Validation Plan Addendum 1

VSDVAC_66_VP_Addend1

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
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Richmond, Virginia 23230
(804) 359-1900

Issue Date: 21-Oct-2020

Confidentiality Statement

PPD Approval

PPD Project: RPPF2

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

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

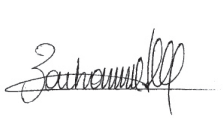
Carl Breidenbach

Signature/Date

Adrienne Howlett

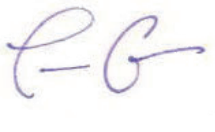
Signature/Date

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 the IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

This validation addendum plan has been reviewed by the undersigned.

(b) (6)
(b) (6)
I reviewed this document
22 Oct 2020 11:25:36 -04:00
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 the IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

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

(b) (6)

(b) (6)
I confirm that this approval was given via email and housed in ECM under the project code(s) listed in the plan.
21 Dec 2020 11:17:31 -04:00

Rolando Pajon, Ph.D.
Director, Clinical Biomarkers

DocuSign

Signature/Date

If a signature cannot be obtained, see ECM for email containing client approval.

Validation Addendum 1

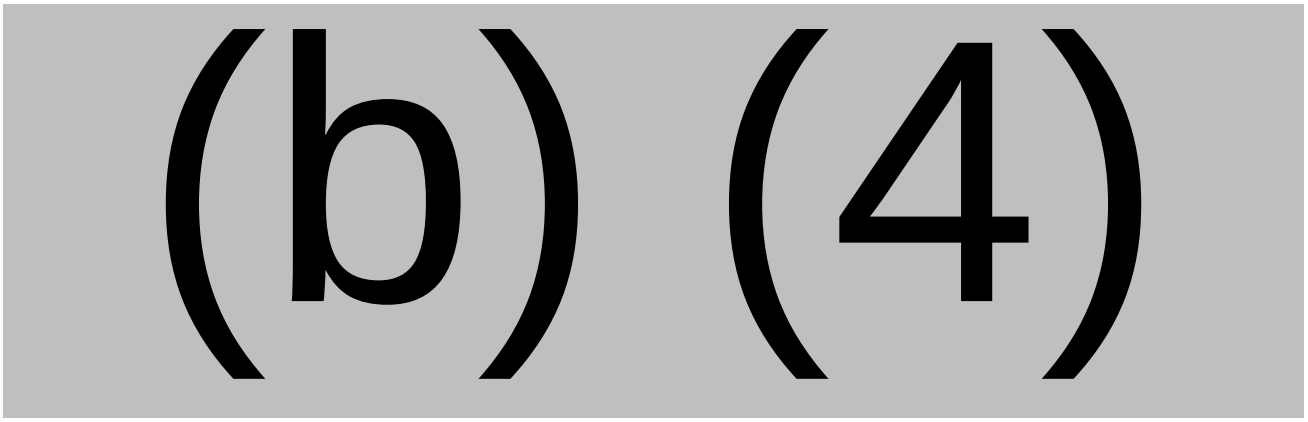
Addendum to the Validation of an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

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].

