



Method Qualification Plan Addendum 1 Amendment 1

VSDVAC_66_VP_Adden1_Amend1

PPD Project Code: RPPF2

Amendment to the 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

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
2244 Dabney Road
Richmond, Virginia 23230
(804) 359-1900**

Issue Date: 02-Nov-2020

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PPD Approval

Client: Moderna


PPD Project: RPPF2

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

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

Carl Breidenbach

Carl Breidenbach
Associate Group Leader
I approve this document
02 Nov 2020 16:19:57 -05:00




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Signature/Date

Adrienne Howlett

Adrienne Howlett
Manager Labs
I approve this document
03 Nov 2020 07:57:54 -05:00

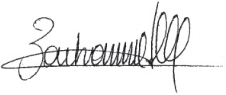


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Signature/Date

Marie Bonhomme, Ph.D.

Marie Bonhomme
Associate Director
I approve this document
02 Nov 2020 16:26:38 -05:00




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Signature/Date

Biostatistician Reviewer

Victoria A. Piscella
Senior Biostatistician II
I reviewed this document
02 Nov 2020 16:21:48 -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 the Addendum to the Validation of an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

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

QA Reviewer

(b) (6)
(b) (6) I reviewed this document
03 Nov 2020 05:06:33 -05:00

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Signature/Date

Sponsor Approval

Client: Moderna

PPD Project: RPPF2

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

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

Exception:

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

(b) (6)

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Rolando Pajon, Ph.D.
Director, Clinical Biomarkers



Signature/Date

Method Validation Plan Addendum 1 Amendment 1

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

1. A typographical error in the Nucleocapsid Antigen Experimental Design^[1] section states

(b) (4)

References

1. Method Validation Amendment: *Addendum to the Validation of an ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum*. RPPF2, v1.00. 21Oct2020.