OFFICIAL

Owner: ███████	**Number:** Bio-BEE-Form-42
Author: ███████	**Version:** 1
Active: 2/07/2021	**Review:** <QPulse_DocReviewDate>
Title: Bacterial Endotoxin - Appendix 1K - Kinetic LAL Routine Assay Sample Results	

Appendix 1K - Kinetic LAL Routine Assay Sample Results Sheet

Assay ID: <u>28Oct2021/2</u>   Operator: ████

LAL Reagent Water (LRW) Lot Number: <u>0000837899</u>   LRW Expiry: <u>18 March 2022</u>

Other Reagent: <u>Pyrosperse</u>   Batch# <u>0000904583</u>   Expiry: <u>29 June 2022</u> Use By: <u>19 November 2021</u>

1 - Product Details

Product Name	Batch Number	Expiry	LIMS Number
Pfizer Comirnaty	FL7649	<u>28 February 2022</u>	2110003905-R1
Product Concentration	**Endotoxin Limit**	**MVD**	**Test Dilution**
<u>n</u>/a	████	<u>2</u>500	<u>1</u>/1000

2 - Product Dilutions

Dilution	Volume of Dilution	Volume of LRW	Volume of Other
<u>F</u>or 1/1000 do: 1/50	<u>2</u>0uL of vaccine	<u>9</u>75uL	<u>5</u>uL pyrosperse
<u>1</u>/20	<u>5</u>0uL of 1/50 dilution	<u>9</u>45uL	<u>5</u>uL pyrosperse
<u>n</u>/a	<u>-</u>	<u>-</u>	<u>-</u>
<u>n</u>/a	<u>-</u>	<u>-</u>	<u>-</u>
<u>n</u>/a	<u>-</u>	<u>-</u>	<u>-</u>

Recording of Results

The results are recorded by the WinKQCL software. Transcribe results from the WinKQCL report to assay sheet.

Test CV (%)	Result (EU/ml)	PPC CV (%)	% PPC Recovery
N/A (Undefined)	<5.00	0.24	164

For the sample test to be valid, the PPC recovery must be 50-200% of the expected value and the coefficient of variation (CV) of the sample and PPC duplicates should be < 10%. Many samples do not reach an endpoint and are not assigned a %CV. In these instances, contact the person in charge of the assay.

Validity Criteria	
Were the standard curve validity criteria met?	Yes
Were the sample validity criteria met?	Yes
Was the result within the endotoxin limit?	Yes

This Appendix is used for recording the sample results. Use the SOP (Appendix 8K) for the detailed method.

Notes:

Checked ▮▮▮▮ **28Oct2021**