



Qualification Statistical Report

Method: VSDVAC 64 Version 0.00, An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

PPD Project Code: ROZD2

Qualification of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

Version: 1.0

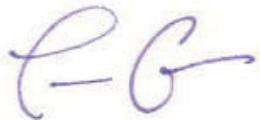
Conducted for PPD Laboratory

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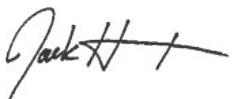
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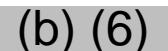
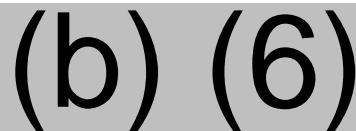
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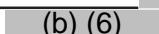


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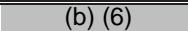
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EXPERIMENT BACKGROUND AND PURPOSE

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 was qualified by PPD® Laboratories, in Richmond, Virginia, USA. The qualification of this new method was conducted under PPD Project Code “ROZD2”. The new method, VSDVAC 64^[1], will be finalized to version 1.00 after qualification.

A qualification plan^[2] was developed and approved to qualify the SARS-CoV-2 Nucleocapsid ELISA. The purpose of the qualification experiment was to establish the (b) (4)

(b) (4)

(b) (4)

of the SARS-CoV-2 Nucleocapsid protein. The

purpose of this report is to document the operating characteristics of the assay. The SARS-CoV-2 operating characteristics are summarized below and in [Table 1](#).

Qualification Results Summary

Assay

Characteristic

Qualification Results

(b) (4) (4)

**Assay
Characteristic****Qualification Results**

(b) (4)

Assay Characteristic	Qualification Results
	(b) (4)

Scientific Contribution

The SARS-CoV-2 nucleocapsid ELISA is considered qualified. The (b) (4)
(b) (4) were deemed acceptable upon completion of the statistical analysis.

(b) (4)

(b) (4)

Conclusion

The SARS-CoV-2 nucleocapsid ELISA will be considered qualified with regard to (b) (4)
(b) (4) (b) (4) will be documented in an addendum.

The method will be finalized upon completion of all addenda.

Table 1
Parameter Summary Table
All limits are inclusive unless otherwise noted.

Assay Characteristic	SARS-CoV-2 N
(b) (4)	

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ACRONYMS AND DEFINITIONS

Acronyms	Definitions
Abs	Absolute
Ab[C]	Antibody Concentration
ADHS	Antibody-depleted Human Serum
AU/mL	Arbitrary Antibody Units per Milliliter
BB	Blocking Buffer (assay diluent)
Conc.	Antibody Concentration Measured in AU/mL
Diff	Difference
	(b) (4)
EC50	Concentration Corresponding to the Median Response
ELISA	Enzyme-Linked Immunosorbent Assay
Exp.	Expected

(b) (4)

GM	Geometric Mean
GMC	Geometric Mean Antibody Concentration
GMedC	Geometric Median Concentration
IgG	Immunoglobulin-G

(b) (4)

mL	Milliliter(s)
NA	Not Applicable
NE	Not Estimable
NIH	National Institute of Health
NT	Not Tested
Obs.	Observed
OD	Optical Density
PF	Plate Failure
QA	Quality Assurance
QC	Quality Control
QCS	Quality Control Serum or Samples
	(b) (4)
Ratio	Maximum(OD)/Minimum(OD)
Rep	Replicate

(b) (4)

Run	A group of analytical samples consisting of standard curve, QCS, blank and test samples processed across a minimum of one plate.
SARS	Sudden Acute Respiratory Syndrome
SAS	Statistical Analysis Software
	(b) (4)
SOP	Standard Operating Procedure
SPAR	See Periodic Analysis Results (trending)
	(b) (4)
TBD	To be determined.
	(b) (4)
VSD	Vaccine Sciences Department
Work Order	Unique run identifier assigned by LIMS
	(b) (4)

SCOPE

The scope of this qualification is limited to documenting the operating characteristics of the method for the detection of IgG specific to SARS-CoV-2 Nucleocapsid protein in human serum. All sample test results will be used for assay qualification purposes only and will not be included in the analysis of any clinical trial or epidemiology study. The assay and data are not designed for medical or diagnostic purposes and will be used to support Phase I/II studies only.

STUDY OBJECTIVES & DESIGN

Study Objectives

For the assay under evaluation, the objectives of the qualification experiments were to:

(b) (4)

Plate Layout

The following sample types were analyzed in each qualification run:

(b) (4)

An example of the typical plate layout is provided in [Figure 1](#).

