

Evaluation of VACUETTE[®] K₃EDTA 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[®] K₃EDTA 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[®] K₃EDTA tube to the Becton Dickinson Vacutainer[®] PLUS K₂EDTA 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 ₃ EDTA, 3 mL (13x75 mm)
2	Becton Dickinson Vacutainer [®] PLUS K ₂ EDTA, 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[®] K₃EDTA, 3.0mL, 13x75mm tube and 2) one Becton Dickinson Vacutainer[®] PLUS K₂EDTA, 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[®] K₃EDTA 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[®] K₃EDTA tubes when compared to the BD Vacutainer[®] PLUS K₂EDTA tubes.^{8,9,10,11}

Antibody Screening and Identification

Antibody screening was performed on fifty patients using the Greiner VACUETTE[®] K₃EDTA 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[®] K₃EDTA 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 a fifty patients using the Greiner VACUETTE[®] K₃EDTA tubes and the BD Vacutainer[®] PLUS K₂EDTA tubes. There was only one positive DAT result among the patient samples. Concordant results were obtained with the Greiner VACUETTE[®] K₃EDTA tubes and the BD Vacutainer[®] PLUS K₂EDTA tubes.^{18,19,20}

References:

1. Greiner Bio-One. Evacuated Blood Collection System For In Vitro Diagnostic Use. Product Insert. Kremsmünster, Austria. 2001.
2. Gruber H. Greiner Bio-One. Product Manual. Kremsmünster, Austria. 2003.
3. Immucor[®]. Inc. Immucor[®] ABS2000 Operator's Guide, Versions 2.05.00A SR-2 & 2.05.00B SR-2. Norcross, Georgia. Revision April 2002.
4. Immucor[®]. Inc. Immucor[®] 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.
 7. Sandler, G.S., M.D. Personal Communication. Georgetown University Hospital. March 2003.
 8. Immucor[®]. Inc. Immucor[®] 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[®]. Inc. Immucor[®] Blood Grouping Reagent Anti-D (Series 4) (Monoclonal Blend) For Slide, Tube, Microplate and ABS2000 Tests. Product Insert. Norcross, Georgia. May 1998.
 10. Immucor[®]. Inc. Immucor[®] Blood Grouping Reagent Anti-D (Series 5) (Monoclonal Blend) For Slide, Tube, Microplate and ABS2000 Tests. Product Insert. Norcross, Georgia. May 1998.
 11. Immucor[®]. Inc. Immucor[®] Reagent Red Blood Cells Referencells[®] – 2 Vial Set (Group A1 and B). Product Insert. Norcross, Georgia. July 1999.
 12. Immucor[®]. Inc. Immucor[®] 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[®]. Inc. Immucor[®] Capture-R[®] Ready Indicator Cells. Product Insert. Norcross, Georgia. July 1998.
 14. Immucor[®]. Inc. Immucor[®] 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.
 15. Immucor[®]. Inc. Immucor[®] Modified Capture-R[®] Solid Phase Assay for the Detection of IgG Antibodies to Red Cells and IgG Crossmatch on the ABS2000. Product Insert. Norcross, Georgia. October 2000.
 16. Immucor[®]. Inc. Immucor[®] pHix Phosphate Buffer Concentrate to Buffer Saline Used in Capture[®] or Hemagglutination Antibody Detection Assays. Product Insert. Norcross, Georgia. March 1993.
 17. Immucor[®]. Inc. Immucor[®] Reagent Red Cells Panocell. Product Insert. Norcross, Georgia. November 2001.
 18. Immucor[®]. Inc. Immucor[®] ABS QC Test System 4 Vials. Product Insert. Norcross, Georgia. March 1996.
 19. Immucor[®]. Inc. Immucor[®] Capture-R[®] Control Cells. Product Insert. Norcross, Georgia. March 1996.
 20. Immucor[®]. Inc. Immucor[®] corQC[®] Test System For Laboratory Evaluation of Reagents Not For In Vitro Diagnostic Testing. Product Insert. Norcross, Georgia. August 2001.
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