



Owner: [REDACTED]	Number: Bio-BEE-Form-42
Author: [REDACTED]	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: 18Nov2021

Operator: [REDACTED]

LAL Reagent Water (LRW) Lot Number: 0000837899LRW Expiry: 18 March 2022Other Reagent: Pyrospense Batch# 0000904583
November 2021Expiry: 29 June 2022 Use By: 19

1 - Product Details

Product Name	Batch Number	Expiry	LIMS Number
<u>Pfizer Covid Vaccine</u>	<u>FL5333</u>	<u>28 February 2022</u>	<u>2111004115-R1</u>
Product Concentration	Endotoxin Limit	MVD	Test Dilution
<u>n/a</u>	[REDACTED]	<u>2500</u>	<u>1/1000</u>

2 - Product Dilutions

Dilution	Volume of Dilution	Volume of LRW	Volume of Other
<u>For 1/1000 do:</u> <u>1/50</u>	<u>20uL of vaccine</u>	<u>975uL</u>	<u>5uL Pyrospense</u>
<u>1/20</u>	<u>50uL of 1/50</u>	<u>945uL</u>	<u>5uL Pyrospense</u>
<u>n/a</u>	=	=	=
<u>n/a</u>	=	=	=
<u>n/a</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
<u>1.43</u>	<u><5.00</u>	<u>1.32</u>	<u>115</u>

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 [REDACTED] 18Nov2021