



Food & Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

**DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO**

**To:** Biologics License Application, STN 125832/0

**From:** Alicia Howard, Ph.D. LBVI/DBSQC/OCBQ/CBER/FDA

**Through:** Maryna Eichelberger, Ph.D.  
Division Director, DBSQC/OCBQ/CBER/FDA

**Sponsor:** Precigen, Inc.

**Subject:** Review of analytical methods used for lot release of *zopapogene imadenovec*; PRGN-2012 (PAPZIMEOS™) drug substance and drug product

**Recommendation:** Approval

**Executive Summary:**

Analytical methods used for lot release of PAPZIMEOS™ were reviewed by Seth Schulte (LMIVTS), Hsiaoling (Charlene) Wang (LAC), and Alicia Howard (LBVI). Their review memoranda are attached to this cover letter.

**Conclusion:** The analytical methods and their validations/qualifications were reviewed for PAPZIMEOS™ and were found to be adequate for their intended use.