



(b) (6)

Center for Biologics Evaluation & Research, Food & Drug Administration

MEMORANDUM

FROM: (b) (6)

TO: Biologics License Application, STN 125869

SUBJECT: In-support Testing Results for (b) (4) total RNA content, (b) (4) and RNA purity in MFLUSIVA (mRNA-1010, Influenza Vaccine) Drug Product (DP)

THROUGH: (b) (6)

(b) (6)

SPONSOR: ModernaTX, Inc.

Summary:

To support the review of BLA125869, tests have been performed by (b) (6) reviewers on three lots of MFLUSIVA DPs: results obtained for (b) (4), total RNA content, (b) (4) RNA purity, are all within the respective specifications proposed for MFLUSIVA DP.

Results:

(b) (4)

(b) (4)

(b) (4)

(b) (4)

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(b) (4)

(b) (4)

3. Total RNA Content by (b) (4)

The total RNA content assay was performed on July 14, 2026 per SOP-0999 (Version 7.0) "Determination of RNA Concentration in LNPs by (b) (4)

. In the analytical procedure, (b) (4)

. Test results from (b) (6) are comparable to those of the firm and meet the proposed specification, (b) (4) with Relative standard deviations (RSDs) from the (b) (4) preparations meeting the set limit of (b) (4). The test results are summarized in Table 3.

Table 3. Total RNA content

DP Lot	CBER result (b) (4)	RSD	Firm Result ((b) (4)
(b) (4)			

4. mRNA purity and product related impurities

Analysis of mRNA purity and product-related impurities was performed on June 30, 2026, in accordance with SOP-5401 (Version 2.0), "Assessment for the Integrity of Multivalent mRNA Purity and Associated Impurities in Drug Product by (b) (4)

" The analytical method (b) (4)

(b) (4)

Test results from (b) (6) are comparable to those from the firm and meet the proposed specifications, (b) (4) for purity and (b) (4) for impurity; all system suitability criteria of method for mRNA standard and sample were also met in (b) (6) analytical run. The test results obtained by (b) (6) and those from the firm are summarized in Table 4.

Table 4: Results of mRNA purity and product related impurities

DP Lot	CBER RNA	CBER RNA	Firm RNA	Firm RNA
	(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)				