Evaluation of the Greiner Bio-One VACUETTE® 3.15mL, 3.2% (109M) Sodium Citrate Evacuated Blood Collection Tube for Coagulation Testing

Device Name
Greiner Bio-One VACUETTE®, 3.2% (109M) Sodium Citrate 3.15mL, 13x75mm, Twist Cap Tube Product Listing #454327

Comparator Device
Becton Dickinson Vacutainer® Glass, 3.13% (105M) Sodium Citrate, 4.5mL, 13x75mm, Hemogard™ Closure Tube, Product Listing #369714

Intended Use
The Greiner Bio-One VACUETTE® 3.2% (109M) Sodium Citrate tube is made of plastic and provides a means of collecting collecting and transporting an undiluted blood specimen in a closed evacuated system. The tubes contain buffered sodium citrate which yields a 9 to 1 blood to anticoagulant ratio when the evacuated tube is filled correctly to its fill volume. The citrate binds calcium ions, which block the coagulation cascade.

Rationale of Study
The purpose of this study was to determine if the Greiner Bio-One VACUETTE® 3.2% (109M) 3.15mL, 13x75mm, Twist Cap Tube and the Becton Dickinson Vacutainer® Glass 3.13% (105M) 4.5mL, 13x75mm, Hemogard™ Closure blood collection tubes are significantly different with respect to PT and aPTT tests in Normal Donors, PT tests and INR values in patients on Warfarin therapy, and aPTT and anti-Xa tests in patients receiving Unfractionated Heparin.

Specimen Collection
Blood specimens were obtained using the site's standard phlebotomy techniques, which referenced each site's Standard Operating Procedures and OSHA's safety requirements for blood collection. Inclusion and exclusion criteria were used to determine the eligibility of the donors. The Normal Donors were free of any aspirin-containing medications or other non-steroidal anti-inflammatory drugs. In addition, the Normal Donors were non-pregnant and non-smokers. The eligibility of the Coumadin and Unfractionated Heparin Donors were determined by the Investigator. To ensure that the 9:1 blood:anticoagulant ratio was acquired, all donors and patients had hematocrits no less than 20% and no greater than 55%. This reflected the criteria used at the testing site. The order of draw was randomized.

The following tubes were drawn from each Normal, Warfarin and Unfractionated Heparin Donors: 1) one Greiner VACUETTE® 3.2% (109M) 3.15mL, Sodium Citrate, 13x75mm, Twist Cap Tube and 2) one Becton Dickinson Vacutainer® Glass 3.2% (109M) 4.5mL Sodium Citrate, 13x75mm, Hemogard™ Closure Tube.

Handling Techniques
All samples were gently mixed using four complete inversions immediately following blood collection. The tubes were centrifuged using the laboratory's standard procedure to achieve a platelet count of less than 10,000 platelets/uL. Separation of plasma was achieved within two hours of collection. Coagulation testing was performed within six hours of collection.

Study Design
The study received approval from the site's Institutional Review Board. Informed Consent was obtained from all donors prior to blood being obtained. On all normal samples, the testing site performed PT and aPTT determinations (singlet test, half volume). These tests were performed using high sensitivity reagents within 2 hours +/- 15 minutes of blood collection. For Warfarin Donors, the testing site performed PT determinations (singlet test, half volume) and INR values using a high sensitivity reagent within 2 hours +/- 15 minutes of blood collection. For Unfractionated Heparin Donors, APTT determinations (singlet test, half volume) were performed using a high sensitivity reagent and Anti Xa using the Diagnostica Stago Stachrom FXa Assay. Heparinized specimens were centrifuged within 1 hour of collection and tested within 2 hours +/- 15 minutes of blood collection.

Table #1 (Page 2) lists the tests, assays or instruments used at the testing site.

Table #1				
Instruments, Assays and Tests				
Donors	N#	Tests	Reagents	Instrument
Normal	50	PT APTT	Dade® Innovin® Reagent (ISI=1.0) Dade®Actin® FSL Activated APTT Reagent	Trinity Biotech AMAX™ 190
Coumadin	50	PT, INR	Dade® Innovin® Reagent(ISI=1.0)	Trinity Biotech AMAX™ 190
Unfractionated Heparin	50	APTT FXa assay	Dade®Actin® FSL Activated APTT Reagent Diagnostica Stago Stachrom FXa Assay	Trinity Biotech AMAX™ 190

Statistical Analysis

The results of all tests were summarized using Mean and Standard Deviation (SD) to determine if the Greiner Bio-One tubes were significantly different from the Becton Dickinson tubes. Linear Regression Analysis was also used to assess the correlation of results between the collection tubes.

