
16.2 SUBJECT DATA LISTINGS

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Appendix 16.2.2

Listing 16.2.2-1 Protocol deviations

Listing 16.2.2-1 Protocol deviations (All subjects)

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Listing 16.2.2-1 Protocol deviations (All subjects)

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Appendix 16.2.3

Listing 16.2.3-1 Population definitions

Listing 16.2.3-1 Population definitions (All subjects)

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Appendix 16.2.4

Listing 16.2.4-1 Demography

Listing 16.2.4-2 Medical/surgical History

Listing 16.2.4-3 Prior and concomitant medications

Listing 16.2.4-4 History of nicotine use

Listing 16.2.4-1 Demography (Full analysis set)

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Listing 16.2.4-2 Medical/surgical History (Full analysis set)

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Listing 16.2.4-2 Medical/surgical History (Full analysis set)

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Listing 16.2.4-3 Prior and concomitant medications (Full analysis set)

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Listing 16.2.4-4 History of nicotine use (Full analysis set)

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Listing 16.2.4-4 History of nicotine use (Full analysis set)

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Appendix 16.2.5

Listing 16.2.5-1 Product ad-libitum use

Listing 16.2.5-2 Residual nicotine, NNK, and NNN in used pouches

Listing 16.2.5-3 Reference pouches

Listing 16.2.5-1 Product ad-libitum use (Full analysis set)

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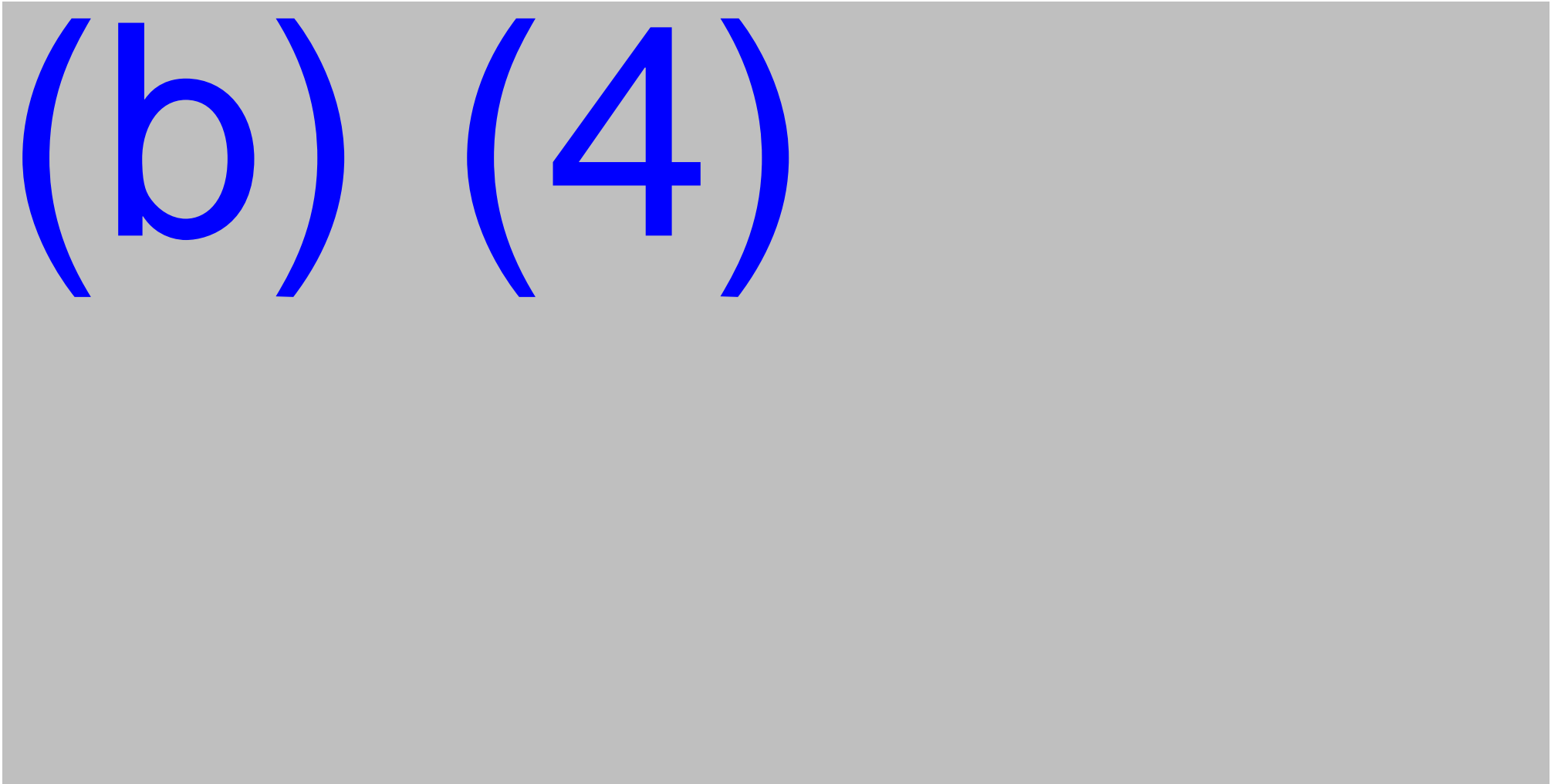
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Appendix 16.2.6

