Panel Question

- Do committee members believe that **special controls**, in addition to general controls, are necessary and sufficient to **mitigate the risks** to health presented by quantitative CMV viral load assays?
  - In addressing this question, please discuss the proposed special controls and any additional special controls that would be recommended if reclassification could be considered for quantitative CMV viral load assays

CMV Reference Standards

- As a follow-up to this question, in the discussion of special controls by panel members, the following should be addressed:
  - Commutability of FDA-approved assays calibrated to standard reference materials
  - Challenges of commutability at concentrations near the limit of quantitation
  - Benefit of BAC or whole virus standard reference material
  - Effect of sample matrix