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

A. 510(k) Number:

k091292

B. Purpose for Submission:

New device

C. Measurand:

Not applicable - blood collection system

D. Type of Test:

Not applicable

E. Applicant:

Becton, Dickinson and Company

F. Proprietary and Established Names:

BD Vacutainer® Rapid Serum Tube Plus Blood Collection Tube

G. Regulatory Information:

1. Regulation section:

   21CFR 862.1675 (Blood specimen collection devices)

2. Classification:

   Class II

3. Product code:

   JKA

4. Panel:

   75 (Chemistry)

H. Intended Use:

1. Intended use(s):

   See Indication for use below.

2. Indication(s) for use:

   The BD Vacutainer® Rapid Serum Tube Plus Blood Collection Tube (BD RST) is a single use tube used to collect, transport, separate, and process venous blood specimens to obtain serum for chemistry determinations for *in vitro* diagnostic use. It is used in settings where a venous blood sample is collected by a trained healthcare worker. The BD RST is not recommended for patients on heparin therapy, direct thrombin inhibitor therapy or with Factor I deficiency.

3. Special conditions for use statement(s):

   Prescription Use only.

   These blood collection tubes are not intended to be used to collect blood specimens for blood banking, infectious disease, therapeutic drug monitoring, and Di(2-ethylhexyl) phthalate determinations.

4. Special instrument requirements:

   Specific analyzers used to evaluate the device are listed in the labeling and below in section M. 2. a. method comparison.

I. Device Description:

The BD Vacutainer® Rapid Serum Tube Plus Blood Collection Tube (BD RST) a 13 x 100 mm, 4.0 mL, plastic evacuated tube with an orange conventional stopper. The interior of the tube wall is coated with thrombin to promote rapid clotting. The tube contains a gel barrier polymer at the tube bottom. The density of this material causes it to move upward during centrifugation to the serum-clot interface, where it forms a barrier separating serum from the clot. Serum may be aspirated directly from the collection tube, eliminating the need to transfer to another container. The tube interior is sterile and the product is for single use only.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   BD Vacutainer® SST™ Plus Blood Collection Tube

2. Predicate 510(k) number(s):

k023075

3. <u>Comparison with predicate:</u>

Similarities and Differences between the candidate device and the predicate device

Items	BD Vacutainer® RST Plus Tube (Candidate device)	BD Vacutainer® SST™ Plus Tube (Predicate device)
Intended use	Single use tube used to collect, separate, transport, and process venous blood specimens to obtain serum for chemistry determinations for *in vitro* diagnostic use. It is used in settings where a venous blood sample is collected by a trained healthcare worker. The BD RST is not recommended for patients on heparin therapy, direct thrombin inhibitor therapy or with Factor I deficiency.	Single use tube used to collect, separate, transport, and process venous blood specimens to obtain serum for chemistry determinations for *in vitro* diagnostic use. It is used in a clinical laboratory setting. The BD SST™ has additional claims for routine blood banking and infectious disease testing, as well as therapeutic drug monitoring (TDM).
TUBE COMPARISON		
Tube Dimension	13 x 100 mm	• 13 x 75 mm • 13 x 100 mm • 16 x 100 mm
Draw Volume	4.0 mL	3.0 mL – 10.0 mL
Closure	Conventional rubber closure	Conventional rubber closure and BD Hemogard™ closure
Clot Activator	Thrombin	Silica
Clotting Time	5 minutes	30 minutes
Tube Shelf Life	12 months at $4 – 25^{o}C$	Same
Tube Sterility	Sterile	Same
PACKAGING COMPARISON		
Shelf	Plastic film barrier bag in cardboard shelf carton	Shrink-wrapped EPS tray
Case	Corrugated cardboard	Same

