

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

**A. 510(k) Number:**

k101502

**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 Blood Collection Tube with Hemogard™ Closure (BD RST HG)

**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 RST HG is a 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.

Clot time has not been established for patients on heparin therapy, direct thrombin inhibitor therapy or with Factor I deficiency. As a result, the use of BD RST HG in these patients is not recommended.

3. Special conditions for use statement(s):

Prescription use only.

BD RST HG Tubes are not recommended for amino acid determinations.

Therapeutic drug monitoring (TDM), blood banking and infectious disease performance has not been established, except for anti-CMV IgG and anti-CMV IgM.

Clot time has not been established for patients on heparin therapy, direct thrombin inhibitor therapy or with Factor I deficiency. As a result, the use of BD RST HG in these patients is not recommended.

The flow properties of the barrier material are temperature-related. Centrifuge the tubes between 23°C and 27°C (73-81°F).

Tubes should not be re-centrifuged once barrier has formed.

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 Blood Collection Tube with Hemogard™ Closure (BD RST HG) is a sterile, single use, 13 x 100 mm, 5.0mL plastic evacuated tube with a plastic shield and rubber stopper safety closure. The BD RST HG contains a thrombin clot activator, tube wall coating, and inert barrier gel. The BD RST HG is intended to be placed inside a tube holder or an adaptor that contains a needle designed to pierce the tube closure and allow blood to flow into the tube. Once the vein has been penetrated (using either a standard blood collection needle or a blood collection set) the tube is pushed into the holder,

and the blood enters the tube. The Hemogard™ safety closure prevents exposure of healthcare workers to blood components in the tube.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

BD Vacutainer® SST™ Plus Blood Collection Tube

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

k023075

3. Comparison with predicate:

**Similarities and Differences between the candidate device and the predicate device**

Items	BD Vacutainer® RST HG 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 <i>in vitro</i> diagnostic use. It is used in settings where a venous blood sample is collected by a trained healthcare worker.	Same
Limitations	Clot time not been established for patients on heparin therapy, direct thrombin inhibitor therapy, or with Factor I deficiency. As a result, the use of BD RST HG in these patients is not recommended.	No limitation
TUBE COMPARISON		
Tube Dimension	13 x 100 mm	<ul style="list-style-type: none"> <li>• 13 x 75 mm</li> <li>• 13 x 100 mm</li> <li>• 16 x 100 mm</li> </ul>
Draw Volume	5.0 mL	3.0 mL – 10.0 mL
Closure	BD Hemogard™ closure	Conventional rubber closure and BD Hemogard™ closure
Gel Barrier Additive	Polyacrylic gel	Polyester gel
Clot Activator	Thrombin	Silica
Clotting Time	5 minutes	30 minutes

Tube Shelf Life	12 months at 4 – 25°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 00980 Graphical symbols for use in the labeling of medical devices (2008)
2. ISO 9001 Quality Management System (2000)
3. ISO 13485 Medical Devices -- Quality Management Systems Requirements for Regulatory Purposes (2003)
4. ISO 11137 Sterilization of Health Care Products - Requirements for the Validation and Routine Control - Radiation Sterilization (2006)
5. ISO 14971 Application of Risk Management to Medical Devices (2007)

**L. Test Principle:**

The BD Vacutainer® Rapid Serum Tube HG 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 45 apparently healthy subjects in an internal testing site. Each subject has a venous blood collected into six blood collection tubes: 3 BD SST tubes (predicate device) with 3 different lot numbers and 3 BD RST HG tubes (candidate device) with 3 different lot numbers. Each tube was tested in duplicates for each of the 12 analytes and on 2 different instrument platforms except IgG,

which was tested on a single instrument. Samples were excluded if: 1) serum with greater than trace hemolysis, or 2) incomplete gel barrier/incomplete separation of serum from clot, or 3) tubes not filled to approximate stated draw volume (i.e., no “short draw”). Results are summarized in the tables below:

Table 1 through Table 6 give the estimates from the variance components analysis for the BD RST HG 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) Roche Integra® 800

