

# **mRNA-1273 LNP Certificates of Analysis Attachment**

## **Contents:**

### **Scale A 15 g mRNA Lots (ModernaTX, Inc.):**

- **5006820002** (GMP)
- **5006820003** (GMP)
- **5006820004** (GMP)
- **5006820005** (PPQ)
- **5006820006** (PPQ)
- **5006820007** (PPQ)

### **Scale B Initial 100 g mRNA Lots (ModernaTX, Inc.):**

- **5007320002** (GMP)
- **5007320004** (GMP)
- **5007320005** (PPQ)
- **5007320006** (PPQ)
- **5007320007** (PPQ)

### **Scale B Final 200 g Lipid Lots (ModernaTX, Inc. and Lonza – Portsmouth):**

- **5007520001** (GMP, ModernaTX, Inc.)
- **5007520002** (PPQ, ModernaTX, Inc.)

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820002		
Moderna Lot Number:	5006820002	Specification:	SPC-1005
Date of Manufacture:	15May2020	Expiry Date:	15Aug2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 19-Jun-2020

FDA-CBER-2022-1614-4622872

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820002		
Moderna Lot Number:	5006820002	Specification:	SPC-1005
Date of Manufacture:	15May2020	Expiry Date:	15Aug2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
USP <467>	Advantar MRNA-C0000-GTM0018	Ethanol		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 19-Jun-2020

FDA-CBER-2022-1614-4622873

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820002		
Moderna Lot Number:	5006820002	Specification:	SPC-1005
Date of Manufacture:	15May2020	Expiry Date:	15Aug2020

Product Attribute	Method	Parameter	Specification	Result
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This material meets specification: Yes

Revision History:

1.0 - Original

Document Approvals  
Approved Date: 19 Jun 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 19-Jun-2020 14:12:28 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Assurance Approval 19-Jun-2020 15:26:54 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820003		
Moderna Lot Number:	5006820003	Specification:	SPC-1005
Date of Manufacture:	16Jun2020	Expiry Date:	16Sep2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 20-Jul-2020

FDA-CBER-2022-1614-4622876

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820003		
Moderna Lot Number:	5006820003	Specification:	SPC-1005
Date of Manufacture:	16Jun2020	Expiry Date:	16Sep2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 20-Jul-2020

FDA-CBER-2022-1614-4622877

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820003		
Moderna Lot Number:	5006820003	Specification:	SPC-1005
Date of Manufacture:	16Jun2020	Expiry Date:	16Sep2020

Product Attribute	Method	Parameter	Specification	Result
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This material meets specification: Yes

Revision History:

1.0 - Original



Document Approvals  
Approved Date: 20 Jul 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 20-Jul-2020 14:49:08 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 20-Jul-2020 16:16:10 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820004		
Moderna Lot Number:	5006820004	Specification:	SPC-1005
Date of Manufacture:	24Jun2020	Expiry Date:	24Sep2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 24-Jul-2020

FDA-CBER-2022-1614-4622880

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820004		
Moderna Lot Number:	5006820004	Specification:	SPC-1005
Date of Manufacture:	24Jun2020	Expiry Date:	24Sep2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		RRT 1		
		RRT 2		
		RRT 3		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

This material meets specification: Yes

Revision History:  
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FDA-CBER-2022-1614-4622881

Document Approvals  
Approved Date: 24 Jul 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 24-Jul-2020 13:04:25 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 24-Jul-2020 13:51:11 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820005		
Moderna Lot Number:	5006820005	Specification:	SPC-1005
Date of Manufacture:	02Jul2020	Expiry Date:	02Oct2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 09-Aug-2020

FDA-CBER-2022-1614-4622883

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820005		
Moderna Lot Number:	5006820005	Specification:	SPC-1005
Date of Manufacture:	02Jul2020	Expiry Date:	02Oct2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 09-Aug-2020

FDA-CBER-2022-1614-4622884

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820005		
Moderna Lot Number:	5006820005	Specification:	SPC-1005
Date of Manufacture:	02Jul2020	Expiry Date:	02Oct2020

Product Attribute	Method	Parameter	Specification	Result
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This material meets specification: Yes

Revision History:

1.0 - Original

Document Approvals  
Approved Date: 13 Aug 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 10-Aug-2020 17:21:16 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 12-Aug-2020 11:09:01 GMT+0000



## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820006		
Moderna Lot Number:	5006820006	Specification:	SPC-1005
Date of Manufacture:	11Jul2020	Expiry Date:	11Oct2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 17-Aug-2020

FDA-CBER-2022-1614-4622887

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820006		
Moderna Lot Number:	5006820006	Specification:	SPC-1005
Date of Manufacture:	11Jul2020	Expiry Date:	11Oct2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 17-Aug-2020