Figure 1
Generic Plate Layout

(b) (4)

EXPERIMENTAL DESIGN

The ELISA assay qualification was

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Refer to Table 4 and Table 5 for the experimental design and list of samples used in each experiment.

(b) (4)

To accomplish these experiments, all samples were analyzed

(b) (4)

(b) (4)
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(b) (4)

example plate layout in Figure 2.

Refer to

Table 2

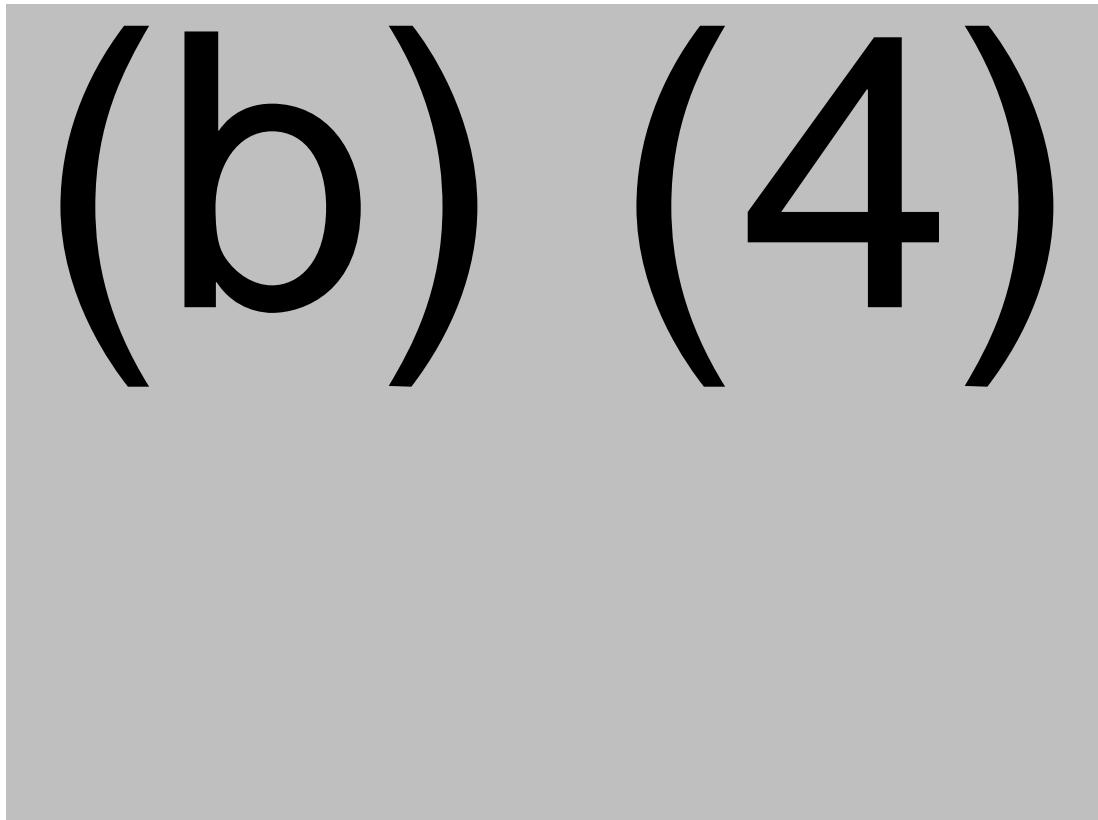
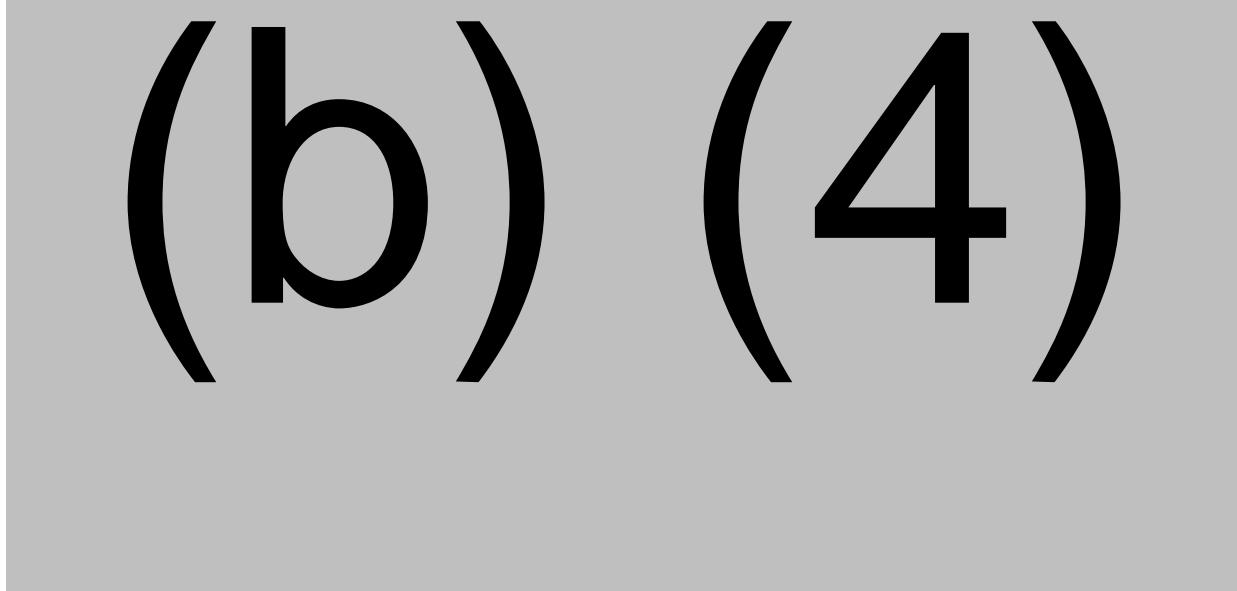


