Qualification Statistical Report

Method: VSDVAC 58 Version 0.00, An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum

PPD Project Code: ROQP2

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

Version: 1.0

Conducted for PPD Laboratory

by PPD® Laboratories
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Original Document Date: 19 June 2020
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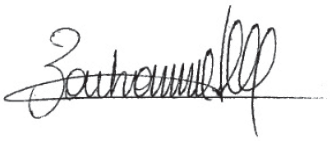

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EXPERIMENT BACKGROUND AND PURPOSE

A proprietary serological method, *An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike 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 "ROQP2". The new method, VSDVAC 58[1], will be finalized to version 1.00 after qualification.

A qualification plan[2] was developed and approved to qualify the SARS-CoV-2 ELISA. The purpose of the qualification experiment was to establish the (b) (4) (b) (4) (b) (4) of the SARS CoV-2 spike proteins. 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)	
Assay Validity Criteria	***The assay plate is considered invalid if*** (b) (4) ***The assay run is considered invalid if*** (6) (b) (4) of the plates fail (using the validity criteria described above).
Standard Curve Modeling	(b) (4)

Assay Characteristic	• Qualification Results
(b) (4)	

Scientific Contribution

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

(b) (4)

Conclusion

The SARS-CoV-2 ELISA is considered qualified with regard to (b) (4) (b) (4) The assay is also considered acceptably (b) (4) however, (b) (4) will be further confirmed in an Addendum to the Qualification Report.

The SARS-CoV2 spike ELISA is considered acceptable for use in the assessment of phase II clinical samples. (b) (4) (b) (4)

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

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

TABLE OF CONTENTS

ACRONYMS AND DEFINITIONS

Acronyms	Definitions
Abs	Absolute
Ab[C]	Antibody Concentration
(b) (4)	
Conc.	Antibody Concentration Measured in µg/mL
Diff	Difference
(b) (4)	
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)
SR	Spike and Recovery
(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 Spike 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)

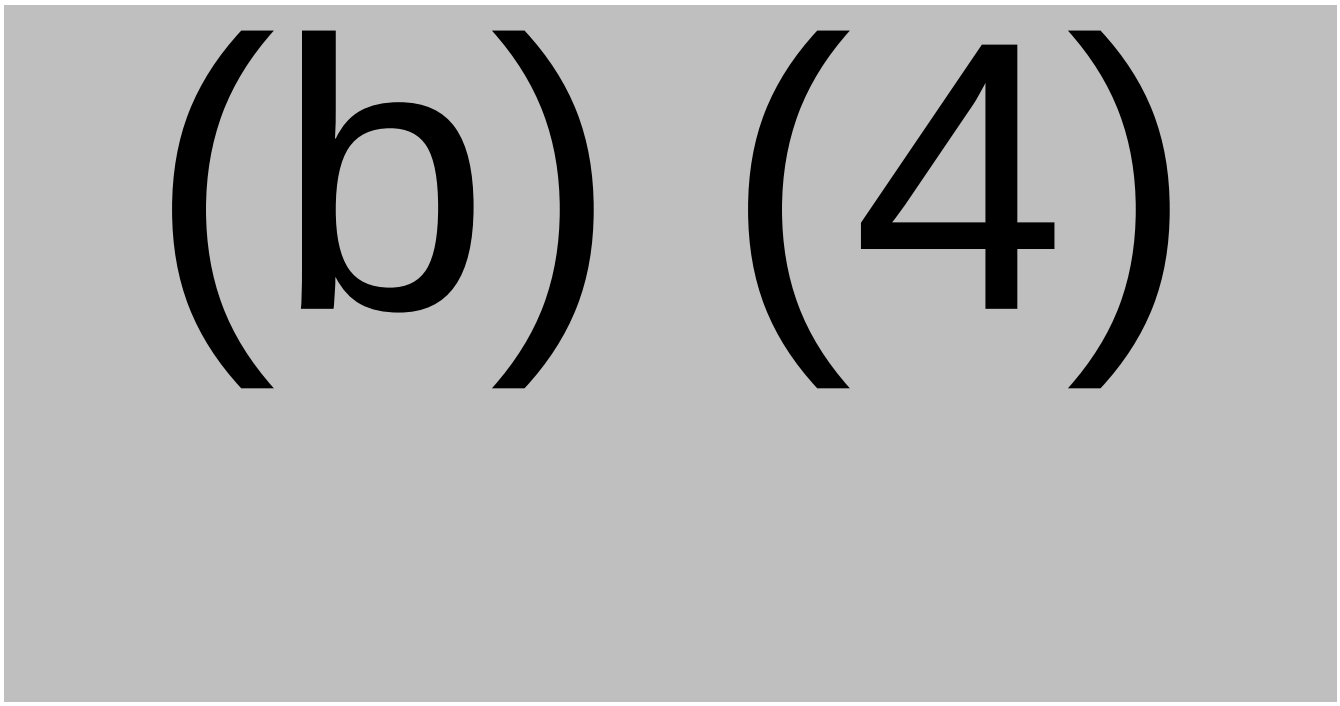
Plate Layout

The following sample types were analyzed in each qualification run:

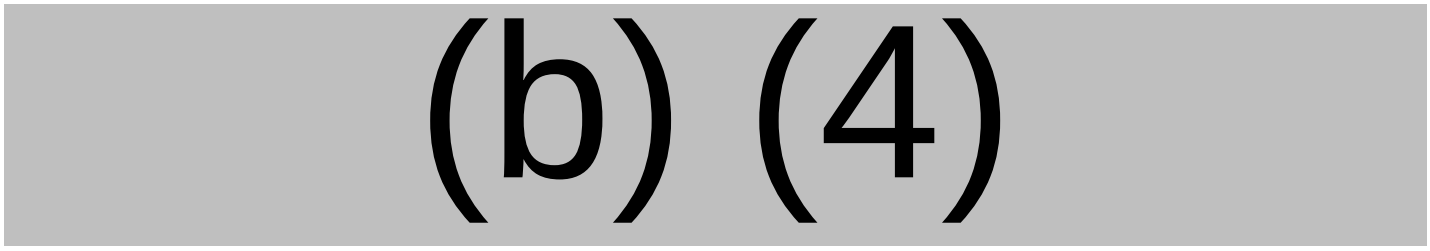
(b) (4)

An example of the typical plate layout is provided in Figure 1.

Figure 1
Generic Plate Layout



EXPERIMENTAL DESIGN



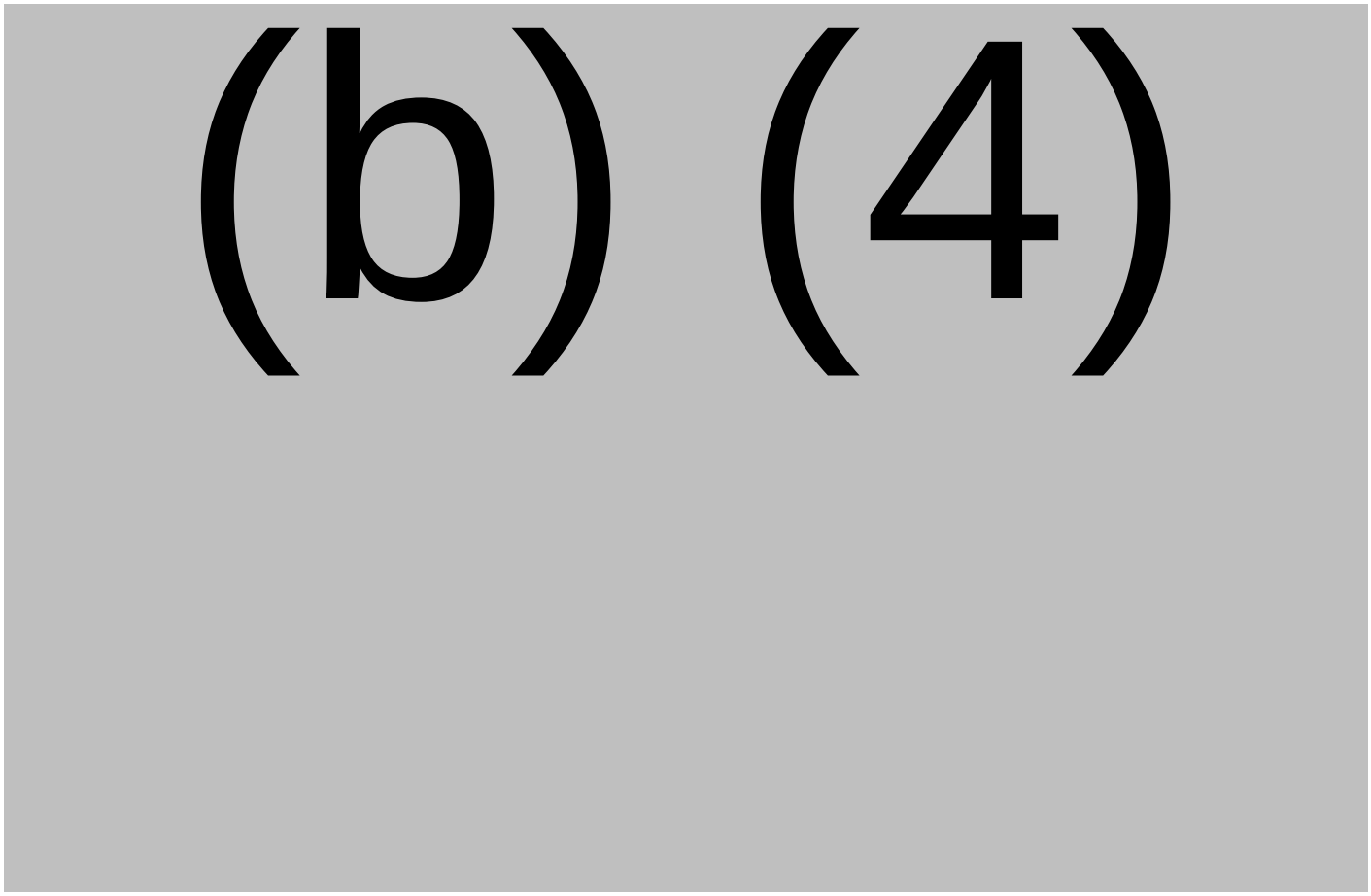

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Table 2
(b) (4)

(b) (4)

Figure 2

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Table 3

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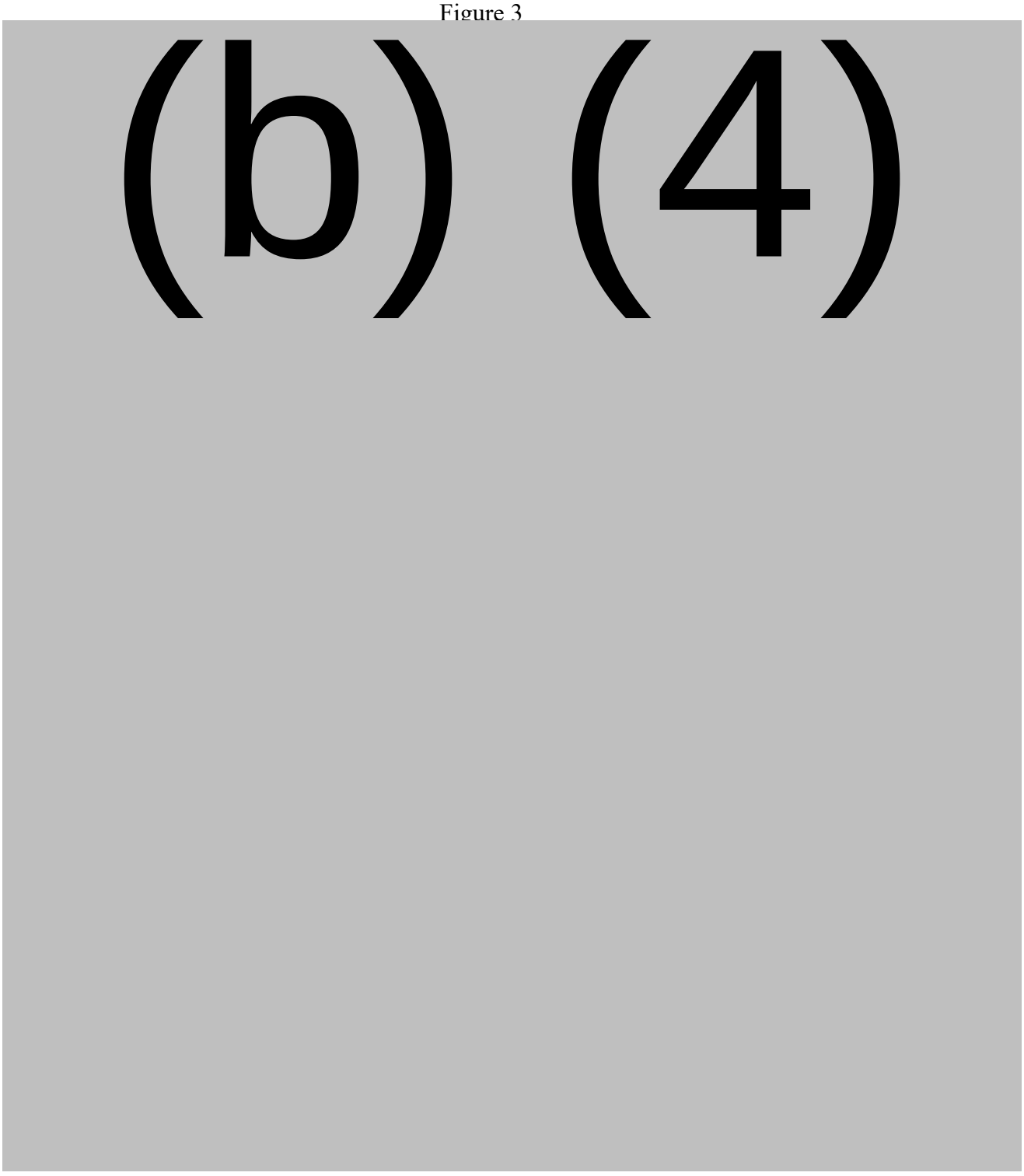
(b) (4)

Figure 3



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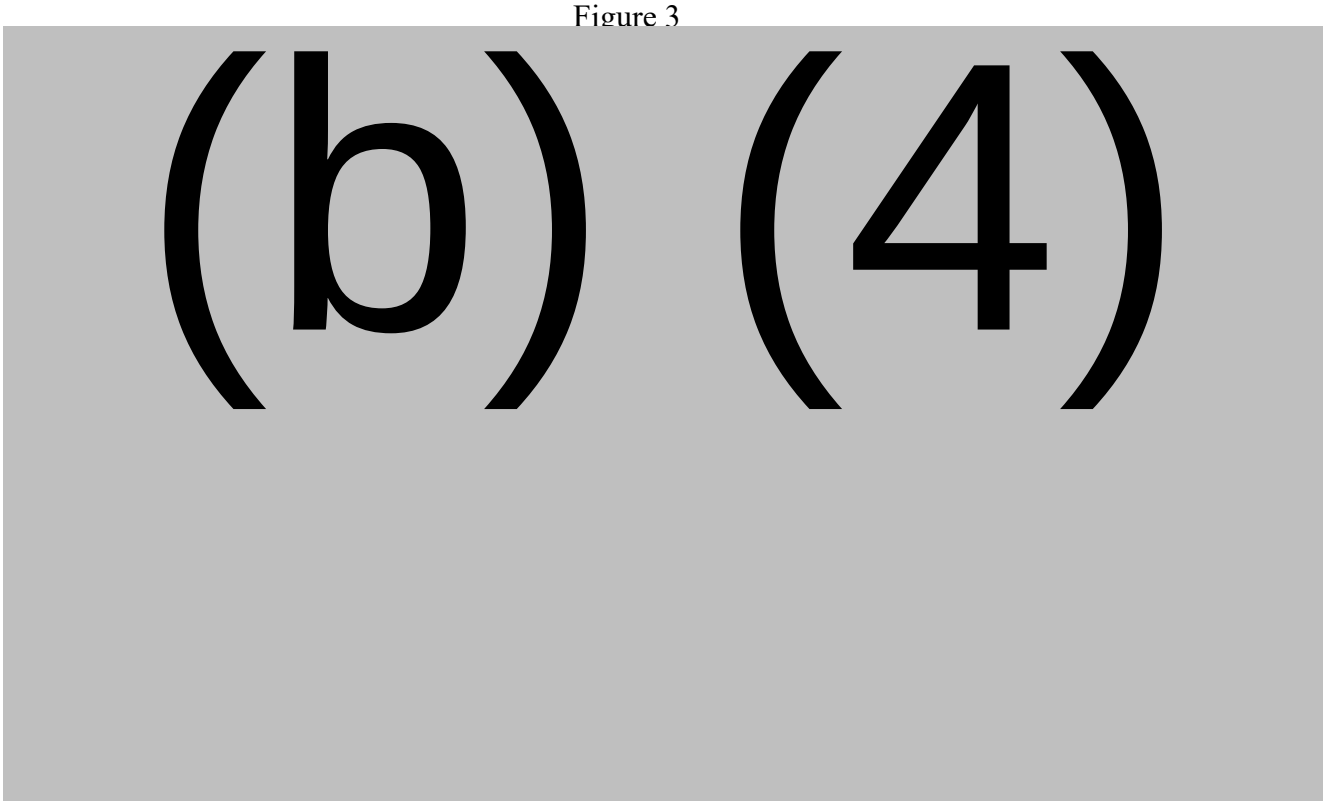