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

1. EN 00552 Sterilization of Medical Devices - Validation and Routine Control of Sterilization by Irradiation (1994)
2. EN 00980 Graphical symbols for use in the labeling of medical devices (2003)
3. EN 14820 Single-Use Containers for Human Venous Blood Specimen Collection (2004)
4. ISO 11137-1 Sterilization of Health Care Products - Requirements for the Validation and Routine Control - Radiation Sterilization (2006)

5. ISO 14001 Environmental Management Systems - Requirements with Guidance for Use (2004)
6. ISO 15223 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied (2000)
7. JIS T 3233 Evacuated Single - Use Containers for Venous Blood Specimen Collection (except color coding) (2005)
8. JIS T 14971 Medical Devices - Application of Risk Management to Medical Devices (2003)

L. Test Principle:

The BD Vacutainer® Rapid Serum Tube (RST) is intended to be placed inside either a holder or an adapter of a blood collection system. Once the vein of the patient has been penetrated using a standard needle, the tube is pushed fully into the needle holder so that the non-patient's end of the needle pierces the rubber septum of the stopper of the tube. The tube uses a controlled vacuum to pull a specific volume of blood into the sterile interior of the tube. The pressure differential caused the venous blood to flow into the tube. Once pressure is equalized, the blood flow ceases and the tube is withdrawn from the needle holder or needle. After blood has been drawn, the tube shall be immediately inverted gently for 5 to 6 times to mix the blood with the additives, and then allowed to clot and stand for 5 minutes. Once clotting is complete, the tube is to be centrifuged for 10 minutes, at a minimum g force of 1500g to initiate movement of gel and to obtain separation of serum.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Precision/repeatability studies were performed using fifty-three apparently healthy subjects in an internal testing site. Each subject has a venous blood collection into six blood collection tubes: 3 BD SST tubes (predicate device) with three different lot numbers and 3 BD RST tubes (candidate device) with three different lot numbers. Each tube was tested in duplicates for each of the 12 analytes and on multiple different instrument platforms. Results are summarized in the tables below:

   Table 1 through Table 6 give the estimates from the variance components analysis for the BD RST tube type: the within-tube, within-lot, between-lot and total coefficient of variation (%CV) or standard deviation (SD) along with 95% confidence limits.

Table 1. Precision Summary (SD) for Roche Integra® 800

Analyte/ Unit	Tube Type	Mean	Variance Component	SD	95% Lower Confidence Limit (LCL)	95% Upper Confidence Limit (UCL)
ALT U/L	BD RST	27.12	Between Lot	0.26	0.10	0.36
			Between Tubes, Within Lot	0.11	<0.005	0.24
			Within Tubes	0.44	0.39	0.50
			Total	0.52	0.40	0.66
TBIL Mg/dL	BD RST	8.60	Between Lot	0.18	<0.005	0.27
			Between Tubes, Within Lot	0.06	<0.005	0.21
			Within Tubes	0.43	0.38	0.49
			Total	0.47	0.38	0.60

