cc: 125752_0 /2256/FC
Lot Number: _____
Licensed Name of Product: COVID-19 Vaccine, mRNA

Electronic Filename:_____

Reason for Submission
_X_For Release
___For Surveillance
___For Licensing Action
STN/Supp #:
___Corrected Protocol

Lot Release Protocol

Manufacturer Name/Address:

STN:

Manufacturer Address:

Trade name: _____

Date of Manufacturing: 00/00/0000 Expiration Date: 00/00/0000

Label Strength: 00%

Source Material:

Processing Method:

Stabilizer: _____
Manufacturer / Lot Number

Other:

Reprocessing/Heating:

Fill Information

Filling Date: 00/00/0000

Location:

Total Volume: 000 mL Volume per Vial: 000 mL

Number of Vials filled: 0000 Number of Rejected Vials: 0000

Recommended Reconstitution Volume:

Storage Temperature:

All tests conducted on this lot are reported and pass specifications as required.

Signature: _____ Date: _____

Printed Name: _____

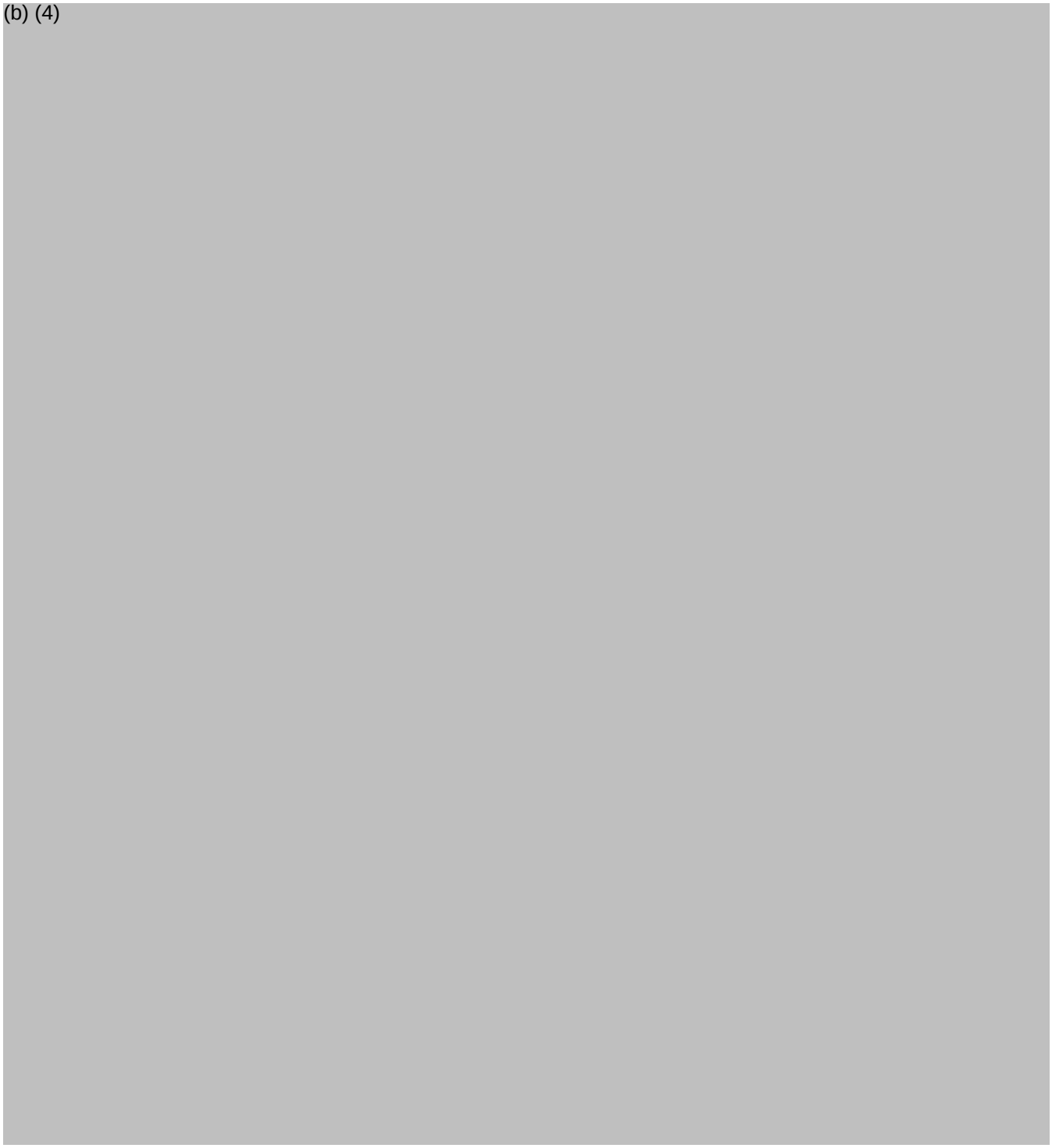
Title: _____

ModernaTX, Inc.
One Moderna Way
Norwood, MA 02062

cc: 125752_0 /2256/FC
Lot Number:
Licensed Name of Product: COVID-19 Vaccine, mRNA

Genealogy of the Lot

(b) (4)



ModernaTX, Inc.
One Moderna Way
Norwood, MA 02062

cc: 125752_0 /2256/FC
Lot Number:
Licensed Name of Product: COVID-19 Vaccine, mRNA

(b) (4)

1. Manufacture of CX-024414 mRNA [complete below or COA attached]

Date of Manufacture: _____ Lot Number: _____
Final Volume: _____ Storage Temperature: _____

Test	Test method	Acceptance Criteria	Date of Test	Results	Comments
Appearance	Visual SOP-0278	(b) (4)			
Identity	RT/Sanger sequencing SOP-1019	(b) (4)			
Total RNA content	UV, SOP-0995				
Purity	RP-IP-HPLC, SOP-1142				

ModernaTX, Inc.
One Moderna Way
Norwood, MA 02062

cc: 125752_0 /2256/FC
Lot Number:
Licensed Name of Product: COVID-19 Vaccine, mRNA

Test	Test method	Acceptance Criteria	Date of Test	Results	Comments
Product-related Impurities	RP-IP-HPLC SOP-1142	(b) (4)			
% 5' Capped	HPLC-UV SOP-0997				
% Poly A tailed RNA	RP-HPLC SOP-0994				
% Tailless RNA	RP-HPLC SOP-0994				
