Evaluation of VACUETTE® K_3EDTA Evacuated Blood Collection Tube Using the Immucor® ABS 2000

Background:

Greiner Bio-One, Austria has sold plastic evacuated tubes (VACUETTE®) for venous blood collection since 1986.

Greiner VACUETTE® K_3EDTA 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 1.8 mg/mL of blood when evacuated tube is filled correctly to its fill volume. EDTA binds calcium ions which blocks the coagulation cascade. [1,2]

VACUETTE® EDTA tubes are used for testing whole blood in the clinical laboratory and may be used for testing in routine immunohematology i.e. red cell grouping, Rh typing and antibody screens.

Study Objective:

A clinical evaluation was carried out to compare the performance of the Greiner VACUETTE® K_3EDTA tube to the Becton Dickinson Vacutainer® PLUS K_2EDTA tube using the Immucor® ABS 2000.

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).

The following tube types were used in this study:

Sample No.	Description
1	VACUETTE® K_3EDTA, 3 mL (13x75 mm)
2	Becton Dickinson Vacutainer® PLUS K_2EDTA, 3 mL (13x75 mm) (comparator device)

Specimen Collection

Blood specimens were obtained using the test site's standard phlebotomy techniques, which referenced the site's Standard Operating Procedures and OSHA's safety requirements for blood collection. The order of draw was randomized. The following two tubes were drawn from each patient at the University Hospital:

1) one Greiner VACUETTE® K_3EDTA, 3.0mL, 13x75mm tube and 2) one Becton Dickinson Vacutainer® PLUS K_2EDTA, 3.0mL, 13x75mm tube.

A. University Hospital

The following fifty patients were drawn:

1) Multi-transfused [Hb SS (2), thalassemia (1) and others with antibodies (2)] (5)
2) Cardiology (5)
3) Leukemia (5)
4) Bone Marrow Transplant (5)
5) Liver Disease (5)
6) General Surgery (10)
7) General Medicine (15)

Handling Techniques

The tubes were gently mixed 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. Approximately ninety-five percent of the plasma samples were tested within eight hours of collection, while the remaining five percent were tested within 16 hours of collection.

Instrumentation, Methods and Tests

- Immucor® ABS2000: ABO, Rh, Antibody Screening
- Hemagglutination/Dilution Strips For Use in Hemagglutination Microtitration Plate Testing and For Hemagglutination Assays and Dilution Wells on the ABS2000: The principle of typing red cells with Anti-A, Anti-B and Anti-A,B antisera or unknown plasma or serum with commercially prepared-known red cells is based on the principle of hemagglutination. This principle is defined as the clumping of specific red cell as (antigens) by the corresponding antibodies. The test can be performed automated – the Immucor® ABS2000 Analyzer or by a manual method. The ABS2000 has adapted the principle of hemagglutination to microtiter wells (hemagglutination/dilution strips) to perform ABO, Rh and antibody screening tests.[3],[4]
- Manual Tube Method: ABO, Rh and DAT
- Standard LISS Tube Method: Antibody Screening and Identification

Conclusion:

The Greiner VACUETTE® K_3EDTA tubes demonstrated substantial equivalence to the Becton Dickinson Vacutainer® PLUS K_2EDTA tubes with standard immunohematology assays using a recipient population.[5,6,7]

Results/Discussion:

ABO/Rh Typing

ABO/Rh typing was performed on matching tubes of blood from fifty patients. The testing was performed using an Immucor® ABS2000, according to the manufacturer's recommended procedures. In addition, ABO/Rh typing was manually performed on these patients, in parallel to the Immucor® ABS2000 testing. There were no inaccurately reported results with the Greiner VACUETTE® K_3EDTA tubes when compared to the BD Vacutainer® PLUS K_2EDTA tubes.[8,9,10,11]

Antibody Screening and Identification

Antibody screening was performed on fifty patients using the Greiner VACUETTE® K_3EDTA tubes and the BD Vacutainer® PLUS K_2EDTA tubes. The testing was performed using the Immucor® ABS2000, according to the manufacturer's recommended procedures. Antibody screening was also manually performed on the fifty patients in parallel with the Immucor® ABS2000 testing. All positive antibody screening samples were followed up with antibody identification.

Concordant results were obtained between the Greiner VACUETTE® K_3EDTA tubes and the BD Vacutainer® PLUS K_2EDTA tubes. However, in some of the comparisons, there was a 1+ difference, but none of these results demonstrated a change to a negative reading. This variation is within the expected reproducibility of a subjective grading system.[12,13,14,15,16,17]

DAT

Antibody screening was performed on a fifty patients using the Greiner VACUETTE® K_3EDTA tubes and the BD Vacutainer® PLUS K_2EDTA tubes. There was only one positive DAT result among the patient samples. Concordant results were obtained with the Greiner VACUETTE® K_3EDTA tubes and the BD Vacutainer® PLUS K_2EDTA tubes.[18,19,20]

References:

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