Table 2. Precision Summary (%CV) for Roche Integra® 800

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
Ca Mg/dL	BD RST	2.351	Between Lot	0.65%	0.35%	0.87%
			Between Tubes, Within Lot	<0.005%	<0.005%	<0.005%
			Within Tubes	1.31%	1.17%	1.50%
			Total	1.47%	1.22%	1.73%
Creat Mg/dL	BD RST	68.54	Between Lot	0.77%	<0.005%	1.17%
			Between Tubes, Within Lot	<0.005%	<0.005%	0.69%
			Within Tubes	1.79%	1.59%	2.05%
			Total	1.95%	1.59%	2.45%
Gluc Mg/dL	BD RST	6.538	Between Lot	1.15%	0.70%	1.55%
			Between Tubes, Within Lot	<0.005%	<0.005%	<0.005%
			Within Tubes	1.64%	1.45%	1.88%
			Total	2.01%	1.61%	2.44%
IgG Mg/dL	BD RST	10.53	Between Lot	1.11%	0.62%	1.52%
			Between Tubes, Within Lot	<0.005%	<0.005%	0.54%
			Within Tubes	1.53%	1.35%	1.75%
			Total	1.89%	1.49%	2.38%
K mmol/L	BD RST	4.173	Between Lot	2.70%	1.90%	3.30%
			Between Tubes, Within Lot	1.02%	0.65%	1.29%
			Within Tubes	1.12%	1.00%	1.29%
			Total	3.09%	2.24%	3.77%
Mg Mg/dL	BD RST	0.879	Between Lot	0.66%	0.32%	0.90%
			Between Tubes, Within Lot	<0.005%	<0.005%	<0.005%
			Within Tubes	1.73%	1.53%	1.98%
			Total	1.85%	1.57%	2.17%
Phos Mg/dL	BD RST	1.208	Between Lot	1.08%	0.66%	1.46%
			Between Tubes, Within Lot	<0.005%	<0.005%	<0.005%
			Within Tubes	1.44%	1.28%	1.64%
			Total	1.80%	1.44%	2.20%
TP g/dL	BD RST	73.37	Between Lot	0.98%	0.53%	1.30%
			Between Tubes, Within Lot	<0.005%	<0.005%	<0.005%
			Within Tubes	2.17%	1.93%	2.48%
			Total	2.38%	2.00%	2.80%

Table 3. Precision Summary (SD) for Ortho Clinical Diagnostics Vitros® 250

Analyte/ Unit	Tube Type	Mean	Variance Component	SD	SD 95% LCL	SD 95% UCL
ALT U/L	BD RST	31.9	Between Lot	0.09	<0.005%	0.38
			Between Tubes, Within Lot	0.35	<0.005%	0.95
			Within Tubes	1.85	1.64	2.12
			Total	1.88	1.64	2.35
TBIL mg/dL	BD RST	0.47	Between Lot	<0.005%	<0.005%	0.02
			Between Tubes, Within Lot	0.01	<0.005%	0.02
			Within Tubes	0.04	0.03	0.04
			Total	0.04	0.03	0.05

Table 4. Precision Summary (%CV) for Ortho Clinical Diagnostics Vitros® 250

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
Ca mg/dL	BD RST	9.86	Between Lot	0.60%	0.20%	0.92%
			Between Tubes, Within Lot	0.44%	0.27%	0.57%
			Within Tubes	0.52%	0.46%	0.59%
			Total	0.91%	0.57%	1.23%
Creat mg/dL	BD RST	0.94	Between Lot	1.42%	<0.005%	2.11%
			Between Tubes, Within Lot	1.68%	0.62%	2.30%
			Within Tubes	2.66%	2.36%	3.04%
			Total	3.45%	2.44%	4.36%
Gluc mg/dL	BD RST	119	Between Lot	0.91%	0.41%	1.30%
			Between Tubes, Within Lot	0.93%	0.71%	1.11%
			Within Tubes	0.53%	0.47%	0.60%
			Total	1.41%	0.94%	1.82%
K mmol/L	BD RST	4.32	Between Lot	2.47%	1.67%	3.08%
			Between Tubes, Within Lot	1.39%	1.03%	1.66%
			Within Tubes	0.93%	0.83%	1.07%
			Total	2.98%	2.13%	3.66%
Mg mg/dL	BD RST	1.9	Between Lot	1.09%	<0.005%	1.70%
			Between Tubes, Within Lot	0.96%	0.32%	1.32%
			Within Tubes	1.56%	1.38%	1.78%
			Total	2.13%	1.42%	2.79%
Phos mg/dL	BD RST	4.14	Between Lot	0.50%	<0.005%	0.74%
			Between Tubes, Within Lot	0.54%	0.28%	0.71%
			Within Tubes	0.73%	0.65%	0.84%
			Total	1.04%	0.71%	1.32%
TP g/dL	BD RST	7.59	Between Lot	1.20%	0.75%	1.61%
			Between Tubes, Within Lot	0.54%	0.19%	0.75%
			Within Tubes	0.87%	0.77%	1.00%
			Total	1.58%	1.09%	2.03%