Listing 16.2.6-1 Biomarkers in plasma

Listing 16.2.6-2 Biomarkers in urine

Listing 16.2.6-3 Extracted amounts of nicotine, NNK, and NNN per pouch and per subject

Listing 16.2.6-4 Calculated average extracted amounts and fractions of, and total exposure to, nicotine, NNK, and NNN per subject

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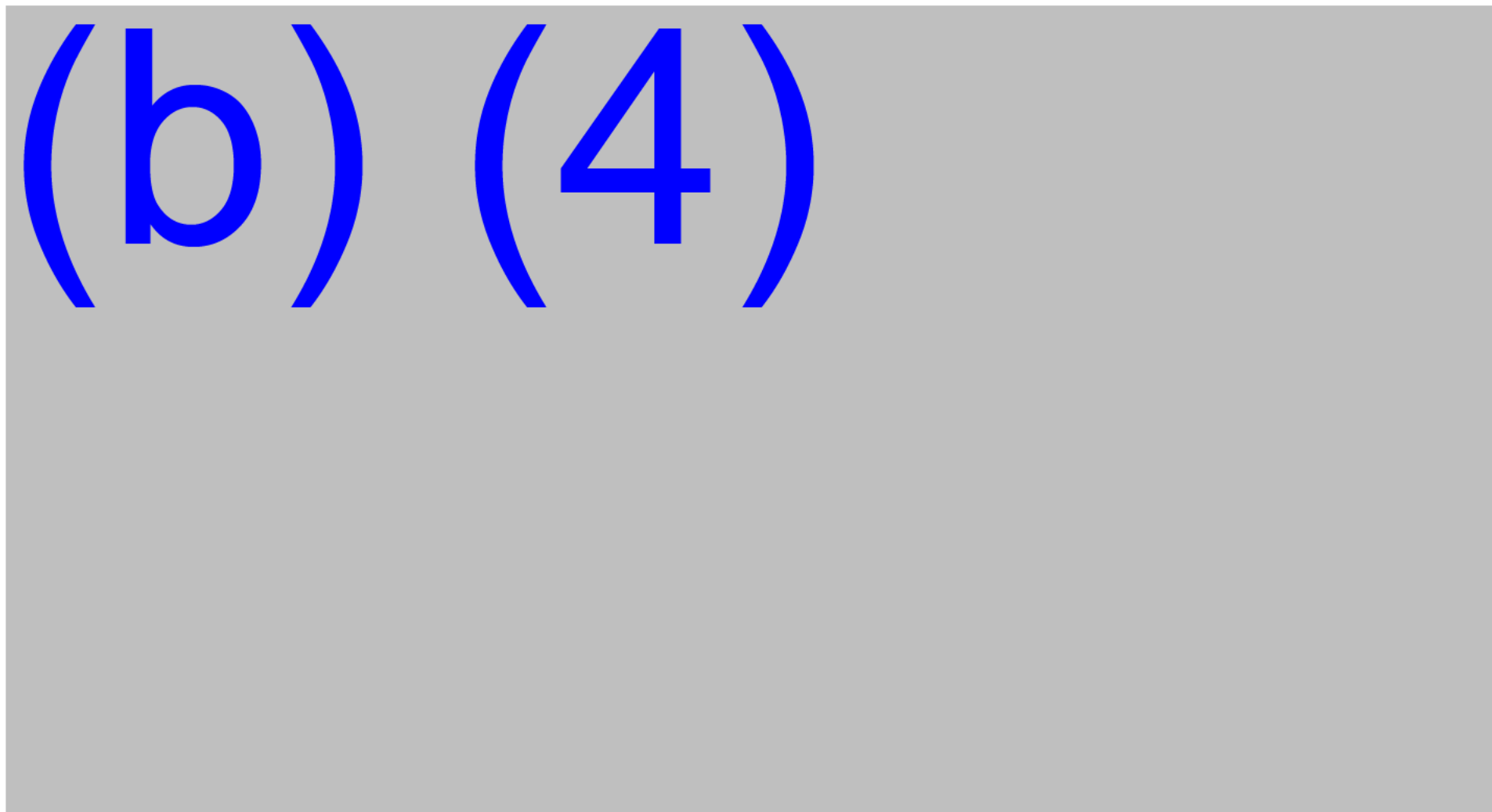
Listing 16.2.6-2 Biomarkers in urine (Full analysis set)

