

GREINER VACUETTE® BLOOD COLLECTION TUBES IMMUNOHEMATOLOGY TESTING CLINICAL TRIALS OUTLINE

VACUETTE® tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. VACUETTE® Blood Bank tubes containing K_3 EDTA or K_2 EDTA are used in immunohematology testing that requires red cells and plasma for tests such as ABO grouping, Rh typing and antibody screening/identification.

Clinical Trials Outline:

	Site 1	Site 2	Site 3:
	Blood Center	Blood Center	University Hospital
Evaluation Tube	 Greiner K₃EDTA, 6.0mL, 13x100mm, #456099 (full draw); Greiner K₃EDTA, 6.0mL, 13x100mm, #456099 (half draw) (2 tubes) 	Greiner K₃EDTA, 6.0mL, 13x100mm, #456099	Greiner K₃EDTA, 3.0mL, 13x75mm, #454217
	 Greiner K₂EDTA, 6.0mL, 13x100mm, #456023 (full draw); Greiner K₂EDTA, 6.0mL, 13x100mm, #456023 (half draw) (2 tubes) 	• Greiner K ₂ EDTA, 6.0mL, 13x100mm, #456023	Greiner K ₂ EDTA, 3.0mL, 13x75mm, #454246 (second study)
Comparator Tube	Becton Dickinson Glass K ₃ EDTA, 7.0mL, 13x100mm, #366450	Becton Dickinson Glass K ₃ EDTA, 7.0mL, 13x100mm, #366450	Becton Dickinson PLUS K ₂ EDTA, 3.0mL, 13x75mm, #367856
Total	Number of tubes drawn = 7; Total blood drawn = 31 mL	Number of tubes drawn = 3; Total blood drawn = 19 mL	Number of tubes drawn = 2; Total blood drawn = 6 mL
Population	Apparently Healthy Adults	Apparently Healthy Adults	Inpatients and Outpatients
Number of participants tested	1) 50 prospectively collected donors (full draw); 2) Subset: 10 prospectively collected donors for antigen phenotyping (full draw) 3) Subset: 10 prospectively collected donors for delayed antigen phentotyping (full draw) 4) 15 known red cell antibody positive donors (full draw) 5) Subset: 10 known antibody positive individuals (full and half draw) 6) Subset: 10 of antibody positive individuals for delayed testing (full and half draw) 7) Panel of 5 simulated DAT positive samples for delayed testing (full draw)	Subset: 10 prospectively collected donors for antigen phenotyping Nown antibody positive donors	50 patients whose physician has ordered a blood transfusion • Multi-transfused (HbSS, thalassemia, others with antibodies) • Cardiology • Leukemia • Bone Marrow Transplant • Liver Disease • General Surgery • General Medicine
Instruments	Olympus® PK7200™	Ortho ID-Micro Typing System™ (ID-MTS) Gel Test™	Immucor® ABS2000 Manual testing
Tests Performed	ABO/Rh, DAT, Antigen Phenotyping, Antibody Screen, Antibody Identification, Sample Stability Study 0 -19 Days	ABO/Rh, DAT, Antigen Phenotyping, Antibody Screen, Antibody Identification	ABO/Rh, DAT, Antibody Screen, Antibody Identification