Table 5. Precision Summary (%CV) for Beckman Coulter Access® 2

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
Cortisol µg/dL	BD RST	10.138	Between Lot	3.16%	1.93%	4.05%
			Between Tubes, Within Lot	0.54%	<0.005%	1.43%
			Within Tubes	2.74%	2.42%	3.15%
			Total	4.25%	3.11%	5.37%
TSH µIU/mL	BD RST	1.441	Between Lot	<0.005%	<0.005%	2.74%
			Between Tubes, Within Lot	5.77%	4.46%	6.84%
			Within Tubes	2.56%	2.27%	2.94%
			Total	6.32%	5.00%	7.93%

Table 6. Precision Summary (%CV) for Bayer ADVIA Centaur®

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
Cortisol µg/dL	BD RST	9.965	Between Lot	<0.005%	<0.005%	1.21%
			Between Tubes, Within Lot	0.26%	<0.005%	2.11%
			Within Tubes	4.45%	3.93%	5.13%
			Total	4.46%	3.93%	5.71%
TSH µIU/mL	BD RST	1.528	Between Lot	<0.005%	<0.005%	1.92%
			Between Tubes, Within Lot	2.34%	<0.005%	3.48%
			Within Tubes	4.65%	4.11%	5.36%
			Total	5.24%	4.11%	6.75%

Results of the predicate tube type, BD SST, were very similar to the candidate tube type, BD RST. Calculated SD for the BD SST tube was <1 U/L for ALT and <0.6 mg/dL for T.Bili. and % CVs for all other analytes are <10% .

b. Linearity/assay reportable range:

Not applicable.

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

Real Time stability testing of the BD Rapid Serum Tubes showed that the tube is stable for 12 months when stored at 4° to 25°C.

To demonstrate analyte stability in the BD RST tubes at room temperature, analyte stability studies were performed at 0 hrs and 24 hrs after collecting blood into the BD RST and SST tubes. Studies are summarized below:

1. Study 1: 35 apparently healthy adults were enrolled internally at the manufacturer facility. Testing was performed internally on-site and at a reference laboratory.

A. 31 analytes (ALB, ALK, ALT, AST, Amy, BUN, Ca, Chol, Cl, CK, CO2, Creat, DBIL, Fe, Ferritin, GGT, Gluc, HDL, K, LD, LDL, Lip, Mg, Na, Phos, TBIL, TP, Transferrin, TRIG, UA, UIBC) were tested on the Roche Cobas Integra 800.

B. 12 analytes (Cortisol, Ferritin, Folate, FSH, Free T3, Free T4, LH, TSH, Testosterone, Total T3, Total T4, and Vitamin B12) were tested on the Bayer ADVIA Centaur.

2. Study 2: 84 adult subjects (43 for cardiac marker and 41 for female hormone) were recruited and tested in a hospital in New York. 6 analytes (hCG, Estradiol, Progesterone, CKMB, Myoglobin, and Troponin I) were tested on the Beckman Coulter Access 2.

3. Study 3: 78 adult patients were enrolled in an external hospital. A total of 8 analytes were tested. C3, C4, CRP, IgG, IgM, and RF were tested on Beckman Coulter UniCel DxC 800 analyzer. Anti-CMV IgG and Anti-CMV IgM were tested on the Biomerieux VIDAS analyzer.

4. Study 4: 42 healthy adult patients were tested internally for LDL, Triglycerides, and Rheumatoid factor for additional time-points stability study. Testing was performed at 0, 6, 12 and 24 hours after blood have been collected and separated from the centrifuge.

The results of the study support the sponsor's claimed that the BD RST tubes have analyte stability for 24 hours at room temperature except for LDL (19 hours) and triglycerides (5 hours). This information is provided in the sponsor's package insert. Acceptance criteria for analyte stability on a representative platform was provided and found to be acceptable.

