Greiner Bio-One VACUETTE®
No Additive and Serum Clot Activator
Evacuated Blood Collection Tubes
For Viral Marker Testing

Device Names
Greiner VACUETTE® No Additive, 6.0mL, 13x100mm tube, Product Listing #456001
Greiner VACUETTE® Serum Clot Activator, 6.0mL, 13x100mm tube, Product Listing #456092

Comparator Device
Becton Dickinson Vacutainer™ Glass No Additive, Non-Siliconized, 7.0ml, 13x100mm tube, Product Listing, #366442
Becton Dickinson Vacutainer™ Glass No Additive, Non-Coated Interior, 7.0ml, 13x100mm tube, Product Listing, #369626

Intended Use
VACUETTE® Tubes, Holders and Needles are used together as a system for the collection of venous blood. VACUETTE® tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. VACUETTE® No Additive Tubes and VACUETTE® Serum Clot Activator tubes may be used for viral marker testing in screening and clinical laboratories.

Specimen Collection
Blood specimens were obtained using each site's standard phlebotomy techniques, referencing Standard Operating Procedures and OSHA's safety requirements for blood collection. The order of draw was randomized.

The following tubes were drawn from each donor at the two Donor Centers:
1) one Greiner VACUETTE No Additive, 6.0mL, 13x100mm tube
2) one Greiner VACUETTE Serum Clot Activator, 6.0mL, 13x100mm tube and
3) one Becton Dickinson Vacutainer™ Glass No Additive, Non-Coated Interior, 7.0mL, 13x100mm tube

In addition, two Greiner VACUETTE No Additive 6.0mL half evacuated to simulate half draw, 13x100mm tubes and two Greiner VACUETTE Serum Clot Activator 6.0mL half evacuated to simulate half draw, 13x100mm tubes were collected from 10 healthy donors and 10 positive patients at Donor Center #2.
The following three tubes were drawn from each individual at the Reference Laboratories:
1) one Greiner VACUETTE No Additive, 6.0mL, 13x100mm tube
2) one Greiner VACUETTE Serum Clot Activator, 6.0mL, 13x100mm tube
3) one Becton Dickinson Vacutainer™ Glass No Additive, Non-Siliconized Interior, 7.0mL, 13x100mm tube

A. Donor Center - #1:
1) 50 apparently healthy donors

B. Donor Center - Site #2:
1) 50 apparently healthy donors (full draw tubes)
2) Subset: 5 healthy donors (full and half draw) for delayed testing (Day 0 and Day 7)
3) Subset of 10 patients positive for at least one viral marker (full and half draw)
4) Subset of 6 positive patients for one viral marker (full & half draw) for delayed testing (Day 0 & Day 7)
5) Subset of 6 positive patients for one viral marker full & half draw) for delayed tube mixing (Day 0 & Day 7)

C. Reference Laboratories – Site #3:
1) 51 known positive patients for HBV, HCV and/or HIV

Handling Techniques
The tubes were gently mixed using 8-10 complete inversions immediately following blood collection. Tubes were centrifuged using the laboratory's standard procedure to separate cellular elements completely from the serum.

Study Design
the study design was based on recommendations made by reviewers from the FDA Center for Biologics Evaluation and Research, Division of Blood Applications (CBER).