Analyte/ Unit	Tube Type	Mean	Variance Component	SD	SD 95% Lower Confidence Limit (LCL)	SD 95% Upper Confidence Limit (UCL)
ALT U/L	BD RST HG	26.64	Between Lot	0.11	<0.005	0.24
			Between Tubes, Within Lot	0.09	<0.005	0.23
			Within Tubes	0.45	0.40	0.51
			Total	0.47	0.29	0.61
TBIL mg/dL	BD RST HG	9.71	Between Lot	<0.005	<0.005	0.15
			Between Tubes, Within Lot	<0.005	<0.005	0.20
			Within Tubes	0.48	0.43	0.55
			Total	0.48	0.32	0.62

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

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
Ca mg/dL	BD RST HG	2.408	Between Lot	0.43%	<0.005%	0.67%
			Between Tubes, Within Lot	0.18%	<0.005%	0.48%
			Within Tubes	0.93%	0.83%	1.07%
			Total	1.04%	0.67%	1.35%
Creat mg/dL	BD RST HG	71.18	Between Lot	1.23%	0.42%	1.69%
			Between Tubes, Within Lot	0.86%	0.36%	1.16%
			Within Tubes	1.31%	1.16%	1.50%
			Total	1.99%	1.29%	2.54%
Glu mg/dL	BD RST HG	5.303	Between Lot	1.75%	0.97%	2.27%
			Between Tubes, Within Lot	1.02%	0.72%	1.25%
			Within Tubes	0.89%	0.79%	1.02%
			Total	2.29%	1.48%	2.90%
IgG mg/dL	BD RST HG	9.91	Between Lot	0.77%	<0.005%	1.25%
			Between Tubes, Within Lot	0.89%	0.39%	1.20%
			Within Tubes	1.33%	1.18%	1.52%
			Total	1.78%	1.08%	2.30%
K mmol/L	BD RST HG	4.219	Between Lot	1.92%	1.26%	2.41%
			Between Tubes, Within Lot	1.00%	0.79%	1.17%
			Within Tubes	0.34%	0.30%	0.39%

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
			Total	2.20%	1.52%	2.71%
Mg mg/dL	BD RST HG	0.91	Between Lot	<0.005%	<0.005%	0.47%
			Between Tubes, Within Lot	0.47%	<0.005%	0.69%
			Within Tubes	0.95%	0.85%	1.09%
			Total	1.05%	0.64%	1.38%
Phos mg/dL	BD RST HG	1.207	Between Lot	0.61%	<0.005%	0.87%
			Between Tubes, Within Lot	0.27%	<0.005%	0.55%
			Within Tubes	0.96%	0.85%	1.10%
			Total	1.17%	0.76%	1.50%
TP g/dL	BD RST HG	76.60	Between Lot	0.96%	0.58%	1.23%
			Between Tubes, Within Lot	<0.005%	<0.005%	0.21%
			Within Tubes	0.99%	0.88%	1.13%
			Total	1.33%	0.89%	1.68%

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

Analyte/ Unit	Tube Type	Mean	Variance Component	SD	SD 95% LCL	SD 95% UCL
ALT U/L	BD RST HG	30.7	Between Lot	<0.005	<0.005	0.53
			Between Tubes, Within Lot	0.84	0.19	1.18
			Within Tubes	1.43	1.27	1.64
			Total	1.59	0.94	2.09
TBIL mg/dL	BD RST HG	0.57	Between Lot	0.01	<0.005	0.02
			Between Tubes, Within Lot	0.00	<0.005	0.02
			Within Tubes	0.03	0.03	0.04
			Total	0.03	0.02	0.04

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

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
Ca mg/dL	BD RST HG	10.05	Between Lot	0.24%	<0.005%	0.49%
			Between Tubes, Within Lot	0.53%	0.34%	0.67%
			Within Tubes	0.59%	0.53%	0.68%
			Total	0.83%	0.52%	1.07%
Creat mg/dL	BD RST HG	0.87	Between Lot	<0.005%	<0.005%	1.33%
			Between Tubes, Within Lot	1.96%	0.96%	2.60%
			Within Tubes	2.78%	2.46%	3.18%
			Total	3.32%	2.03%	4.32%
Glu mg/dL	BD RST HG	89.6	Between Lot	1.63%	0.84%	2.15%
			Between Tubes, Within Lot	0.91%	0.68%	1.09%
			Within Tubes	0.58%	0.52%	0.66%
			Total	1.96%	1.20%	2.50%
K mmol/L	BD RST HG	4.46	Between Lot	1.96%	1.16%	2.52%
			Between Tubes, Within Lot	1.18%	0.88%	1.41%