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:

To demonstrate comparable performance with the predicate device, apparently healthy subjects and patients admitted into hospitals with various diseases were used. Testing was performed both internally and externally at 4 different clinical sites. All subjects in the comparative studies have blood samples collected into the BD RST (candidate device) and the BD SST (predicate tubes) at the same time. The specimens were allowed to clot, and the serum was removed for testing immediately after centrifugation according to the instructions provided in the labeling. Evaluations were performed on a selective common chemistry analytes, immunology analytes, and serological analytes on certain instrument platforms. A total of fifty-seven analytes were evaluated and demonstrated comparable results between the BD RST tubes and the BD SST tubes. A small number of spiked samples were used to supplement the analyte ranges. Summary of the results of one representative study on one representative platform with the analytes and instruments evaluated are provided in the tables below:

Table 8. Deming regressions correlations with 95% confidence intervals from one representative platform/study:

Analyte	Instrument(s)	Slope (95% CI)	Intercept (95% CI)
Alanine Aminotransferase	8, 10, 11, 12	1.01 (0.99, 1.03)	-0.05 (-0.12, 0.03)
Albumin	8, 11	1.00 (0.84, 1.16)	0.00 (-0.25, 0.24)
Alkaline Phosphatase	8, 11	1.02 (0.98, 1.06)	-0.09 (-0.26, 0.08)
Amylase	8, 11	1.00 (0.96, 1.04)	-0.01 (-0.15, 0.13)
Aspartate Aminotransferase	8, 11	1.03 (0.84, 1.22)	-0.10 (-0.66, 0.45)
Bilirubin, Direct	8, 11	1.008 (0.923, 1.092)	0.002 (-0.01, 0.013)
Bilirubin, Total	8, 10, 11, 12	0.99 (0.99, 1.0)	0.00 (-0.01, 0.01)
Blood Urea Nitrogen	8, 11	0.90 (0.8, 1.0)	1.3 (0.3, 2.4)
C-Reactive Protein	4, 10	1.00 (0.99, 1.01)	-0.02 (-0.04, 0.01)
Calcium	8, 10, 11, 12	0.99 (0.97, 1.01)	0.07 (-0.13, 0.27)
Carbon Dioxide, Total	8, 11	0.97 (0.81, 1.14)	0.11 (-0.41, 0.62)
Chloride	8, 11	1.00 (0.9, 1.2)	-4.1 (-18.3, 10.1)
Cholesterol	8, 11	0.97 (0.92, 1.02)	0.16 (-0.13, 0.44)
Complement C3	4, 10	1.01 (1.0, 1.02)	-0.04 (-0.1, 0.02)
Complement C4	4, 10	1.00 (0.98, 1.01)	0.00 (-0.05, 0.05)
Cortisol	2, 6	1.00 (0.94, 1.06)	-0.02 (-0.16, 0.12)
Creatine Kinase- MB fraction	1, 3	1.00 (0.99, 1.02)	0.01 (-0.03, 0.05)
Creatine Kinase, Total	8, 11	1.00 (0.99, 1.01)	-0.02 (-0.08, 0.05)
Creatinine	8, 10, 11, 12	1.001 (0.996, 1.007)	0.013 (-0.013, 0.04)
Cytomegalovirus Antibodies, IgG	5, 7	See table 9. below	See table 9. below
Cytomegalovirus Antibodies, IgM	5, 7	See table 10. below	See table 10. below
Estradiol	3, 9	1.00 (0.97, 1.02)	0.02 (-0.17, 0.22)
Ferritin	2, 11	1.01 (0.99, 1.02)	-0.04 (-0.1, 0.02)
Folate	2, 3	0.947 (0.920, 0.975)	0.153 (0.070, 0.236)
Follicle Stimulating Hormone	2, 3, 6	1.021 (0.998, 1.044)	-0.042 (-0.104, 0.020)