Table #1			
Instrumentation, Assays, Tests			
Tests	Site #1 Donor Center	Site #2 Donor Center	Site #3 Reference Laboratory
Anti-HBs (detects HBsAg)	Abbott AUSZYME® MONOCLONAL Enzyme Immunoassay Abbott Commander® System	ORTHO® Antibody to HBsAg ELISA Test System 2 Ortho® Summit™ Processor	Abbott AUSZYME® MONOCLONAL Enzyme Immunoassay Abbott Commander® System
HBcAg (detects total anti-HBc)	Abbott CORZYME® Enzyme Immunoassay Abbott Commander® System	ORTHO® HBc ELISA Test System Ortho® Summit™ Processor	Abbott CORZYME® Enzyme Immunoassay Abbott Commander® System
HCV (detects anti-HCV)	Abbott HCV EIA 2.0 Enzyme Immunoassay Abbott Commander® System	ORTHO® HCV Version 3.0 ELISA Test System Ortho® Summit™ Processor	Abbott HCV EIA 2.0 Enzyme Immunoassay Abbott Commander® System
HCV RIBA (Confirmatory)		Chiron™ RIBA™ HCV 3.0 SIA Ortho® Summit™ Processor	
HIV 1/2 (detects anti-HIV 1/2)	Abbott HIV AB™ HIV-1/ HIV-2 (rDNA) EIA Enzyme Immunoassay Abbott Commander® System	BIO-RAD Genetic Systems™ HIV-1 / HIV-2 Peptide EIA Ortho® Summit™ Processor	Abbott HIV AB™ HIV-1/ HIV-2 (rDNA) EIA Enzyme Immunoassay Abbott Commander® System
HTLV I/II (detects anti-HTLV I/II)	Abbott HTLV-I/HTLV-II Enzyme Immunoassay Abbott Commander® System	Organon Teknika Vironstika® HTLV I/II Microelisa System Ortho® Summit™ Processor	Abbott HTLV-I/HTLV-II Enzyme Immunoassay Abbott Commander® System
Anti-CMV (detects antibodies to CMV, total)	Olympus® PK™TP CMV-PA System Olympus® PK7200™ Automated Microplate System	Abbott CMV Total AB EIA (List#6163) Abbott Commander® System	Abbott CMV Total AB EIA Abbott Commander® System
Syphilis Screen	Olympus® PK™ TP System Olympus® PK7200™ Automated Microplate System	Olympus® PK™ TP System Olympus® PK7200™ Automated Microplate System	Biokit Sure-Vue™ RPR
RPR/TPA (Confirmatory)		Fujirebio Diagnostics Serodia® TP*PA	
ALT	Abbott AEROSET® Clinical Chemistry System	Olympus® AU640e™ Chemistry Immuno Analyser	Ortho-Clinical Diagnostics VITROS® 950 Chemistry System

Discussion

Anti- HBs (detects HBsAg)

Testing for HBsAg was performed on samples from 100 apparently healthy adults [AHA] (Sites #1 and 2) and 55 patients (4 at Site #2; 51 at Site #3), using the Abbott AUSZYME® MONCLONAL Enzyme Immunoassay (Sites #1 and 3) or the ORTHO® Antibody to HBsAg ELISA Test System 2 (Site #2). There were 100 non-reactive AHA samples and 4 initially reactive patient samples. The initially reactive results were repeated in duplicate and were repeatedly reactive. All results for the Greiner tubes were 100% concordant with the BD tubes.

HBcAg (detects total anti-HBc)

Testing for total anti-HBc was performed on samples from 100 apparently healthy adults [AHA] (Sites #1 and 2) and 60 patients (9 at Sites #2; 51 at Site #3), using the Abbott CORZYME® Enzyme Immunoassay (Sites #1 and 3) or the ORTHO® HBc ELISA Test System (Site #2). There were 97 non-reactive AHA samples and 25 initially reactive patient samples. The initially reactive results were repeated in duplicate and were repeatedly reactive. All results for the Greiner tubes were 100% concordant with the BD tubes.

HCV (detects anti-HCV)

Testing for anti-HCV was performed on samples from 100 apparently healthy adults [AHA] (Sites #1 and 2) and 57 patients (6 at Site #2; 51 at Site #3), using the Abbott HCV EIA 2.0 Enzyme Immunoassay (Sites #1 and 3) or the ORTHO® HCV Version 3.0 ELISA Test System (Site #2). There were 100 non-reactive AHA samples and initially reactive patient samples. Thirty-five (35) of the initially reactive results were repeated in duplicate and were repeatedly reactive. One sample was QNS for repeat testing with the Greiner VACUETTE® No Additive Tube. All results for the Greiner tubes were 100% concordant with the BD tubes.

HIV 1/2 (detects anti-HIV 1/2)

Testing for anti-HIV 1/2 was performed on samples from 100 apparently healthy adults [AHA] (Sites #1 and 2) and 51 patients (Site #3), using the Abbott HIVAB™ HIV-1/HIV-2 Enzyme Immunoassay (Sites #1 and 3) or the BIO-RAD Genetic Systems™ HIV-1/HIV-2 Peptide EIA (Site #2). There were 100 non-reactive AHA samples and 29 initially reactive patient samples. Twenty-eight (28) of the initially reactive results were repeated in duplicate and were repeatedly reactive. One sample was QNS for repeat testing with the Greiner VACUETTE® No Additive Tube. All results for the Greiner tubes were 100% concordant with the BD tubes.

