Validation Plan Addendum 2

VSDVAC_66_VP_Addend2

Method: VSDVAC 66 v0.00, An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

PPD Project Code: RPPF2

Addendum to the Validation of an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

Version: 1.00

To be Conducted for Moderna

by PPD® Laboratories
2244 Dabney Road
Richmond, Virginia 23230
(804) 359-1900

Issue Date: 05-Nov-2020

Confidentiality Statement

PPD Approval

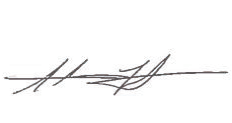
PPD Project: RPPF2

PPD Report Title: Addendum to the Validation of an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum Additional (b) (4) Runs

This validation addendum plan has been reviewed and approved by the undersigned.

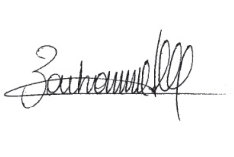
Carl Breidenbach

Signature/Date



Adrienne Howlett

Signature/Date



Marie Bonhomme, Ph.D.

Signature/Date

Biostatistical Reviewer

Signature/Date

Note: Analyst(s) performing these experiments are stating that she/he has read the document, has had an opportunity to ask questions on the design of the plan and understands the expectations before performing the work by signing electronically in eSheet.

PPD QA Review

PPD Project: RPPF2

PPD Report Title: Addendum to the Validation of an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum Additional (b) (4) Runs

This validation addendum plan has been reviewed by the undersigned.

(b) (6)

(b) (6)
I reviewed this document
05 Nov 2020 11:44:22 -05:00
DocuSign

QA Reviewer

Signature/Date

Sponsor Approval

Client:	Moderna
PPD Project:	RPPF2
PPD Report Title:	Addendum to the Validation of an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum Additional (b) (4) Runs

This validation addendum plan has been reviewed and approved by the undersigned.

Exception:
Approval of the original plan may be granted by the client in the form of written communication and will be stored in PPD's ECM system.

(b) (6)

(b) (6)
I confirm that this approval was given via email and located in ECM under the project code(s) listed in the plan.
03 Nov 2020 11:17:52 -05:00

Rolando Pajon, Ph.D.
Director, Clinical Biomarkers

DocuSign

Signature/Date

Validation Addendum 2

Addendum to the Validation of an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum Additional (b) (4) Runs

Introduction

A proprietary serological method, "An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum" was developed and has been qualified by PPD® Laboratories, in Richmond, Virginia, USA. The qualification of this new method was conducted under PPD Project Code "ROZD2"[1].

At the request of Moderna, the PPD proprietary serological method, "An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum" will be validated by PPD® Laboratories, in Richmond, Virginia, USA. The new method, VSDVAC 66[2], will be finalized to version 1.00 after validation. The client specific validation of this method will be conducted under PPD Project Code "RPPF2"[3].

The purpose of this addendum is to detail the experimental design and statistical analysis in accordance with SOP LP-PAL-7023[4] to perform additional (b) (4) runs to establish a (b) (4)

The purpose of this experiment is to perform additional (b) (4) runs based on preliminary statistical analysis indicating (b) (4) (b) (4) as noted in Figure 1 and Figure 2. As shown in Figure 1, at the (b) (4) dilution, several runs had (b) (4)

(b) (4)

(b) (4) The additional runs will be utilized to supplement the (b) (4) over which the assay is acceptably (b) (4) in order to establish the (b) (4)

Figure 1. (b) (4)

