

Purpose

Evaluation of samples in regards to VACUETTE® tube sample quality in Drucker DASH Apex 6 and Apex 24 centrifuges to demonstrate post centrifugation appearance of plasma/serum; quality of gel and gel separation; qualitative amount of RBCs in gel barrier; and existence of fibrin.

Tubes Used:

Item/Lot#_	Description
454008P /B16103FP	4 ml LH Lithium Heparin Separator Activator 13x75
456087P /B170236P	5 ml LH Lithium Heparin Separator Activator 13x100
455099P /B16123FP	7 ml Z Serum Separator Clot Activator 16x100

Procedure:

This protocol was written and used for this evaluation.

- Blood collections were performed on 11 subjects (3 tubes from each donor); 33 tubes (total) on July 13, 2017.
- Handling of the tubes was as per <u>GBO VACUETTE® Blood Collection Tubes IFU.</u>
- All tubes were gently inverted 5-10 times directly after blood collection.
- All serum tubes were allowed to clot for a minimum of 30 minutes.
- All tubes were centrifuged in either the Drucker Apex 6 or the Drucker Apex 24 for 10 minutes at 2000g.
- All tubes were centrifuged within 2 hours of collection. Both centrifuges are swing bucket style.

Abbreviations key	
N: None	1: negligible
VG: very good	2: minimal
G: good	3: moderate
P: poor	4: gross

<u>Abbreviations key for the table that follows:</u>



Subject	Tube	Gel on tube wall	Floating gel particles	Gel Separation	Fibrin	RBCs in gel	Appearance of serum/plasma
	1	N	Ν	VG	N	2	VG
А	2	N	N	VG	N	3	VG
	3	N	Ν	VG	N	3	VG
	1	N	Ν	VG	1	2	G
В	2	N	N	VG	N	3	VG
	3	Ν	Ν	VG	N	3	VG
	1	N	Ν	VG	N	2	G
С	2	N	Ν	VG	N	3	G
	3	Ν	Ν	VG	Ν	3	VG
	1	Ν	Ν	VG	N	2	G
D	2	N	Ν	VG	N	2	VG
	3	Ν	Ν	VG	Ν	3	VG
	1	Ν	Ν	VG	1	2	VG
E	2	N	N	VG	N	1	VG
	3	N	N	VG	N	2	VG
	1	Ν	Ν	VG	N	2	VG
F	2	N	N	VG	N	3	VG
	3	N	Ν	VG	N	3	VG
	1	Ν	Ν	VG	N	1	VG
G	2	N	N	VG	N	3	VG
	3	N	N	VG	N	3	VG
	1	Ν	Ν	VG	N	1	VG
Н	2	N	N	VG	N	3	VG
	3	N	N	VG	N	3	VG
	1	Ν	Ν	VG	N	2	VG
I	2	N	N	VG	N	3	VG
	3	Ν	Ν	VG	N	3	VG
	1	Ν	Ν	VG	1	1	VG
J	2	N	N	VG	N	3	VG
	3	Ν	Ν	VG	N	3	VG
К	1	Ν	Ν	VG	1	1	VG

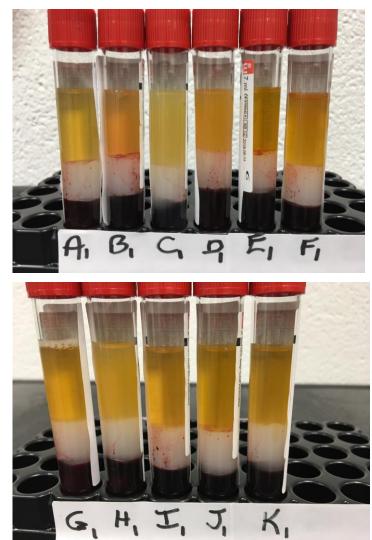


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2	Ν	Ν	VG	Ν	3	VG
3	Ν	Ν	VG	Ν	3	VG