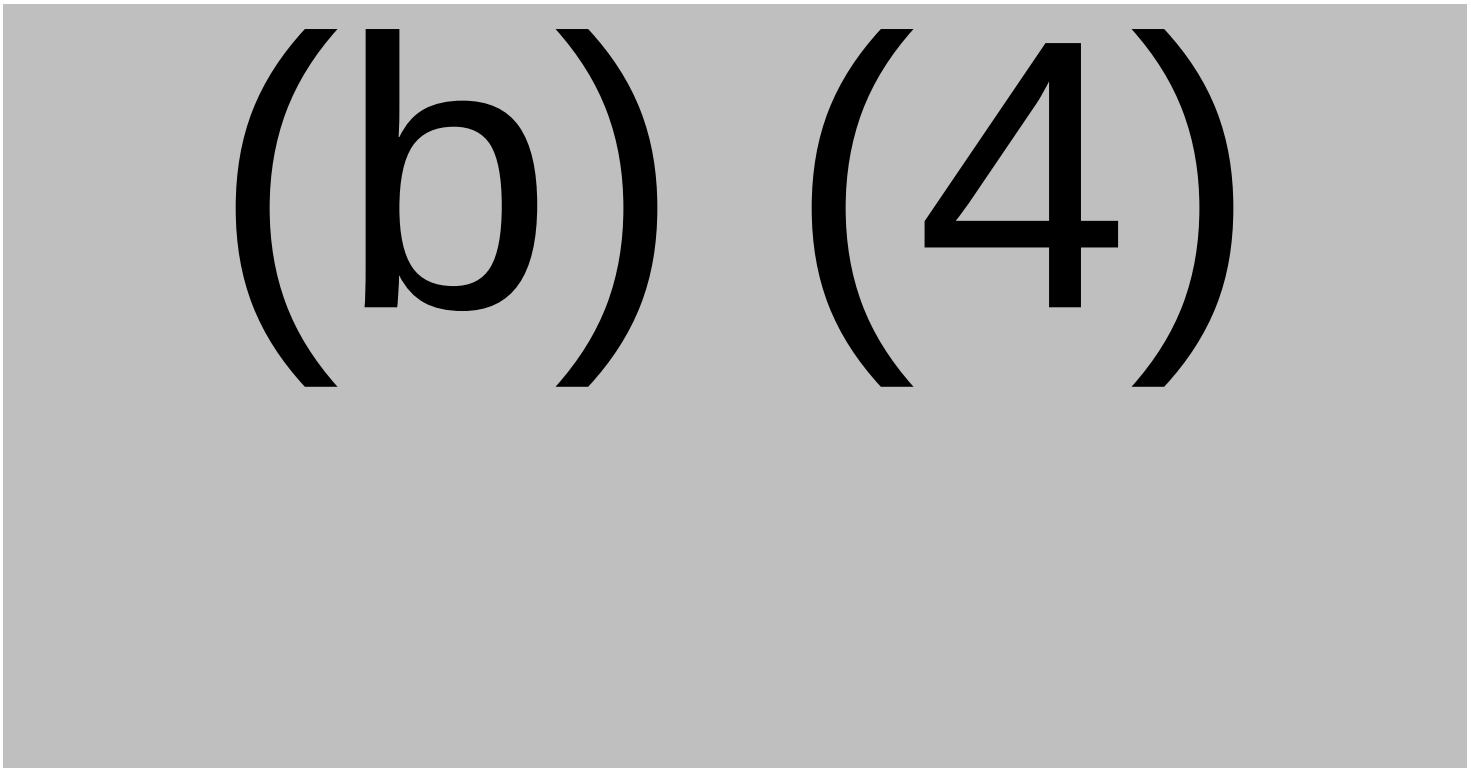

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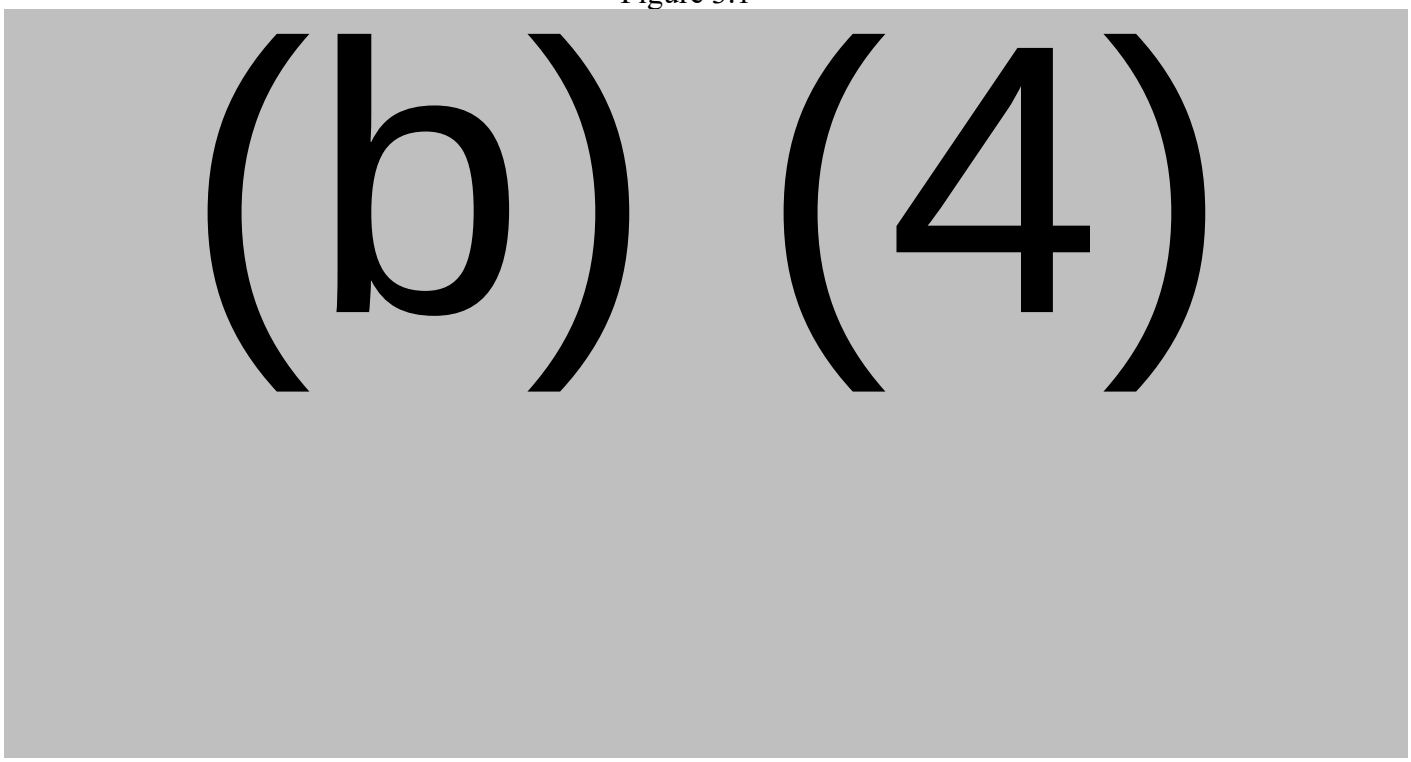

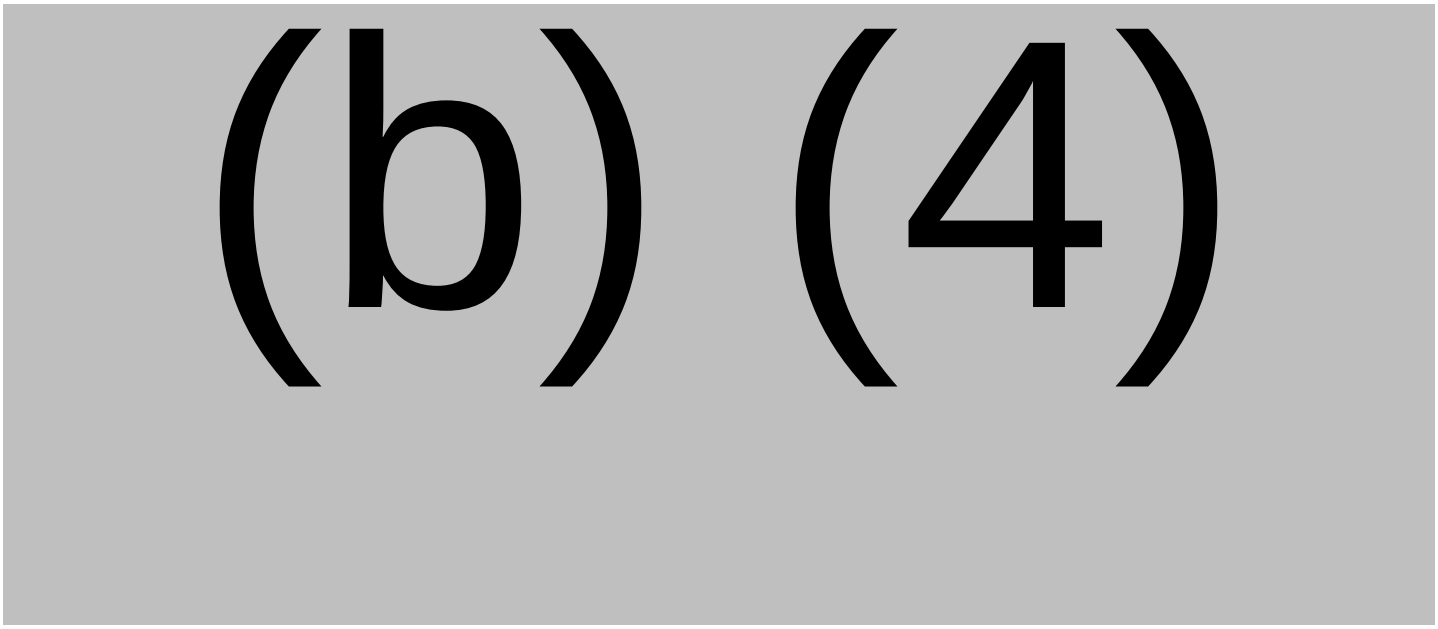

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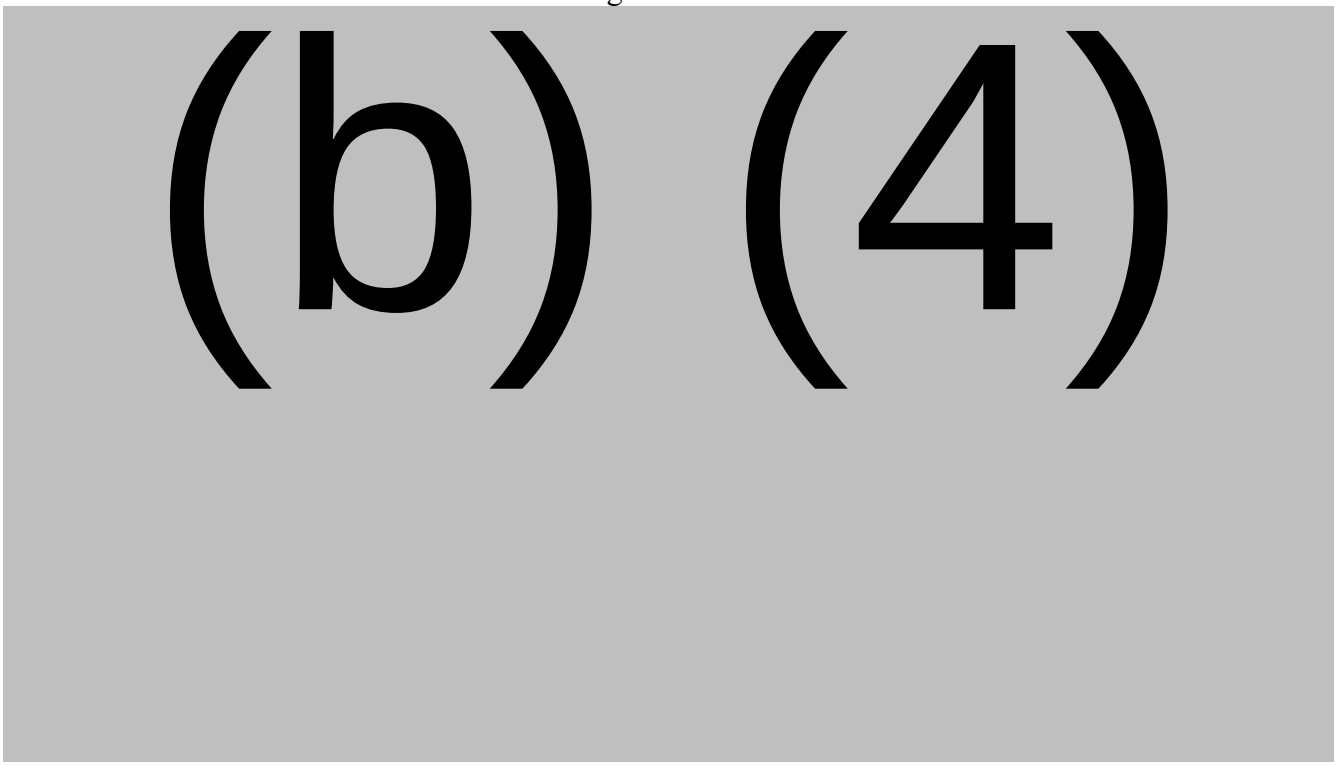

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Experimental Design

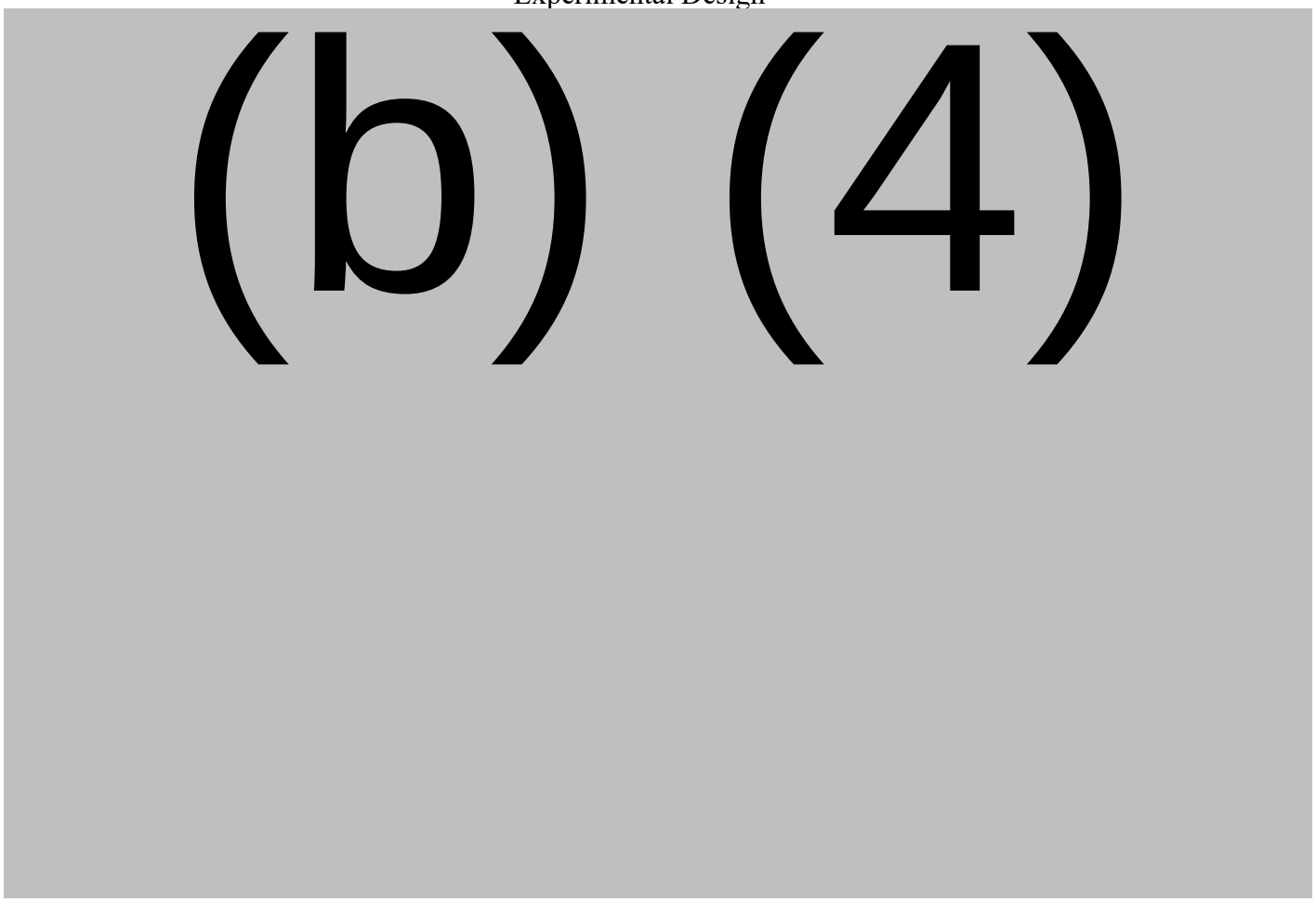

Table 5
Sample Description for Samples Used within Each of the Experiments

Experiment	Sample	Serum ID	Experiment	Sample	Serum ID
(b) (4)					