Results and Discussion: Normal, Warfarin and Unfractionated Heparin Donors

Normal Donors PT Results

The Greiner Bio-One VACUETTE® 3.15mL, 109M (3.2%) Sodium Citrate, 13x75mm Twist CapTubes demonstrated clinically equivalent mean PT test results when compared to the Becton Dickinson Vacutainer® Glass 105M (3.13%) Sodium Citrate, 4.5mL, 13x75mm Hemogard Tube. The PT mean, SD, reference interval and linear regression data are summarized in Table #2.

Normal Donors APTT Results

The Greiner Bio-One VACUETTE® 109M (3.2%) 3.15mL Sodium Citrate, 13x75mm Twist Cap Tubes demonstrated substantially equivalent mean APTT test results when compared to the Becton Dickinson Vacutainer® Glass 105M (3.13%) Sodium Citrate, 4.5mL, 13x75mm Hemogard Tube. The APTT mean, SD, reference interval and linear regression data are summarized in Table #3.

Table #2		
Normal Donors, PT		
Dade Behring Innovin™ Reagent		
	BD	Greiner
N#	50	50
Mean	8.6	8.74
SD	0.49	0.54
Reference Interval	8.62-9.58	7.66-8.82
Linear Regression (R)		0.9730

Table #3		
Normal Donors, APTT		
Dade Behring Actin FSL Reagent		
	BD	Greiner
N#	49	49
Mean	28.97	28.29
SD	3.00	2.91
Reference Interval	22.97-34.97	22.47-34.11
Linear Regression (R)		0.9850

Results and Discussion: Normal, Warfarin and Unfractionated Heparin Donors *continued*

Warfarin Donors PT Results

The Greiner Bio-One VACUETTE® 109M (3.2%) 3.15mL Sodium Citrate, 13x75mm Twist Cap Tubes demonstrated substantially equivalent mean PT and INR values when compared to the Becton Dickinson Vacutainer® Glass 105M (3.13%) Sodium Citrate, 4.5mL, 13x75mm Hemogard Tube. The PT and INR mean, SD and linear regression data are summarized in Table #4.

Unfractionated Heparin Donors APTT and Anti-Xa Results:

The Greiner Bio-One VACUETTE® 109M (3.2%) 3.15mL Sodium Citrate, 13x75mm Twist Cap Tubes demonstrated substantially equivalent mean APTT and Anti-Xa test results when compared to the Becton Dickinson Vacutainer® Glass 105M (3.13%) Sodium Citrate, 4.5mL, 13x75mm Hemogard Tube. The APTT and INR mean, SD and linear regression data are summarized in Table #5.

Table #4

Warfarin Donors, PT & INR

Dade Behring Innovin™ Reagent

		N#	Mean	SD	Linear Regression (R)
BD	PT	49	26.26	10.40	
	INR		2.76	1.06	
Greiner	PT	49	27.57	11.06	0.9963
	INR		2.90	1.13	0.9834

Table #5

Unfractionated Heparin Donors APTT & Anti-XA

Dade Behring Actin FSL Reagent

		N#	Mean	SD	Linear Regression (R)
BD	APTT	49	67.77	26.05	
	XA	49	0.546	0.367	
Greiner	APTT	49	66.23	26.84	0.9707
	XA	49	0.528	0.334	0.9321

Conclusion

The Greiner Bio-One VACUETTE™ 3.15mL , 3.2% (109M), Sodium Citrate 13x75mm Twist Cap Tubes demonstrated substantial equivalence to the Becton Dickinson Vacutainer® Glass 4.5mL, Glass, 3.13% (105M), 13x75mm, Hemogard™ Closure Tubes with various standard coagulation assays using different donor populations.

References

Ens, G. E., Fristma, G.A., Jensen, R., Newlin, F.H. and Quarles, L.A. (1998). Coagulation Handbook. Clinical Hemostasis Review.

NCCLS H21-A3. (December 1998). Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline – Third Edition. Vol. 18 No. 20. Wayne, PA.

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