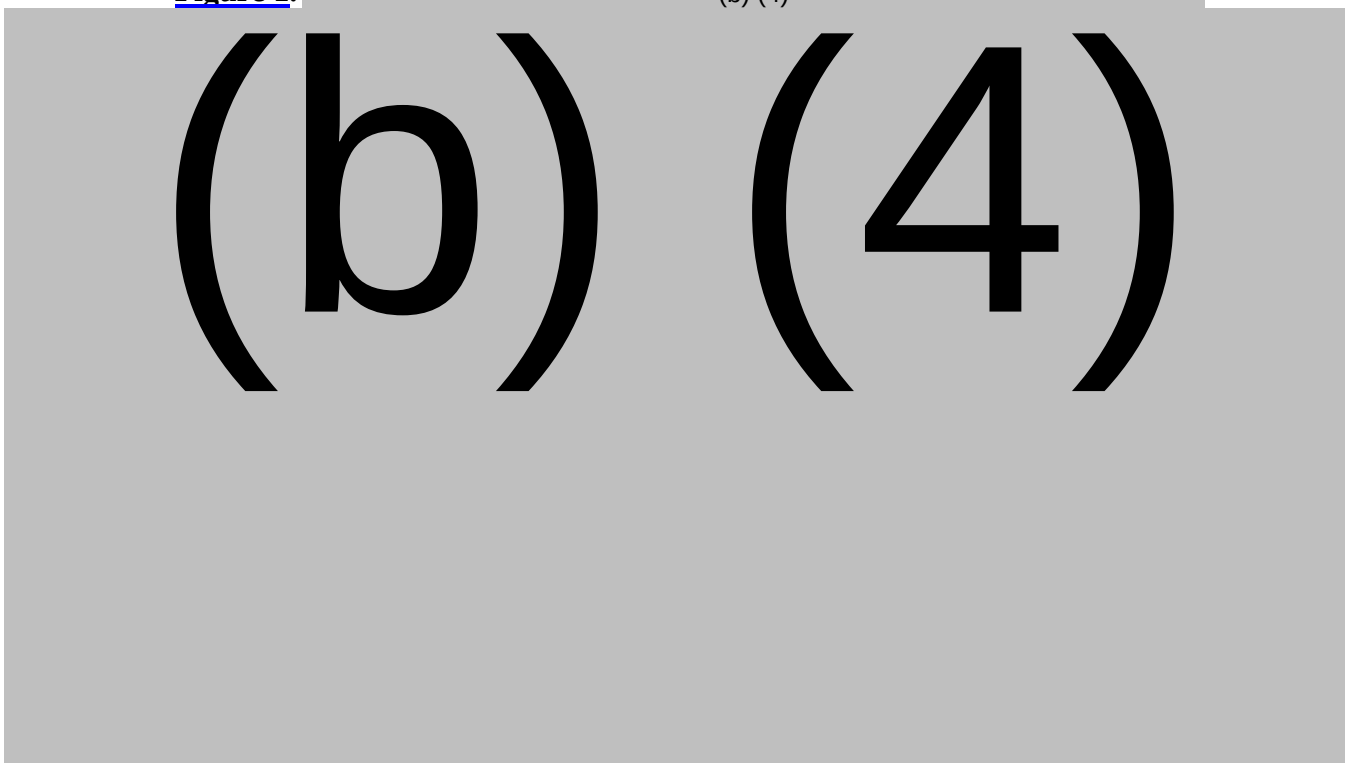
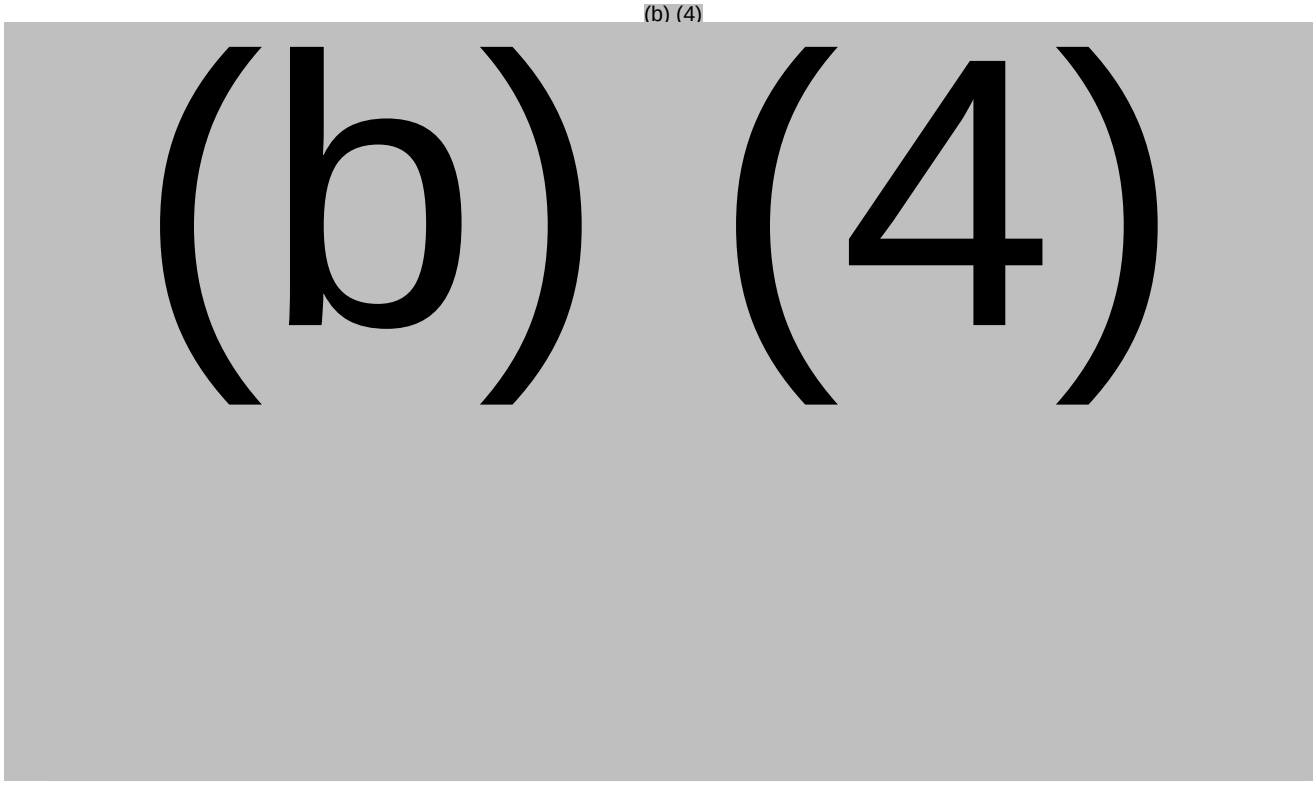


