moderna

1.0 PURPOSE

The purpose of this procedure is to confirm protein expression from mRNA [redacted]

[redacted]

2.0 SCOPE

This method will be applied to mRNA-1273.

3.0 REFERENCED DOCUMENTS

Document #	Title
FRM-0679	In-Vitro Translation Assay Worksheet – mRNA-1273, SOP-0937
SOP-0017	Maintaining a RNase Free Work Environment
SOP-0254	Operation and Maintenance of [redacted]
SOP-0295	Operation and Maintenance of the [redacted]
SOP-0403	[redacted] Lab Operations Procedure
SOP-0820	Reconstitution of Lyophilized Drug Product

4.0 RESPONSIBILITIES

Department/ Functional Area	Responsibility
Quality Control Laboratory Personnel	• Following all procedures outlined in this document, as applicable. • Maintaining a RNase free work environment per SOP-0017. • Following proper safety measures in the cGMP laboratory. • Documenting all materials, reagents, equipment, sample information, preparation and results in [redacted] per SOP-0403, the appropriate laboratory notebook or QC controlled document.
Quality Control Manager	• Ensuring that laboratory personnel are trained in this procedure. • Ensuring that all procedures in this document are followed when applicable. • Ensure that this procedure is revised as necessary. • Data Review

5.0 DEFINITIONS

Term	Definition
[redacted]	
DP	Drug Product
[redacted]	
GMP	Good Manufacturing Practices
MPI	mRNA Product Intermediate
PPE	Personal Protective Equipment
QC	Quality Control
UV	Ultraviolet
Vis	Visible

6.0 EQUIPMENT AND MATERIALS

6.1. Reagents

Item	Vendor	Item #
[redacted] (assembled kit as received)	[redacted]	
[redacted] (included in kit)		
[redacted] (included in kit)		
[redacted] (included in kit)		
[redacted]		
	N/A	N/A
	[redacted]	

6.2. Consumables

NOTE: Equivalent consumables may be used.

Item	Vendor	Item #
[redacted]	[redacted]	[redacted]
[redacted] pipette tips	[redacted]	[redacted]
[redacted] pipette tips	[redacted]	[redacted]
[redacted] pipette tips	[redacted]	[redacted]
[redacted] pipette tips	[redacted]	[redacted]
[redacted] Tips, standard, round	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted] Microcentrifuge tubes	[redacted]	[redacted]
[redacted] Microcentrifuge tubes	[redacted]	[redacted]
[redacted]	Various	Various
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

6.3. Equipment

NOTE: Equivalent equipment may be used unless otherwise indicated.

Item	Vendor	Model #
[redacted] pipette	[redacted]	[redacted]
[redacted] pipette	[redacted]	[redacted]
[redacted] pipette	[redacted]	[redacted]
[redacted] pipette	[redacted]	[redacted]
Calibrated Timer	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted] (Do Not Substitute)	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	Various	Various
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

6.4. Controls

Control Type	Material
Negative Control	[redacted]
Positive Controls	[redacted]

7.0 SAFETY

7.1. Wear proper PPE (Lab coat, gloves, safety glasses. Use ModernaTX, Inc. Safety Manual as a reference. Follow all safety information provided on material SDSs.

8.0 PROCEDURE

8.1. [redacted]

8.1.1. [redacted]

8.1.1.1. [redacted]

8.1.1.2.

8.1.1.3.

8.1.2. [redacted]

8.1.2.1. [redacted]

8.1.2.2.

8.1.2.3.

8.1.2.4.

8.1.2.5.

8.1.2.6.

8.1.2.7.

8.1.2.8.

8.1.2.9.

8.1.2.10. [redacted]

8.1.2.11. [redacted]

8.1.2.12. [redacted]

8.1.2.13. [redacted]

8.1.2.14. [redacted]

8.1.2.15. [redacted]

8.1.2.16. [redacted]

8.1.2.17. [redacted]

8.1.2.18. [redacted]

8.1.2.19. [redacted]

8.1.2.20. [redacted]

8.1.2.21. [redacted]

8.1.2.22. [redacted]

8.1.3. [redacted]

8.1.3.1. [redacted]

8.1.3.2. [redacted]

8.1.3.3. [redacted]

8.1.3.4. [redacted]

8.1.3.5. [redacted]

8.1.3.6. [redacted]

8.1.3.7. [redacted]

8.1.3.8. [redacted]

8.1.3.9. [redacted]

8.1.3.10 [redacted]

8.1.3.11 [redacted]

8.1.3.12 [redacted]

8.1.3.13 [redacted]

8.1.3.14 [redacted]

8.1.3.15 [redacted]

8.1.3.16 [redacted]

8.1.3.17 [redacted]

8.1.3.18 [redacted]

8.1.3.19 [redacted]

8.1.3.20 [redacted]

8.2. [redacted]

8.2.1. [redacted]

8.2.1.1. [redacted]

[redacted] (Table 1).

