

# Evaluation of VACUETTE<sup>®</sup> K<sub>2</sub>EDTA Evacuated Blood Collection Tubes Using the Immucor<sup>®</sup> ABS2000

**Background:**

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

The Greiner VACUETTE<sup>®</sup> K<sub>2</sub>EDTA 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.<sup>1,2</sup>

VACUETTE<sup>®</sup> 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<sup>®</sup> K<sub>2</sub>EDTA tubes to the Becton Dickinson Vacutainer<sup>®</sup> K<sub>2</sub>EDTA tube using the Immucor<sup>®</sup> 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:*

Sample No.	Description
1	Greiner VACUETTE <sup>®</sup> K <sub>2</sub> EDTA, 3 mL, 13x75mm tube
2	Becton Dickinson Vacutainer <sup>®</sup> PLUS K <sub>2</sub> EDTA, 3 mL, 13x75mm tube (comparator device)

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<sup>®</sup> K<sub>2</sub>EDTA, 3 mL, 13x75mm tube and
- 2) one Becton Dickinson Vacutainer<sup>®</sup> PLUS K<sub>2</sub>EDTA, 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<sup>®</sup> 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<sup>®</sup> 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.<sup>3,4</sup>

Manual Tube Method:

ABO, Rh and DAT

Standard LISS Tube Method:

Antibody Screening and Identification

**Conclusion:**

The Greiner VACUETTE<sup>®</sup> K<sub>2</sub>EDTA tubes demonstrated substantial equivalence to the Becton Dickinson Vacutainer<sup>®</sup> PLUS K<sub>2</sub>EDTA tubes with standard immunohematology assays using a recipient population.<sup>5,6,7</sup>

## **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<sup>®</sup> ABS2000, according to the manufacturer's recommended procedures. In addition, ABO/Rh typing was manually performed on these patients, in parallel to the Immucor<sup>®</sup> ABS2000 testing. There were no inaccurately reported results with the Greiner VACUETTE<sup>®</sup> K<sub>2</sub>EDTA tubes when compared to the BD Vacutainer<sup>®</sup> PLUS K<sub>2</sub>EDTA tubes.<sup>8,9,10,11</sup>

### **Antibody Screening and Identification**

Antibody Screening was performed on fifty patients using the Greiner VACUETTE<sup>®</sup> K<sub>2</sub>EDTA tubes and the BD Vacutainer<sup>®</sup> PLUS K<sub>2</sub>EDTA tubes. The testing was performed using the Immucor<sup>®</sup> ABS2000, according to the manufacturer's recommended procedures. Antibody screening was also manually performed on the fifty patients in parallel with the Immucor<sup>®</sup> ABS2000 testing. All positive antibody screening samples were followed up with antibody identification.

Concordant results were obtained between the Greiner VACUETTE<sup>®</sup> K<sub>2</sub>EDTA tubes and the BD Vacutainer<sup>®</sup> PLUS K<sub>2</sub>EDTA 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.<sup>12,13,14,15,16,17</sup>

### **DAT**

Antibody Screening was performed on fifty patients using the Greiner VACUETTE<sup>®</sup> K<sub>2</sub>EDTA tubes and the BD Vacutainer<sup>®</sup> PLUS K<sub>2</sub>EDTA tubes. There were four positive DAT results among the patient's samples. Concordant results were obtained with the Greiner VACUETTE<sup>®</sup> K<sub>2</sub>EDTA tubes and the BD Vacutainer<sup>®</sup> PLUS K<sub>2</sub>EDTA tubes.<sup>18,19,20</sup>

## **References:**

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3. Immucor<sup>®</sup>. Inc. Immucor<sup>®</sup>-ABS2000 Operator's Guide, Versions 2.05.00A SR-2 & 2.05.00B SR-2. Norcross, Georgia. Revision April 2002.
4. Immucor<sup>®</sup>. Inc. Immucor<sup>®</sup> Hemagglutination/Dilution Strips For Use in Hemagglutination Microtitration Plate Testing and For Hemagglutination Assays and Dilution Wells on the ABS2000. Product Insert. Norcross, Georgia. March 1996.
5. Greiner Bio-One 510(k) Submission. Blood Collection Tube – EDTA K3 Pre-Market Notification Addition of Immunohematology Claim. Monroe, NC. December 2002.

6. Langeberg, A. Personal Communication. Georgetown University Hospital. March 24, 2003.

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8. Immucor<sup>®</sup>. Inc. Immucor<sup>®</sup>-Blood Grouping Reagent Anti-A (Murine Monoclonal) Series 1, Anti-B (Murine Monoclonal) Series 1, Anti-B (Murine Monoclonal) Series 3, Anti-A,B (Murine Monoclonal Blend) Series 1. Product Insert. Norcross, Georgia. July 2001.

9. Immucor<sup>®</sup>. Inc. Immucor<sup>®</sup>-Blood Grouping Reagent Anti-D (Series 4) (Monoclonal Blend) For Slide, Tube, Microplate and ABS2000 Tests. Product Insert. Norcross, Georgia. May 1998.

10. Immucor<sup>®</sup>. Inc. Immucor<sup>®</sup>-Blood Grouping Reagent Anti-D (Series 5) (Monoclonal Blend) For Slide, Tube, Microplate and ABS2000 Tests. Product Insert. Norcross, Georgia. May 1998.

11. Immucor<sup>®</sup>. Inc. Immucor<sup>®</sup>-Reagent Red Blood Cells Referencells™ – 2 Vial Set (Group A1 and B). Product Insert. Norcross, Georgia. July 1999.

12. Immucor<sup>®</sup>. Inc. Immucor<sup>®</sup>-Capture LISS, Low Ionic Strength Medium and Sample Addition Indicator for Capture Solid Phase Antibody Detection Tests. Product Insert. Norcross, Georgia. July 1998.

13. Immucor<sup>®</sup>. Inc. Immucor<sup>®</sup>-Capture-R™ Ready Indicator Cells. Product Insert. Norcross, Georgia. July 1998.

14. Immucor<sup>®</sup>. Inc. Immucor<sup>®</sup>-Capture-R™ Ready-Screen™ (4) Solid Phase System for the Detection of Unexpected IgG Antibodies to Red Cells and For the IgG Antibody Screening Assay Performed by the ABS2000. Product Insert. Norcross, Georgia. May 1998.

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