# Method Validation Plan Addendum 3

**VSDVAC_65_VP_Addend3**

**PPD Project Code: RPPF**

# Assessment of Plate Coating Stability for an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum

**Version 0.00**

**To be Conducted for PPD Laboratory**

**by PPD® Laboratories**
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**Richmond, Virginia 23230**
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**Issue Date: 23-Dec-2020**

## PPD Approval

**PPD Project:** RPPF

**PPD Report Title:** Assessment of Plate Coating Stability for an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum

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

Jack Hester
Associate Group Leader
I approve this document
06 Jan 2021 15:45:16 -05:00

DocuSign

Jack Hester

Signature/Date

Adrienne Howlett
Manager Labs
I approve this document
06 Jan 2021 15:42:47 -05:00

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Adrienne Howlett

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Marie Bonhomme
Associate Director
I approve this document
06 Jan 2021 15:49:10 -05:00

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Marie Bonhomme, Ph.D.

Signature/Date

Victoria A. Pisciella
Senior Biostatistician II
I reviewed this document
06 Jan 2021 15:47:38 -05:00

DocuSign

Statistical 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:** RPPF

**PPD Report Title:** Assessment of Plate Coating Stability for an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum

This validation plan addendum has been reviewed by the undersigned.

(b) (6)
(b) (6)
I reviewed this document
07 Jan 2021 07:28:01 -05:00

(b) (6)

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QA Reviewer

Signature/Date

## Sponsor Approval

| | |
|---|---|
| **Client:** | Moderna |
| **PPD Project:** | RPPF |
| **PPD Report Title:** | Assessment of Plate Coating Stability for an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum |

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

(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.
06 Jan 2021 15:57:57 -05:00

DocuSign

Bethany Girard, PhD
Clinical Biomarker Sr. Manager, Clinical Operations

Signature/Date

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

## Method Validation Plan Addendum

## Assessment of Assay Process Stability for 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 qualified by PPD® Laboratories, in Richmond, Virginia, USA. The qualification of this new method was conducted under PPD Project Code "ROQP2". The new method, VSDVAC 58[1] was finalized to Version 1.00 post qualification experiments [2].

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 be validated by PPD® Laboratories, in Richmond, Virginia, USA. The new method, VSDVAC 65[3], was approved for use as Version 0.00 prior to the execution of validation experiments by senior PPD laboratory management; the method was finalized to Version 1.00 after validation. The client specific validation of this method was conducted under PPD Project Code "RPPF"[4].

This method describes the procedure for the analysis of the SARS-CoV-2 total IgG in human serum. This quantitative ELISA assay was designed to detect IgG antibody to the SARS-CoV-2 virus in human serum. Microtiter plates were coated with commercially available SARS-CoV-2 full-length spike (S) glycoprotein and serum containing the SARS-CoV-2 IgG antibody was added. Bound antigen-antibody complex was detected using purified goat anti-human IgG horseradish peroxidase (HRP) conjugate. Color development occurred during the addition of 3,3',5,5'tetramethylbenzidine (TMB) substrate and color intensity was measured spectrophotometrically (b) (4) The intensity of the color was directly proportional to the IgG antibody concentration. Quantitation of the human IgG antibody to SARS-CoV-2, or antibody concentration (µg/mL), was determined by interpolation from a standard curve analyzed on each assay plate.

The purpose of this plan is limited to assessing plate coating stability at (b) (4) for the SARS-CoV-2 Spike Protein IgG Assay at PPD Richmond, VA. This experimental plan will be conducted under PPD Project Code RPPF following method VSDVAC 65 v1.01, current version or higher.

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.*

## Experimental Design

(b) (4)

(b) (4) Refer to Figure 1 for proposed plate map.

Plate coating will follow VSDVAC 65 v1.01, current version or higher with the following exceptions:

(b) (4)

Refer to Table 2 for a description of the (b) (4) storage conditions.

All samples will be analyzed in (b) (4) as per VSDVAC 65 v1.01, current version or higher.

