Evaluation of the Greiner Bio-One VACUETTE® EDTA K3 Tube for Molecular Diagnostic Testing

Device Name

Greiner Bio-One VACUETTE® EDTA K3, 6.0mL, 13x100mm tube, Product Listing #456099

Comparator Device

Becton Dickinson Vacutainer® PPT™ (Plasma Preparation Tube), 5.0mL, 13x100mm tube, Product Listing #362788

Becton Dickinson Vacationer® Glass K3EDTA, 7.0mL, 13x100mm tube, Product Listing #366450

Intended Use

The VACUETTE® EDTA K3 tube is made of plastic and is used for the collection of venous blood, which upon centrifugation separates undiluted plasma for use in molecular diagnostic test methods (such as but not limited to PCR - Polymerase Chain Reaction), or other procedures where an undiluted plasma specimen is required as determined by the laboratory.

Study Design

A study was conducted at two commercialized blood banks and one reference laboratory to evaluate the use of the Greiner VACUETTE® EDTA K3 tube in NAT/PCR testing. IRB approval was obtained at each site based on the protocol described below. Informed Consent was signed by each participant.

Specimen Collection

Blood specimens were obtained using each site's standard phlebotomy techniques, which referenced each site's Standard Operating Procedures and OSHA's safety requirements for blood collection. The order of draw was also randomized.

Two tubes were drawn from each donor. At Donor Center #1, one Greiner VACUETTE® EDTA K3, 6.0mL, 13x100mm and one Becton Dickinson Vacutainer™ PPT™, 5.0mL, 13x100mm tube were drawn. At Donor Center #2, one Greiner VACUETTE® EDTA K3, 6.0mL, 13x100mm and one Becton Dickinson Vacutainer™ Glass K3EDTA, 7.0mL, 13x100mm tube were drawn. And at the Reference Laboratory, one Greiner VACUETTE® EDTA K3, 6.0mL, 13x100mm and one Becton Dickinson Vacutainer™ PPT™, 5.0mL, 13x100mm tube were drawn.

The following donors were drawn:

A. Donor Center - Site #1:
   1) 50 prospectively collected donors
B. Donor Center - Site #2:
   1) 50 prospectively collected donors
C. Reference Laboratory - Site #3:
   1) 50 known patients for HIV-1 and/or HCV

Handling Techniques

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

Assays

A. Donor Center - Site #1:
   1) Chiron® Procleix™ HIV-1/HCV Assay
B. Donor Center - Site #2:
   1) Roche COBAS Ampliscreen™ HIV-1 Assay
   2) Roche COBAS Ampliscreen™ HCV Assay
C. Reference Laboratory - Site #3:
   1) Roche AMPLICOR® HIV-1 MONITOR™ Assay (UltraSensitive)
   2) Bayer VERSANT® HCV RNA 3.0 Assay (bDNA)

Discussion

Donor Centers

In this study, two commercialized blood banks tested 50 samples each from healthy adults for HIV-1 and HCV using test methods for pools as described in the assays' package inserts. Donor Center #1 tested three pools, each consisting of sixteen donors. The remaining two samples were tested individually, in accordance with the instructions for use as provided in the Chiron® Procleix™ HIV-1/HCV Assay Package Insert. Separate pools were prepared from the samples collected in the Becton Dickinson Vacutainer® PPT™ tubes. Donor Center #2 tested two pools, each consisting of twenty-four donors. The remaining two samples were tested individually, in accordance with the instructions for use as provided in the Roche COBAS Ampliscreen™ HIV-1 and HCV Assay Product Inserts. Separate pools were prepared from the samples collected in the Becton Dickinson Vacutainer® Glass K3EDTA tubes. The results for the Greiner tubes were concordant with the results from the BD tubes. The pools and individual samples from the two types of tubes were non-reactive for HIV- 1 and HCV RNA.
The Greiner VACUETTE® EDTA K3 tubes are therefore substantially equivalent to Becton Dickinson Vacutainer® PPT™ Plasma Preparation and K3EDTA Glass tubes when testing pools or individual samples for HIV-1 and HCV Molecular Diagnostics (PCR) tests.

Reference Laboratory

Twenty-five samples were tested using the Roche AMPLICOR® HIV-1 MONITOR™ Quantitative Assay. Due to reproducibility issues previously seen in this assay, testing was performed in triplicate, sample volumes permitting. The Lower Limit of Detectable (LLD) of the Assay was 50 viral copies/uL. Using qualitative results comparison (<LLD or >LLD), 21/25 results were in agreement between the Greiner tube and the BD tube. Of the 4 samples which did not agree, 2 samples had 3 results with the BD tube and 1 result with the Greiner tube that were <50. The other 2 samples had 2 results with the BD tube and 3 results with the Greiner tube that were <50. Since these samples were near the LLD, the slight differences in mean results caused the qualitative results to be discordant. In addition, due to poor precision of this assay near the LLD, some samples with results < 300 showed discordant results within a tube type. One example is the sample which had values of 34, 24, and 29 with the BD tube, and values of 37, 82, and 78 with the Greiner tube. In addition, another sample had values of 294, TND, 26 with the BD tube, and 35, TND, and TND with the Greiner tube.

The results from these samples were evaluated by performing a Student t Test Paired Two Sample for Means using the average of the multiple results from these two tubes. There was no statistically significant difference in the recovery for HIV-1 test results with either tube type, as demonstrated, when calculated by $p>0.05$ and calculated t<critical t. Therefore, it can be concluded that there is no effect on the tests results when plasma is collected in the Greiner Vacuette® EDTA K3 tube and the BD PPT™ tube.

Twenty-seven samples were tested using the Bayer VERSANT® HCV RNA 3.0 Quantitative Assay (bDNA). Using qualitative results comparison, 27/27 results were within agreement between the Greiner tube and the BD tube. The Lower Limit of Detection of the assay was 615 IU/mL. The results from these samples were evaluated by performing a Student t Test Paired Two Sample for Means using the average of the multiple results from these two tubes There was no statistically significant difference in the recovery for HCV PCR test results when using either tube type, as demonstrated when calculated by $p>0.05$ and calculated t<critical t. Therefore, it can be concluded that there is no effect on test results when plasma is collected in the Greiner Vacuette® EDTA K3 tube and the BD PPT™ tube.

Conclusion

The Greiner VACUETTTE® EDTA K3 tubes demonstrated substantial equivalence to the Becton Dickinson Vacutainer® PPT™ and Glass K3EDTA tubes with molecular diagnostic (PCR/NAT) assays using a donor and recipient population.

References

1. Bayer VERSANT® HCV RNA 3.0 Quantitative Assay (bDNA) Product Insert.
   02616244 Rev C., 2004.

2. Becton Dickinson Vacutainer® PPT™ Product Insert. Franklin Lakes, NJ. 2002.

3. Chiron® Procleix™ HIV-1/HCV Assay Product Insert. IN0076 Rev H. Gen-Probe Incorporated 2000-2003.

4. Greiner Bio-One 510(k) Submission. Blood Collection Tube - EDTA K3 Tube Pre-Market Notification Addition of Greiner VACUETTE® EDTA K3 Tubes. Monroe, NC. October, 2004.

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

6. Roche COBAS Ampliscreen™ HIV-1 Test, version 1.5. Product Insert. Roche Molecular Systems, Inc. 2003.

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