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
			Within Tubes	0.78%	0.69%	0.89%
			Total	2.41%	1.61%	3.02%
Mg mg/dL	BD RST HG	1.97	Between Lot	<0.005%	<0.005%	0.77%
			Between Tubes, Within Lot	1.04%	0.44%	1.40%
			Within Tubes	1.57%	1.40%	1.80%
			Total	1.85%	1.13%	2.41%
Phos mg/dL	BD RST HG	3.99	Between Lot	0.44%	<0.005%	0.79%
			Between Tubes, Within Lot	0.46%	<0.005%	0.71%
			Within Tubes	1.01%	0.90%	1.16%
			Total	1.19%	0.71%	1.57%
TP g/dL	BD RST HG	7.42	Between Lot	0.93%	0.43%	1.24%
			Between Tubes, Within Lot	0.46%	<0.005%	0.74%
			Within Tubes	1.12%	1.00%	1.28%
			Total	1.52%	1.02%	1.93%

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

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
Cortisol µg/dL	BD RST HG	11.405	Between Lot	2.86%	1.28%	3.84%
			Between Tubes, Within Lot	0.74%	<0.005%	1.93%
			Within Tubes	3.72%	3.30%	4.26%
			Total	4.75%	3.14%	6.05%
TSH µIU/mL	BD RST HG	1.745	Between Lot	0.69%	<0.005%	1.99%
			Between Tubes, Within Lot	2.76%	1.97%	3.37%
			Within Tubes	2.31%	2.05%	2.64%
			Total	3.66%	2.26%	4.72%

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

Analyte/ Unit	Tube Type	Mean	Variance Component	CV(%)	95% LCL	95% UCL
Cortisol* µg/dL	BD RST HG	12.629	Between Lot	2.24%	<0.005%	3.99%
			Between Tubes, Within Lot	<0.005%	<0.005%	1.68%
			Within Tubes	4.67%	4.13%	5.36%
			Total	5.05%	2.33%	6.97%
TSH* µIU/mL	BD RST HG	1.78	Between Lot	<0.005%	<0.005%	1.32%
			Between Tubes, Within Lot	0.45%	<0.005%	1.76%
			Within Tubes	3.63%	3.21%	4.16%
			Total	3.59%	2.19%	4.73%

\*Estimates based on log-model.

*b. Linearity/assay reportable range:*

Not applicable.

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

Real Time stability testing of the BD RST HG 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 HG tubes at room temperature, analyte stability studies were performed at 0 hrs and 24 hrs after collecting blood into the BD RST HG and the predicate SST tubes. Studies are summarized below:

- 1) Internal Study: 47 apparently healthy adults were enrolled and tested at the manufacturing facility.

28 analytes (ALB, ALP, ALT, AST, Amy, BUN, Ca, Chol, Cl, CO<sub>2</sub>, Creat, DBIL, Fe, GGT, Gluc, HDL, K, LDH, LDL, Lip, Mg, Na, Phos, TBIL, TP, Transferrin, TRIG, UA) were tested on a Roche Cobas Integra 800 analyzer.

12 analytes (Cortisol, Ferritin, Folate, FSH, Free T<sub>3</sub>, Free T<sub>4</sub>, LH, TSH, Testosterone, Total T<sub>3</sub>, Total T<sub>4</sub>, and Vitamin B12) were tested on a Bayer ADVIA Centaur analyzer.

- 2) External Studies: Consecutive adult patients from multiple inpatient settings with a range of conditions and diagnoses were enrolled and tested respectively in Hospital Site 1, 2, and 3.

*Hospital Site 1:*

5 analytes (C3, C4, IgG, IgM, and RF) were tested on a Beckman Coulter UniCel DxC 800 analyzer. Subjects with numerical value for both tubes at both time points (C3, C4 and IgG, N=70; IgM, N=66; RF, N=26) were used in the bias analysis.

2 analytes (Anti-CMV IgG and Anti-CMV IgM) were tested on a Biomerieux VIDAS analyzer. Stability was evaluated by concordance of results on 50 subjects.