8.2.1.2. [redacted]

[redacted] (Table 1).

8.2.1.2.1. [redacted]

8.2.1.3. [redacted]

8.2.1.3.1. [redacted]

8.2.1.3.2. [redacted]

Table 1: Sample Dilution for Concentration Determination

	1	2	3	4	5	6	7	8	9	10	11	12
A	[redacted]											
B												
C												
D												
E												
F												
G												
H												

8.2.1.4. [redacted]

$$(\mu L)\ [redacted] = \frac{Concentration\ of\ [redacted] \times (\ [redacted]}{100\ [redacted]} - (\ [redacted]$$

8.3. [redacted]

8.3.1. [redacted]

8.3.2. [redacted]

8.4. [redacted]

NOTE: [redacted]

8.4.1. [redacted]

8.4.1.1. [redacted]

8.4.1.1.1. [redacted]

8.4.1.1.2.

8.4.1.1.3.

8.4.1.1.4.

8.4.1.1.5.

8.4.1.2. [redacted]

8.4.1.2.1. [redacted]

8.4.1.2.2.

8.4.1.2.3.

8.4.1.2.4.

8.4.1.2.5.

8.4.2. [redacted]

8.4.2.1. [redacted]

8.4.2.2.

8.5. [redacted]

8.5.1. [redacted]

(Table 2).

Table 2: Preparation of [redacted]

Reagent:	A For [redacted] Reaction Vol [redacted]	B Multiplier (n samples [redacted]	C Actual Volume [redacted] (Columns A x B)
[redacted]	[redacted]		
Total Volume			

8.5.2. [redacted]

8.5.3. [redacted] (Step 8.3)

8.5.4. [redacted]

8.5.5. [redacted]

8.6. [redacted]

8.6.1. [redacted]

8.6.2.

8.6.3.

8.6.4.

8.7. [redacted]

8.7.1. [redacted] (**Table 3**)

Table 3: [redacted]

[redacted]

8.7.2. [redacted]

8.7.2.1. [redacted]

8.7.2.1.1. [redacted]

8.7.2.1.2. [redacted]

8.7.2.1.3. [redacted]

8.7.2.2. [redacted]

8.7.2.2.1. [redacted]

8.7.2.2.2. [redacted]

8.7.2.3. [redacted]

8.7.2.4. [redacted]

8.7.2.5. [redacted]

8.7.2.5.1. [redacted]

8.7.2.5.2. [redacted]

8.7.2.5.3. [redacted]

8.7.3. [redacted] per **Table 4**.

Table 4: Example [redacted]

Lane	Contents
1	[redacted]
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	

8.7.1. [redacted]

8.7.2.

8.7.3.

8.7.4.

8.7.5.

8.8. [redacted]

8.8.1.

8.8.2.

8.8.3.

8.8.4.

8.8.5.

8.8.6.

8.8.7. [redacted]

8.8.8. [redacted] An example is shown below.

[redacted]

Figure 1: [redacted]

[redacted]

8.9. [redacted]

8.9.1. [redacted]

8.9.1.1. [redacted]

8.9.1.2. [redacted]

8.9.1.3. [redacted]

[redacted]

8.9.2 [redacted]

8.9.2.1. [redacted]

8.9.2.2.

8.9.2.3.

Table 5: [redacted]

Material	Expected Protein MW (kDa)	MW ± 35% Acceptance Range (kDa)
[redacted]	[redacted]	[redacted]
[redacted]		

Table 6: [redacted]

Material	Protein MW (kDa) Band (+/-) 35%	Band Expected? Yes (+) / No (-)
Negative Control	N/A	[redacted]
[redacted]	[redacted]	

8.10 [redacted]

8.10.1. [redacted]

Example:

[redacted]

8.10.2. [redacted]

9.0 ATTACHMENTS

9.1. N/A

10.0 REVISION HISTORY

Revision #	Effective Date	Change Details	Author
2.0	Refer to Veeva Header for Effective Date	• Updated to new SOP template • Section 6.2, added [redacted] • Added Steps 8.1.2 – 8.1.2.22 for [redacted]	[redacted]
1.0	23Mar20	New Document	

Document Approvals

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