Greiner Bio-One VACUETTE®
EDTA K2 and EDTA K3
Evacuated Blood Collection Tubes
For Viral Marker Testing

Device Names
Greiner VACUETTE® EDTA K2, 6.0mL, 13x100mm tube, Product Listing #456023
Greiner VACUETTE® EDTA K3, 6.0mL, 13x100mm tube, Product Listing #456099

Comparator Device
Becton Dickinson Vacutainer™ Glass No Additive, Non-Siliconized, 7.0ml, 13x100mm tubes, Product Listing #366442
Becton Dickinson Vacutainer™ Glass No Additive, Non-Coated Interior, 7.0ml, 13x100mm tubes, 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® K2 EDTA and VACUETTE® K3 EDTA 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 EDTA K2, 6.0mL, 13x100mm tube
2) one Greiner VACUETTE EDTA K3, 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 EDTA K2 6.0mL half evacuated to simulate half draw, 13x100mm tubes and two Greiner VACUETTE EDTA K3 6.0mL half evacuated to simulate half draw, 13x100mm tubes were collected from 10 healthy donors and 6 positive patients at Donor Center #2.
The following three tubes were drawn from each individual at the Reference Laboratories:
1) one Greiner VACUETTE EDTA K2, 6.0mL, 13x100mm tube
2) one Greiner VACUETTE EDTA K3, 6.0mL, 13x100mm tube and
3) one Becton Dickinson Vacutainer™ Glass No Additive, Non-Siliconized, 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: 10 healthy donors (full and half draw) for delayed testing (Day 0 and Day 7)

3) 6 patients positive for one viral marker (full and half draw) for delayed testing (Day 0 and Day 7)

4) 6 patients positive for one viral marker (full and half draw) for delayed tube mixing (Day 0 and Day 7)

C. Reference Laboratories – Site #3:
1) 50 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 plasma.

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 Immucor Capture CMV® Microplate Assay	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 50 patients (Site #3), using the Abbott AUSZYME® MONOCLONAL 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. 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 55 patients (Sites #2 and 3), using the Abbott CORZYME® Enzyme Immunoassay (Sites #1 and 3) or the ORTHO® HBc ELISA Test System (Site #2). There were 94 non-reactive AHA samples and 31 initially reactive patient samples. The initially reactive results were repeated in duplicate. 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 54 patients (Sites #2 and 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 31 initially reactive patient samples. The initially reactive results were repeated in duplicate and were 100% concordant between the Greiner and 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 50 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 30 initially reactive patient samples. The initially reactive results were repeated in duplicate. 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 50 patients (Site #3), using the Abbott HTLV-I/HTLV-II Enzyme Immunoassay (Sites #1 and 3) or the Organon Teknika HTLV-I/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. All results for the Greiner tubes were 100% concordant with the BD tubes.

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 (Site #3). The Olympus® PK™ CMV-PA System was used at Site #1, with the Immucor Capture-CMV® Microplate Assay for some sample testing. Site #2 and Site #3 used the Abbott Commander® System.

There were 37 negative AHA samples and 41 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 EDTA K3 tube and the BD tube, but was positive by the Greiner EDTA K2 tube. The Olympus PK™ result for the Greiner EDTA K2 tube printed out as a positive result with question marks, indicating that this questionable result could be caused by a dirty well or old plate. The laboratory takes a conservative position on these types of results and reports them as positive with no repeat testing.

Syphilis Screening

The STS screening test for Syphilis was performed on samples from 100 apparently health adults [AHA] (Site #1 and 2) and 50 patients (Site #3). Sites #1 and 2 used the Olympus PK™TP System, a fully automated hemagglutinaltion 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 6 positive patient samples. The initially reactive result from the AHA population was confirmed reactive by TPA testing. In the AHA population, all results for the Greiner tubes were 100% concordant with the BD tube. In the patient population, there were 2 samples (GR07 and GR08) which were discordant: GR07 was non reactive in the BD tube but reactive in the Greiner EDTA K2 and K3 tubes; GR08 was non reactive in the BD tube and the Greiner EDTA K3 tube but was reactive in the Greiner EDTA K2 tube. Testing was not repeated on these samples. However, testing of new samples drawn from the two patients showed negative results which were 100% concordant between the Greiner and BD tubes.