STATISTICAL METHODS AND RESULTS

(b) (4)

Figure 5

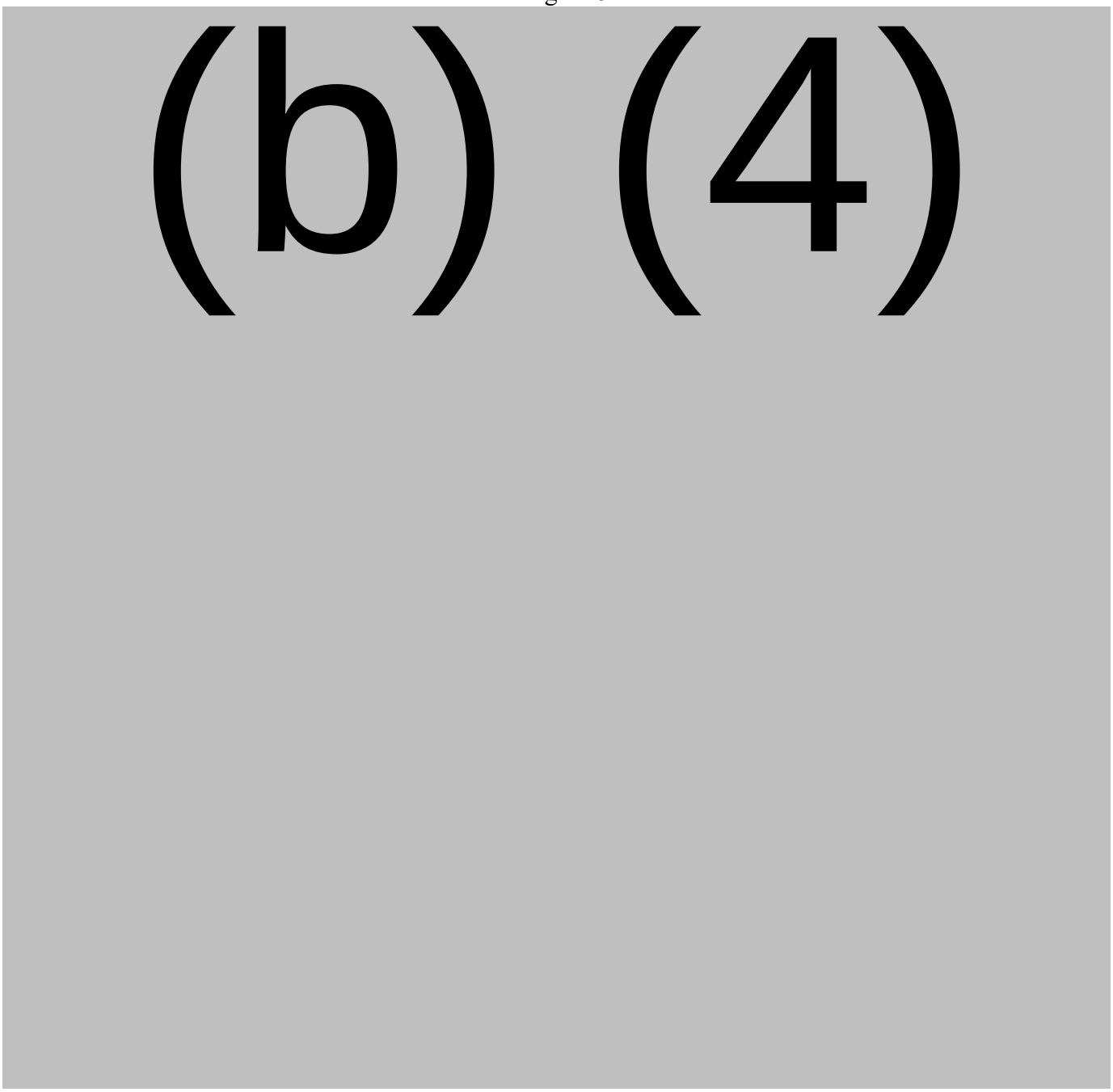

Table 7

(b) (4)

(b) (4)

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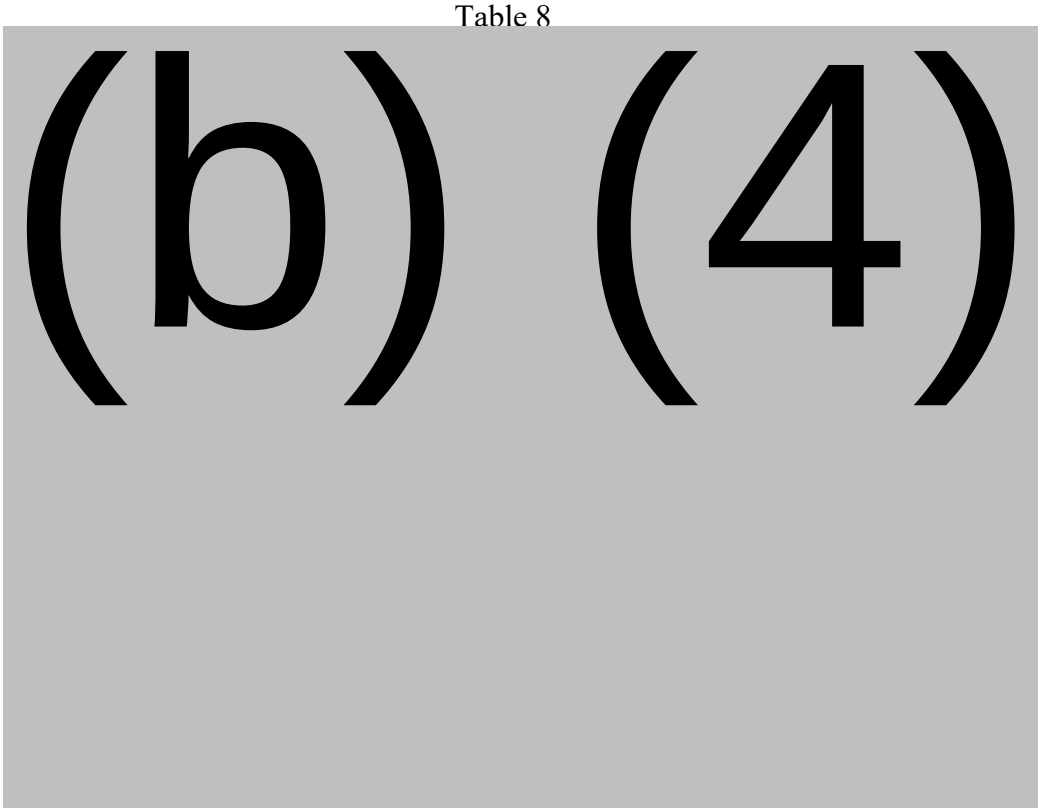

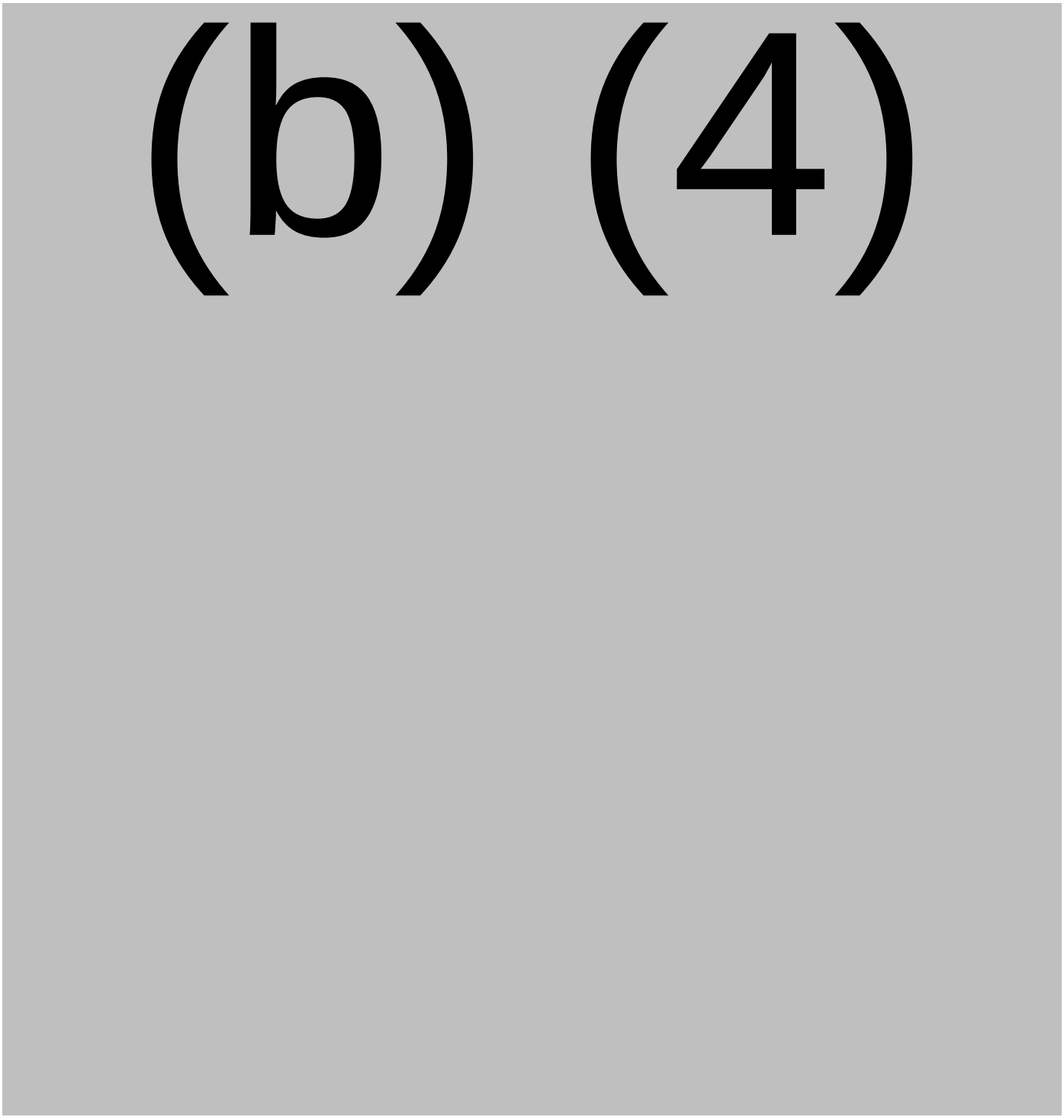
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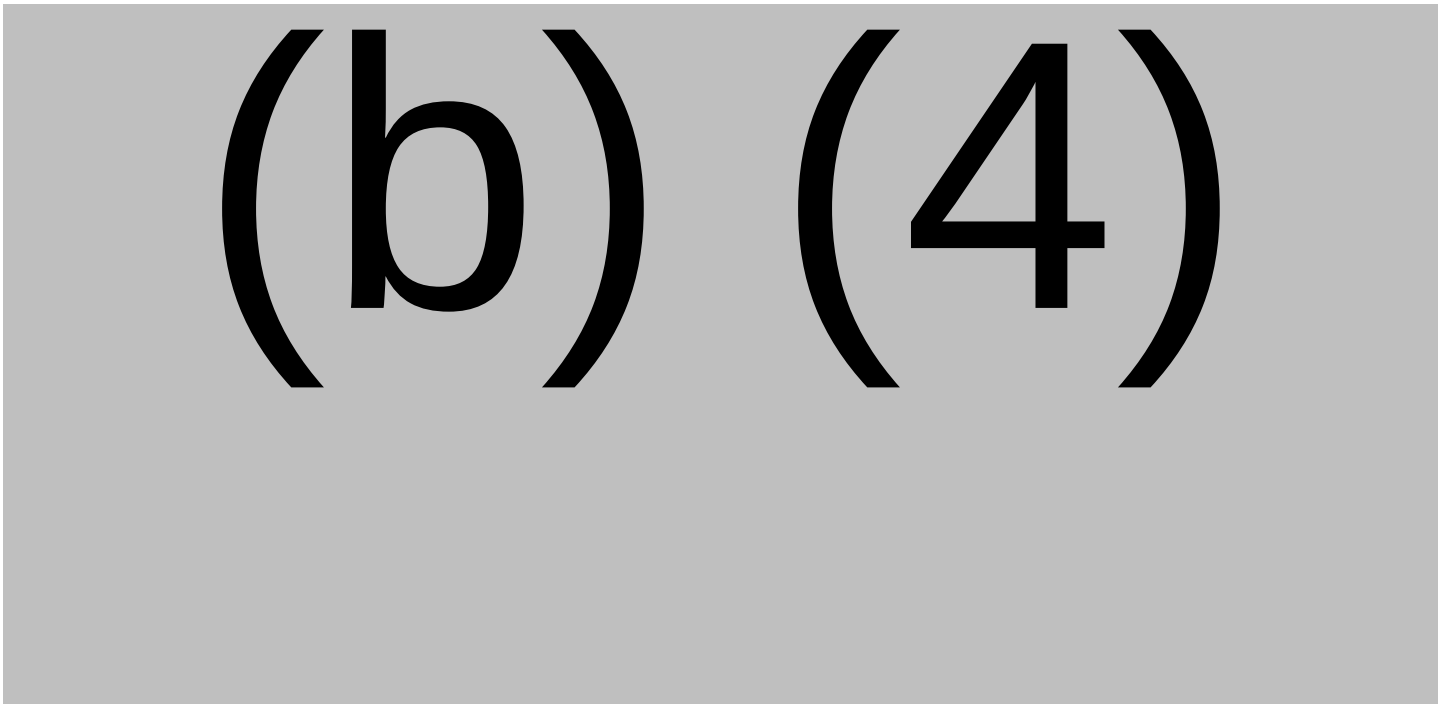
Quality Control Samples (QCS)