FDA-CBER-2022-1614-4622888

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820006		
Moderna Lot Number:	5006820006	Specification:	SPC-1005
Date of Manufacture:	11Jul2020	Expiry Date:	11Oct2020

Product Attribute	Method	Parameter	Specification	Result
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This material meets specification: Yes

Revision History:

1.0 - Original

Document Approvals  
Approved Date: 18 Aug 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 17-Aug-2020 17:27:09 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 18-Aug-2020 18:30:39 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820007		
Moderna Lot Number:	5006820007	Specification:	SPC-1005
Date of Manufacture:	17Jul2020	Expiry Date:	15Oct2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 18-Aug-2020

FDA-CBER-2022-1614-4622891

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820007		
Moderna Lot Number:	5006820007	Specification:	SPC-1005
Date of Manufacture:	17Jul2020	Expiry Date:	15Oct2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Page 2 of 3

Generated Date: 18-Aug-2020

FDA-CBER-2022-1614-4622892

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50068
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5006820007		
Moderna Lot Number:	5006820007	Specification:	SPC-1005
Date of Manufacture:	17Jul2020	Expiry Date:	15Oct2020

Product Attribute	Method	Parameter	Specification	Result
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This material meets specification: Yes

Revision History:

1.0 - Original

Document Approvals  
Approved Date: 19 Aug 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 18-Aug-2020 23:28:36 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 19-Aug-2020 16:21:22 GMT+0000



## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320002		
Moderna Lot Number:	5007320002	Specification:	SPC-1005
Date of Manufacture:	24Sep2020	Expiry Date:	23Dec2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Page 1 of 3

Generated Date: 22-Oct-2020

FDA-CBER-2022-1614-4622895

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320002		
Moderna Lot Number:	5007320002	Specification:	SPC-1005
Date of Manufacture:	24Sep2020	Expiry Date:	23Dec2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		% Total Impurities		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Page 2 of 3

Generated Date: 22-Oct-2020

FDA-CBER-2022-1614-4622896

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320002		
Moderna Lot Number:	5007320002	Specification:	SPC-1005
Date of Manufacture:	24Sep2020	Expiry Date:	23Dec2020

Product Attribute	Method	Parameter	Specification	Result
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This material meets specification: Yes

Revision History:

1.0 - Original

Document Approvals  
Approved Date: 23 Oct 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 23-Oct-2020 00:17:45 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 23-Oct-2020 21:43:07 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320004		
Moderna Lot Number:	5007320004	Specification:	SPC-1005
Date of Manufacture:	30Sep2020	Expiry Date:	29Dec2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Page 1 of 2

Generated Date: 22-Oct-2020

FDA-CBER-2022-1614-4622899

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320004		
Moderna Lot Number:	5007320004	Specification:	SPC-1005
Date of Manufacture:	30Sep2020	Expiry Date:	29Dec2020

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		RRT 1		
		RRT 2		
		RRT 3		
		% Total Impurities		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

This material meets specification: Yes

Revision History:

1.0 - Original

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Page 2 of 2

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QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 23-Oct-2020 21:34:29 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320005		
Moderna Lot Number:	5007320005	Specification:	SPC-1005
Date of Manufacture:	11Oct2020	Expiry Date:	09Apr2021

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 09-Nov-2020

FDA-CBER-2022-1614-4622902



## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320005		
Moderna Lot Number:	5007320005	Specification:	SPC-1005
Date of Manufacture:	11Oct2020	Expiry Date:	09Apr2021

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		% Area 5		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		RRT 5		
		% Total Impurities		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		

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Generated Date: 09-Nov-2020

FDA-CBER-2022-1614-4622903

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320005		
Moderna Lot Number:	5007320005	Specification:	SPC-1005
Date of Manufacture:	11Oct2020	Expiry Date:	09Apr2021

Product Attribute	Method	Parameter	Specification	Result
Bioburden	SOP-0480	TAMC	(b) (4)	
		TYMC		

This material meets specification: Yes

Revision History:

1.0 - Original

Document Approvals  
Approved Date: 12 Nov 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 10-Nov-2020 16:58:05 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 12-Nov-2020 01:43:16 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320006		
Moderna Lot Number:	5007320006	Specification:	SPC-1005
Date of Manufacture:	17Oct2020	Expiry Date:	15Apr2021

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 09-Nov-2020

FDA-CBER-2022-1614-4622906

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320006		
Moderna Lot Number:	5007320006	Specification:	SPC-1005
Date of Manufacture:	17Oct2020	Expiry Date:	15Apr2021

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		% Total Impurities		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 09-Nov-2020

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## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320006		
Moderna Lot Number:	5007320006	Specification:	SPC-1005
Date of Manufacture:	17Oct2020	Expiry Date:	15Apr2021

