

Validation Plan Addendum 1

VSDVAC_65_VP_Adden1

Method: VSDVAC 65 v 1.01, An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum

PPD Project Code: RPPF

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

(b) (4)

Version: 1.00

To be Conducted for Moderna

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

Issue Date: 11-Dec-2020

Confidentiality Statement

The information in this document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by applicable law or regulations. In any event, persons to whom the information is disclosed must be informed that the information is privileged or confidential and may not be further disclosed by them. These restrictions on disclosure will apply equally to all future information supplied to you which is indicated as privileged or confidential.

PPD Approval

PPD Project:

RPPF

PPD Report Title:

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

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

Jack Hester Associate Group Leader I approve this document 11 Dec 2020 12:55:57 -05:00

Adrienne Howlett Manager Labs I approve this document 14 Dec 2020 08:17:30 -05:00

Docu*Sign*

Signature/Date

Docu*Sign*

Signature/Date

Marie Bonhomme Associate Director I approve this document 11 Dec 2020 12:59:11 -05:00

Docu*Sign*

Signature/Date

Victoria A. Pisciella Senior Biostatistician II I reviewed this document 11 Dec 2020 13:18:50 -05:00

DocuSign

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.

Adrienne Howlett

Jack Hester

Marie Bonhomme, Ph.D.

Biostatistical Reviewer

PPD QA Review

PPD Project:

RPPF

PPD Report Title:

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

This validation addendum plan has been reviewed by the undersigned.



QA Reviewer

Signature/Date

Sponsor Approval

Client: Moderna

PPD Project:

PPD Report Title:

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

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RPPF

Exception:

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

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Bethany Girard, Ph.D. Sr. Manager, Clinical Biomarkers Docu*Sign*

Signature/Date

Validation Addendum 1

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

Introduction

A proprietary serological method, "An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike 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 "ROQP2"^[1].

At the request of Moderna, the PPD proprietary serological method, "An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum" was validated by PPD® Laboratories, in Richmond, Virginia, USA. The new method, VSDVAC 65^[2], was finalized to version 1.00 after validation. The current version of VSDVAC 65 is Version 1.01. The client specific validation of this method was conducted under PPD Project Code "RPPF"^[3].

The purpose of this plan is limited to assessing the equivalency of plate preparation using the (b) (4) product and subsequent stability of the prepared plates for the SARS-CoV-2 Spike Protein IgG Assay at PPD Richmond, VA. The current procedure limits operational efficiency by only allowing plate coating to (b) (4) The plate is then blocked for approximately (b) (4) The (b) (4) product will allow (b) (4) (b) (4) This

experimental plan will be conducted under PPD Project Code RPPF following method VSDVAC 65 V 1.01.

If additional experiments 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 evaluation 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*.

Reference Standard and Critical Reagents

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



Note: If the content of the Certificate of Analysis differs from this plan, updated information will be included in the final report. Any changes to the lot of reagent will be included in the reagent qualification statistical report.

Experimental Design (4)(b)



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







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Data Validity

All analysis will be performed following method VSDVAC 65, v1.01, with the following exceptions:



Analysis Plan





Expectations



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

(b) (4)

Records Retention

All raw data, documentation, records, Validation Plan Addendum 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.

References

- 1. PPD Qualification Plan: *Qualification of An ELISA Method for the Detection of IgG* Specific to SARS-CoV-2 Spike Protein in Human Serum, ROQP2, 04Jun2020
- 2. PPD Method: VSDVAC 65: *An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum*, v1.00, RPPF, 19Oct2020. PPD Method:
- 3. PPD Method: VSDVAC65: An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum, v1.01, RPPF, 05Nov 2020
- 4. PPD Nonclinical Statistics: *Statistical Methods Reference Guide* v1.0, 21Dec2009.
- 5. PPD Statistical Report: Validation of an ELISA method for the detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum, RPPF, 19Oct2020.

Appendix A

Reagents and Chemicals

(b) (4)

Materials and Equipment



Reagent Preparation