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

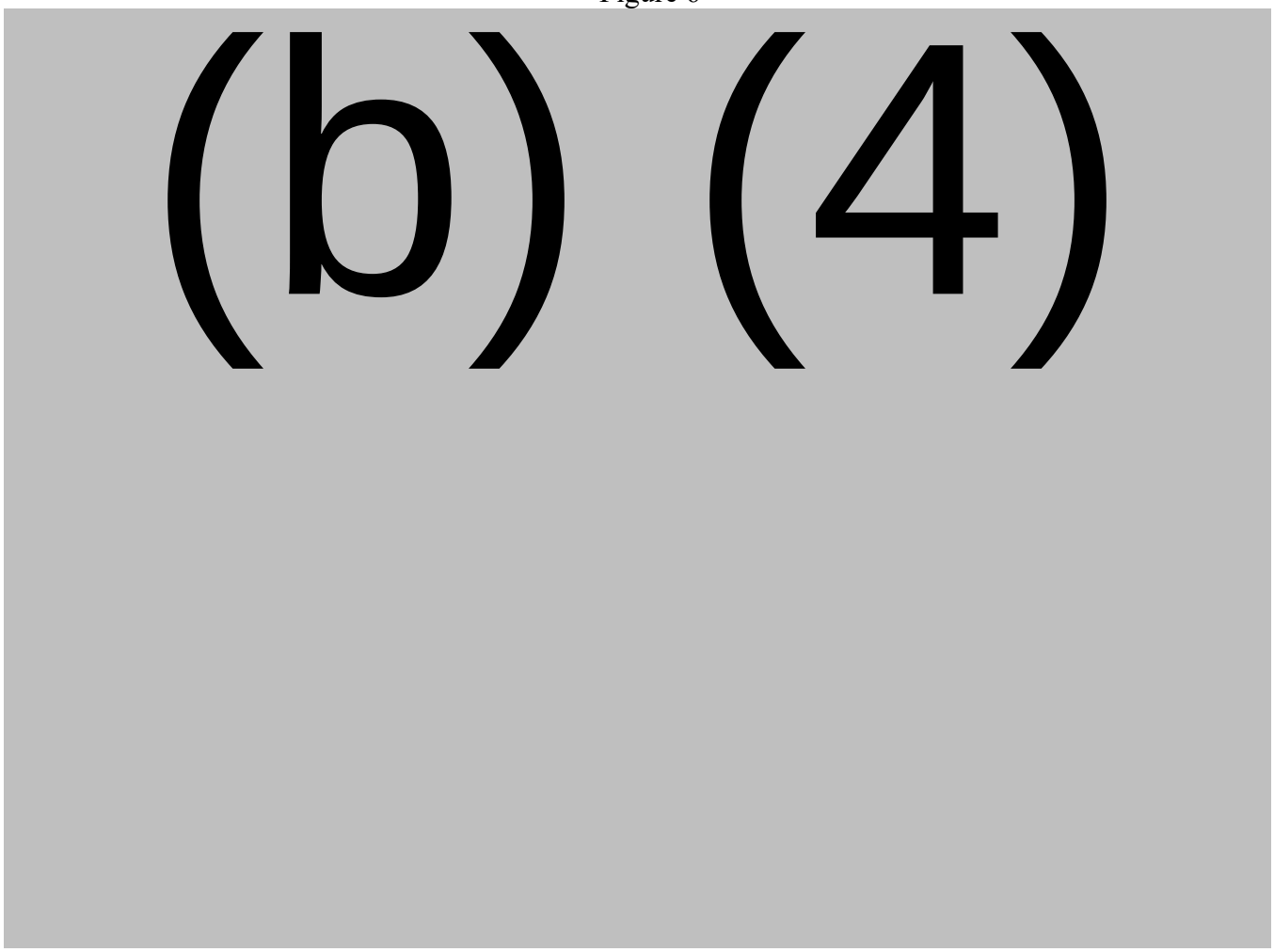
(b) (4)

(b) (4)

Table 11

(b) (4)

Figure 6



(b) (4)

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(b) (4)

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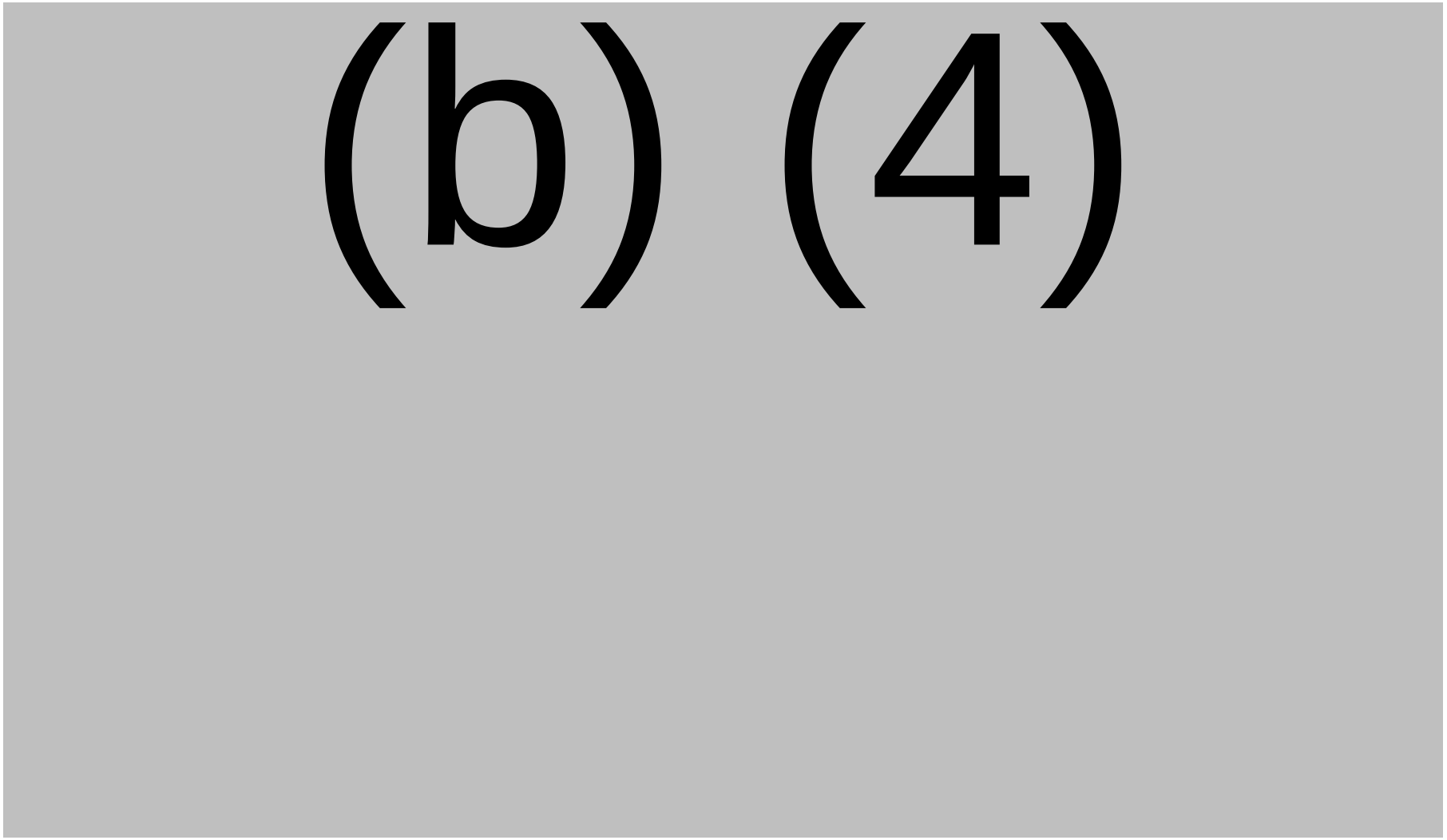


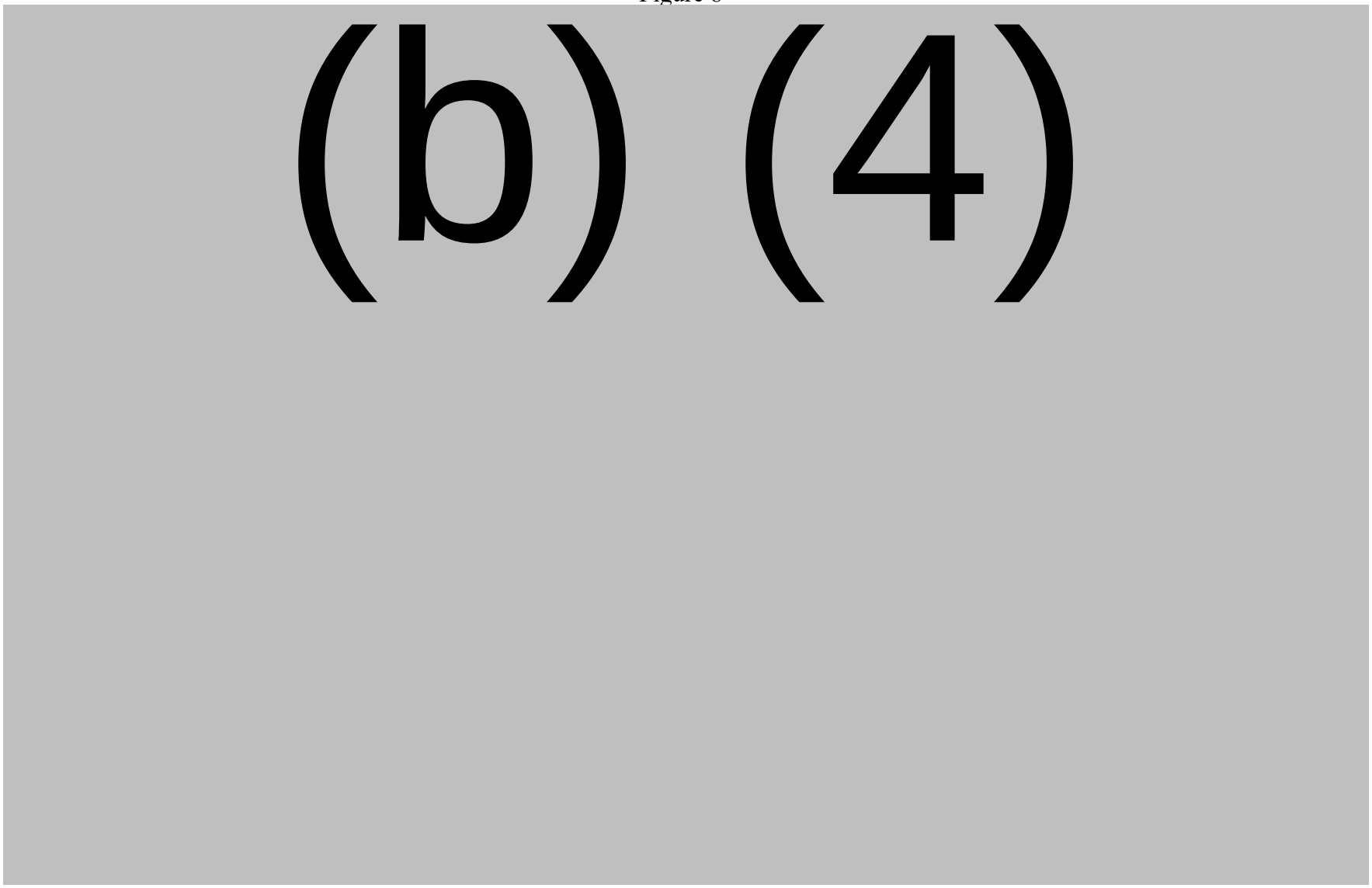
Table 13

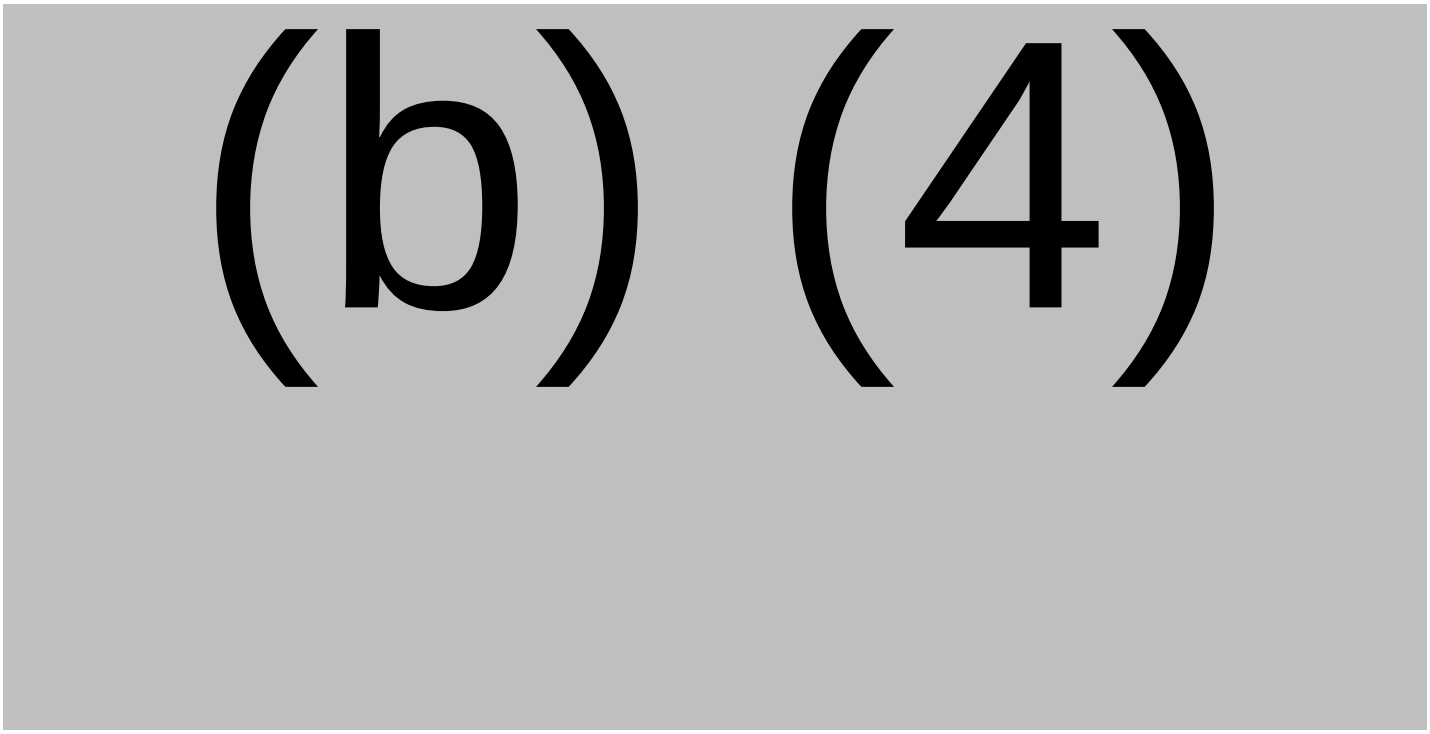
(b) (4)

Table 14

(b) (4)

Figure 8

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(b) (4)

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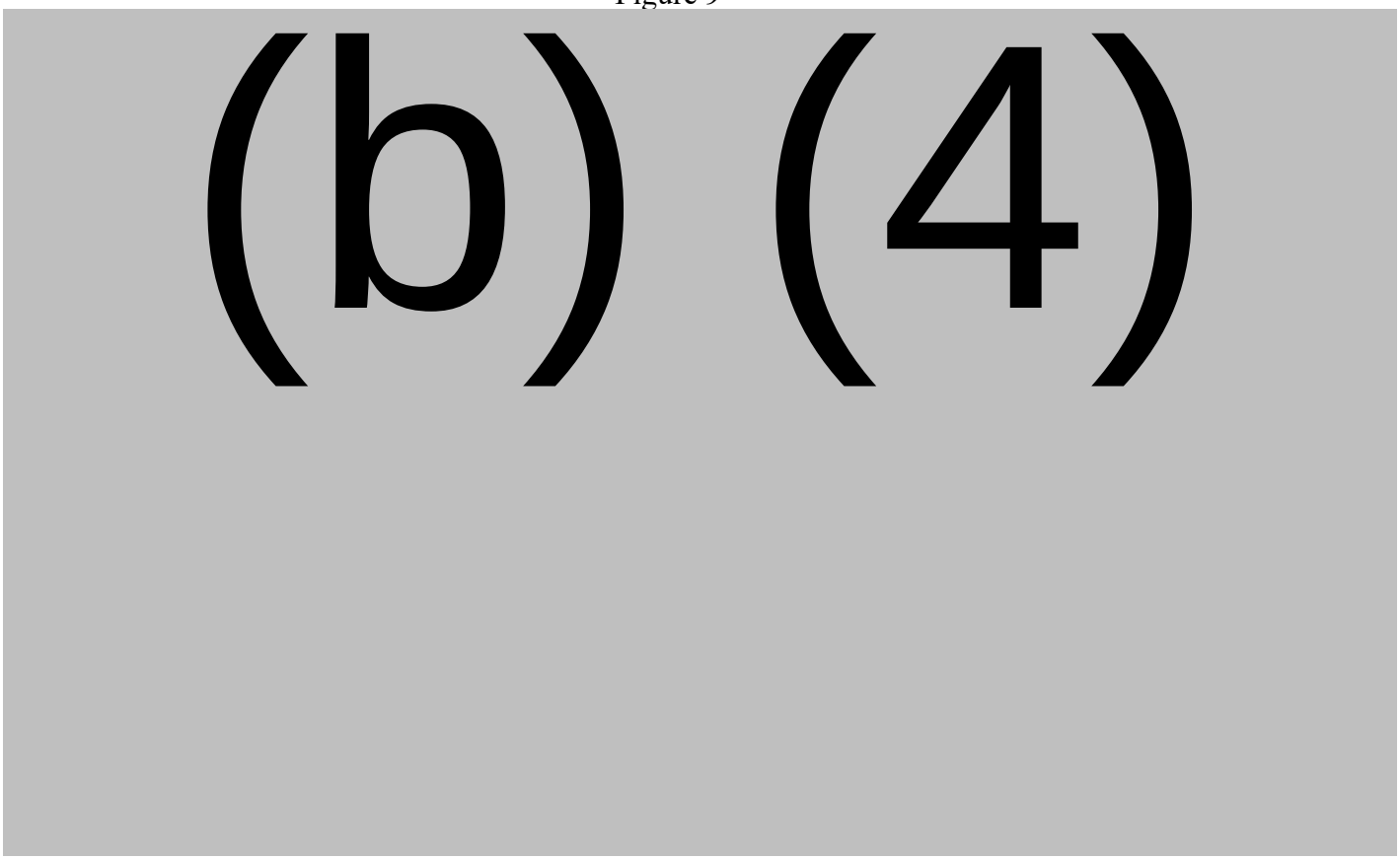

