



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

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125835/0

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

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

Sponsor: ModernaTX, Inc.

Subject: Suitability of lot-release test methods for MNEXSPIKE (mRNA, 2019 novel coronavirus (SARS-CoV-2) mRNA-1283) drug substance and drug product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of MNEXSPIKE were reviewed by Karla Garcia (LMIVTS), Sang Hysuk Lee (LAC) and M. Nahid Parvin (LBVI). Their review memoranda are attached to this cover letter.

Conclusion:

The analytical methods and their qualifications reviewed for MNEXSPIKE were found to be adequate for their intended use.