*Hospital Site 2:*

3 analytes (hCG, Estradiol and Progesterone) were tested on a Siemens ADVIA Centaur® XP analyzer. Subjects with numerical value for both tubes at both time points (E<sub>2</sub>, <100 pg/mL, N=24; E<sub>2</sub>, ≥100 pg/mL, N=25; hCG, ≥5 mIU/mL, N=49; Prog, <10ng/mL, N=30; and Prog, ≥10ng/mL, N=31) were used in the bias analysis. Additional concordance table was provided for hCG.

*Hospital Site 3:*

2 analytes (CK, CRP) were tested on a Roche Modular analyzer. 3 analytes (CKMB, Myo, and TnI) were tested on a Beckman Coulter Access® analyzer.

Subjects with numerical value for both tubes at both time points (CK, N=46; CRP, N=43; CKMB, N=50; Myo, N=50; and TnI, <0.04 ng/mL, N=41; >0.04 ng/mL, N=7; <0.06 ng/mL, N=44; >0.06 ng/mL, N=6; <0.5 ng/mL, N=51) were used in the bias analysis. Additional concordance table was provided on TnI at 0.5 ng/mL cutoff.

3) Supplemental Studies:

40 healthy adult patients were tested internally for LDL and Triglycerides for additional time-points stability study. Testing was performed on a Roche Cobas Integra 800 analyzer at 0, 6, 12 and 24 hours after blood have been collected and separated from the centrifuge.

30 healthy adult patients were tested internally for Progesterone for additional time-points stability study. Testing was performed on a Siemens ADVIA Centaur analyzer at 0, 6, 12 and 24 hours after blood have been collected and separated from the centrifuge.

**Summary:** The results of the studies support the sponsor's claim that the BD RST HG tubes have analyte stability for 24 hours at room temperature except for LDL (12 hours), triglycerides (12 hours) and Progesterone (6 hours). This information is provided in the sponsor's package insert.

*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 enrolled. Enrollment included inpatient populations from selected clinical settings where it was

expected that the test results for one or more of the analytes to be tested will be outside the normal reference range. Testing was performed at the manufacturing facility and at 4 different clinical sites. All subjects in the comparative studies have blood samples collected into the BD RST HD (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 selected panel of common chemistry analytes, immunology analytes, and serological analytes on several instrument platforms. A total of 55 analytes were evaluated and demonstrated comparable results between the BD RST HG tubes and the BD SST tubes. A small number of spiked samples were used to supplement the analyte ranges. A list of the analytes and instrument platforms tested are summarized in Table 7. Deming regressions correlations with 95% confidence intervals were taken from one representative platform/study.

Table 7. Deming regressions correlations with 95% confidence intervals from one representative platform/study

Analyte	Instrument	Intercept (95% CI)	Slope (95% CI)
Alanine Aminotransferase	7,8,9	-0.01 (-0.1, 0.07)	1 (0.98, 1.02)
Albumin	7,8,9	0.01 (-0.03, 0.06)	0.99 (0.96, 1.02)
Alkaline Phosphatase	7,8,9	-0.01 (-0.05, 0.02)	1 (0.99, 1.01)
Amylase	2,7,8	0 (-0.03, 0.02)	1 (0.99, 1.01)
Aspartate Aminotransferase	7,8,9	0.03 (-0.03, 0.1)	0.99 (0.98, 1.01)
Bilirubin, Direct*	2,7,8	0 (0, 0.01)	0.99 (0.97, 1.01)
Bilirubin, Total*	7,8,9	0 (-0.01, 0.2)	0.99 (0.98, 1.01)
Blood Urea Nitrogen*	7,8,9	0 (-0.3, 0.3)	1 (1, 1)
C-Reactive Protein	8,9	-0.03 (-0.06, -0.01)	1.01 (0.99, 1.04)
Calcium*	7,8,9	0.09 (-0.11, 0.29)	0.99 (0.97, 1.01)
Carbon Dioxide, Total	2,7,8	0.18 (-0.07, 0.44)	0.95 (0.87, 1.02)
Chloride*	2,7,8	1.6 (-2.4, 5.6)	1 (0.9, 1)
Cholesterol	6,7,8	0.18 (-0.13, 0.49)	0.96 (0.9, 1.02)
Complement C3	2,6	0.27 (0.00, 0.55)	0.94 (0.88, 1.00)

