

Application Brief

Transplant Viral Panel

Unique All-In-One-Well Viral Load Multiplex Assay with High Sensitivity and Specificity

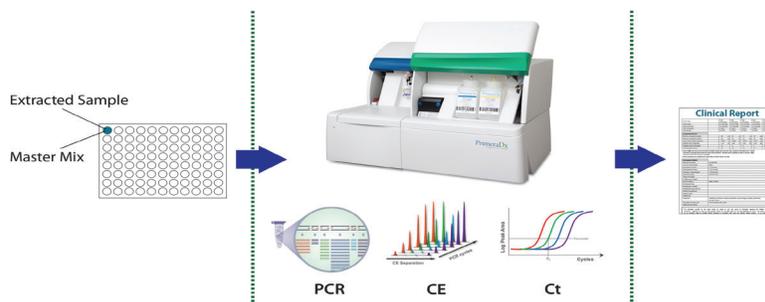
INTRODUCTION

Solid organ and bone marrow transplant patients are particularly susceptible to viral infections due to the use of immunosuppressive drugs to lessen the chance of rejection. A number of closely related Herpes and BK viruses are common causes of such infections. Clinicians need viral load information to select and monitor appropriate anti-viral therapy, especially in cases of co-infection by more than one agent. PrimeraDx has developed an all-in-one-well Transplant Viral Panel that can detect, differentiate and quantify five viruses simultaneously:

- Cytomegalovirus (CMV)
- Epstein Barr virus (EBV)
- BK virus (BK)
- Human Herpes virus 6 (HHV6)
- Human Herpes virus 7 (HHV7)

The high multiplex capability of the ICEPlex® system enables inclusion of a process control for monitoring extraction efficiency, as well as calibration standards for quantification of the targets of interest in a single PCR reaction. Additionally, embedded sensitivity controls for each virus are used as positive controls in the absence of their bona fide targets.

MULTIPLE ANSWERS IN LESS THAN 4 HOURS



SUMMARY

- Detects and quantifies 5 viruses in a single PCR reaction.
- Tests DNA from versatile sample types: whole blood, serum, plasma or urine samples.
- Utilizes all-in-one well approach that simplifies lab operation and improves lab economics.
- Expedites sample turn-around time to less than 4 hours.

METHOD HIGHLIGHTS

- Primers were designed using PrimeraDx's exclusive strategy that can selectively amplify unique genomic region for each target in the panel. One of the primers in each primer set was labeled with FAM dye.
- Nucleic acids were extracted using commercially available extraction systems from whole blood, serum, plasma or urine samples.
- The extraction control served as whole process or extraction efficiency control.
- Multiplex PCR reactions were subjected to thermocycling in a standard 96-well PCR plate on the ICEPlex system.
- Fluorescently labeled amplicons were then automatically injected, separated and detected in the capillary electrophoresis module of the ICEPlex system.
- Amplification curves for all targets and controls were generated automatically by the ICEPlex software and cycle thresholds (Cts) were calculated. The proprietary built-in software converted Cts of all targets and controls in copies per ml.

TYPICAL DATA

The PrimeraDx Transplant Viral Panel detected and quantified 5 viruses that could cause opportunistic infections in transplant patients. The results from the test on the ICEPlex system were automatically generated and reported after the end of the run, which took about 3 1/2 hours.

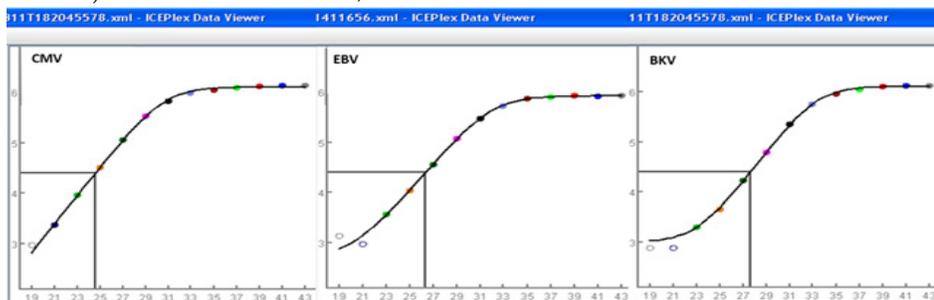


Figure 1. Representative amplification curves for 3 Transplant Viral Panel targets on the ICEPlex system.

		EBV	CMV	BKV	HHV6	HHV7
Sample 1	Ct		24.6			
	Result	No	4.20E+05	No	No	No
Sample 2	Ct	26.4				
	Result	2.80E+05	No	No	No	No
Sample 3	Ct			27.6		
	Result	No	No	6.10E+04	No	No

Table 1. Representative results for three samples on the ICEPlex system.

FOR MORE INFORMATION

For a list of publications and to find out more about how PrimeraDx can help your lab, please contact us at 508.618.2300 or visit www.primeradx.com.

The ICEPlex system and ICEPlex Transplant Viral Panel are for Research Use Only and have not been approved for in vitro diagnostic use by the FDA. The presented information is for demonstration purposes only.