



**Method Validation Plan Addendum 3 Amendment 1**

**VSDVAC\_66\_VP\_Adden3\_Amend1**

**PPD Project Code: RPPF2**

**Amendment to Addendum 3 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**

**VSDVAC 66, v1.00, An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum**

**To be Conducted for Moderna**

**by PPD® Laboratories  
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Richmond, Virginia 23230  
(804) 359-1900**

**Issue Date: 11-Jan-2021**

**Confidentiality Statement**

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## PPD Approval

**Client:** Moderna

**PPD Project:** RPPF2

**PPD Report Title:** Amendment to Addendum 3 to the Validation of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

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

Carl Breidenbach

Carl Breidenbach  
Associate Group Leader  
I approve this document  
11 Jan 2021 13:55:53 -05:00



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Signature/Date

Adrienne Howlett

Adrienne Howlett  
Manager Labs  
I approve this document  
11 Jan 2021 13:41:44 -05:00



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Signature/Date

Marie Bonhomme, Ph.D.

Marie Bonhomme  
Associate Director  
I approve this document  
11 Jan 2021 13:20:09 -05:00



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Signature/Date

Biostatistician Reviewer

Victoria A. Piscella  
Senior Biostatistician II  
I reviewed this document  
11 Jan 2021 13:29:40 -05:00



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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**

**Client:** Moderna  
**PPD Project:** RPPF2  
**PPD Report Title:** Amendment to Addendum 3 to the Validation of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

This validation plan addendum amendment has been reviewed by the undersigned.

QA Reviewer

(b) (6) (b) (6)  
I reviewed this document  
11 Jan 2021 15:58:50 -05:00  
  
\_\_\_\_\_  
Signature/Date

## Sponsor Approval

**Client:** Moderna

**PPD Project:** RPPF2

**PPD Plan Title:** Amendment to Addendum 3 to the Validation of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

This validation plan addendum amendment 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.

Bethany Girard, Ph.D.  
Senior Manager, Clinical Assays and Biomarkers

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Signature/Date

## Method Validation Plan Addendum 3 Amendment 1

### Amendment to Addendum 3 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 qualified by PPD<sup>®</sup> Laboratories, in Richmond, Virginia, USA. The qualification of this new method was conducted under PPD Project Code “ROZD2”. The new method, VSDVAC 64<sup>[1]</sup> was finalized to Version 1.00 post qualification experiments<sup>[2]</sup>.

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” was validated by PPD<sup>®</sup> Laboratories, in Richmond, Virginia, USA. The validation of this new method was conducted under PPD Project Code “RPPF2”. The new method, VSDVAC 66<sup>[3]</sup> was finalized to Version 1.00 post validation experiments<sup>[4]</sup>.

(b) (4)

**Table 1:** (b) (4)  
(b) (4)

(b) (4)

## References

1. VSDVAC 64: *An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum*, v1.00.
2. PPD Statistical Report Addendum: *Qualification of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum* – (b) (4) Addendum, ROZD2, 24Aug2020.
3. VSDVAC 66: *An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum*, v1.00.
4. PPD Statistical Report: *Validation of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum*, RPPF2, 02Dec2020.
5. PPD Validation Plan Addendum: *Addendum to the Validation of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum*, RPPF2, 15Dec2020.