Analyte	Instrument	Intercept (95% CI)	Slope (95% CI)
Complement C4	2,6	-0.05 (-0.18, 0.08)	1.01 (0.97, 1.05)
Cortisol	3,10	0.01 (-0.07, 0.09)	1 (0.97, 1.03)
Creatine Kinase- MB fraction*	1,9	0 (-0.23, 0.24)	0.96 (0.86, 1.07)
Creatine Kinase, Total	8,9	0 (-0.33, 0.34)	0.99 (0.93, 1.06)
Creatinine*	7,8,9	0.009 (-0.007, 0.025)	1.002 (0.998, 1.006)
Cytomegalovirus Antibodies, IgG	4,5	See table, below	See table, below
Cytomegalovirus Antibodies, IgM	4,5	See table, below	See table, below
Estradiol $\geq 100$ pg/mL	3,10	0.13 (-0.06, 0.31)	0.99 (0.97, 1.01)
Ferritin	3,10	-0.01 (-0.07, 0.05)	1 (0.99, 1.02)
Folate	3,10	-0.01 (-0.11, 0.08)	1.01 (0.97, 1.05)
Follicle Stimulating Hormone $\geq 10$ mIU/mL	3,10	-0.07 (-0.19, 0.05)	1.01 (0.98, 1.05)
Free Thyroxine*	3,10	0 (-0.02, 0.03)	0.99 (0.97, 1.01)
Free Triiodothyronine	3,10	0 (-0.04, 0.05)	1 (0.96, 1.04)
Gamma-glutamyltransferase	2,7,9	-0.09 (-0.19, 0.02)	1.02 (0.99, 1.04)
Glucose	7,8,9	0.04 (0.01, 0.08)	0.99 (0.99, 1)
High Density Lipoprotein	6,7,8	0.01 (-0.13, 0.15)	1.00 (0.96, 1.03)
Human Chorionic Gonadotropin $\geq 5$ mIU/mL	3,10	-0.03 (-0.1, 0.05)	1 (0.99, 1.01)
Immunoglobulin G	2,6	-0.20 (-1.04, 0.65)	1.03 (0.91, 1.15)
Immunoglobulin M	2,6	0.04 (-0.14, 0.22)	0.99 (0.94, 1.03)
Iron	6,7,8	-0.03 (-0.30, 0.23)	1.00 (0.94, 1.07)
Lactate Dehydrogenase	2,7,9	-0.06 (-0.27, 0.16)	1 (0.96, 1.05)
Lipase	2,7,8	-0.03 (-0.07, 0.01)	1.01 (1, 1.02)
Low Density Lipoprotein	6,7,8	0.09 (-0.09, 0.28)	0.98 (0.94, 1.02)

Analyte	Instrument	Intercept (95% CI)	Slope (95% CI)
Luteinizing Hormone ≥10 mIU/ml	3,10	0.11 (0, 0.22)	0.96 (0.93, 1)
Magnesium*	7,8,9	-0.04 (-0.08, 0.01)	1.01 (0.99, 1.03)
Myoglobin	1,9	0.02 (-0.06, 0.1)	0.99 (0.98, 1.01)
Phosphorus*	7,8,9	0.02 (-0.02, 0.06)	1 (0.99, 1.01)
Potassium*	2,7,8	0.06 (-0.018, 0.139)	0.985 (0.966, 1.003)
Progesterone ≥10 ng/mL	3,10	0.11 (-0.17, 0.4)	0.96 (0.87, 1.04)
Rheumatoid Factor	2,6	-0.03 (-0.16, 0.1)	1.01 (0.98, 1.04)
Sodium*	2,7,8	1.8 (-3.3, 6.9)	1 (1, 1)
Testosterone ≥100 ng/dL	3,10	0.09 (-0.03, 0.21)	0.99 (0.97, 1.01)
Thyroid Stimulating Hormone ≥1.0 μIU/mL	1,3,10	0.02 (-0.02, 0.06)	0.98 (0.96, 1.01)
Total Protein	7,8,9	0.01 (-0.03, 0.04)	0.99 (0.98, 1.01)
Total Thyroxine	1,3,10	0.02 (-0.20, 0.23)	0.99 (0.89, 1.09)
Total Triiodothyronine*	1,3,10	-0.07 (-0.127, -0.013)	1.02 (0.96, 1.079)
Transferrin	2,7,9	0.02 (-0.24, 0.29)	0.99 (0.94, 1.04)
Triglycerides	6,7,8	0.1 (-0.02, 0.22)	0.98 (0.95, 1)
Troponin I >0.07 ng/mL	1,9	-0.02 (-0.05, 0.01)	1.01 (0.99, 1.03)
Troponin I >0.14 ng/mL	1,9	-0.02 (-0.04, 0.01)	1.01 (0.99, 1.02)
Troponin I <0.6 ng/mL	1,9	0.14 (-0.11, 0.39)	1.08 (0.97, 1.2)
UA	2,7,9	-0.05 (-0.09, 0)	1.02 (1, 1.04)
Vitamin B12	3,10	-0.03 (-0.4, 0.34)	1 (0.94, 1.06)