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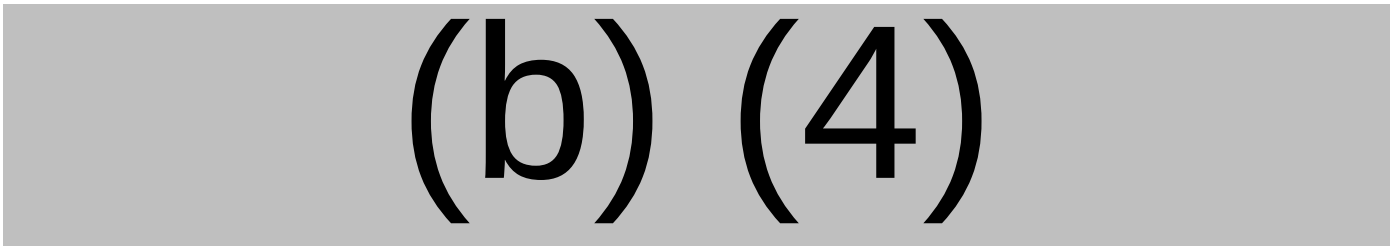

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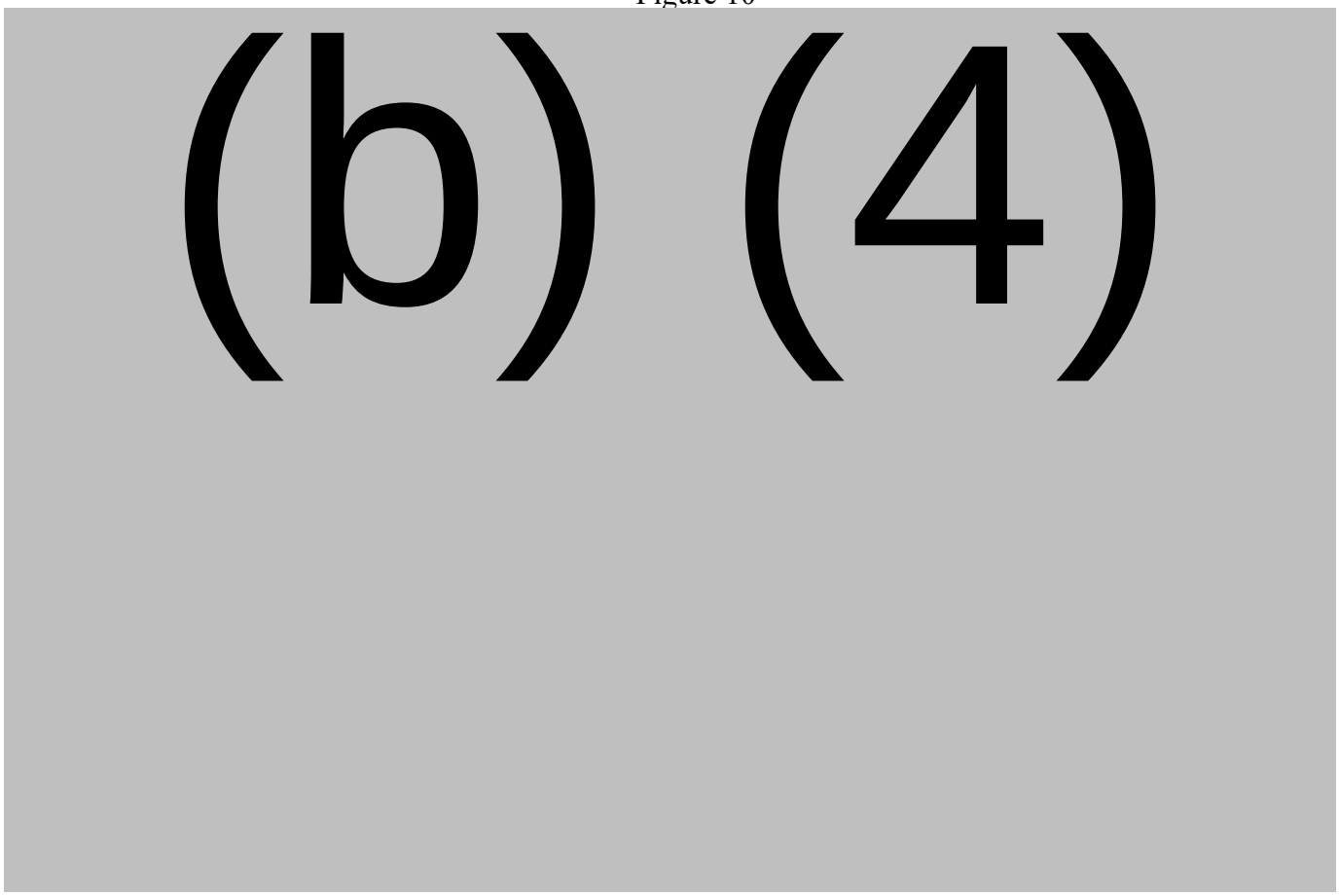

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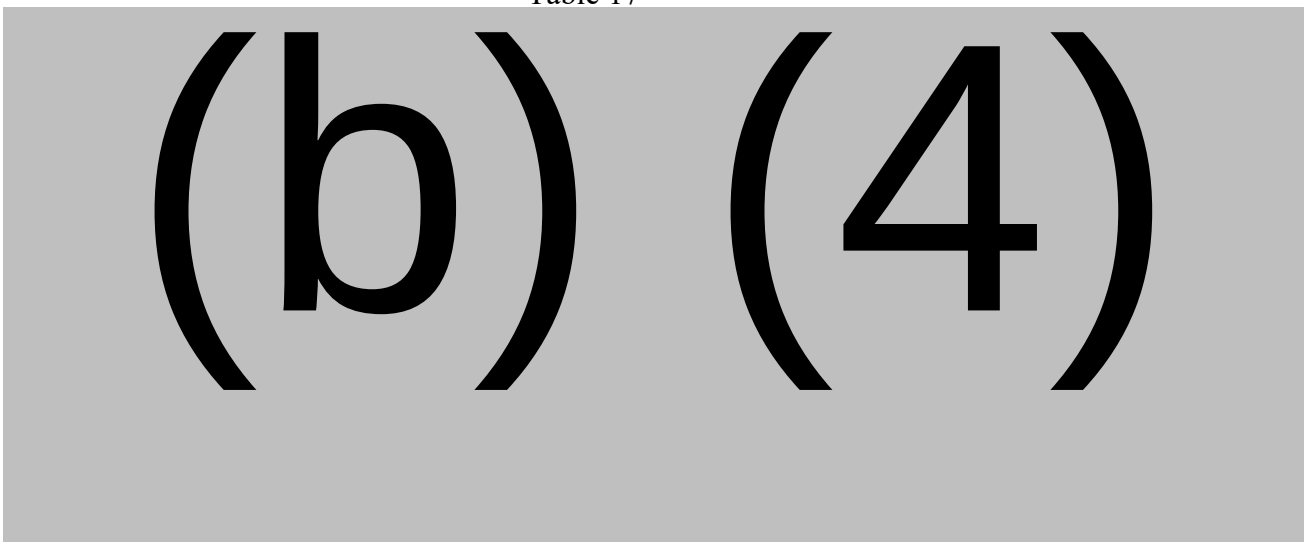

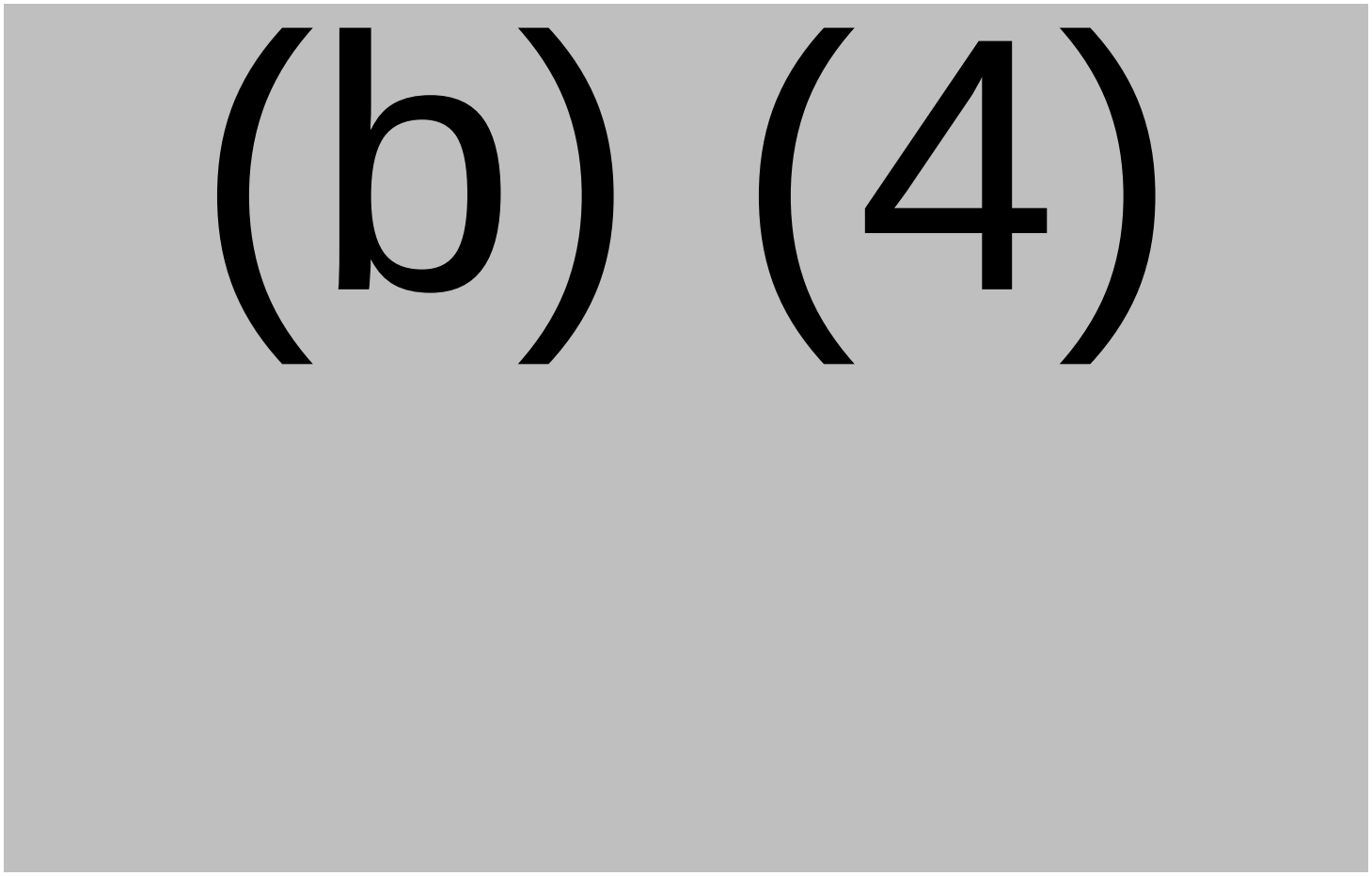
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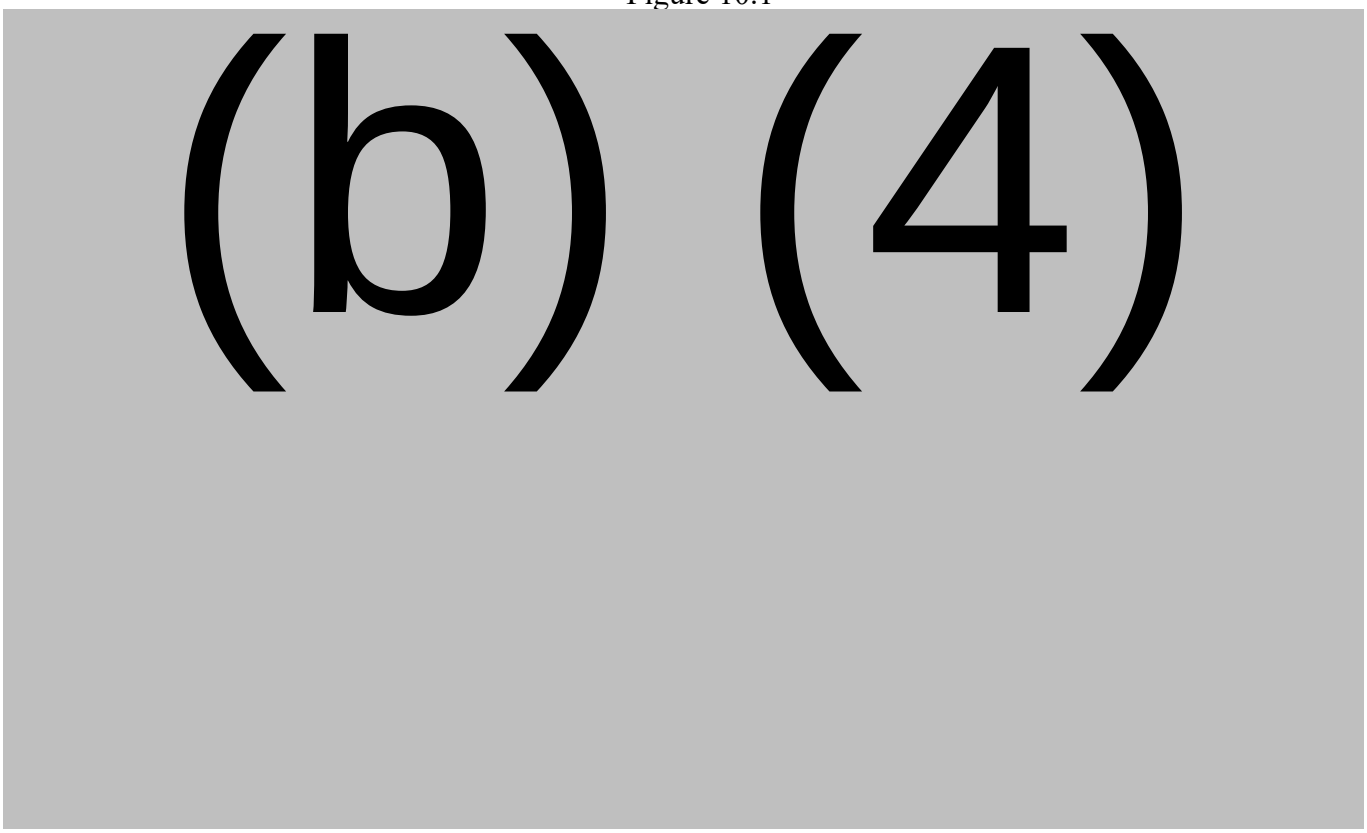