pH	USP <791> SOP-0288				
Bacterial Endotoxin[1]	USP <85> Ph. Eur. 2.6.14 SOP-0352				
Bioburden	USP <61>, Ph. Eur. 2.6.12 SOP-0480				

Abbreviations: RP-IP-HPLC = reverse phase ion-pair high performance liquid chromatography; HPLC-UV = high-performance liquid chromatography with ultraviolet detection; RTSS = reverse transcription Sanger sequencing; TAMC = total aerobic microbial count; TYMC = total combined yeasts and molds count; UV = ultraviolet; w/w = weight/weight

[1] **Refer to Appendix 1**

cc: 125752_0 /2256/FC
Lot Number:
Licensed Name of Product: COVID-19 Vaccine, mRNA

2. Manufacture of mRNA-1273 Drug Product (DP) [complete below or COA attached]

Date of Manufacture: _____ Lot Number: _____
Fill Volume: _____ Storage Temperature: _____
Number of Vials Filled: _____

cc: 125752_0 /2256/FC
Lot Number:
Licensed Name of Product: COVID-19 Vaccine, mRNA

Test	Test method	Acceptance Criteria	Date of Test	Results	Comments
Appearance	Visual SOP-0278	White to off white dispersion. May contain visible white or translucent product related particulates.			
Identity	RT/Sanger Sequencing SOP-1032	(b) (4)			
Total RNA content	AEX-HPLC SOP-0999				
Purity Product-related Impurities	RP-IP-HPLC SOP-1142 RP-IP-HPLC SOP-1142				
% RNA Encapsulation	(b) (4) SOP-1000				
In Vitro Translation	In Vitro Translation / methionine labeling SOP-0937		Sample: Positive Control: Lot #:		
Particle Size Polydispersity	Dynamic Light Scattering SOP-0998				
Lipids Identification SM-102 Cholesterol DSPC PEG2000-DMG	HPLC-CAD SOP-1001				
Lipids content SM-102 Cholesterol DSPC PEG2000-DMG	HPLC-CAD SOP-1001				

Test	Test method	Acceptance Criteria	Date of Test	Results	Comments
Lipid impurity	HPLC-CAD SOP-1001	(b) (4)			
Particulate Matter ≥ 25 µm ≥ 10 µm	USP <788> Method 2 SOP-0509				
Container Content	USP <697> SOP-1229[a]				
pH	USP<791> SOP-0288				
Osmolality	USP <785> Freezing Point Depression SOP-0279				
Bacterial Endotoxin[2]	USP <85> Ph. Eur. 2.6.14				
Sterility[3]	USP <71> Ph. Eur. 2.6.1				

