

METTLER TOLEDO

Channel: L
 Format: GLP
 Date: Aug-18-2021
 Time: 18:11
 Sensor-ID: ~~280581p~~ N/A
 Sensor-SN: 6074260
 Inst. ID: QDB 000494
 Inst. SN: 1228035028
 Exp.-U. ID:
 Exp.-U. SN: 280581p
 User: Tao Pan
 Method: 000482
 Endpoint: Auto
 Stability: Normal
 ATC/MTC: ATC
 Cal. Mode: Linear
 B1(25°C): 4.01
 mV1: 180.6mV
 Temp. 1: 21.5°C
 B2(25°C): 10.01
 mV2: -164.6mV
 Temp. 2: 22.0°C
 Slope: -57.82mV/pH
 Slope[%]: 97.7%
 Offset: 9.4mV
 Alarm: None
 Signature: Tao Pan
 (Slope @ 25°C)

METTLER TOLEDO

Channel: L
 Format: GLP
 Date: Aug-18-2021
 Time: 18:17
 Sensor-ID: N/A
 Sensor-SN: 6074260
 Last-Cal.: Aug-18-2021
 Cal. time: 18:11
 Inst. ID: QDB 000494
 Inst. SN: 1228035028
 Exp.-U. ID:
 Exp.-U. SN: 280581p
 User: Tao Pan
 Method: 000482
 Endpoint: Auto
 Stability: Normal
 ATC/MTC: ATC
 Time-Int.: Off
 Automation: Off
 Sample-ID: FD7228
 Result: (b) (4) pH
 mV: -17.1mV
 Temperature: 21.4°C
 Alarm: None
 Signature: Tao Pan

METTLER TOLEDO

Channel: L
 Format: GLP
 Date: Aug-18-2021
 Time: 18:18
 Sensor-ID: N/A
 Sensor-SN: 6074260
 Last-Cal.: Aug-18-2021
 Cal. time: 18:11
 Inst. ID: QDB 000494
 Inst. SN: 1228035028
 Exp.-U. ID:
 Exp.-U. SN: 280581p
 User: Tao Pan
 Method: 000482
 Endpoint: Auto
 Stability: Normal
 ATC/MTC: ATC
 Time-Int.: Off
 Automation: Off
 Sample-ID: FE3592
 Result: (b) (4) pH
 mV: -15.4mV
 Temperature: 22.1°C
 Alarm: None
 Signature: Tao Pan

METTLER TOLEDO

Channel: L
 Format: GLP
 Date: Aug-18-2021
 Time: 18:19
 Sensor-ID: N/A
 Sensor-SN: 6074260
 Last-Cal.: Aug-18-2021
 Cal. time: 18:11
 Inst. ID:
 Inst. SN: 1228035028
 Exp.-U. ID:
 Exp.-U. SN: 280581p
 User: Tao Pan
 Method: 000482
 Endpoint: Auto
 Stability: Normal
 ATC/MTC: ATC
 Time-Int.: Off
 Automation: Off
 Sample-ID: FF2587
 Result: (b) (4) pH
 mV: -14.6mV
 Temperature: 21.7°C
 Alarm: None
 Signature: Tao Pan



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)
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 _____ Date _____

QA Review _____ Date _____



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

<u>Lot Number(s)</u>	<u>Dilution</u>	<u>Dilution Calculations</u>
NA	8/18/21 AK	<p><i>Preparation of Samples:</i> Dilute the sample appropriately following the manufacturer's protocol (TM-00-894A-01); report (BET-102720-R0-HC)</p> <p>(b) (4)</p>
FD 7220 FE 3592 FF 2587	Total dilution Total dilution Total dilution	(b) (4)

Comments: *Reagent*

Analyst Signature: 
 Reviewed by: _____
 QA Review: _____

Date: 8/18/21
 Date: _____
 Date: _____

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)

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 : _____ Date/Time : _____