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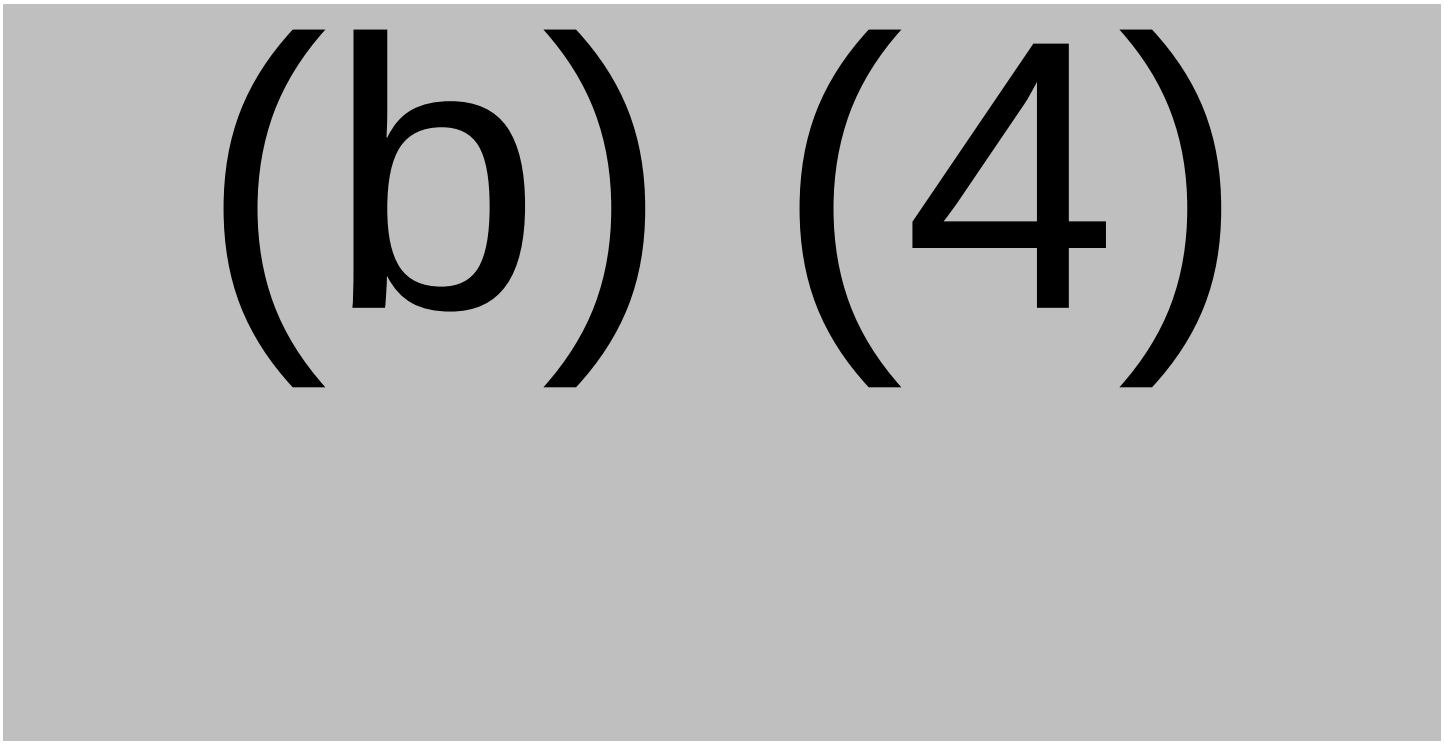


(b) (4)

Table 18

(b) (4)

References

1. Draft Method: VSDVAC58: *An ELISA method for the detection of IgG specific to SARS-CoV-2 Spike protein in human serum,* V0.00.

2. (b) (4)
(b) (4)

3. PPD Method Qualification Plan: *An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum.* ROQP2, 04Jun2020

4. PPD Method Qualification Plan Amendment 1: *Qualification of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum*. ROQP2, 05Jun2020

5. PPD Method Qualification Plan Amendment 2: *Qualification of An ELISA Method for the Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum*. ROQP2, 09Jun2020.

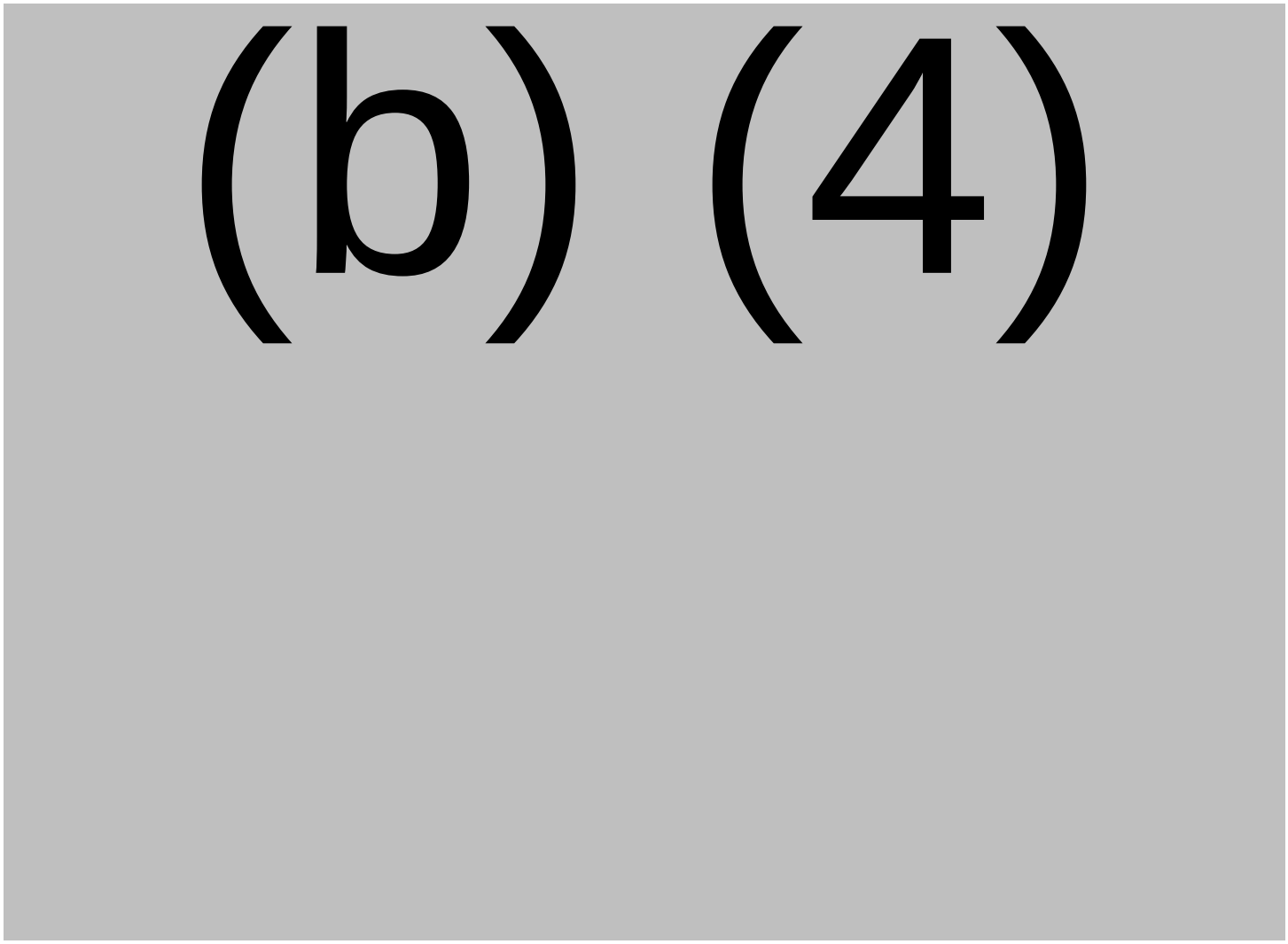
6. Event QEI #780. ROQP2: VSDVAC 58_QP (b) (4) Repeat, Date opened 11Jun2020.

7. Event QEI #694: ROQP2: Errors found in the VSDVAC 58 Qualification Plan, Date opened 08Jun2020.

Revision History

Version	Date	Author	Reason for Revision
1.0	19-June-2020	Tina Green	Original Version

Attachment I



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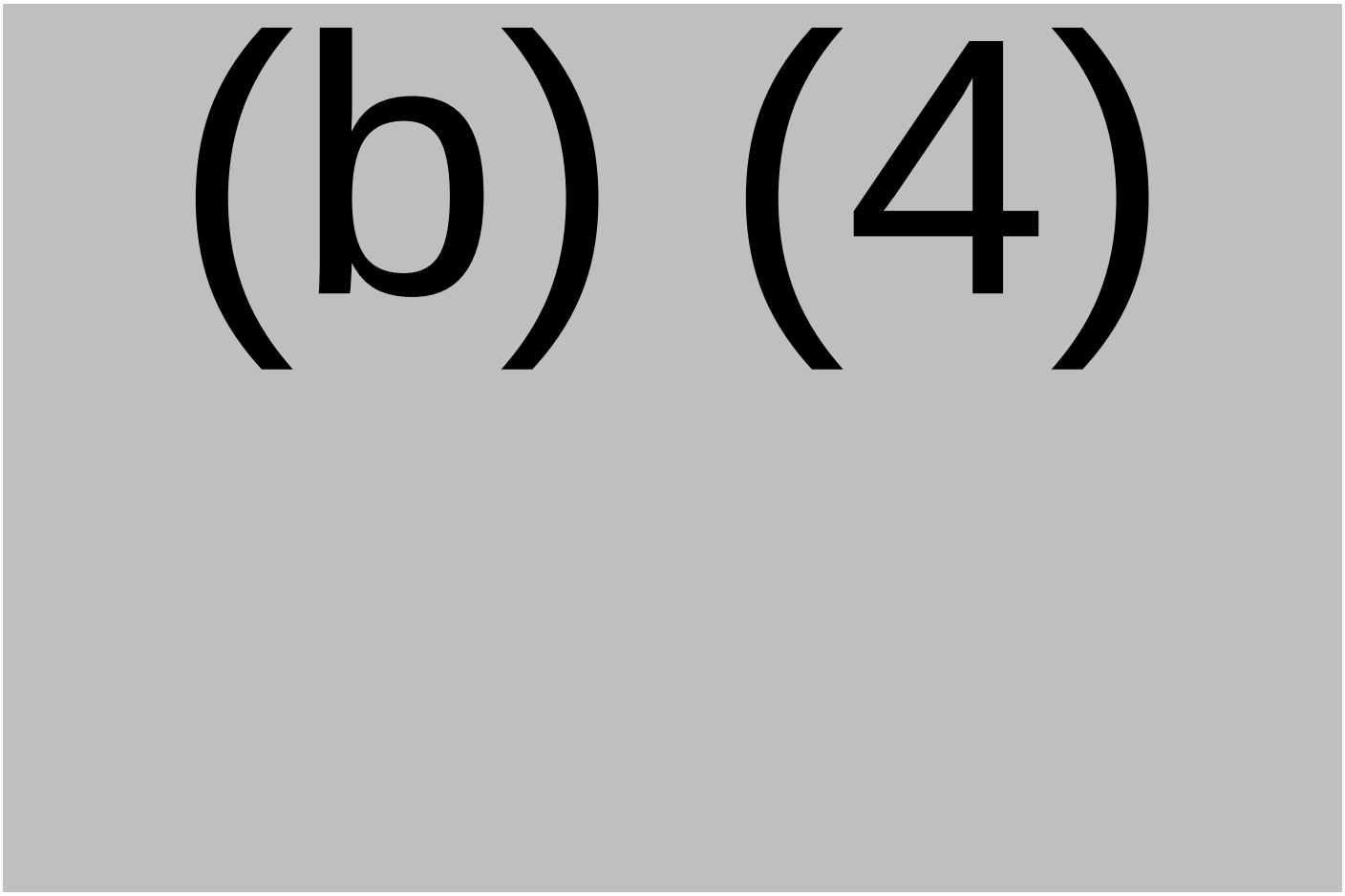

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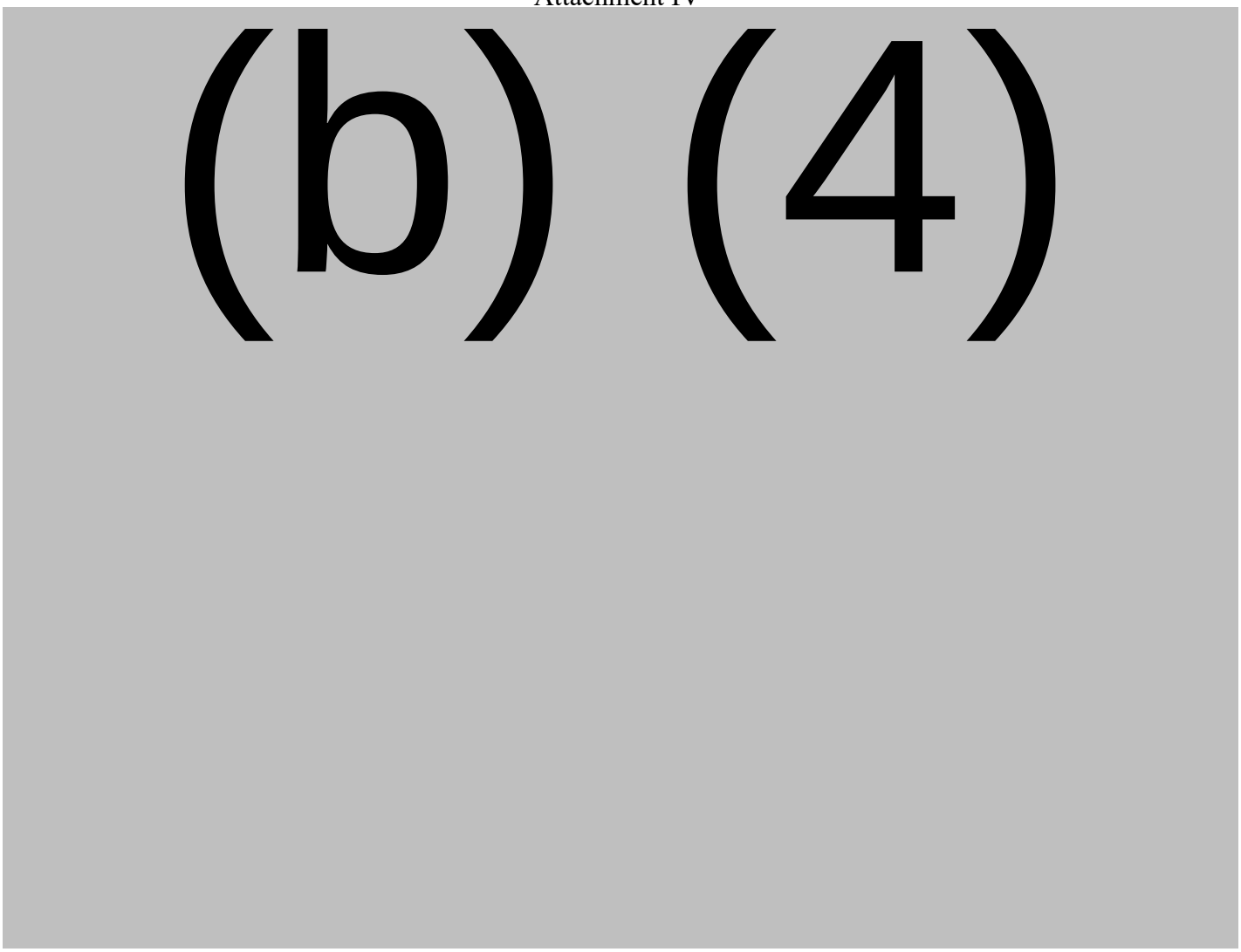