Figure 2: (b) (4)

(b) (4)



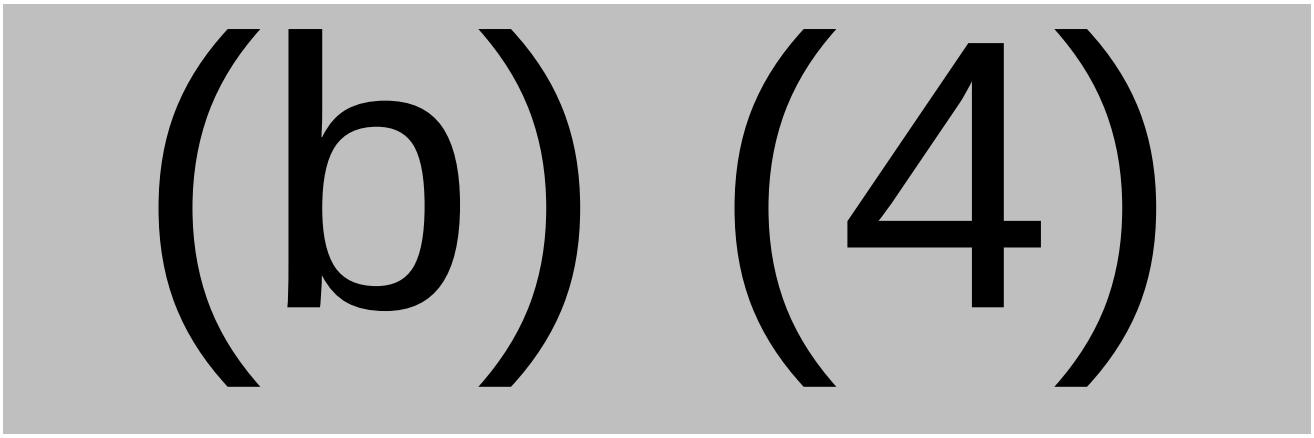
Reference Standard and Critical Reagents

The following reference standard and critical reagents will be used during this reagent addendum:

Compound	Purpose	Source	Lot	Conc.	Exp. Date	Storage Conditions
(b) (4)						

Validation Addendum Experiments

(b) (4) Experimental Design



All testing will be performed following draft method VSDVAC 66 v0.00[2], unless otherwise noted. The data generated within each of the experimental runs will be used in the (b) (4) (b) (4) determination for the validation of the VSDVAC 66 method per the analysis section. A complete run summary table will be provided, and formal analysis of the data will be performed by PPD Statistics.

