



LAL TEST RESULT COVER PAGE

18 August 2021

Test Method: (b) (4) LAL (b) (4) LAL)  
Analyst: Hyesuk Kong  
Reason for Test: License Support/Confirmatory Routine  
LAL Test Date: 8/18/21

STN number: 125742  
Mfr Lot number(s): FD7220, FE3592 and FF2587  
Manufacturer: BioNTech Manufacturing GmbH  
Product: Covid-19 Vaccine, mRNA  
Calculated MVD: (b) (4)

Endotoxin Acceptance Limit: (b) (4)

(b) (4) LAL test results

Lot Number	Test Dilution	% Spike Recovery	Results (IU/mL)
FD7220	(b) (4)		
FE3592			
FF2587			

- Comments: 1. Lot numbers FD7220, FE3592 and FF2587 were assayed at a (b) (4) fold dilution (See attached testing dilution calculation worksheet).
2. Positive Product Control (PPC) samples were spiked with (b) (4) endotoxin to provide PPC results (b) (4) standard curve was used, with concentrations at: (b) (4) (b) (4)
3. The test result displayed no inhibition or enhancement of the expected PPC; thereby, meeting the test qualification criteria and the bacterial endotoxin result met their specification of (b) (4)
4. (b) (4) LAL test result worksheets are also attached.

Analyst Signature

Date

8/18/21

Supervisor Review

James L. Kenney -S

Date

QA Review

Nadine S. Kaelber -S

Date

Digitally signed by James L. Kenney -S  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, ou=20210818, cn=James L. Kenney -S  
Date: 2021.08.18 17:31:11

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Date: 2021.08.18 17:31:11



Center for Biologics Evaluation and Research Laboratory Quality System  
Laboratory Quality System Laboratory Procedure

Attachment 2: (b) (4) Endotoxin Dilution Calculation Worksheet  
Document ID: 000575 Revision Level: 04  
Total Pages: 1 Effective Date: 12/04/2019

(b) (4) Endotoxin Dilution Calculation Worksheet

STN Number: 125742

Test Date: 8/18/2021

Lot Number(s)	Dilution	Dilution Calculations
<del>NA</del>	<del>8/18/21 HAK</del>	<p>Preparation of Samples :            Dilute the sample appropriately following the manufacturer's protocol (TM-00-8914A-01); report (BET-102720-RD-HC)</p>
FD 7220	Total dilution	(b) (4)
FE 3592	Total dilution	(b) (4)
FF 2587	Total dilution	(b) (4)

Comments: Reagent.

Analyst Signature: 

Date: 8/18/21

Reviewed by: James L. Kenney -S

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13004316521, cn=James L. Kenney -S  
Date: 2021.08.18 17:15:34 -04'00'

QA Review: Nadine S. Kaelber -S

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002096693, cn=Nadine S. Kaelber -S  
Date: 2021.08.18 17:31:57 -04'00'

LAL Kit Number  
(b) (4) Exp. 3/28/23  
8/18/21 HK

DBSQC/OCBQ, CBER/FDA  
LQDB#000539

Analyst ID : KONG H  
Routine Assay  
Template : 20210818 125742r  
Temp : 36.9°C - 37.0°C

LAL Lot No. (b) (4)  
Water Lot No. (b) (4)  
Endotoxin Lot No. (b) (4)

Exp : 3/28/2023 Time : 11:42:05AM  
Exp : 8/24/2023 Date : 8/18/2021  
Exp : 10/19/2024 (b) (4)  
S/N (b) (4)

(b) (4)

Performed By :  Date/Time : 8/18/21

Reviewed By : James L. Kenney -S Date/Time :

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300431652,  
cn=James L. Kenney -S  
Date: 2021.08.18 11:42:05 -0400

(!! = (b) (4) \*\*\*\* = (b) (4) out of range; ???? = atypical; # = Modified; ; >>> = (b) (4) CBER-2021-5683-1150742

**DBSQC/OCBQ, CBER/FDA  
LQDB#000539**

(b) (4)

Analyst ID : KONG H	LAL Lot No. (b) (4)	Exp : 3/28/2023	Time : 11:42:05AM
Routine Assay	Water Lot No.	Exp : 8/24/2023	Date : 8/18/2021
Template : 20210818 125742r	Endotoxin Lot No.	Exp : 10/19/2024	(b) (4)
Temp : 36.9°C - 37.0°C			S/N (b) (4)

(b) (4)

**125742 — Lot No. FD7220**

SAMPLES	DILUTION	(b) (4)
S1	(b) (4)	(b) (4)
PPC		(b) (4)
	PPC Value:	(b) (4)