Figure 2

(b) (4) Plate Map for (b) (4) (b) (4)

(b) (4)



(b) (4)

(b) (4)

experimental design and plate layout are depicted in [Table 4](#) and [Figure 3](#), respectively.

The

(b) (4)

Table 3

(b) (4)

Figure 3

(b) (4)

Plate Map for

(b) (4)

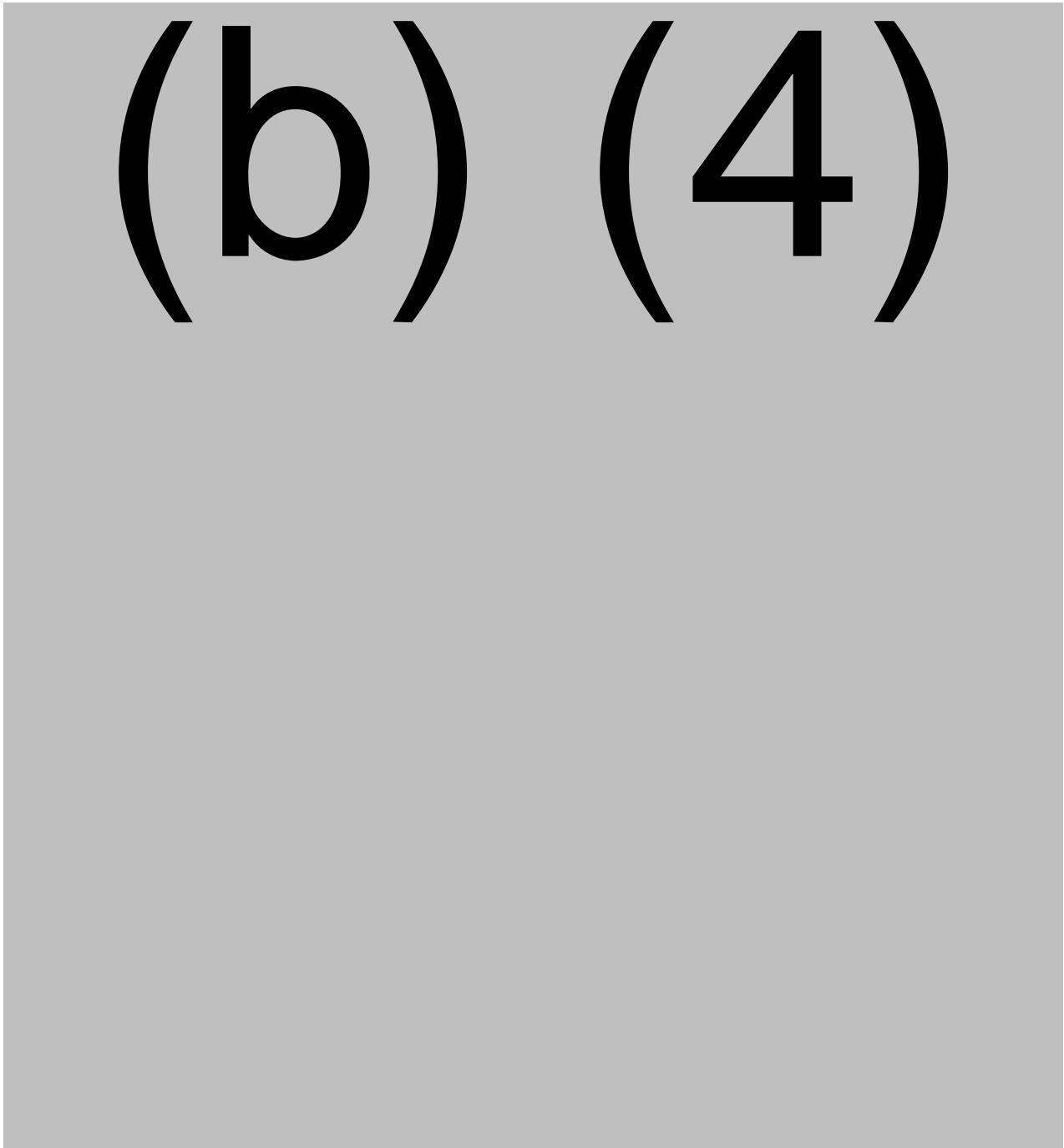


Figure 3

(b) (4)

Plate Map for

(b) (4)



(b) (4)

– Addendum 1

