Greiner Bio-One VACUETTE®
EDTA K3 and EDTA K2
Evacuated Blood Collection Tubes Evaluation Using the ID-Micro Typing System™ (ID-MTS) Gel Test™

Device Names

Greiner VACUETTE® EDTA K3, 6.0mL, 13x100mm tube, Product Listing #456099

Greiner VACUETTE® EDTA K2, 6.0mL, 13x100mm tube, Product Listing #456023

Comparator Device

Becton Dickinson Vacutainer™ Glass K_3EDTA, 7.0mL, 13x100mm tube, Product Listing #366450

Intended Use

Greiner VACUETTE® EDTA K3 and EDTA K2 tubes provide a means of collecting and transporting an undiluted plasma specimen in a closed evacuated system. The tubes contain spray-dried EDTA, yielding a ratio of 1.8mg/mL of blood when the evacuated tube is filled correctly to its fill volume. The EDTA binds calcium ions which blocks the coagulation cascade. [1,2]

Specimen Collection

Blood specimens were obtained using the test 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 donors were drawn:

1) 52 apparently healthy donors
2) Subset: 10 apparently healthy donors for antigen phenotyping
3) 10 apparently healthy donors with known red cell antibodies

The following tubes were drawn from each donor: 1) one Greiner VACUETTE® EDTA K3, 6.0mL, 13x100mm tube 2) one Greiner VACUETTE® EDTA K2, 6.0mL, 13x100mm tube and 3) one Becton Dickinson Vacutainer™ Glass K_3EDTA, 7.0mL, 13x100mm tube.

Handling Techniques

The tubes were gently mixed by using eight complete inversions immediately following blood collection. Tubes were centrifuged using the laboratory's standard procedure, to separate cellular elements completely from the plasma. Plasma was tested within 24 hours.

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).

ID-Micro Typing System™ (ID-MTS) Gel Test™

The ID-MTS is a gel card test that performs the conventional serum and cell tube reactions in a microtubule reaction chamber. Each microtubule is composed of a dexrean-acrylamide gel, suspended in a buffered saline solution. This gel may be specifically manufactured to contain other additives such as, albumin, bromelin and ABO and Rh antisera. A reagent, red cell suspension or serum is added to a specific microtubule. The ID-MTS Gel Card is then incubated for a defined time and temperature. Upon completion of this incubation, the card is centrifuged at a pre-defined speed and time in an MTS centrifuge. After centrifugation, the cards are removed and the front and back of each microtubule is read macroscopically to determine the presence of positive, negative or other end-point reactions. [3,4,5]

Tests Performed

ABO, Rh, DAT and Antibody Screens were performed on 52 donors' three blood samples. Antigen phenotyping was performed on a subset of 10 of the donors. An additional ten known positive donors had positive antibody panels and antibody identifications performed, using Ortho's Resolve® Panel A and the ID-MTS Gel Test™.

Discussion

ABO/Rh/DAT Antibody Screening

ABO/Rh/DAT and Antibody Screening were performed on matching tubes of blood from 52 apparently healthy blood donors.The testing was performed using the ID-MTS Gel Test™, according to the manufacturer's recommended procedures. The Ortho Selectogen® Reagent Red Blood Cells Two Cell Panel was used for antibody screening.[6] The results from each matched group of samples were compared. There were no discordances noted. All matched results showed the same reaction strength, with a few results differing only by one reaction grade. [7]

Antigen Phenotyping

Ten of the donors were also phenotyped using a panel of ten antisera. The samples were screened for the most common antigens of the Rh (C, E, c, e), Kell (K), Duffy (Fy^a, Fy^b), Kidd (Jk^a, Jk^b), and MNS (M, N, S, s) blood group systems. The distribution of results is summarized in Table #1. The ID-MTS Gel Test™ was used for phenotyping the donor cells after internal validation was performed using the manufacturer's guidelines for IgG gel testing.[8,9,10,11]

Table # 1
Antigen Phenotyping

Antigen	EDTA K3 (#Pos/#Neg)	EDTA K2 (#Pos/#Neg)
C	5/5	5/5
E	2/8	2/8
c	NT	NT
E	NT	NT
K	1/9	1/9
k	10/0	10/0
Fy^a	6/4	6/4
Fy^b	5/5	5/5
Jk^a	9/1	9/1
Jk^b	7/3	7/3
S	4/6	4/6
s	10/0	10/0
M	NT	NT
N	NT	NT

*NT = Not Tested

Antibody Identification

Ten known positive donors had positive antibody panels and antibody identifications performed, using Ortho's Resolve® Panel A and ID-MTS Gel Test™. [12]

The identification results were as follows:

Table # 2
Antibody Identification

Known Ab+ Donors	ABO	Rh	Antibody	Details
1	O	+	Anti-E	*one E heterozygous cell reacted with the Greiner EDTA K3
2	B	-	Anti-SC1	*SC1 is a high incident antigen with 99% cells positive (Note: donor historically known to have underlying Anti-D)
3	A	-	Anti-D, Anti-C, Anti-E	*one heterozygous C cell negative with all tubes
4	A	-	Anti-D, Anti-C, Anti-Fy^a	
5	A	-	Anti-D	
6	O	-	Anti-D	
7	O	+	Anti-K	
8	O	+	Anti-M	*historical conclusion, weak reactions detected on M homozygous cells only, probably due to the IgM nature of antibody
9	A	-	Anti-D	
10	O	-	Anti-K	

Conclusion

The Greiner VACUETTTE® EDTA K3 and EDTA K2 tubes yielded comparable results to the Becton Dickinson Vacutainer™ Glass K_3EDTA tube for ABO/Rh, DAT, Antibody Screening and where necessary, Antibody Identification tests, using the ID-Micro Typing System™ with a donor population. [13,14,15,16]

References

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