

# **CX-024414 Certificates of Analysis Attachment**

## **Contents:**

### **Scale A 10L IVT Lots (ModernaTX, Inc):**

- **4007220001** (GMP)
- **4007220002** (GMP)
- **4007220003** (PPQ)
- **4007220004** (PPQ)
- **4007220005** (PPQ)

### **Scale B Initial 20L IVT Lots (Lonza - Portsmouth):**

- **4007520001** (GMP)
- **4007520002** (PPQ)
- **4007520003** (PPQ)
- **4007520004** (PPQ)

### **Scale B Final 60L IVT Lots (ModernaTX, Inc. and Lonza - Portsmouth):**

- **4007420001** (GMP, ModernaTX, Inc.)
- **4007420002** (GMP, ModernaTX, Inc.)
- **4007420003** (PPQ, ModernaTX, Inc.)

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220001		
Moderna Lot Number:	4007220001	Specification:	SPC-0995
Date of Manufacture:	03Apr2020	Expiry Date:	30Sep2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 08-Jun-2020

FDA-CBER-2022-1614-4622922

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220001		
Moderna Lot Number:	4007220001	Specification:	SPC-0995
Date of Manufacture:	03Apr2020	Expiry Date:	30Sep2020

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

Revision History:

1.0 - Original

Document Approvals  
Approved Date: 09 Jun 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 08-Jun-2020 13:17:38 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 09-Jun-2020 11:38:35 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220002		
Moderna Lot Number:	4007220002	Specification:	SPC-0995
Date of Manufacture:	04May2020	Expiry Date:	31Oct2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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FDA-CBER-2022-1614-4622925

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220002		
Moderna Lot Number:	4007220002	Specification:	SPC-0995
Date of Manufacture:	04May2020	Expiry Date:	31Oct2020

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

Revision History:

1.0 - Original

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220003		
Moderna Lot Number:	4007220003	Specification:	SPC-0995
Date of Manufacture:	20May2020	Expiry Date:	16Nov2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 03-Aug-2020

FDA-CBER-2022-1614-4622927

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220003		
Moderna Lot Number:	4007220003	Specification:	SPC-0995
Date of Manufacture:	20May2020	Expiry Date:	16Nov2020

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

### Revision History:

1.0 - Original

2.0 - Corrected SOP-0291 pre-main peak acceptance criteria from (b) (4) in alignment with the approved specification SPC-0995



Document Approvals  
Approved Date: 04 Aug 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 03-Aug-2020 17:26:31 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 04-Aug-2020 21:36:00 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220004		
Moderna Lot Number:	4007220004	Specification:	SPC-0995
Date of Manufacture:	04Jun2020	Expiry Date:	01Dec2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 16-Jul-2020

FDA-CBER-2022-1614-4622930

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220004		
Moderna Lot Number:	4007220004	Specification:	SPC-0995
Date of Manufacture:	04Jun2020	Expiry Date:	01Dec2020

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

Revision History:

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Document Approvals

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QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 18-Jul-2020 00:06:55 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220005		
Moderna Lot Number:	4007220005	Specification:	SPC-0995
Date of Manufacture:	18Jun2020	Expiry Date:	18Sep2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 17-Aug-2020

FDA-CBER-2022-1614-4622933

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40072
Manufacturer Name:	Moderna	Container/Closure:	(b) (4)
Manufacturer Lot:	4007220005		
Moderna Lot Number:	4007220005	Specification:	SPC-0995
Date of Manufacture:	18Jun2020	Expiry Date:	18Sep2020

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

Revision History:

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Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 17-Aug-2020 15:53:08 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 18-Aug-2020 22:10:07 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40075
Manufacturer Name:	Lonza Biologics Inc (Portsmouth)	Container/Closure:	(b) (4)
Manufacturer Lot:	918988		
Moderna Lot Number:	4007520001	Specification:	SPC-1118
Date of Manufacture:	28Jul2020	Expiry Date:	28Oct2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	USP <61>	TAMC		
		TYMC		

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Generated Date: 21-Sep-2020

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## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40075
Manufacturer Name:	Lonza Biologics Inc (Portsmouth)	Container/Closure:	(b) (4)
Manufacturer Lot:	918988		
Moderna Lot Number:	4007520001	Specification:	SPC-1118
Date of Manufacture:	28Jul2020	Expiry Date:	28Oct2020

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

### Revision History:

1.0 - Original, Note: Bioburden Testing USP <61> tested using (b) (4) . Refer to deviation QE-002523

Document Approvals  
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QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 21-Sep-2020 13:36:29 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40075
Manufacturer Name:	Lonza Biologics Inc (Portsmouth)	Container/Closure:	(b) (4)
Manufacturer Lot:	922693		
Moderna Lot Number:	4007520002	Specification:	SPC-1118
Date of Manufacture:	12Aug2020	Expiry Date:	12Nov2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	USP <61>	TAMC		
		TYMC		

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Generated Date: 21-Sep-2020

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## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40075
Manufacturer Name:	Lonza Biologics Inc (Portsmouth)	Container/Closure:	(b) (4)
Manufacturer Lot:	922693		
Moderna Lot Number:	4007520002	Specification:	SPC-1118
Date of Manufacture:	12Aug2020	Expiry Date:	12Nov2020

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

Revision History:

1.0 - Original

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FDA-CBER-2022-1614-4622940

Document Approvals  
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QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 21-Sep-2020 13:38:28 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40075
Manufacturer Name:	Lonza Biologics Inc (Portsmouth)	Container/Closure:	(b) (4)
Manufacturer Lot:	928769		
Moderna Lot Number:	4007520003	Specification:	SPC-1118
Date of Manufacture:	25Aug2020	Expiry Date:	25Nov2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	USP <61>	TAMC		
		TYMC		

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Generated Date: 21-Sep-2020

FDA-CBER-2022-1614-4622942

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40075
Manufacturer Name:	Lonza Biologics Inc (Portsmouth)	Container/Closure:	(b) (4)
Manufacturer Lot:	928769		
Moderna Lot Number:	4007520003	Specification:	SPC-1118
Date of Manufacture:	25Aug2020	Expiry Date:	25Nov2020

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

Revision History:

1.0 - Original

Document Approvals  
Approved Date: 21 Sep 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 21-Sep-2020 13:15:14 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 21-Sep-2020 13:40:31 GMT+0000



## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40075
Manufacturer Name:	Lonza Biologics Inc (Portsmouth)	Container/Closure:	(b) (4)
Manufacturer Lot:	930143		
Moderna Lot Number:	4007520004	Specification:	SPC-1118
Date of Manufacture:	31Aug2020	Expiry Date:	30Nov2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	USP <61>	TAMC		
		TYMC		

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Generated Date: 21-Sep-2020

FDA-CBER-2022-1614-4622945

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40075
Manufacturer Name:	Lonza Biologics Inc (Portsmouth)	Container/Closure:	(b) (4)
Manufacturer Lot:	930143		
Moderna Lot Number:	4007520004	Specification:	SPC-1118
Date of Manufacture:	31Aug2020	Expiry Date:	30Nov2020

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

Revision History:

1.0 - Original

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QA Approval Verdict: Approved	(b) (6) @modernatx.com) (b) (6) @modernatx.com) Quality Assurance Approval 21-Sep-2020 13:42:31 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40074
Manufacturer Name:	Moderna	Container/Closure:	Mobius (b) (4)
Manufacturer Lot:	4007420001		
Moderna Lot Number:	4007420001	Specification:	SPC-1149
Date of Manufacture:	20Sep2020	Expiry Date:	19Dec2020

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Page 1 of 2

Generated Date: 23-Oct-2020

FDA-CBER-2022-1614-4622948

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40074
Manufacturer Name:	Moderna	Container/Closure:	Mobius (b) (4)
Manufacturer Lot:	4007420001		
Moderna Lot Number:	4007420001	Specification:	SPC-1149
Date of Manufacture:	20Sep2020	Expiry Date:	19Dec2020

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

Revision History:

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Page 2 of 2

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Approved Date: 23 Oct 2020

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QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 23-Oct-2020 18:08:30 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40074
Manufacturer Name:	Moderna	Container/Closure:	Mobius (b) (4)
Manufacturer Lot:	4007420002		
Moderna Lot Number:	4007420002	Specification:	SPC-1149
Date of Manufacture:	03Oct2020	Expiry Date:	01Jan2021

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 21-Oct-2020

FDA-CBER-2022-1614-4622951

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40074
Manufacturer Name:	Moderna	Container/Closure:	Mobius (b) (4)
Manufacturer Lot:	4007420002		
Moderna Lot Number:	4007420002	Specification:	SPC-1149
Date of Manufacture:	03Oct2020	Expiry Date:	01Jan2021

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

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Approved Date: 23 Oct 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 22-Oct-2020 12:22:56 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 22-Oct-2020 22:56:13 GMT+0000

## CERTIFICATE OF ANALYSIS

Product Description:	CX-024414	Moderna Part #:	40074
Manufacturer Name:	Moderna	Container/Closure:	Mobius (b) (4)
Manufacturer Lot:	4007420003		
Moderna Lot Number:	4007420003	Specification:	SPC-1149
Date of Manufacture:	19Oct2020	Expiry Date:	17Jan2021

Product Attribute	Method	Parameter	Specification	Result
Appearance	SOP-0278	Clarity	(b) (4)	
		Color		
		Particulates		
Identity	SOP-0492	Identity		
Total RNA Content	SOP-0249	Concentration		
Purity / Product Related Impurities	SOP-0321	Main Peak Area		
		% Pre-Main Peak		
		% Post Main Peak		
% 5' Capped	SOP-0467	Cap1		
% PolyA tailed RNA / % Tailless RNA	SOP-0291	Main Peak Area		
		Pre-Main Peak Area		
Residual DNA template	SOP-0491	Residual DNA Template		
pH	SOP-0288	pH		
Bacterial Endotoxins	USP <85>	Bacterial Endotoxins		
Bioburden	SOP-0480	TAMC		
		TYMC		

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Generated Date: 18-Nov-2020

FDA-CBER-2022-1614-4622954

## CERTIFICATE OF ANALYSIS

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Date of Manufacture:	19Oct2020	Expiry Date:	17Jan2021

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

Revision History:

1.0 - Original

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FDA-CBER-2022-1614-4622955

Document Approvals  
Approved Date: 18 Nov 2020

Approval Verdict: Approved	Steven Anderson, (b) (6) @modernatx.com) Quality Control Approval 18-Nov-2020 16:20:24 GMT+0000
QA Approval Verdict: Approved	(b) (6) (b) (6) @modernatx.com) Quality Assurance Approval 18-Nov-2020 16:27:36 GMT+0000