(b) (4)

Figure 3.1

(b) (4)

Plate Map for

(b) (4)

Addendum

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4) The experimental design and plate layout are depicted in [Table 4](#) and [Figure 4](#) respectively.

(b) (4)

(b) (4)

Figure 4
Plate Map for (b) (4)

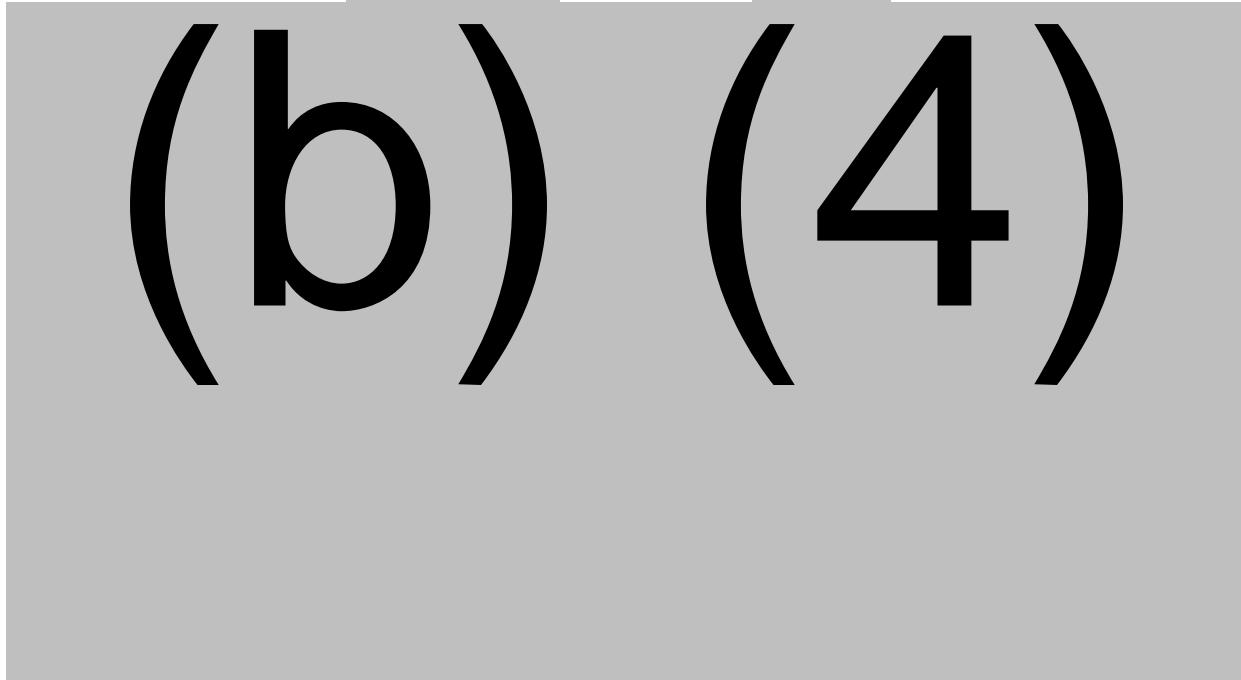


Table 4
Experimental Design

(b) (4), (b) (6)