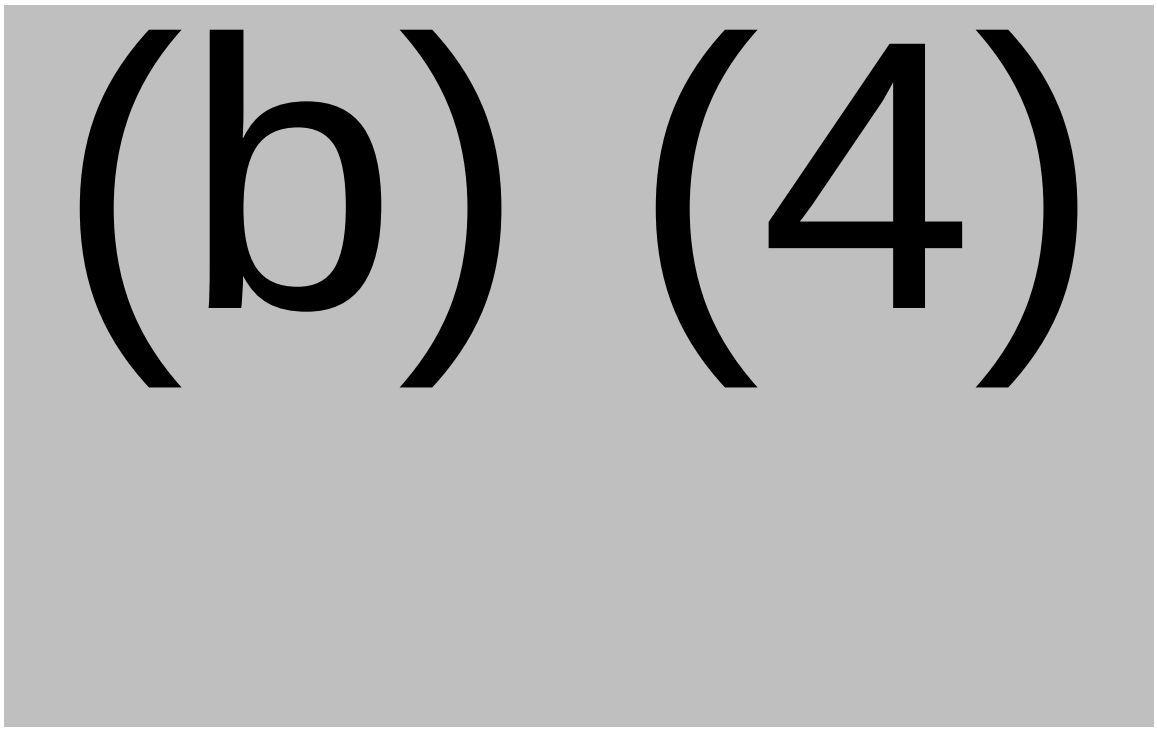
**Table 1. Proposed Plate Coating Panel Samples**

| Sample ID | Barcode |
|---|---|
| (b) (4) | |

**Table 2. Description of Plate Coating Storage Time at (b) (4)**

(b) (4)

**Figure 1: Proposed Plate Map for Plate Coating Stability**




## Data Validity

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

1. If plate failures occur during any of the runs, the lab will retest the failed plate(s) at most (b) (4) times to obtain a final antibody concentration.
2. (b) (4)
3. (b) (4)

## Analysis Plan

Formal analysis of the data will be performed by PPD Biostatistics. Analysis will be performed once all experimental work for the stability experiment has been completed and any changes to the analysis plan will be documented within the statistics report. The statistical report will include the calculated durations rather than duration range for each experiment.

(b) (4)

Expectations:

(b) (4)

## Records Retention

All raw data, documentation, records, Validation Plan Addendum, 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. VSDVAC 58: *An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum,* v1.01.

2. PPD Statistical Report: *Qualification of an ELISA method for the detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum,* ROQP2, 19Jun2020.

3. VSDVAC 65: *An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum,* v1.01.

4. PPD Statistical Report: *Validation of an ELISA method for the detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum,* RPPF, 16Oct2020.