7-13-2017								
<u>Subject</u>	Tube	Gel on tube wall	Floating gel particles	Gel Separation	Fibrin	RBCs in gel	Appearance of serum/plasma	
А	1	N	Ν	VG	Ν	2	VG	
	2	N	N	VG	Ν	3	VG	
	3	N	Ν	VG	Ν	3	VG	
	1	N	N	VG	1	2	G	
В	2	N	N	VG	Ν	3	VG	
	3	N	Ν	VG	Ν	3	VG	
	1	N	N	VG	Ν	2	G	
С	2	N	N	VG	N	3	G	
-	3	N	Ν	VG	Ν	3	VG	
	1	N	Ν	VG	Ν	2	G	
D	2	N	N	VG	N	2	VG	
	3	N	Ν	VG	Ν	3	VG	
	1	N	N	VG	1	2	VG	
E	2	N	N	VG	N	1	VG	
	3	N	N	VG	Ν	2	VG	
	1	N	Ν	VG	Ν	2	VG	
F	2	N	Ν	VG	Ν	3	VG	
	3	N	Ν	VG	Ν	3	VG	
	1	N	Ν	VG	Ν	1	VG	
G	2	N	Ν	VG	Ν	3	VG	
	3	N	N	VG	Ν	3	VG	
	1	Ν	Ν	VG	Ν	1	VG	
н	2	N	Ν	VG	Ν	3	VG	
	3	N	Ν	VG	Ν	3	VG	
	1	N	Ν	VG	Ν	2	VG	
I	2	N	Ν	VG	Ν	3	VG	
	3	N	Ν	VG	Ν	3	VG	
	1	N	Ν	VG	1	1	VG	
J	2	N	N	VG	Ν	3	VG	
	3	N	Ν	VG	Ν	3	VG	
	1	N	N	VG	1	1	VG	
К	2	N	N	VG	Ν	3	VG	
	3	N	N	VG	Ν	3	VG	

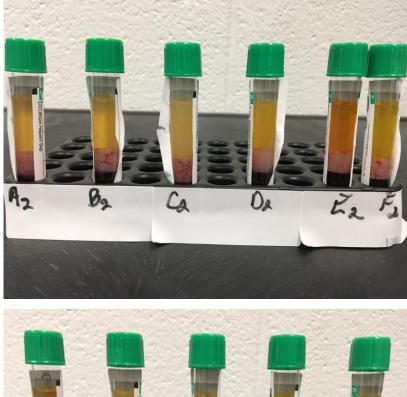


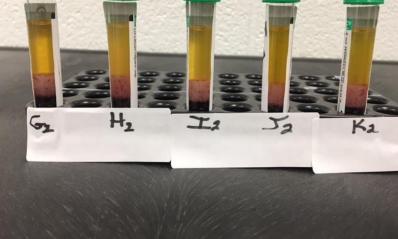


VACUETTE® Item 455099P/B16123FP



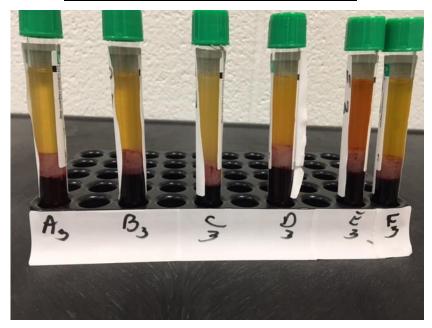
VACUETTE® Item 454008P/B16103FP

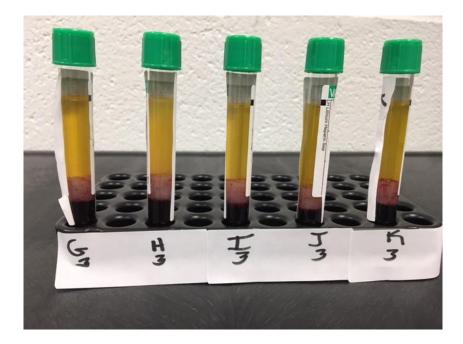






VACUETTE® Item 456087P /B170236P







Evaluation of Sample Quality with Drucker DASH Apex 6 and Apex 24 Centrifuge 7-13-2017 Results / Conclusion:

Gel barrier formed correctly in all samples and very good separation of serum or plasma was observed. There was no gel on the tube walls or floating gel particles. Negligible fibrin strands were observed in 4 of the 11 SST tubes. None were observed in the PST tubes. The appearance of the serum or plasma was overall very good.

The serum samples showed minimal traces of red cells in the gel barrier. The plasma samples showed moderate red cells trapped in the gel barrier, including on top of the gel.

Note:

The <u>Drucker DASH Apex 6 and Apex 24 centrifuges</u> are swing out rotor design with time and rpm (g-force) adjustable. Adjustment is clumsy and not user friendly. There is also no time or speed display making it necessary to manually check both (also very not user friendly). This would also necessitate applying a label to the exterior of the instrument indicating what time and speed are currently set. The website and information sheets also state that the DASH series was built for the BD Barricor[™].

Evaluated by Jean Hogsed, Technical Services PreAnalytics 7-17-2017