Table 5
Sample Description for Samples Used within Each of the Experiments

Experiment	Sample # in Report	Sample	Serum ID
(b) (4)			

Experiment	Sample # in Report	Sample	Serum ID
(b) (4)			

STATISTICAL METHODS AND RESULTS

(b) (4)

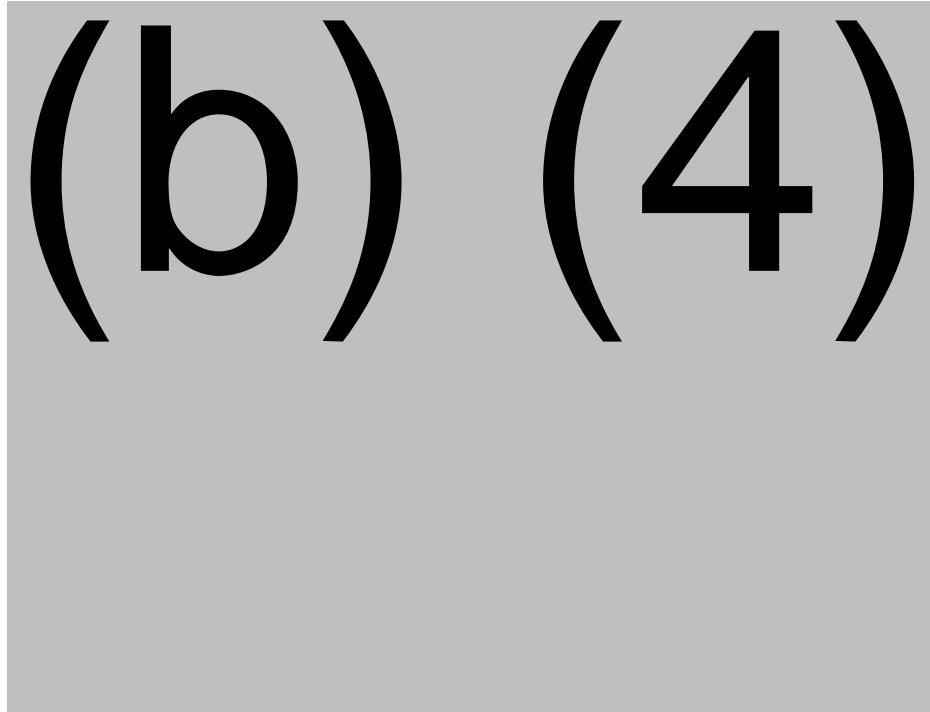
Figure 5

(b) (4)

Table 7

(b) (4)

Table 8



(b) (4)

Blank Well

(b) (4)

Quality Control Samples (QCS)

(b) (4)

Run Suitability

Using the criteria stated above, the assay run is considered invalid if > (b) (4) of the plates fail.

Table 9

(b) (4)

Table 10

(b) (4)

(b) (4)

Table 11

(b) (4)

Figure 6

(b) (4)

(b) (4)

(b) (4)

Figure 7

(b) (4)

Table 13

(b) (4)

Table 14

(b) (4)

Figure 8

(b) (4)

(b) (4)

Table 15

(b) (4)

(b) (4)

Figure 9

(b) (4)

(b) (4)

Table 17

(b) (4)

Table 17.1

(b) (4)

Figure 10

(b) (4)

(b) (4)

Table 18

(b) (4)

References

1. Draft Method: VSDVAC 64: *An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum*, V0.00.
2. (b) (4).
3. PPD Method Qualification Plan: *Qualification of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum*, ROZD2, 18Jun2020.
4. PPD Method Qualification Plan Amendment 1: *Qualification of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum*, ROZD2, 24Jun2020.
5. PPD Method Qualification Plan Addendum 1: Qualification of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum, ROZD2, 29Jun2020.
6. Event QEI #1867. ROZD2 - (b) (4) plate reader output Experiment File Name field entered incorrectly, Date opened 02Jul2020.

Revision History

Version	Date	Author	Reason for Revision
1.0	06-July-2020	Tina Green	Original Version

Attachment I

(b) (4)

Attachment II
QCS Graphs

(b) (4)

Attachment III
Standard Curve and QCS Summary

(b) (4)

(b) (4)

Attachment IV

(b) (4)

Attachment V

(b) (4)

Attachment V

(b) (4)

Attachment V

(b) (4)

Attachment VI

(b) (4)

Attachment VII

(b) (4)

Attachment VII

(b) (4)

Attachment VIII

(b) (4)

Attachment VIII.1

(b) (4)

Attachment IX

(b) (4)