Free Thyroxine	2, 3	0.929 (0.859, 0.998)	-0.032 (-0.058, -0.006)
Free Triiodothyronine	2, 3	0.942 (0.800, 1.083)	0.065 (-0.094, 0.224)
Gamma-glutamyltransferase	8, 11	1.05 (1.01, 1.08)	-0.15 (-0.27, -0.04)
Glucose	8, 10, 11, 12	0.99 (0.99, 1.0)	0.04 (0, 0.07)
High Density Lipoprotein	8, 11	0.99 (0.93, 1.05)	0.04 (-0.20, 0.27)
Human Chorionic Gonadotropin	3, 9	1.00 (0.99, 1.00)	0.02 (-0.02, 0.05)
Immunoglobulin G	4, 10	1.00 (0.99, 1.01)	0.0 (-0.1, 0.1)
Immunoglobulin M	4, 10	1.00 (1.0, 1.01)	-0.02 (-0.06, 0.02)
Iron	8, 11	1.00 (0.96, 1.03)	-0.01 (-0.16, 0.15)
Lactate Dehydrogenase	8, 11	1.11 (1.02, 1.21)	-0.6 (-1.09, -0.12)
Lipase	8, 11	0.97 (0.93, 1.02)	0.09 (-0.06, 0.24)
Low Density Lipoprotein	8, 10, 11, 12	0.99 (0.98, 1.0)	0.03 (-0.02, 0.07)
Luteinizing Hormone	2, 3	1.052 (1.013, 1.091)	-0.100 (-0.191, -0.010)
Magnesium	8, 10, 11, 12	1.01 (0.99, 1.03)	-0.02 (-0.07, 0.03)
Myoglobin	1, 3	1.02 (1.0, 1.04)	-0.1 (-0.17, -0.02)
Phosphorus	8, 10, 11, 12	1.01 (1.0, 1.01)	-0.01 (-0.05, 0.02)
Potassium	8, 10, 11, 12	1.00 (0.98, 1.01)	0.0 (-0.08, 0.08)
Progesterone	3, 9	0.96 (0.90, 1.01)	0.14 (-0.04, 0.32)
Rheumatoid Factor	4, 10	0.99 (0.97, 1.01)	0.09 (-0.01, 0.19)
Sodium	8, 11	1.10 (0.80, 1.40)	-14.5 (-50.9, 22)
Unsaturated Iron Binding Capacity	11	0.96 (0.93, 1.00)	0.14 (-0.01, 0.28)
Testosterone	2, 3, 6	1.01 (0.96, 1.07)	-0.16 (-0.48, 0.16)
Thyroid Stimulating Hormone	1, 2, 3, 6	1.00 (0.98, 1.02)	0.01 (-0.02, 0.04)
Total Iron Binding Capacity	8	0.97 (0.84, 1.09)	0.18 (-0.54, 0.91)
Total Protein	8, 10, 11, 12	0.99 (0.98, 1.0)	0.01 (-0.01, 0.03)
Total Thyroxine	2, 3, 6	1.12 (0.85, 1.39)	-0.28 (-0.85, 0.3)
Total Triiodothyronine	2, 3, 6	1.12 (0.83, 1.40)	-0.63 (-2.03, 0.76)
Transferrin	8, 11	1.04 (0.72, 1.36)	-0.27 (-22.10, 1.57)
Triglycerides	8, 11	0.99 (0.98, 1.00)	0.04 (-0.03, 0.10)
Troponin I	1, 3	1.03 (1.01, 1.06)	0.26 (0.2, 0.33)
Uric Acid	8, 11	1.01 (0.98, 1.03)	-0.02 (-0.06, 0.02)
Vitamin B12	2, 3	0.973 (0.933, 1.013)	0.174 (-0.059, 0.407)

Table 9. Concordance Table: anti-CMV IgG
(Biomerieux VIDAS®)