ALT Testing

Testing for alanine aminotransferase (ALT) was performed on samples from 100 apparently healthy adults [AHA] (Sites #1 and 2) and 50 patients (Site #3). The Abbott AEROSET® Clinical Chemistry System was used at Site #1, the Olympus® AU640e™ Chemistry Immuno Analyzer (ALT Slides) 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 96 negative AHA samples and 13 positive patient samples. All results for the Greiner tubes were 100% concordant with the BD tubes.

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 10 AHAs and 6 patients at Site #2 using the Greiner VACUETTE® EDTA K2 and K3 tubes at half draw and full draw and the BD Vacutainer® Glass No Additive Non-Coated tube 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 #2. Of the 5 AHAs tested, all 5 were negative for HBsAg, anti-HCV, and ALT, one was repeatedly reactive for total anti-HBc, and all 5 were positive for anti-CMV. There was 100% concordance between results obtained with the Greiner VACUETTE® EDTA K2 and K3 half draw tubes as compared to the Greiner VACUETTE® EDTA K2 and K3 full draw tubes and the BD full tubes.

Table #2

Results from First Five AHAs

AHA	Tube	HBsAg	Total Anti-HBc	Anti-HCV	Anti-CMV	ALT
n = 5	BD full	neg	1(RR[e])	neg	pos	neg
	Gr K2 full[a]	neg	1(RR[e])	neg	pos	neg
	Gr K2 half[b]	neg	1(RR[e])	neg	pos	neg
	Gr K3 full[c]	neg	1(RR[e])	neg	pos	neg
	Gr K3 half[d]	neg	1(RR[e])	neg	pos	neg

[a] Gr K2 full = Greiner EDTA K2 full draw tube
[b] Gr K2 half = Greiner EDTA K2 half draw tube
[c] Gr K3 full = Greiner EDTA K3 full draw tube
[d] Gr K3 half = Greiner EDTA K3 half draw tube
[e] RR = repeatedly reactive

Samples from an additional five AHAs were tested for detection of HIV 1/2, HTLV I/II, and STS. The results are summarized in Table #3. Of the 5 AHAs tested, all 5 were negative for anti-HIV 1/2, HTLV I/II, and STS. There was 100% concordance between results obtained with the Greiner VACUETTE® EDTA K2 and K3 half draw tubes as compared to the Greiner VACUETTE® EDTA K2 and K3 full draw tubes and the BD full tubes.

Table #3

Results from Second Five AHAs

AHA	Tube	HIV 1/2	HTLV I/II	STS
n = 5	BD full	neg	neg	neg
	Gr K2 full[a]	neg	neg	neg
	Gr K2 half[b]	neg	neg	neg
	Gr K3 full[c]	neg	neg	neg
	Gr K3 half[d]	neg	neg	neg

[a] Gr K2 full = Greiner EDTA K2 full draw tube
[b] Gr K2 half = Greiner EDTA K2 half draw tube
[c] Gr K3 full = Greiner EDTA K3 full draw tube
[d] Gr K3 half = Greiner EDTA K3 half draw tube

The samples from five of the six patients were tested for detection of total anti-HBc and the samples from four of the six patients were tested for detection of anti-HCV. The results are summarized in Table #4. Of the five patients tested for total anti-HBc, all 5 were repeatedly reactive. Of the four patients tested for anti-HCV, 2 were repeatedly reactive.

Table #4

Full/Half Draw Study-Patient Results

Patients	Tube	Total anti-HBc n = 5	Anti-HCV n = 4
n = 6	BD full	5 (RR[e])	2(RR[e])
	Gr K2 full[a]	5 (RR[e])	2(RR[e])
	Gr K2 half[b]	5 (RR[e])	2(RR[e])
	Gr K3 full[c]	5 (RR[e])	2(RR[e])
	Gr K3 half[d]	5 (RR[e])	2(RR[e])

[a] Gr K2 full = Greiner EDTA K2 full draw tube
[b] Gr K2 half = Greiner EDTA K2 half draw tube
[c] Gr K3 full = Greiner EDTA K3 full draw tube
[d] Gr K3 half = Greiner EDTA K3 half draw tube
[e] RR = repeatedly reactive

