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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 Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test

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 purpose of the enclosed study** entitled *Evaluation of the Effect of Specimen Handling Conditions in BD Vacutainer® PPT on the Stability of HIV-1 Viral Load using the Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test (CAP/CTM)* was to validate the performance of the BD PPT with the Roche assay and evaluate the effect of the following parameters on HIV-1 viral load:

1. Storage of whole blood in PPT for six hours prior to centrifugation.
2. Storage of plasma *in situ* in the PPT tube at room temperature (RT) or 4°C for up to 5 days.
3. Agitation (to simulate transport) of the tube followed by a re-centrifugation.

* 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.

** Abstract: 2009 Association for Molecular Pathology Annual Meeting. ¹H Fernandes, ¹M Ramanathan, ²S Morosyuk, ³T Do, ²L Rainen. ¹University of Medicine and Dentistry of New Jersey, Newark, NJ; ²BD Diagnostics, Franklin Lakes, NJ; ³Roche Molecular Systems, Pleasanton, CA.

Key Findings

This study shows that with the Roche TaqMan HIV-1 viral load assay (CAP/CTM), HIV VL overall agreement with EDTA is unaffected by:

- Storage of whole blood in PPT for 6h at room temperature before centrifugation.
- Storage of plasma overnight *in situ* in PPT at room temperature.
- Storage of plasma in PPT at 4°C for up to 5 days.

Additionally:

- As compared to EDTA plasma, VLs are increased in a significant number of samples in PPT near or below the (LOQ) when PPT was inverted to simulate agitation and not re-centrifuged.

Conclusions

In conclusion, the BD Vacutainer PPT is equivalent to EDTA plasma for HIV-1 viral load as measured by the Roche TaqMan HIV-1 viral load assay (CAP/CTM) if:

- Whole blood is stored uncentrifuged in PPT for no longer than 6h at ambient temperature.
- Plasma is stored in PPT for no longer than 1 day at ambient temperature or 5 days at 4° C.
- PPT is re-centrifuged at 600 x g for 5 minutes in the receiving laboratory prior to aliquoting, testing, or further storage.

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