HTLV I/II (detects anti-HTLV I/II)

Testing for anti-HTLV I/II was performed on samples from 100 apparently healthy adults [AHA] (Sites #1 and 2) and 51 patients (Site #3), using the Abbott HTLV-I/HTLV-II Enzyme Immunoassay (Sites #1 and 3) or the Organon Teknika HTLV-1/II Vironostika® Microelisa System (Site #2). There were 100 non-reactive AHA samples and 3 initially reactive patient samples. The initially reactive results were repeated in duplicate and were repeatedly reactive. All results for the Greiner tubes were 100% concordant with the BD tubes.

The patients in this study were under active treatment, with most demonstrating very high absorbance levels. However, one patient at Site #3 had moderate absorbance levels for the HTLV I/II (GR #65). The results were similar between the BD and Greiner tubes (Table #2).

Table #2

HTLV Antibody Testing Results for Patients

	Initial Testing		Repeat Testing		
Patient GR #65	OD	Cut Off	Repeat OD	Repeat OD	Cut Off
BD	0.823	0.382	0.720	0.629	0.633
Greiner Non-Additive	0.794	0.382	0.666	0.592	0.363
Greiner Clot Activator	0.699	0.382	0.725	0.775	0.363

Anti-CMV (detects antibodies to CMV)

Testing for anti-CMV was performed on samples from 100 apparently healthy adults [AHA] (Sites #1 and 2) and 50 patients (4 at Site #2; 46 at Site #3). The Olympus® PK™ CMV-PA System was used at Sites #1 and 3. The Abbott Commander® System was used at Site #2.

There were 39 negative AHA samples and 35 positive patient samples. All results from the patient population and all but one from the AHA population showed 100% concordance between the Greiner tubes and the BD tubes. One AHA sample was negative by the Greiner VACUETTE® Clot Activator tube and the BD tube, but was indeterminate by the Greiner VACUETTE® No Additive tube. The Olympus PK™ result for the Greiner VACUETTE® No Additive tube printed out as a positive with question marks. This indicates an indeterminate result and should be repeated in duplicate. The laboratory's procedure on these types of results is to report them as positive with no repeat testing.

Syphilis Screening

The STS screening testing for Syphilis was performed on samples from 100 apparently healthy adults [AHA] (Sites #1 and 2) and 51 patients (Site #3). Sites #1 and 2 used the Olympus® PK™TP System, a fully automated hemagglutination assay in which the instrument reads the cell patterns. Site #3 used the BioKit Sure-Vue™ RPR Assay, a manual charcoal agglutination assay in which the laboratorian reads the aggregate patterns. There were 99 negative AHA samples and 2 reactive patient samples. The initially reactive result from the AHA population was confirmed reactive by TPA testing.

ALT Testing

Testing for alanine aminotransferase (ALT) was performed on samples from 100 apparently healthy adults [AHA] (Sites #1 and 2) and 55 patients (4 at Site #2 and 51 at Site #3). The Abbott AEROSET® Clinical Chemistry System was used at Site #1, the Olympus® AU640e™ Chemistry Immuno Analyzer was used at Site #2, and the Ortho-Clinical Diagnostics VITROS® 950 Chemistry System was used at Site #3.

Samples were considered negative if the ALT concentration was within the manufacturers' published expected ranges. The expected ranges were < 40 U/mL for the Abbott assay, 7-52 U/mL for the Olympus assay, and 11-66 U/L for the Ortho assay. There were 100 negative AHA samples and 12 positive patient samples. All of the AHA results for the Greiner tubes were 100% concordant with the BD tube. Fifty-four (54) of the patient results for the Greiner tubes were 100% concordant with the BD tubes. The results for the three tubes from one patient spanned the defined limit between negative and positive but were within the reproducibility of the assay.

Full and Half-Draw Study

A study was conducted for informational purposes only to evaluate the performance of the viral marker tests in samples simulating partially drawn tubes. The testing was performed on a subset of 5 AHAs and 10 patients at Site #2 using the Greiner VACUETTE® No Additive tubes at full draw and half draw, the Greiner VACUETTE® Clot Activator tubes at full draw and half draw and the BD Vacutainer® Glass No Additive Non-Coated tubes at full draw.

Samples from five of the AHAs were tested for detection of HBsAg, total anti-HBc, anti-HCV, anti-CMV, and ALT. The results are summarized in Table #3. Of the 5 AHAs tested, all five were negative for HBsAg, total anti-HBc, anti-HCV, and ALT. Three were negative for anti-CMV and two were positive for anti-CMV.

