Greiner Bio-One VACUETTE® No Additive Blood Collection Tubes Evaluation for Immunohematology University Hospital

Device Names

Greiner Bio-One VACUETTE® No Additive, 3.0mL, 13x75mm tube, Product Listing #454241

Comparator Device

Becton Dickinson, Vacutainer™ Glass, No Additive, Non-Siliconized Interior, 3.0mL, 10.25x64mm tube, Product Listing #366397

Intended Use

The Greiner Bio-One VACUETTE® No Additive tubes are made of plastic and are used for the collection of venous blood, which upon centrifugation, separates serum from the clotted cells.[1]

Specimen Collection

Blood specimens were obtained using the site's standard phlebotomy techniques referencing 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:

One Greiner Bio-One VACUETTE® No Additive, 3.0mL, 13x75mm and one Becton Dickinson Vacutainer™ Glass, No Additive, Non-Siliconized Interior, 3.0mL, 10.25x64mm tubes.

A. University Hospital:

   50 patients of various disease states whose physician ordered a blood transfusion:

   1) Liver (3)
   2) Cardiovascular (4)
   3) Hematology (Leukemia, Lymphoma, Multiple Myeloma, Sickle Cell Disease) (2)
   4) Orthopedic (10)
   5) Gastrointestinal (7)
   6) Urogenital (8)
   7) Neurology (5)
   8) Pulmonary (2)
   9) ENT (Ear, Nose, Throat) (3)
   10) Renal (5)
   11) Breast (Cancer of the Breast, Mastectomy) (1)

Handling Techniques

The tubes were gently mixed using ten complete inversions immediately following blood collection. Tubes were centrifuged using the laboratory's standard procedure, to separate cellular elements completely from the serum.

Study Design

A study was conducted at a university hospital blood bank to evaluate the use of the Greiner Bio-One VACUETTE® No Additive tubes in Immunohematology testing. IRB approval was obtained on the submitted protocol. Informed Consent was signed by each participant. The study design was based on recommendations made by reviewers from the FDA Center for Biologics Evaluation and Research, Division of Blood Applications (CBER).[2]

Instrumentation and Tests

A. University Hospital:

   1) Manual Method: ABO, Rh, DAT, Antibody Screening and Identification
   2) Standard LISS Tube Method: Antibody Screening and Identification

Discussion

ABO/Rh Testing

ABO/Rh typing was performed on matching tubes of blood from 50 hospitalized patients. The testing was performed manually. Concordant results were obtained with the Greiner Bio-One VACUETTE® No Additive and the BD Vacutainer™ Glass, No Additive, Non-Siliconized Interior tubes.

Antibody Screening and Identification

Antibody screening was performed on 50 patients using the Greiner Bio-One VACUETTE® No Additive tubes and the BD Vacutainer™ Glass, No Additive, Non-Siliconized Interior tubes. The testing was performed manually, according to the manufacturer's recommended procedures. All positive antibody screening samples were followed-up with antibody identification.

Concordant results were obtained between the Greiner Bio-One VACUETTE® No Additive and the BD Vacutainer™ Glass, No Additive, Non-Siliconized Interior tubes. 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.

DAT

Antibody screening was performed on 50 patients using the Greiner Bio-One **VACUETTE**® No Additive tubes and the BD Vacutainer™ Glass, No Additive, Non-Siliconized Interior tubes. Concordant results were obtained with the Greiner Bio-One **VACUETTE**® No Additive and the BD Vacutainer™ Glass, No Additive, Non-Siliconized Interior tubes.

Conclusion

The Greiner Bio-One **VACUETTE**® No Additive tubes demonstrated substantial equivalence to the Becton Dickinson Vacutainer™ Glass, No Additive, Non-Siliconized Interior tubes with various standard assays using a recipient population.[3,4]

References

1. Greiner Bio-One. Evacuated Blood Collection System For In Vitro Diagnostic Use. Product Insert. Monroe, NC, July 2005.

2. FDA Center for Biologics Evaluation and Research Guidance Document. Recommended Methods for Anti-Human Globulin Evaluation. March 1992.

3. Greiner Bio-One 510(k) Submission. Premarket Notification for Greiner **VACUETTE**® No Additive Tube and **VACUETTE**® Clot Activator Tube – For Use in Immunohematology Testing. Monroe, NC. March 18, 2005.

4. Gruber, H. Greiner Bio-One. Product Manual. Kremsmunster, Austria. July 2002.

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