		BD RST			All
		Negative (<4)	Equivocal (≥ 4 to <6)	Positive (≥ 6)	
BD SST™	Negative (<4)	31	1	0	32
	Equivocal (≥ 4 to <6)	0	0	0	0
	Positive (≥ 6)	0	1	71	72
All		31	2	71	104

Table 10. Concordance Table: anti-CMV IgM
(Biomerieux VIDAS®)

		BD RST			All
		Negative (<0.7)	Equivocal (≥ 0.7 to <0.9)	Positive (≥ 0.9)	
BD SST™	Negative (<0.7)	99	1	0	100
	Equivocal (≥ 0.7 to <0.9)	2	1	0	3
	Positive (≥ 0.9)	0	1	0	1
	All	101	3	0	104

Instrument(s):

1- Abbott Axsym
2- Bayer ADVlA Centaur
3- Beckman Coulter Access 2
4- Beckman Coulter UniCel DxC 800
5- Biomerieux Vidas
6- DPC lmmulite 1000
7- Dynex DS2/Wampole Laboratories
8- Olympus AU5200TM / AU5400TM
9- Ortho Clinical Diagnostics VITROS Q ECi
10- Ortho Clinical Diagnostics VITROS 5,l FS
11- Roche COBAS lntegra 800
12- Roche Modular

Summary of all the studies:

Study 1: 35 apparently healthy adults were enrolled internally at the manufacturer facility. Testing was performed internally on-site and at a reference laboratory. Chemistry results were generated for 23 routine chemistry analytes on an Olympus AU5200/AU5400 instrument and 5 immunoassay analytes on a DPC Immulite 1000 instrument.

Study 2: 32 apparently healthy adults were enrolled internally at the manufacturer facility. Testing was performed internally on-site and at a reference laboratory. Chemistry results were generated for 8 routine chemistry analytes on an Olympus AU5200/AU5400 instrument and 31 routine chemistry analytes on a Roche COBAS Integra 800 instrument.

Study 3: 42 apparently healthy adults were enrolled internally at the manufacturer facility. Testing was performed internally on-site. Chemistry results were generated for 1 special chemistry analyte on a DPC Immulite 1000 instrument, 10 special chemistry analytes on a Beckman Coulter Access 2 instrument and 12 special chemistry analytes on a Bayer ADVIA Centaur instrument.

Study 4: 84 adults' subjects (43 for cardiac marker and 41 for female hormone) were recruited and tested in a hospital setting. Testing was performed in that hospital laboratory. Chemistry results were generated for 3 female hormones on a Beckman Coulter Access 2 instrument and an Ortho clinical Diagnostics VITROS ECi instrument. 3 cardiac markers results were generated on a Beckman Coulter Access 2 instrument and on an Abbott Axsym instrument.

Study 5: 86 adults' subjects were enrolled in a hospital setting with various diagnoses and disease states to cover a wide range for the analytes to be tested. 10 chemistry analytes (ALT, calcium, creatinine, glucose, potassium, LDL cholesterol, magnesium, phosphorus, total bilirubin, and total protein) were tested on the Roche Modular analyzer.

Study 6: 78 adults' subjects were enrolled in a hospital setting with various diagnoses and disease states to cover a wide range for the analytes to be tested. Two serological analytes (anti-CNV IgG and IgM) were tested on the BioMerieux and Dynex DS2 analyzers. Two immunoassay analytes (TSH and Troponin) were tested on the Abbott Axsym and Beckman Access analyzers. Six immunological analytes (C3, C4, CRP, IgG, IgM, and RF) were tested on the Beckman UniCel DxC 800 analyzer.

Study 7: 82 adults' subjects were enrolled in a hospital setting and 19 adults' subjects were enrolled in a different hospital setting with various diagnoses and disease states to cover a wide range for the analytes to be tested. Six immunological analytes and 10 general chemistry analytes were tested on the Ortho-Diagnostics Vitros analyzer.

b. Matrix comparison:

Not applicable. These blood collection tubes are for serum only.

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:

    Not applicable

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.