**125742 — Lot No. FE3592**

SAMPLES	DILUTION	(b) (4)
S1	(b) (4)	(b) (4)
PPC		(b) (4)
	PPC Value:	(b) (4)

**125742 — Lot No. FF2587**

SAMPLES	DILUTION	(b) (4)
S1	(b) (4)	(b) (4)
PPC		(b) (4)
	PPC Value:	(b) (4)

**Curve Parameters**

Parameter	Value	Specification	Status
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Performed By : \_\_\_\_\_ *[Signature]* \_\_\_\_\_ Date/Time : 8/18/21

Reviewed By : \_\_\_\_\_ **James L. Kenney -S** \_\_\_\_\_ Date/Time : \_\_\_\_\_

Digitally signed by James L. Kenney S  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300431652  
Date: 2021.08.18 12:16:43 -0400

DBSQC/OCBQ, CBER/FDA  
LQDB#000539

(b) (4)

Analyst ID : KONG H	LAL Lot No. (b) (4)	Exp : 3/28/2023	Time : 11:42:05AM
Routine Assay	Water Lot No. (b) (4)	Exp : 8/24/2023	Date : 8/18/2021
Template : 20210818 125742r	Endotoxin Lot No. (b) (4)	Exp : 10/19/2024	(b) (4)
Temp : 36.9°C - 37.0°C			S/N (b) (4)

(b) (4)

(b) (4)	PASS
	PASS
	PASS

Standards

Concentration	CV	Specification	Status	Notes
(b) (4)			PASS	
			PASS	
			PASS	
			PASS	
			PASS	

( In Notes : ! - (b) (4) \* - (b) (4) ? - Atypical (b) (4) > - (b) (4)

Product Summary

Conc/Dil	Parameter	Result(PC)	Spec	Status	Notes
125742	Lot No. FD7220				
(b) (4)	(b) (4)			Undefined	*
				N/A	
PPC				PASS	
PPC				PASS	
125742	Lot No. FE3592				
(b) (4)	(b) (4)			Undefined	*
				N/A	
PPC				PASS	
PPC				PASS	
125742	Lot No. FF2587				
(b) (4)	(b) (4)			Undefined	*
				N/A	
PPC				PASS	
PPC				PASS	

( In Notes : ! - (b) (4) \* - (b) (4) ? - Atypical (b) (4) # - Modified, > - (b) (4)

Performed By : *JL Kenney* Date/Time : 8/18/21

Reviewed By : James L. Kenney -S

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300431652, cn=James L. Kenney -S  
Date: 2021.08.18 11:42:05 AM

(b) (4)

Analyst ID : KONG H	LAL Lot No.	(b) (4)	Exp : 3/28/2023	Time : 11:42:05AM
Routine Assay	Water Lot No.	(b) (4)	Exp : 8/24/2023	Date : 8/18/2021
Template : 20210818 125742r	Endotoxin Lot No.	(b) (4)	Exp : 10/19/2024	(b) (4)
Temp : 36.9°C - 37.0°C				S/N (b) (4)

(b) (4)

**Accessories Summary**

Name	Lot No.	Manufacturer	Calibration Due	Expiration
100 ul pipette	000874R/T14526	Thermo	12/31/2021	
1000 ul pipette	001401R	Eppendorf	12/31/2021	
1000ul pipette	000873R / S964432	Thermo	12/31/2021	
100ul pipette	000870R /T14525	Finnpipette	12/31/2021	
10-100ul pipette	000904R/EH10878	Thermo	12/31/2021	
10-100ul pipette	000905R	Finnpipette	12/31/2021	
200ul pipette	000872R / S84859	Finnpipette	12/31/2021	
500ul pipette	000871R / T04134	Finnpipette	12/31/2021	
8-channel pipette	001629R	Eppendorf	12/31/2021	
(b) (4)				5/1/2022
				6/30/2023

**Log Summary**

Description (Comment)	User ID	Date
Routine Assay RunDateTime: 8/18/2021 11:42:05 AM Serial # (b) (4)	KONG H	8/18/2021 11:42:05AM

Performed By :  Date/Time : 8/18/21

Reviewed By : James L. Kenney -S

Digitally signed by James L. Kenney -S  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,  
0.9.2342.19200300.1001.1=1300431652, cn=James L. Kenney -S  
Date: 2021.08.18 11:42:05 AM

( ! = (b) (4) \*\*\*\* = (b) (4) out of range; ???? = atypical ; # = Modified ; >>> = (b) (4) CBER-2021-5683-1150745