Product Attribute	Method	Parameter	Specification	Result
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This material meets specification: Yes

Revision History:

1.0 - Original

Document Approvals  
Approved Date: 12 Nov 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) modernatx.com) Quality Control Approval 10-Nov-2020 16:58:51 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 12-Nov-2020 01:52:29 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320007		
Moderna Lot Number:	5007320007	Specification:	SPC-1005
Date of Manufacture:	23Oct2020	Expiry Date:	21Apr2021

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-0544	Identity		
Concentration	SOP-0235	Concentration		
Purity	SOP-0383	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-0298	% Encapsulation		
Dynamic Light Scattering	SOP-0107	Particle Size		
		Polydispersity		
Lipid Identification	SOP-0502	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 09-Nov-2020

FDA-CBER-2022-1614-4622910



## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320007		
Moderna Lot Number:	5007320007	Specification:	SPC-1005
Date of Manufacture:	23Oct2020	Expiry Date:	21Apr2021

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		% Area 5		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		RRT 5		
		% Total Impurities		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		

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Generated Date: 09-Nov-2020

FDA-CBER-2022-1614-4622911

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50073
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007320007		
Moderna Lot Number:	5007320007	Specification:	SPC-1005
Date of Manufacture:	23Oct2020	Expiry Date:	21Apr2021

Product Attribute	Method	Parameter	Specification	Result
Bioburden	SOP-0480	TAMC	(b) (4)	
		TYMC		

This material meets specification: Yes

### Revision History:

1.0 - Original

Document Approvals  
Approved Date: 12 Nov 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 10-Nov-2020 16:57:29 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 12-Nov-2020 01:18:02 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50075
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007520001		
Moderna Lot Number:	5007520001	Specification:	SPC-1213
Date of Manufacture:	31Oct2020	Expiry Date:	29Apr2021

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-1032	Identity		
Concentration	SOP-0999	Concentration		
Purity	SOP-0996	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-1000	% Encapsulation		
Dynamic Light Scattering	SOP-0998	Particle Size		
		Polydispersity		
Lipid Identification	SOP-1001	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 23-Nov-2020

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## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50075
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007520001		
Moderna Lot Number:	5007520001	Specification:	SPC-1213
Date of Manufacture:	31Oct2020	Expiry Date:	29Apr2021

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		% Area 4		
		RRT 1		
		RRT 2		
		RRT 3		
		RRT 4		
		% Total Impurities		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 23-Nov-2020

FDA-CBER-2022-1614-4622915

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50075
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007520001		
Moderna Lot Number:	5007520001	Specification:	SPC-1213
Date of Manufacture:	31Oct2020	Expiry Date:	29Apr2021

Product Attribute	Method	Parameter	Specification	Result
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This material meets specification: Yes

Revision History:

1.0 - Original

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Generated Date: 23-Nov-2020

FDA-CBER-2022-1614-4622916

Document Approvals  
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Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 23-Nov-2020 21:39:21 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 24-Nov-2020 17:09:24 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50075
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007520002		
Moderna Lot Number:	5007520002	Specification:	SPC-1213
Date of Manufacture:	06Nov2020	Expiry Date:	05May2021

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Appearance - Color	(b) (4)	
		Appearance - Particulates		
Identity	SOP-1032	Identity		
Concentration	SOP-0999	Concentration		
Purity	SOP-0996	Purity		
		% IG1		
		% IG2		
		% IG3		
		% Total Impurities		
% RNA Encapsulation	SOP-1000	% Encapsulation		
Dynamic Light Scattering	SOP-0998	Particle Size		
		Polydispersity		
Lipid Identification	SOP-1001	SM102		
		Cholesterol		
		DSPC		
		PEG-DMG		

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Generated Date: 25-Nov-2020

FDA-CBER-2022-1614-4622918



## CERTIFICATE OF ANALYSIS

Product Description:	mRNA-1273	Moderna Part #:	50075
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	5007520002		
Moderna Lot Number:	5007520002	Specification:	SPC-1213
Date of Manufacture:	06Nov2020	Expiry Date:	05May2021

Product Attribute	Method	Parameter	Specification	Result
Lipid Content		SM102	(b) (4)	
		Cholesterol		
		DSPC		
		PEG-DMG		
Lipid Impurities		% Area 1		
		% Area 2		
		% Area 3		
		RRT 1		
		RRT 2		
		RRT 3		
		% Total Impurities		
pH	SOP-0288	pH		
Osmolality	SOP-0279	Osmolality		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

This material meets specification: Yes

Revision History:

1.0 - Original

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Generated Date: 25-Nov-2020

FDA-CBER-2022-1614-4622919

Document Approvals  
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Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 27-Nov-2020 02:38:32 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 27-Nov-2020 13:04:31 GMT+0000