lactase

Comparison Table		
Item	New Device (k110394)	Predicate (k990460)
		dehydrogenase, lipase, UIBC, lactate, salicylate, HBDH
Levels	Single level	Same
Stability	Stable 24 months when stored at 2-8°C Stable 7 days when reconstituted and stored at 2-8°C	Stable until expiration date printed on label when stored at 2-8°C Stable 2 days when reconstituted and stored at 2-8°C

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

ISO 17511:2003. In vitro Diagnostic Medical Devices – Measurement of Quantities in Biological Samples

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable.

b. Linearity/assay reportable range:

Not applicable.

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

Traceability: and:

Calibrators are traceable to the reference material shown in the table below:

Traceability: Reference material	
Albumin	NIST SRM 927
Calcium	NIST SRM 915b
Cholesterol	Cholesterol Reference Method Laboratory Network (CRMLN), NIST SRM 909b/911c
Creatinine	NIST SRM 914
Direct Bilirubin	Manual Jendrassik-Grof / Roche Calibrator for Automated Systems
Glucose	NIST SRM 917b
Iron	NIST SRM 937
Magnesium	NIST SRM 929
Phosphorus	J.T Baker ULTREX, product no. 4921 **

	NIST SRM 3139a now available
Total Bilirubin	NIST SRM 916a
Total Protein	NIST SRM 927
Triglycerides	NIST SRM 1951b / 909b
Urea Nitrogen	NIST SRM 912a
Uric Acid	NIST SRM 913a, SRM 909b

Value Assignment:
Expected values for the ATAC Serum Calibrator kit are determined using selected commercially available reference materials/standards and at least five vials of candidate calibrators, two analyzers, and two lots of reagents. The target value for each analyte is the mean of the observed 16 replicates. Calibrator assigned values are lot dependent and are listed in the labeling. The mean and range are provided in tabular form in the value assignment sheets.

Stability:
Shelf-Life and Open Vial Stability claims were supported by the real time and accelerated stability protocols/testings and acceptance criteria that were described and found to be adequate.
Shelf-Life: ATAC Serum Calibrator Kit is stable for 24 months when stored unopened at 2 – 8°C.
Open-Vial: The reconstituted vials are stable up to 7 days when stored at 2 – 8° C.

d. Detection limit:
Not applicable.

e. Analytical specificity:
Not applicable.

f. Assay cut-off:
Not applicable.

2. Comparison studies:
   a. Method comparison with predicate device:
   Not applicable.
   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 expected values are provided in the labeling, as shown below.

Albumin	4.31 g/dL
Calcium	10.03 mg/dL
Cholesterol	183.9 mg/dL
Creatinine	4.88 mg/dL
Direct Bilirubin	2.15 mg/dL
Glucose	173.9 mg/dL
Iron	194.9 µg/dL
Magnesium	2.49 mEq/L
Phosphorus	5.85 mg/dL
Total Bilirubin	4.56 mg/dL
Total Protein	6.55 g/dL
Triglycerides	206.8 mg/dL
Urea Nitrogen	34.3 mg/dL
Uric Acid	6.34 mg/dL

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.