The two anti-HCV repeatedly reactive samples were confirmed by HCV RIBA. One result was confirmed positive by all tubes and the second result was confirmed positive in the Greiner EDTA K2 half draw tube and indeterminate in the Greiner EDTA K3 half draw tube. The results were indeterminate for this sample in the Greiner EDTA K2 and K3 full draw tubes. 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 the screening for the first sample and seven days after the screening for the second sample. In addition, the difference between an indeterminate and positive result was due to the grading of the c33c band, meaning 1+ or P/N. 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 was repeated after storage of the samples on the red cells at 2-8°C for 7 days from date of collection. This study was performed for information purposes only, to evaluate the performance of the viral marker tests on samples in which the plasma was not separated from the red cells. This is not a recommended procedure. The viral marker assay manufacturers' package inserts state to remove the plasma from the red cells as soon as possible. The results were concordant between Day 0 and Day 7, with the exception of the HCV RIBA, results on one of the repeatedly reactive patients (Patient #726), which is summarized in Table #5. The BD tube, as well as the Greiner tubes, was inconsistent in the 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 #5

HCV RIBA Results on Patient #726-Delayed Testing

Tube	Day 0 Result	Day 7 Result
Greiner EDTA K2 Full Draw	indeterminate	indeterminate
Greiner EDTA K2 Half Draw	positive	indeterminate
Greiner EDTA K3 Full Draw	indeterminate	positive
Greiner EDTA K3 Half Draw	indeterminate	positive
BD full Draw	positive	indeterminate

Delay in Mixing

A study was conducted at Site #2 to evaluate the effect on viral marker results of delayed tube mixing after collection. The participants in the study were the 6 antibody positive patients. 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 for 7 days from date of collection. The results are summarized in Table #6.

One total anti-HBc repeatedly reactive sample was negative in the Greiner EDTA K2 and K3 delayed mix tubes on Day 0 but repeatedly reactive in those tubes on Day 7. This sample had a low reactive absorbance reading (near the cutoff).

Table #6					
Mixed/Delayed Mix Study-Patient Results					
		Total anti-HBc n = 5		Anti-HCV n = 4	
Patients	Tube	Day 0	Day 7	Day 0	Day 7
n = 6	BD mixed	5(RR[a])	5(RR[a])	2(RR[a])	2(RR[a])
	Gr K2 mixed	5(RR[a])	5(RR[a])	2(RR[a])	2(RR[a])
	Gr K2 delayed mix	4(RR[a])	5(RR[a])	2(RR[a])	2(RR[a])
	Gr K3 mixed	5(RR[a])	5(RR[a])	2(RR[a])	2(RR[a])
	Gr K3 delayed mix	4(RR[a])	5(RR[a])	2(RR[a])	2(RR[a])

[a]RR = repeatedly reactive

In the anti-HCV screening test, there was 100% concordance between results obtained with the Greiner VACUETTE® EDTA K2 and K3 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.

The two anti-HCV repeatedly reactive samples were confirmatory tested by HCV RIBA. On Day 0, the first sample was confirmed positive by all tubes (mixed and delayed mix). The second sample (Patient #726) was confirmed positive in the BD tube (mixed) and indeterminate in the Greiner EDTA K2 and K3 tubes (mixed and delayed mix).

Testing on these 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 sample (Patient #726) were positive in the Greiner VACUETTE® EDTA K3 tube and indeterminate in the Greiner VACUETTE® EDTA K2 tube at Day 7. The results are summarized in Table #7. The Greiner tubes and the BD tube were inconsistent in the 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 #7				
HCV RIBA Results on Patient #726-Delayed Mixing				
	Day 0 Result		Day 7 Result	
Tube	Mixed Tube	"Delayed Mix" Tube	Mixed Tube	"Delayed Mix" Tube
Greiner EDTA K2 Full draw	IND	IND	IND	IND
Greiner EDTA K3 Full draw	IND	IND	POS	POS
BD Full Draw	POS	N/A	IND	N/A

IND = Indeterminate
POS = Positive
N/A = Not applicable

Conclusion

The Greiner VACUETTE® EDTA K2 and EDTA K3 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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