Samples from an additional five AHAs were tested for Anti-HIV 1/2, anti-HTLV I/II, and STS. The results are summarized in Table #4. Of the 5 AHAs tested, all 5 were negative for anti-HIV 1/2, anti-HTLV I/II, and STS. There was 100% concordance between results obtained with the Greiner VACUETTE® No Additive and Clot Activator full and half draw tubes and the BD full draw tubes.

Table #3

Results from First Five AHAs

		BD	Greiner Vacuette® No Additive		Greiner Vacuette® Clot Activator	
		Full Draw	Full Draw	Half Draw	Full Draw	Half Draw
HBsAg	5	neg	neg	neg	neg	neg
Total Anti-HBc	5	neg	neg	neg	neg	neg
Anti-HCV	5	neg	neg	neg	neg	neg
Anti-CMV	5	3-neg 2-pos	3-neg 2-pos	3-neg 2-pos	3-neg 2-pos	3-neg 2-pos
ALT	5	neg	neg	neg	neg	neg

Table #4

Results from Second Five AHAs

		BD	Greiner Vacuette® No Additive		Greiner Vacuette® Clot Activator	
		Full Draw	Full Draw	Half Draw	Full Draw	Half Draw
HIV 1/2	5	neg	neg	neg	neg	neg
HTLV I/II	5	neg	neg	neg	neg	neg
STS	5	neg	neg	neg	neg	neg

Samples from subsets of the ten patients were tested for HBsAg, total anti-Hbc, anti-HCV, anti-CMV, and ALT. The results are summarized in Table #5. All initially reactive total anti-Hbc and anti-HCV results were repeated in duplicate and were repeatedly reactive. All results for the Greiner tubes were 100% concordant with the BD tubes.

Table #5						
Full/Half Draw Study-Patient Results						
		BD	Greiner Vacuette® No Additive		Greiner Vacuette® Clot Activator	
		Full Draw	Full Draw	Half Draw	Full Draw	Half Draw
HBsAg	4	neg	neg	neg	neg	neg
Total Anti-HBc	4	5(RR[a])	5(RR[a])	5(RR[a])	5(RR[a])	5(RR[a])
Anti-HCV	9	2(RR[a])	2(RR[a])	1(RR [a,b])	2(RR[a])	2(RR[a])
Anti-CMV	4	neg	neg	neg	neg	neg
ALT	6	neg	neg	neg	neg	neg

[a]RR = repeatedly reactive

[b] One result was indeterminate – the c33c band was P/N; in all other tubes, the c33c band was 1+

The two anti-HCV repeatedly reactive samples were confirmatory tested by HCV RIBA. One sample was confirmed positive by all tubes, the second sample was confirmed positive in all tubes except the Greiner VACUETTE® No Additive half draw tube which was indeterminate. This may have been due to a difference in timing of the HCV RIBA confirmatory testing for these samples. The confirmatory testing was performed four days after screening for the first sample and seven days after screening the second sample. In addition, the difference between an indeterminate and positive result was the grading of the c33c band: 1+ for positive or P/N for indeterminate result. There was no trend in the result differences and no change in result interpretation (i.e., positive to negative or negative to positive). Therefore, it can be concluded that the differences observed were due to the inherent variability in the HCV RIBA methodology and the subjective nature of the band intensity grading.

Delay in Testing

The Full Draw/Half Draw Study performed at Site #2, was repeated after storage on the samples stored on the clot at 2-8C, 7 Days from the date of collection. The only deviation was that the Greiner VACUETTE® No Additive full draw tube was QNS for one of the samples in the first subset of AHAs. This study was performed for information purposes only, to evaluate the performance of the viral marker tests on samples in which the serum was not separated from the clot. This is not a recommended procedure. The viral marker assay manufacturers' package inserts state to remove the serum from the clot as soon as possible. The results were concordant between Day 0 and Day 7, with the following exceptions (Table #6):

1. For one AHA, the BD tube was nonreactive for HBsAg on Day 0, but was initially reactive, repeatedly reactive, and confirmed positive on Day 7.
2. For a second AHA, the BD tube was nonreactive for HBsAg on Day 0, but was initially reactive and repeatedly nonreactive on Day 7.
3. For the HCV RIBA results on one of the repeatedly reactive patients (Patient #726), the BD tube and the Greiner tubes were inconsistent in the results (Table #6).

There was no trend in the result differences and no change in result interpretation (i.e., positive to negative or negative to positive). Therefore, it can be concluded that the differences observed were due to the inherent variability in the HCV RIBA methodology and the subjective nature of the band intensity grading.