Table 1: Proposed Experimental Design

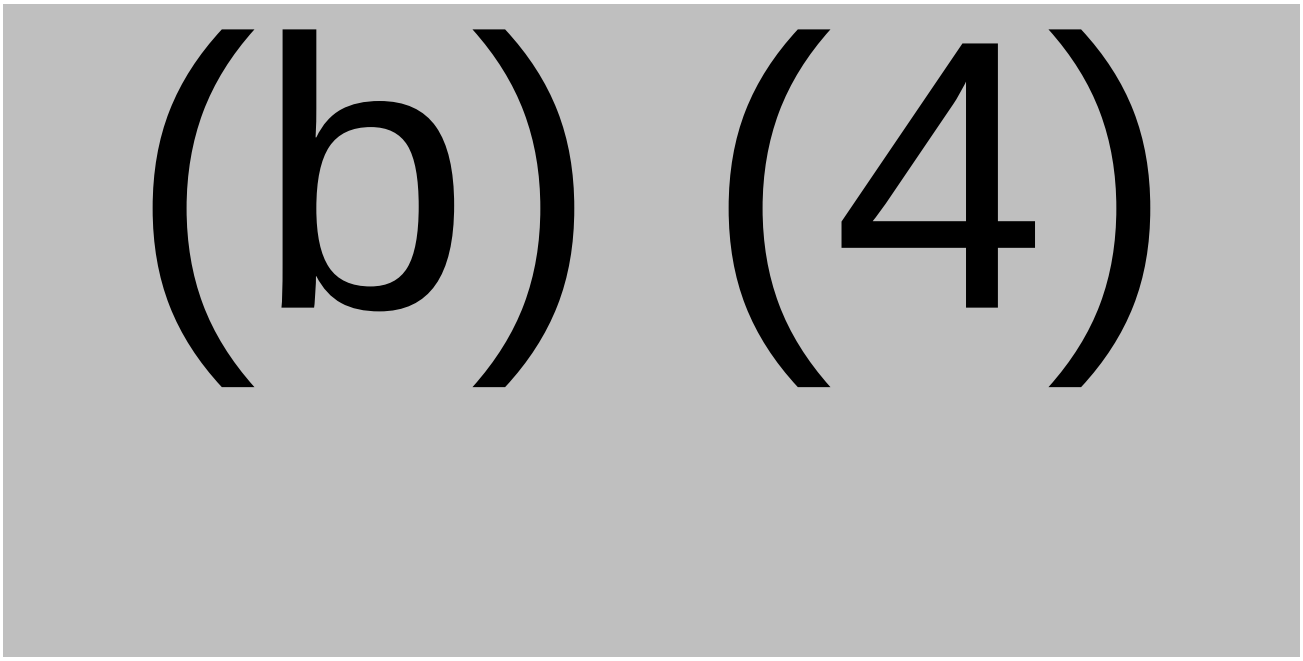
Run #	Plate #	Analyst	Samples	Dilution
(b) (4)				

Table 2: (b) (4)

Sample ID	Barcode	Dilution	(b) (4) (b) (4)
(b) (4)			

Figure 3: Proposed Plate Map

(b) (4)



Method Validation Addendum Data Analysis Plan

(b) (4)

Records Retention

All raw data, documentation, records, Reagent Qualification plan, and the final statistical report generated in support of this project will be archived in the storage facilities of PPD (Richmond) or at another approved site according to approved PPD SOPs following completion of this project.

Exceptions

If additional evaluations not covered by this plan addendum are required, an addendum to the plan addendum can be written. A plan amendment documents an intended change to the plan after the qualification was initiated. Amendments and addenda to plans must be approved at the same levels as the original plan or higher. Any exceptions to this plan will be evaluated to determine if an Event is required per SOP-GQC-42[5], *Quality Event Management*.

Instances in which the pre-specified acceptance criteria are not met will be identified and evaluated in the statistical report. Qualification approval/rejection will not be exclusively determined based on pass/fail outcome. Rather, criteria failures will be evaluated based on the nature of the violation and its assessed impact in the context of clinical testing. (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) The exceptions will be evaluated for impact through an investigation, if necessary. The investigation(s) will be documented through the *Quality Event Management based on SOP effective date*. (SOP-GQC-42).

References

1. Method Qualification Statistical Report: *Qualification of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum*, v1.00. 06Jul2020.

2. Draft Method VSDVAC 66: *An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum,* v0.00

3. Method Validation Plan: *Validation of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum,* v1.00. 29Sep2020.

4. SOP LP-PAL-7023: *Validation of Methods in the Vaccine Sciences Department*, Revision 01. 28Feb2020.

5. SOP-GQC-42: *Quality Event Management*, Revision 02. 02Nov2020.