



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

## **DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO**

**To:** Biologics License Application, STN 125789/0

**From:** M. Nahid Parvin, Ph.D., LBVI/DBSQC/OCBQ

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

**Sponsor:** Adaptimmune

**Subject:** Suitability of lot-release test methods for MAGE-A4-c1032 Lentiviral Vector and TECELRA Drug Product

**Recommendation:** Approval

### **Executive Summary:**

Analytical methods used for lot release of TECELRA were reviewed by Salil Ghosh (LAC), Simleen Kaur (LMIVTS) and M. Nahid Parvin (LBVI). Their review memoranda are attached to this cover letter.

**Conclusion:** The analytical methods and their validations and/or qualifications reviewed for the TECELRA lentiviral vector and/or drug product were found to be adequate for their intended use, except for the outstanding issues for testing sterility of the (b) (4) [redacted] and (b) (4) [redacted] testing of drug product. Adaptimmune has provided written commitments to resolve the issues as Postmarketing Commitments.