\* Deming Regression performed on original scale. For all other analytes, unweighted-log Deming Regression performed, and estimates provided in natural log-transformed domain.

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

		BD RST HG			All
		Negative (<4)	Equivocal (≥4 to <6)	Positive (≥6)	
BD SST™	Negative (<4)	47	0	0	47
	Equivocal (≥4 to <6)	0	0	0	0
	Positive (≥6)	0	0	55	55
All		47	0	55	102

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

		BD RST HG			All
		Negative (<0.7)	Equivocal (≥0.7 to <0.9)	Positive (≥0.9)	
BD SST™	Negative (<0.7)	99	0	0	99
	Equivocal (≥0.7 to <0.9)	0	1	0	1
	Positive (≥0.9)	0	0	2	2
All		99	1	2	102

Instrument(s):

- 1- Beckman Coulter Access®/Access® 2
- 2- Beckman Coulter UniCel® DxI 800
- 3- Beckman Coulter UniCel® DxI 800
- 4- Biomerieux VIDAS®
- 5- Dynex DS2™ / Wampole Laboratories®
- 6- Ortho Clinical Diagnostics VITROS® 5,1 FS
- 7- Roche COBAS Integra® 800
- 8- Roche MODULAR ANALYTICS
- 9- Siemens Dimension® RxL
- 10- Siemens ADVIA Centaur®/Centaur® XP

Summary of all the studies:

- 1) Internal Study: 47 apparently healthy adults were enrolled internally at the manufacturing facility.

Testing for 28 routine chemistry analytes was performed on a Roche Cobas Integra 800 instrument.

Testing for 12 immunoassay analytes was performed on a Siemens ADVIA Centaur instrument.

- 2) External Studies: Consecutive adult patients from multiple inpatient settings with a range of conditions and diagnoses were enrolled and tested respectively in Hospital Site 1, 2, 3 and 4.

*Hospital Site 1:*

Samples from 78 subjects were tested for 19 routine chemistry analytes on a Roche Modular instrument. Samples from an additional 24 subjects from other hospital sites were tested for one or more of the 19 analytes to cover a wide range for the analytes of interest.

*Hospital Site 2:*

A panel of 21 analytes was tested, including 16 chemistry analytes on a Beckman Coulter UniCel DxC 800 instrument, TSH, TT3, and TT4 on a Beckman Coulter Access 2 instrument, and anti-CMV IgG, anti-CMV-IgM on a Biomerieux Vidas instrument. Among the 101 subjects enrolled, samples from 80 subjects were tested for all analytes, samples from 21 subjects were tested on selected analytes only. Samples from an additional 30 subjects from other hospital sites were tested for one or more of the 21 analytes to cover a wide range for the analytes of interest.

*Hospital Site 3:*

A panel of 22 analytes was tested, including 10 chemistry analytes on a Ortho-Diagnostics Vitros analyzer or a Roche Modular, 12 special chemistry analytes on a Beckman Coulter UniCel® Dxi 800 and Siemens ADVIA Centaur® XP analyzer. Among the 71 subjects enrolled, samples from 43 subjects were tested for all analytes. Samples from 28 subjects were tested on a subset of the analytes. Samples from an additional 81 subjects from other hospital sites were tested for one or more of the 22 analytes to cover a wide range for the analytes of interest.

*Hospital Site 4:*

A panel of 26 analytes was tested, including 21 analytes on Siemens Dimension® RxL, 2 analytes on Roche Modular, and 3 analytes on Beckman Coulter Access®. Among the 87 subjects enrolled, samples from 77 subjects were tested for all analytes. Samples from 10 subjects were tested on a subset of the analytes. Samples from an additional 31 subjects from other hospital sites were tested for one or more of the 26 analytes to cover a wide range for the analytes of interest.

*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.