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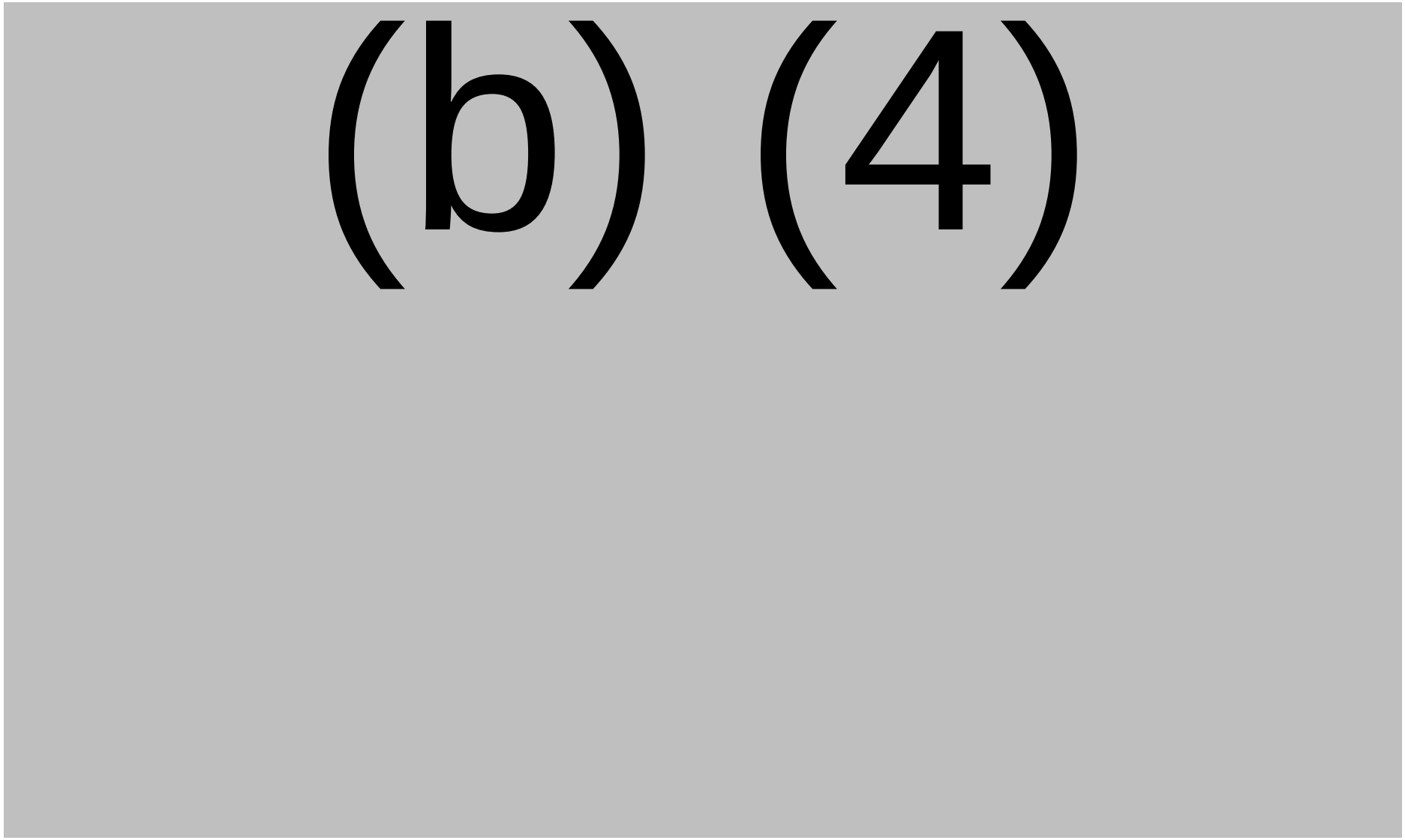

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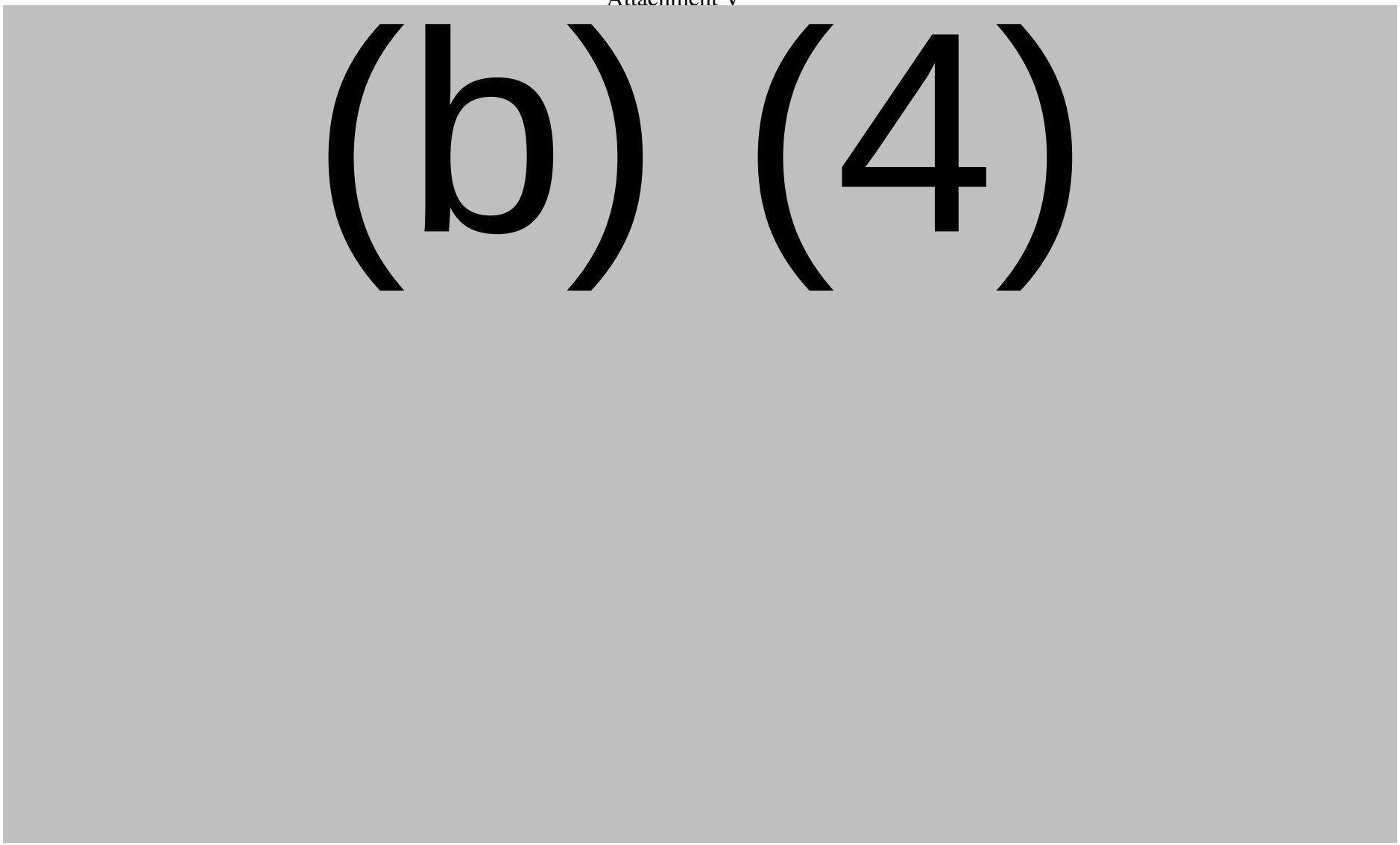

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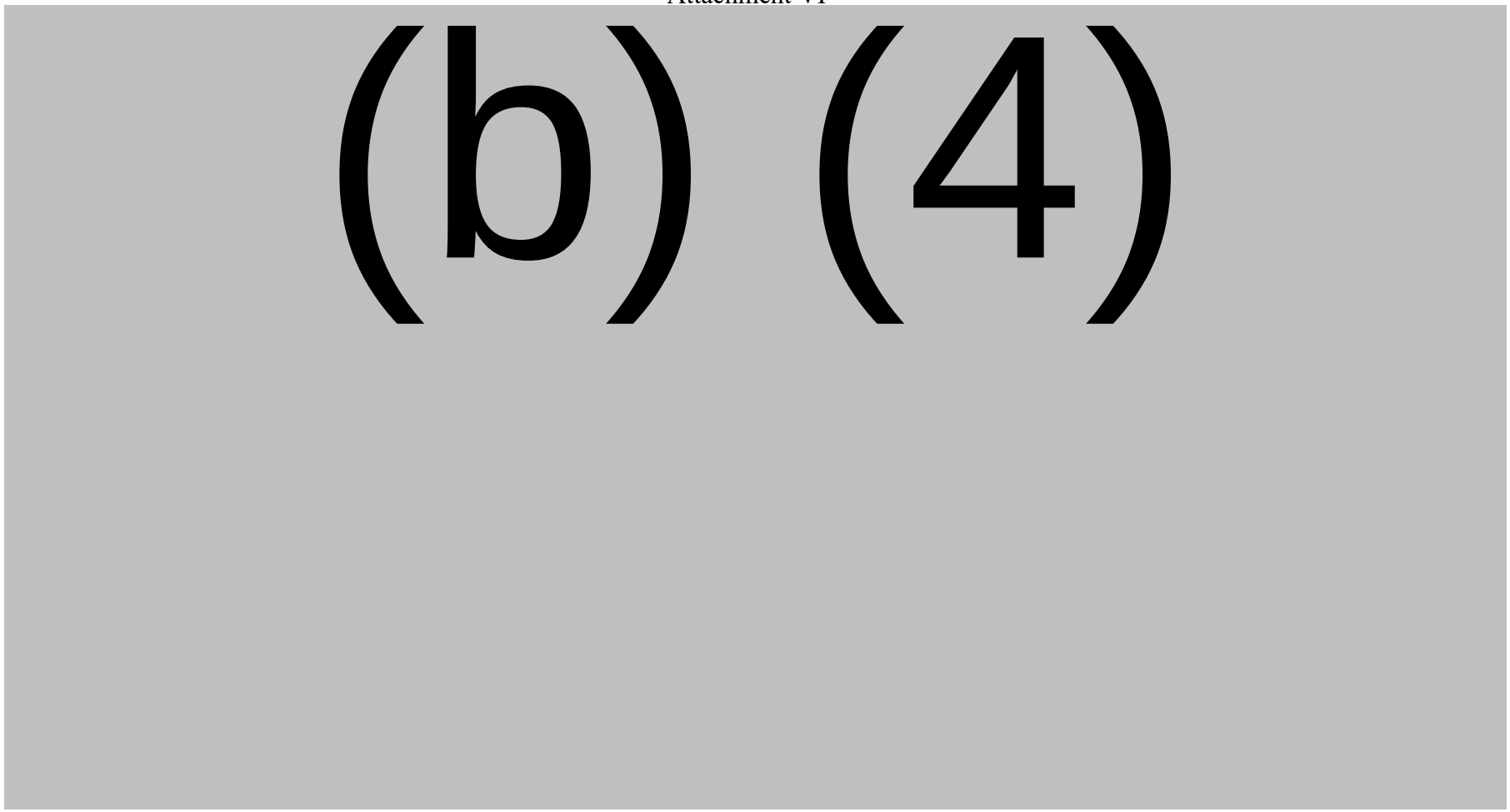

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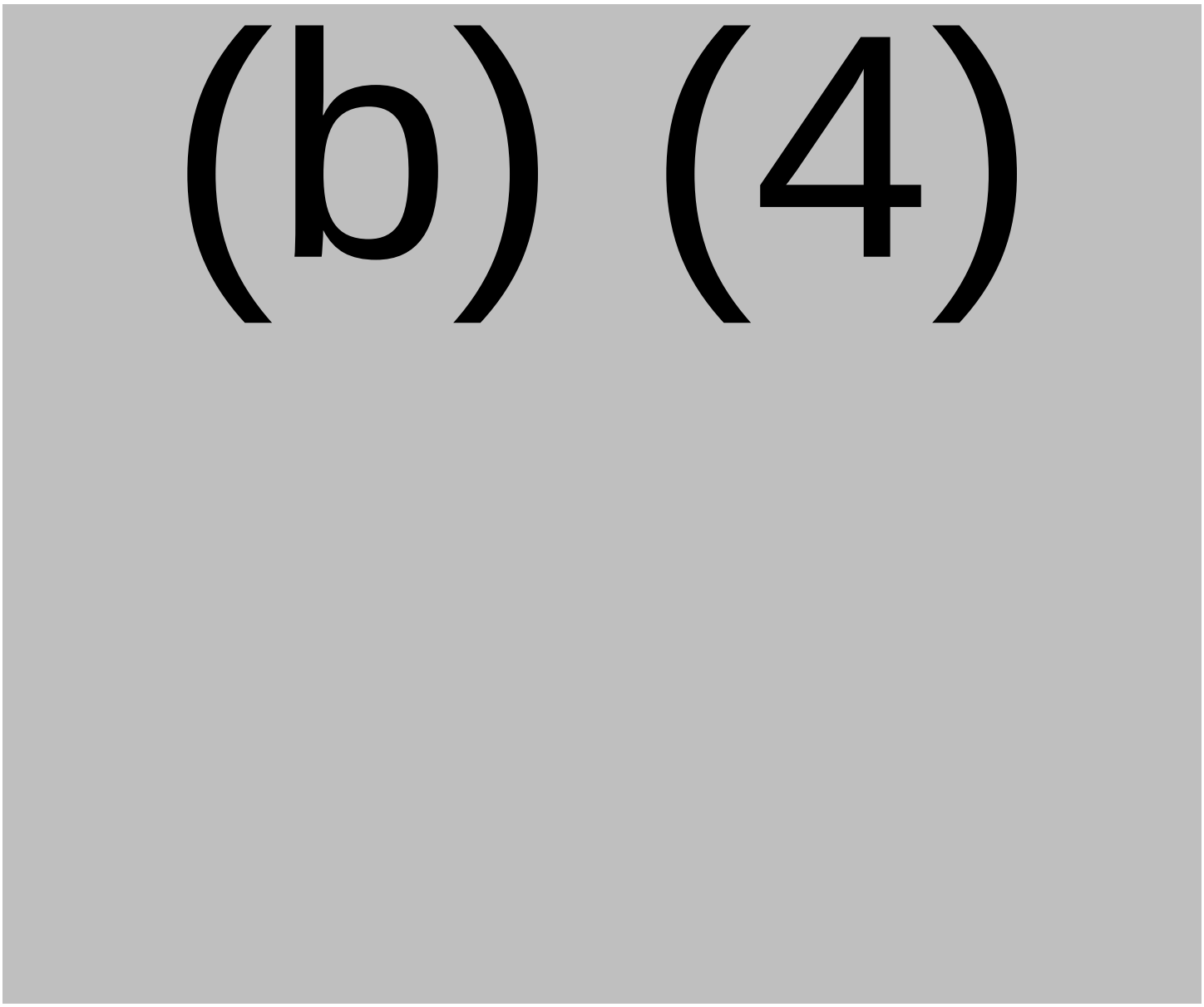

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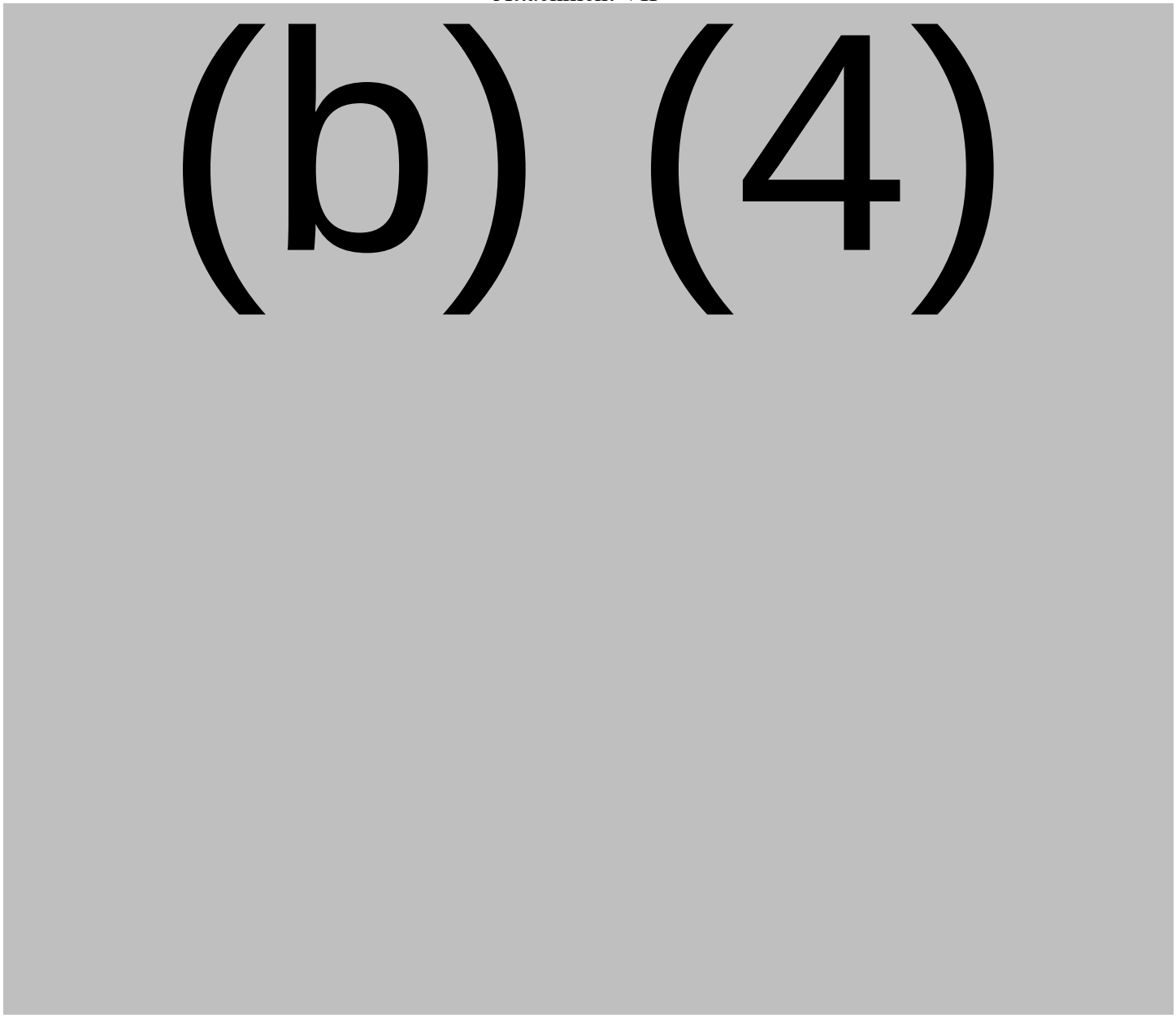

