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January 2011



Updated Product Information BD Vacutainer® Plasma Preparation Tube (PPT™)

Subject:

Recommended Sample Handling Procedures of BD PPT using the Abbott RealTime HIV-1 Assay

Dear Valued Customer:

As a leading worldwide manufacturer of high-quality medical devices, BD continuously validates product performance through clinical studies. The purpose of this letter is to share updated product performance data on the **BD Vacutainer® Plasma Preparation Tube (PPT™)**.

For more than a decade, the BD Plasma Preparation Tube has been the industry standard, offering a one-step closed system for collection, plasma preparation, and transport of plasma while assuring sample integrity and reducing preanalytical errors. In addition, the BD PPT is the trusted product of choice for laboratorians concerned with biosafety and interested in high quality plasma for molecular diagnostic testing. The BD PPT is IVD and CE marked for Molecular Diagnostics.

A number of studies have previously been conducted to determine the effect of specimen handling parameters on the measurement of HIV viral load. Results of some of these studies indicated that freezing of plasma *in situ* in the BD Vacutainer Plasma Preparation Tube (PPT) resulted in an elevated HIV-1 viral load when quantified in the Roche COBAS® Amplicor™ HIV-1 Monitor® assay. An investigation* revealed that the elevated viral loads in specimens that were frozen in PPT (PPT *in situ*) were possibly due to the presence of proviral DNA released from cells associated with the gel barrier, indicating that the assay does not discriminate between amplification of viral RNA and proviral DNA.

The objectives of the enclosed study** entitled, *Evaluation of Specimen Handling Conditions in BD Vacutainer® Plasma Preparation Tube HIV-1 Viral Load as Measured by the Abbott RealTime HIV-1 assay* were to:

1. Evaluate the effect of freezing plasma *in situ* in PPT on the accuracy of HIV-1 viral load results using the Abbott RealTime HIV-1 Assay and
2. Evaluate the effect of whole blood storage in the PPT for 6 hours at room temperature prior to centrifugation (PPT6H) instead of 2 hours as specified in the PPT product insert (PPT control).

*H Wan, P Belem, A Seth and H Fernandes. Co-Amplification of HIV Proviral DNA and Viral RNA in the Roche Cobas Amplicor™ HIV-1 Monitor Assay. Poster presented at the Clinical Virology Symposium 2006.

***Evaluation of the Effect of Specimen Handling Parameters in the Plasma Preparation Tubes on Viral Load Measurements Using the Abbott RealTime HIV-1 Viral Load Assay.* H Fernandes, S Morosyuk, K Abravaya, M Ramanathan, L Rainen. J Clin Microbiol. 2010 May 19.

Key Findings

For subjects with Viral Load Counts (VLCs) above the assay LOQ of 40 copies/mL, ANOVA analysis to estimate the mean bias between tubes and log-log linear regression analysis showed that all handling conditions tested were equivalent with 95% confidence and the mean bias between each PPT handling condition and the EDTA tube was shown to be within the $\pm 0.3 \text{ Log}_{10}$ VLC with 95% confidence.

For subjects with VLCs <LOQ for the assay in all tubes, cross tabulation of specimens over/under the LOQ and the Cochran Q's test was performed to check if the rate of detection for these very low viral load subjects is different among the four tubes. The cross tabulation results and the McNemar's *p*-test yielded the same proportion of subjects over/under the LOQ in all four tubes with an overall *p*-value of 0.33 indicating that there was no difference in the rate of detection among the four different conditions tested.

Conclusions

In conclusion, when using the Abbott RealTime HIV-1 Viral Load Assay, specimens can be collected in BD Plasma Preparation Tubes and:

- Centrifuged within 6 hours of phlebotomy with no effect on viral load results.
- Plasma separated in PPTs can be stored frozen *in situ* until the time of testing with no effect on viral load results.
- **There is no misclassification of HIV viral load status when using PPT in combination with the Abbott RealTime HIV-1 Viral Load Assay for any of the handling conditions tested.**

If you require additional information or to place an order, please contact your local BD Sales Consultant or call Customer Service at 1.888.237.2762.

To reach BD Technical Services, please call 1.800.631.0174 or submit an inquiry at www.bd.com/vacutainer/contact.

Whenever changing any manufacturer's blood collection tube type, use or size for a particular laboratory assay, the Laboratory Director should review the tube manufacturer's data and/or previous data generated to establish/verify your reference range data for your specific instrument and reagent system. Based on such information, the laboratory can then decide if changes are indicated.

Ordering Information

Plasma Preparation Tube (PPT™)							
Reference Number	Glass (G) or Plastic (P)	Tube Size (mm)	Draw Volume (mL)	Closure Type/Color	Label Type	Additive/Concentration	Packaging Box/Case Quantities
362788	P	13 x 100	5.0	BD Hemogard™/ Pearl White	Mylar	K ₂ EDTA 9 mg	100/1000

As always, your continued customer patronage and support are very much appreciated and valued.

Sincerely,



Ana Stankovic

WW Vice President, Medical Affairs