

Greiner Bio-One VACUETTE® EDTA K2 Evacuated Blood Collection Tube Evaluation Using the Immucor® ABS2000

Device Name

Greiner VACUETTE® EDTA K2, 3.0mL, 13x75mm tube,
Product Listing #454246

Comparator Device

Becton Dickinson Vacutainer™ PLUS K₂EDTA,
3.0mL,13x75mm tube, Product Listing # 367856

Intended Use

The Greiner VACUETTE® EDTA K2 tube provides a means of collecting and transporting an undiluted plasma specimen in a closed evacuated system. The tube contains 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, 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® EDTA K2, 3.0mL, 13x75mm tube and 2) one Becton Dickinson Vacutainer™ PLUS K₂EDTA, 3.0mL, 13 x 75mm 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) and
- 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.

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).

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 cells (antigens) by the corresponding antibodies. The test can be performed automated using 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

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® EDTA K2 tubes when compared to the BD Vacutainer™ PLUS K₂EDTA tubes.^{5,6,7,8}

Antibody Screening and Identification

Antibody screening was performed on fifty patients using the Greiner VACUETTE® EDTA K2 tubes and the BD Vacutainer™ PLUS K₂EDTA 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® EDTA K2 tubes and the BD Vacutainer™ PLUS K₂EDTA 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.^{9,10,11,12,13,14}

DAT

Antibody screening was performed on fifty patients using the Greiner VACUETTE® EDTA K2 tubes and the BD Vacutainer™ PLUS K₂EDTA tubes. There were four positive DAT results among the patient's samples. Concordant results were obtained with the Greiner VACUETTE® EDTA K2 tubes and the BD Vacutainer™ PLUS K₂EDTA tubes.^{15, 16, 17}

Conclusion

The Greiner VACUETTE® EDTA K2 tubes demonstrated substantial equivalence to the Becton Dickinson Vacutainer™ PLUS K₂EDTA tubes with standard immunochemistry assays using a recipient population.^{18, 19, 20}

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