Application and Interpretation:

1) Qualitative CMV PCR is useful in the following situations:
   a) Systemic CMV infection in immunocompromised patients.
   b) Antenatal diagnosis of congenital CMV infection.
   c) CMV Retinitis
   d) CMV encephalomyelitis

   **Systemic CMV infection in immunocompromised patients**

2) Testing of blood is the most relevant for the diagnosis of systemic CMV disease in immunocompromised patients, and is largely limited to 2 situations:
   a) Early detection of CMV infection after bone marrow or solid organ transplantation (PCR is the first diagnostic test to become positive)
   b) Suspected systemic CMV disease. In this situation a negative blood PCR result has a high negative predictive value

3) Samples
   a) 1x EDTA or ACD blood in 5mL tube.
   b) Tissue biopsy (culture is also recommended for tissue samples)

4) Interpretation:
   a) Detection of CMV DNA in plasma and serum samples correlates with results from leukocytes. However, plasma- and serum-based assays have a lower sensitivity than leukocyte-based assays. Plasma and serum samples may be preferable in leukopenic patients.
   b) CMV PCR is usually positive 10 or more days before the onset of symptoms following bone marrow transplantation.
   c) CMV DNA is usually only detected in the blood of patients with active (as opposed to latent) disease.

   **Antenatal diagnosis of congenital CMV infection**

For postnatal congenital CMV infection diagnosis refer below

**Sample:**
Amniotic fluid (recommended after 21 weeks gestation, however will test earlier)

**Interpretation:**
Sensitivity is lower if samples are collected before 21 weeks gestation.
d) Multiple samples may need to be tested if there is a high likelihood of congenital CMV infection.
e) A positive CMV PCR resulting from amniotic fluid is a reliable indicator of foetal infection, but does not predict symptomatic infection. Some infants with congenital CMV infection determined by PCR and/or culture have normal outcomes.

**Postnatal diagnosis of congenital CMV infection**

Sample:

5-10mL urine in sterile pottle-collected in first week of life

Interpretation:

Urine PCR for congenital CMV infection is useful for postnatal diagnosis. Infants with congenital infection shed large amounts of CMV virus in the urine. It is important to submit a urine sample within the first week after birth and obtain the PCR result to support that the infection was acquired in utero. A series (3) of urines submitted for Testing is recommended.

**CMV Retinitis**

5) **Sample:**

   a) Vitreous fluid or eye aspirate

6) **Interpretation:**

   a) Dual infections of the retina with CMV and HSV or HIV have been reported. Therefore, detection of CMV DNA does not necessarily rule out other infections.

**CMV encephalomyelitis**

7) **Sample:**

   a) CSF 0.5mL minimum in sterile container.

8) **Interpretation:**

   a) A positive result in an immunocompromised patient with appropriate clinical and radiographic findings is supportive of the diagnosis of CMV encephalomyelitis