Evaluation of VACUETTE®
K₂EDTA Evacuated Blood Collection Tubes Using the Immucor®
ABS2000

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

The Greiner VACUETTE® K₂EDTA 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

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 Bio-One VACUETTE® K₂EDTA tubes to the Becton Dickinson Vacutainer® K₂EDTA tube using the Immucor® ABS2000.

**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:

<table>
<thead>
<tr>
<th>Sample No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Greiner VACUETTE® K₂EDTA, 3 mL, 13x75mm tube</td>
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<tr>
<td>2</td>
<td>Becton Dickinson Vacutainer® PLUS K₂EDTA, 3 mL, 13x75mm tube (comparator device)</td>
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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® K₂EDTA, 3 mL, 13x75mm tube and
2) one Becton Dickinson Vacutainer® PLUS K₂EDTA, 3 mL, 13x75mm tube.

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)

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.

The following tests and instrumentation, methods and tests were used:
- 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.
- Manual Tube Method:
  - ABO, Rh and DAT
- Standard LISS Tube Method:
  - Antibody Screening and Identification

**Conclusion:**
The Greiner VACUETTE® K₂EDTA tubes demonstrated substantial equivalence to the Becton Dickinson Vacutainer® PLUS K₂EDTA 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® K2EDTA tubes when compared to the BD Vacutainer® PLUS K2EDTA tubes.5,9,10,11

Antibody Screening and Identification

Antibody Screening was performed on fifty patients using the Greiner VACUETTE® K2EDTA 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® K2EDTA 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.12,13,14,15,16,17

DAT

Antibody Screening was performed on fifty patients using the Greiner VACUETTE® K2EDTA 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® K2EDTA tubes and the BD Vacutainer® PLUS K2EDTA tubes.18,19,20

References:


VACUETTE is a registered trademark of Greiner Bio-One. Vacutainer is a trademark of Becton, Dickinson and Company.