Abbreviations: AEX-HPLC = anion exchange high-performance liquid chromatography; RP-IP-HPLC = reverse phase ion-pair high performance liquid chromatography; DLS = dynamic light scattering; DSPC = 1,2-distearoyl-sn-glycero-3-phosphocholine; EU = endotoxin unit(s); (b) (4)
(b) (4) ; RP-HPLC = reverse-phase high-performance liquid chromatography; (b) (4)
(b) (4)
RTSS = reverse transcription Sangar sequencing; HPLC-CAD = high-performance liquid chromatography with charged aerosol detection

cc: 125752_0 /2256/FC
Lot Number:
Licensed Name of Product: COVID-19 Vaccine, mRNA

(b) (4)

[2] **Refer to Appendix 2**
[3] **Refer to Appendix 3**

cc: 125752_0 /2256/FC
Lot Number:
Licensed Name of Product: COVID-19 Vaccine, mRNA

Appendix 1: CX-024414 mRNA Endotoxin Test Details

Limulus Amebocyte Lysate Test

Method ☐ (b) (4) ☐ (b) (4)

Test date _____

Name of Lysate Manufacturer _____

Lysate Lot number _____

Standard Curve Information

Endotoxin lot number _____

Endotoxin Mfr/Supplier _____

Standard Curve

	Standard Endotoxin Concentration EU/mL	Mean Onset Time (seconds)	CV%
1			
2			
3			
4			
5			
6			

Correlation coefficient (r): _____ Intercept: _____ Slope: _____

Product Test Summary

MVD _____

	Results EU/mL	Test Dilution	Mean Onset Time	CV%	% Spike Recovery
Beginning					
Middle					
End					

Results (EU/mg): _____ Specifications: _____

Calculations or additional comments

cc: 125752_0 /2256/FC
Lot Number:
Licensed Name of Product: COVID-19 Vaccine, mRNA

Appendix 2: mRNA-1273 Drug Product Endotoxin Test Details

Limulus Amebocyte Lysate Test

Method ☐ (b) (4) ☐ (b) (4)

Test date _____

Name of Lysate Manufacturer _____

Lysate Lot number _____

Standard Curve Information

Endotoxin lot number _____

Endotoxin Mfr/Supplier_____

Standard Curve

	Standard Endotoxin Concentration EU/mL	Mean Onset Time (seconds)	CV%
1			
2			
3			
4			
5			
6			

Correlation coefficient (r): _____ Intercept: _____ Slope: _____

Product Test Summary

MVD _____

	Results EU/mL	Test Dilution	Mean Onset Time	CV%	% Spike Recovery
Beginning					
Middle					
End					

Results (EU/mL): _____ Specifications: _____

Calculations or additional comments

cc: 125752_0 /2256/FC
Lot Number:
Licensed Name of Product: COVID-19 Vaccine, mRNA

Appendix 3: Sterility Test Details

SOP number: _____

Method ☐ **Membrane Filtration** ☐ **Direct Inoculation**

On Test Date	Medium/Temperature	Number of vials tested	Off Test Date

Results: _____ Specifications: _____

Calculations or additional comments

Document Approvals

Approved Date: 14 Jan 2022

Task: Approval Task Verdict: Approve	Huijuan Li, ((b) (6)@modernatx.com) Analytical Development Approval 14-Jan-2022 21:11:03 GMT+0000

Task: Approval Task Verdict: Approve	Emma Harrington, ((b) (6)@modernatx.com) Quality Assurance Approval 14-Jan-2022 21:25:47 GMT+0000

Task: Approval Task Verdict: Approve	Paul Dawidczyk, (b) (6)@modernatx.com) Regulatory Approval 14-Jan-2022 21:47:42 GMT+0000

Task: Approval Task Verdict: Approve	Jennifer White, ((b) (6)@modernatx.com) Quality Assurance Approval 14-Jan-2022 22:25:04 GMT+0000

Task: Approval Task Verdict: Approve	(b) (6) (b) (6)@modernatx.com) Quality Assurance Approval 14-Jan-2022 22:33:29 GMT+0000

Task: QA Approval Task Verdict: Approve	Jennifer White, (b) (6)@modernatx.com) Quality Assurance Approval 14-Jan-2022 22:35:35 GMT+0000