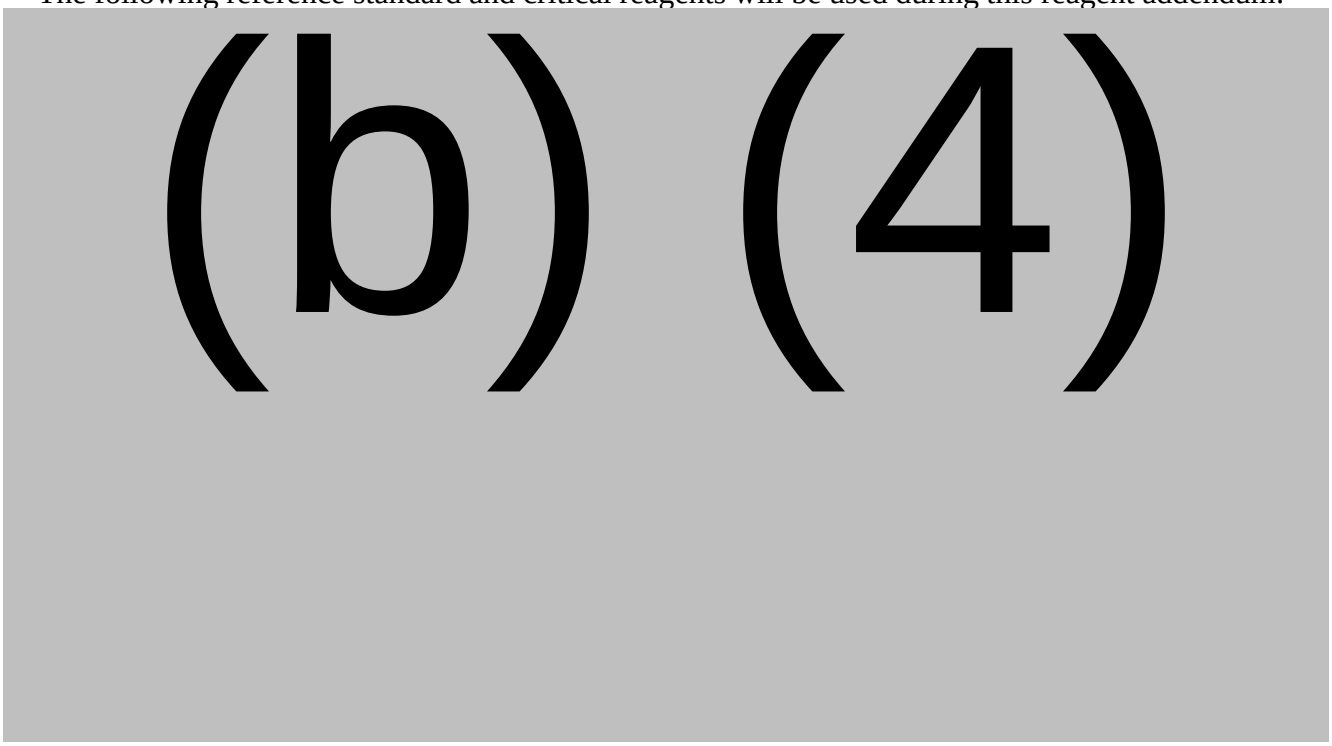
At the request of Moderna, the PPD proprietary serological method, "An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum" will be validated by PPD® Laboratories, in Richmond, Virginia, USA. The new method, VSDVAC 66[2], will be finalized to version 1.00 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 be performed to confirm assessing the suitability of a new lot of (b) (4) for use in the Nucleocapsid IgG ELISA assay.



Reference Standard and Critical Reagents

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



Validation Addendum Experiments

Nucleocapsid Antigen Experimental Design

(b) (4)

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 to determine the suitability of the new lot of (b) (4). 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

(b) (4)

Table 2: Proposed Sample Panel

Sample	Barcode	Sample ID
(b) (4)		

(b) (4)

Assay and Sample Validity

(b) (4)

Equivalency Parameters and Acceptance Criteria

Formal analysis of the data will be performed by PPD Statistics. Described below is the proposed statistical analysis; however, alternative approaches may be utilized if agreed upon by PPD management and the biostatistician. The final statistical method used will be described in the statistical report. Acceptance criteria for the (b) (4) of the comparisons described above are provided below.

Performance Characteristic	Acceptance Criterion
(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 the original plan are required, an addendum to the plan 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, *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. Additionally, the variability across the runs may be such that more runs may be required in order provide a sufficient data set for analysis based on the variability observed, particularly pertaining to confidence interval width. In such cases, an additional set of runs will be performed and the data from those runs will be combined with the previously generated data for analysis. 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.