Table #6		
HCV RIBA Results on Patient #726- Delayed Testing		
Tube	Day 0 Result	Day 7 Result
Greiner Vacuette® No Additive (full draw)	positive	indeterminate
Greiner Vacuette® No Additive (half draw)	indeterminate	indeterminate
Greiner Vacuette® Clot Activator (full draw)	positive	positive
Greiner Vacuette® Clot Activator (half draw)	positive	positive
BD (full draw)	positive	indeterminate

Delay in Mixing

A study was conducted at Site #2 to evaluate the effect of viral marker results on delayed tube mixing after collection. The participants in the study were the 6 antibody positive patients (4 for total anti-HBc, 1 for anti-HCV, and 1 for both). Two Greiner full draw tubes for each tube type were collected from each patient. One tube was mixed immediately after collection, per Greiner instructions. The second tube was laid on the table for 10 minutes immediately after collection and then mixed ("delayed mix"). The samples were tested for total anti-HBc or anti-HCV, depending on the known antibody present, on Day 0 and after storage at 2-8°C, 7 Days from date of collection. The results are summarized in Table #7.

In the anti-HCV screening test, there was 100% concordance between results obtained with the Greiner VACUETTE® No Additive and Clot Activator mixed and delayed mix tubes as compared to the BD mixed tubes. There were two initially reactive and repeatedly reactive samples, which were concordant in all tubes.

Table #7						
Mixed/Delayed Mix Study-Patient Results						
		BD	Greiner Vacuette® No Additive		Greiner Vacuette® Clot Activator	
		Mixed	Mixed	Delayed Mix	Mixed	Delayed Mix
Total Anti-HBc						
Day 0	5	5(RR[a])	5(RR[a])	5(RR[a])	5(RR[a])	5(RR[a])
Day 7	5	5(RR[a])	5(RR[a])	5(RR[a])	5(RR[a])	5(RR[a])
Anti-HCV						
Day 0	2	2(RR)[b]	2(RR)[b]	1[c]	2(RR)[b]	1[c]
Day 7	2	1[c]	1[c]	2(RR)[b]	2(RR)[b]	2(RR)[b]

[a]RR = repeatedly reactive
[b] repeatedly reactive and confirmed positive by HCV RIBA
[c] One result was repeatably reactive but indeterminate on HCV RIBA – the c33c band was P/N; in all other tubes, the c33c band was 1+

The two anti-HCV repeatedly reactive samples were confirmatory tested by HCV RIBA. On Day 0, the first sample was confirmed positive by all the tubes (mixed and delayed mixed). The second sample was confirmed positive in the BD and Greiner tubes (mixed) and indeterminate in the Greiner No Additive and Serum Clot Activator delayed mixed tubes.

Testing on the mixed and delayed mix tubes for the two anti-HCV confirmed positive patients was repeated on Day 7. On the first sample, the mixed and delayed mixed samples were all confirmed positive. The mixed and delayed mix samples from the second patient (Patient #726) were positive in the Greiner VACUETTE® Clot Activator tube and indeterminate in the Greiner VACUETTE® No Additive tube at Day 7. The results are summarized in Table #8. The Greiner tubes and the BD tube were inconsistent in results. There was no trend in the result differences and no change in result interpretation (i.e., positive to negative or negative to positive). Therefore, it can be concluded that the differences observed were due to the inherent variability in the HCV RIBA methodology and the subjective nature of the band intensity grading.

Table #8					
HCV RIBA Results on Patient #726 - Delayed Mixing					
	BD	Greiner Vacuette® No Additive		Greiner Vacuette® Clot Activator	
	Mixed	Mixed	Delayed Mix	Mixed	Delayed Mix
Day 0	POS	POS	IND	POS	IND
Day 7	IND	IND	POS	POS	POS

POS=positive result
IND=Indeterminate result

Conclusions

The Greiner VACUETTE® No Additive and Serum Clot Activator tubes demonstrated substantial equivalence to the Becton Dickinson Vacutainer® Glass No Additive, Non-Coated or No Additive Non-Siliconized tubes in terms of agreement for the viral marker testing results with blood donors and antibody positive individuals. In addition, the tubes demonstrated similar results when delayed testing was performed (Day 7) and compared to initial testing (Day 0), when testing was performed on partially filled tubes and compared to fully drawn tubes, and when testing was performed on tubes that were subjected to delayed mixing.

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