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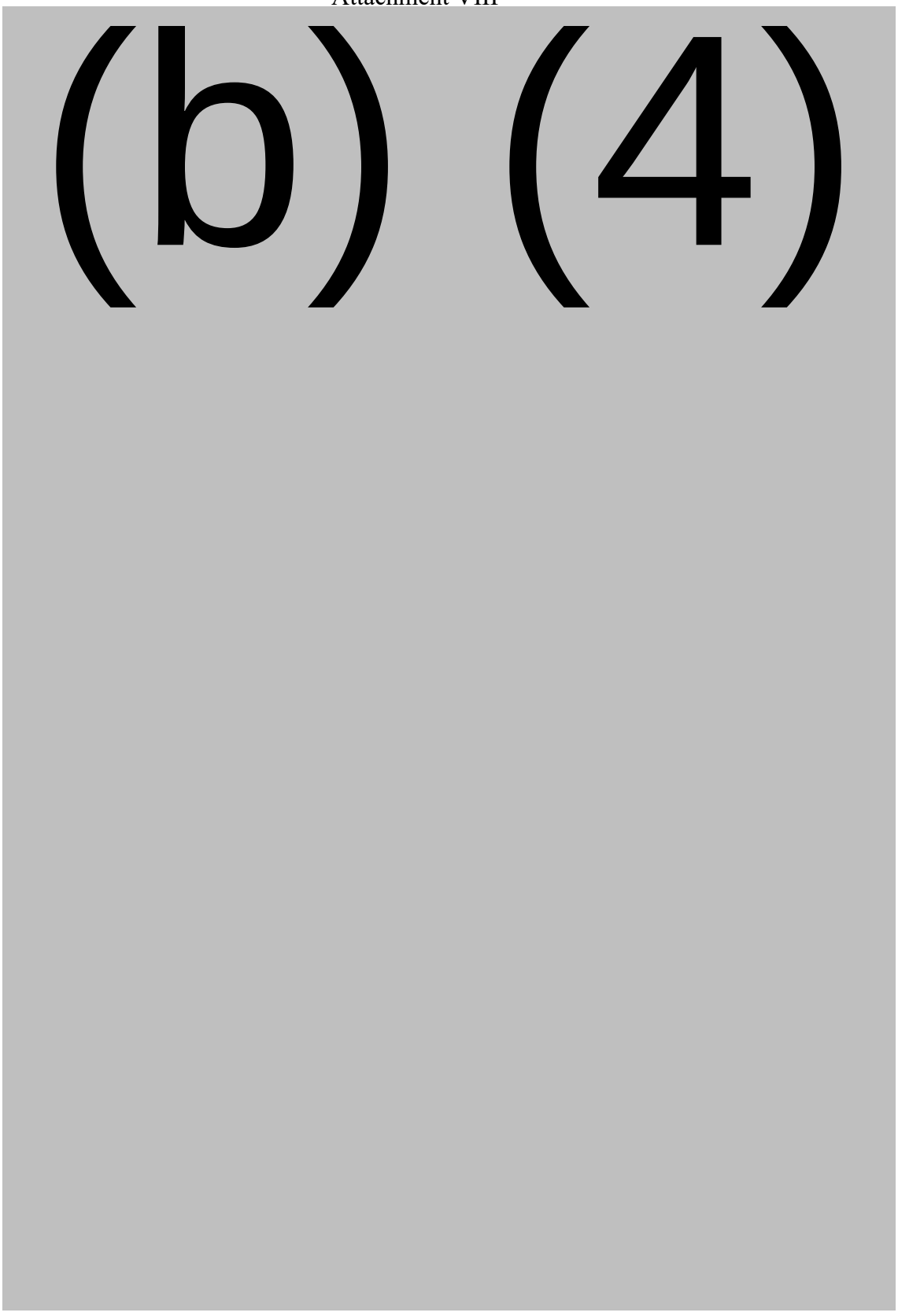

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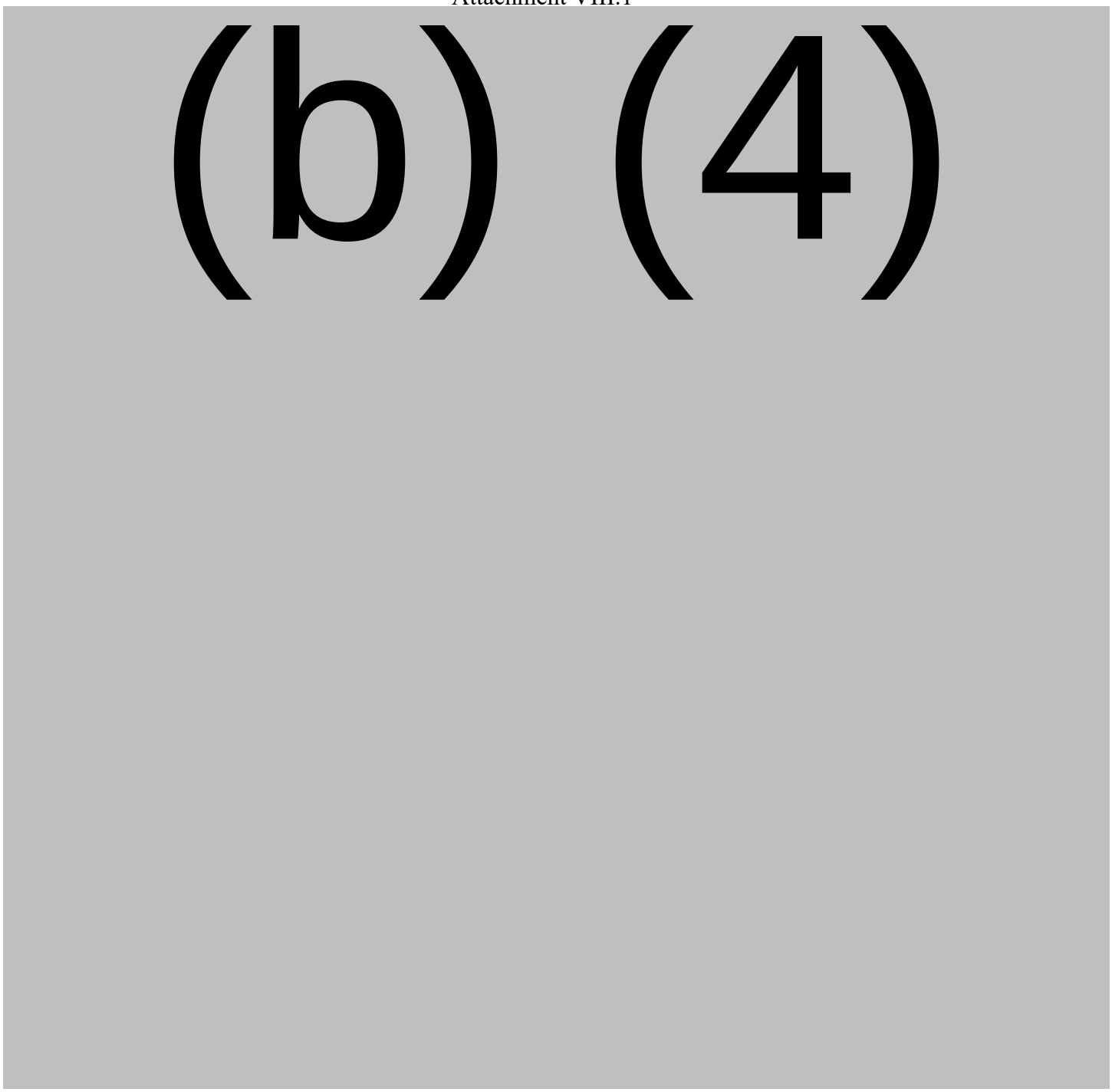

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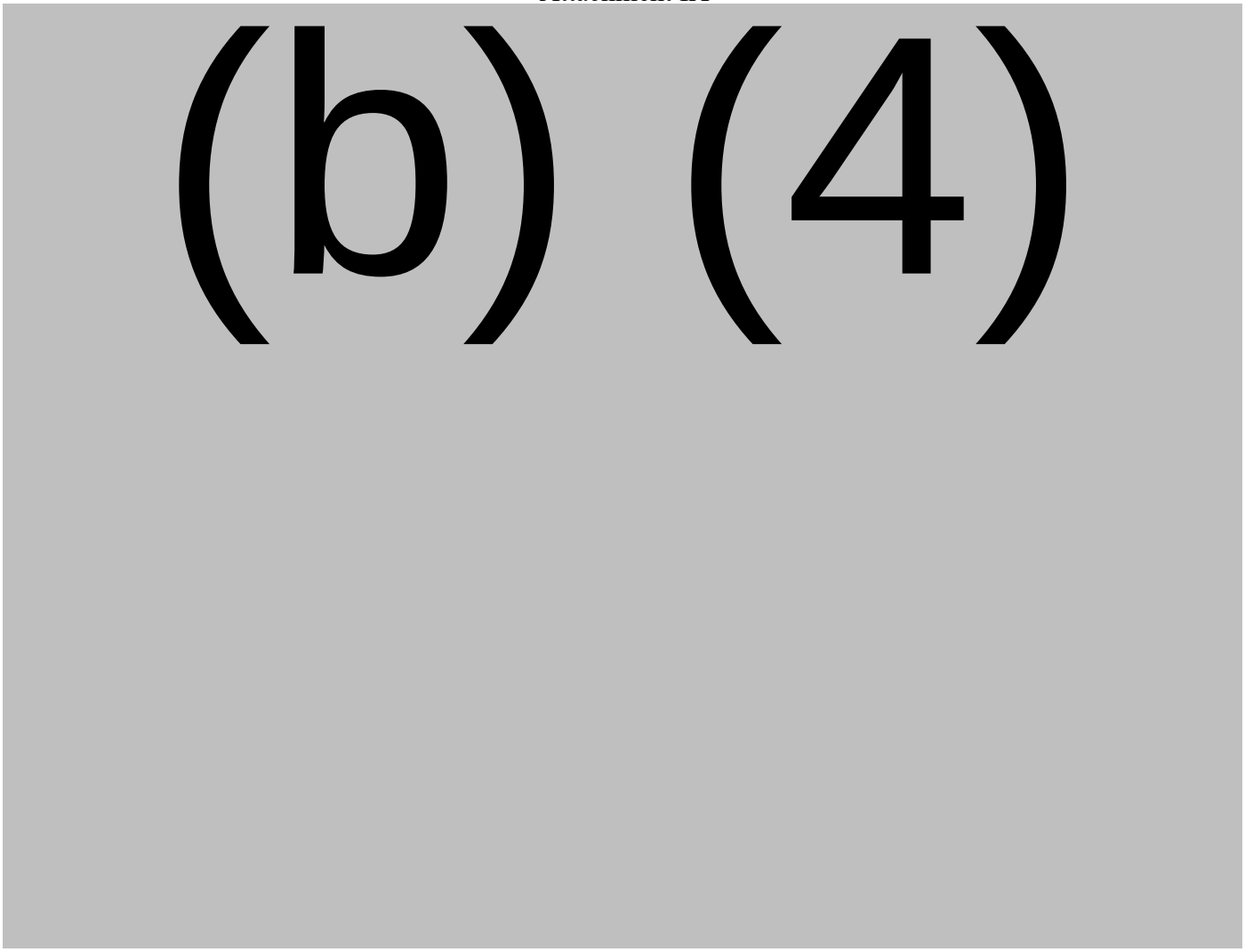

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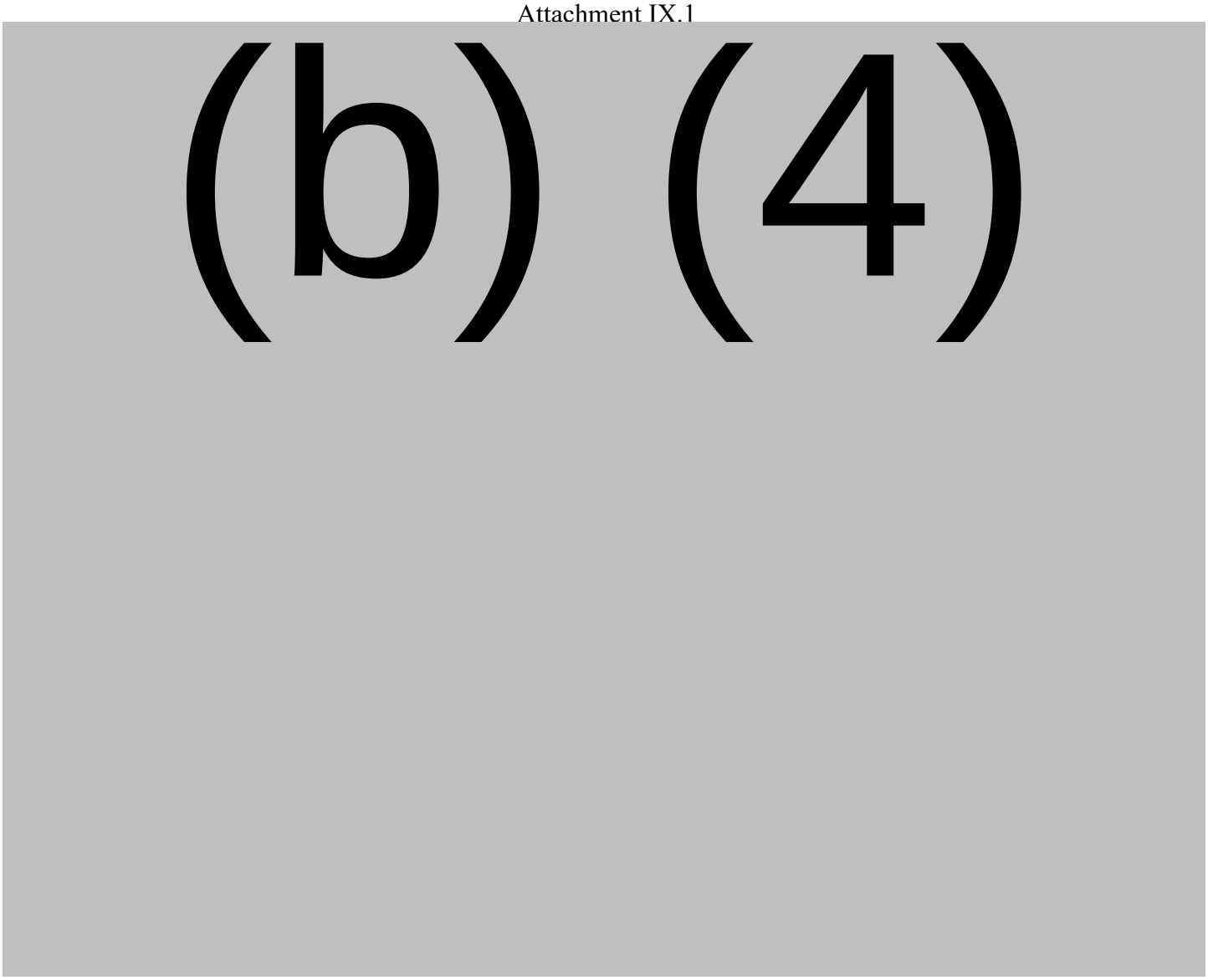

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