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Listing 16.2.6-2 Biomarkers in urine (Full analysis set)

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Listing 16.2.6-3 Extracted amounts of nicotine, NNK, and NNN per pouch and per subject (Full analysis set)

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Listing 16.2.6-4 Calculated average extracted amounts and fractions of, and total exposure to, nicotine, NNK, and NNN per subject (Full analysis set)

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Listing 16.2.6-4 Calculated average extracted amounts and fractions of, and total exposure to, nicotine, NNK, and NNN per subject (Full analysis set)

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Listing 16.2.6-4 Calculated average extracted amounts and fractions of, and total exposure to, nicotine, NNK, and NNN per subject (Full analysis set)

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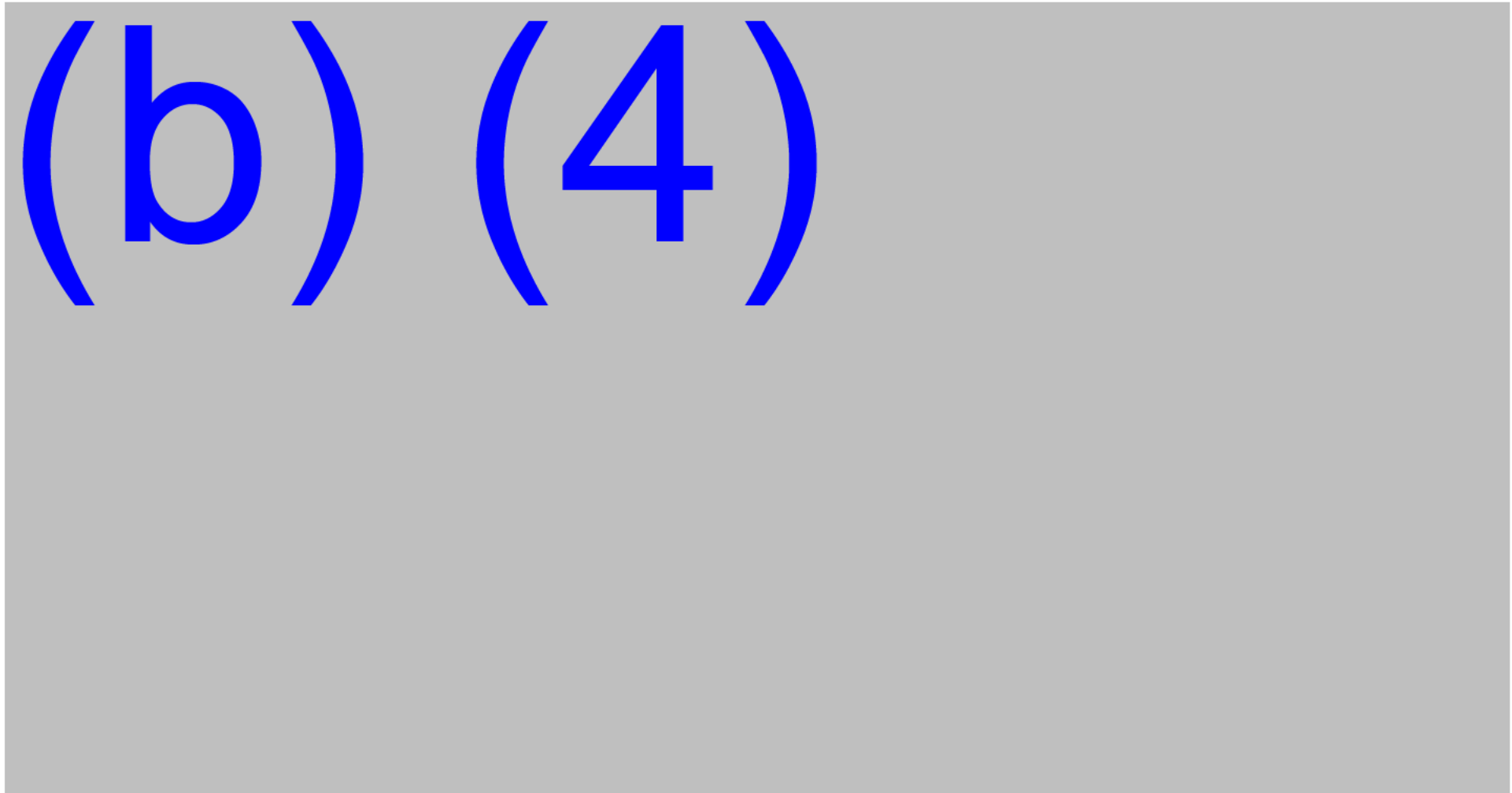
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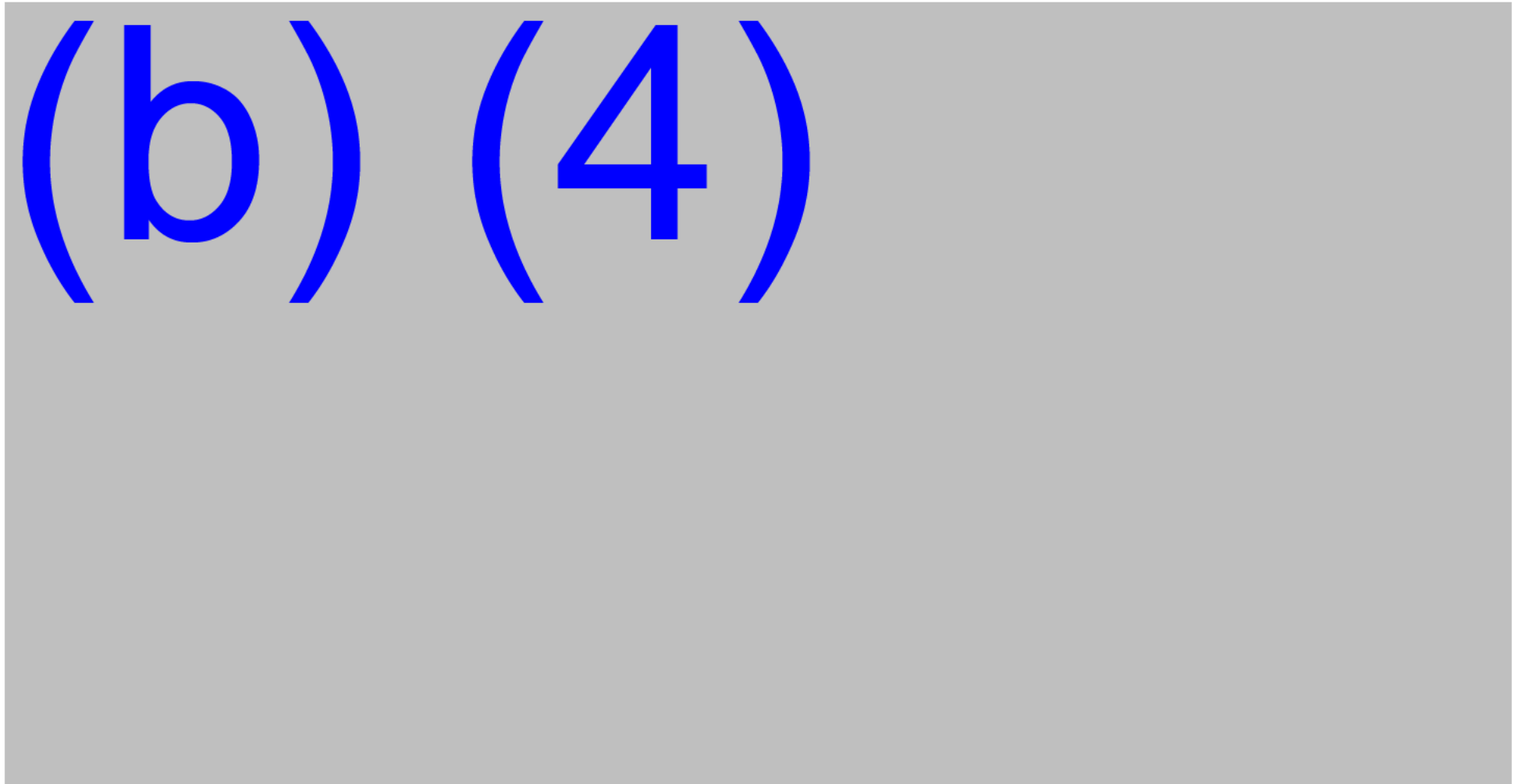
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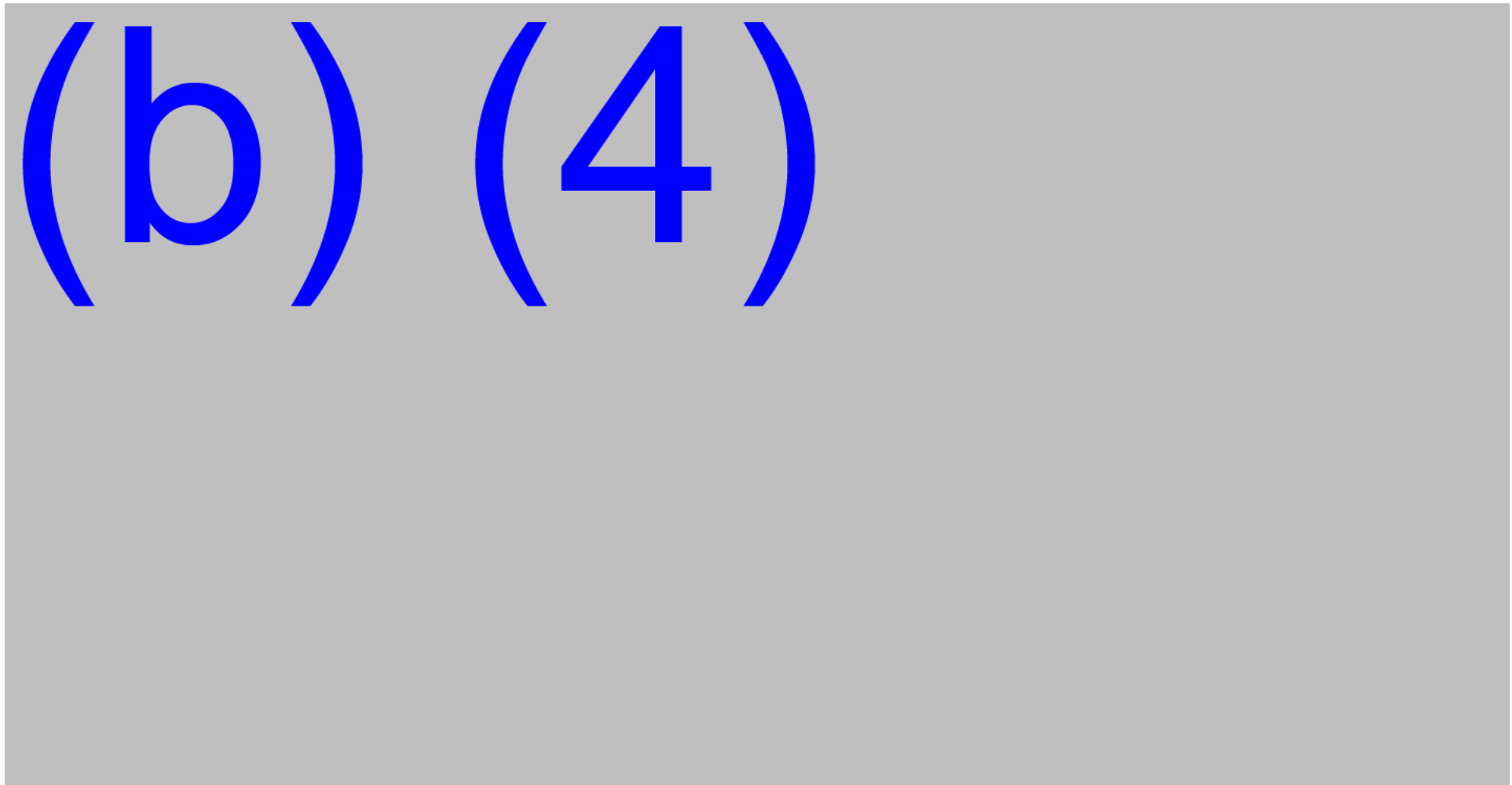
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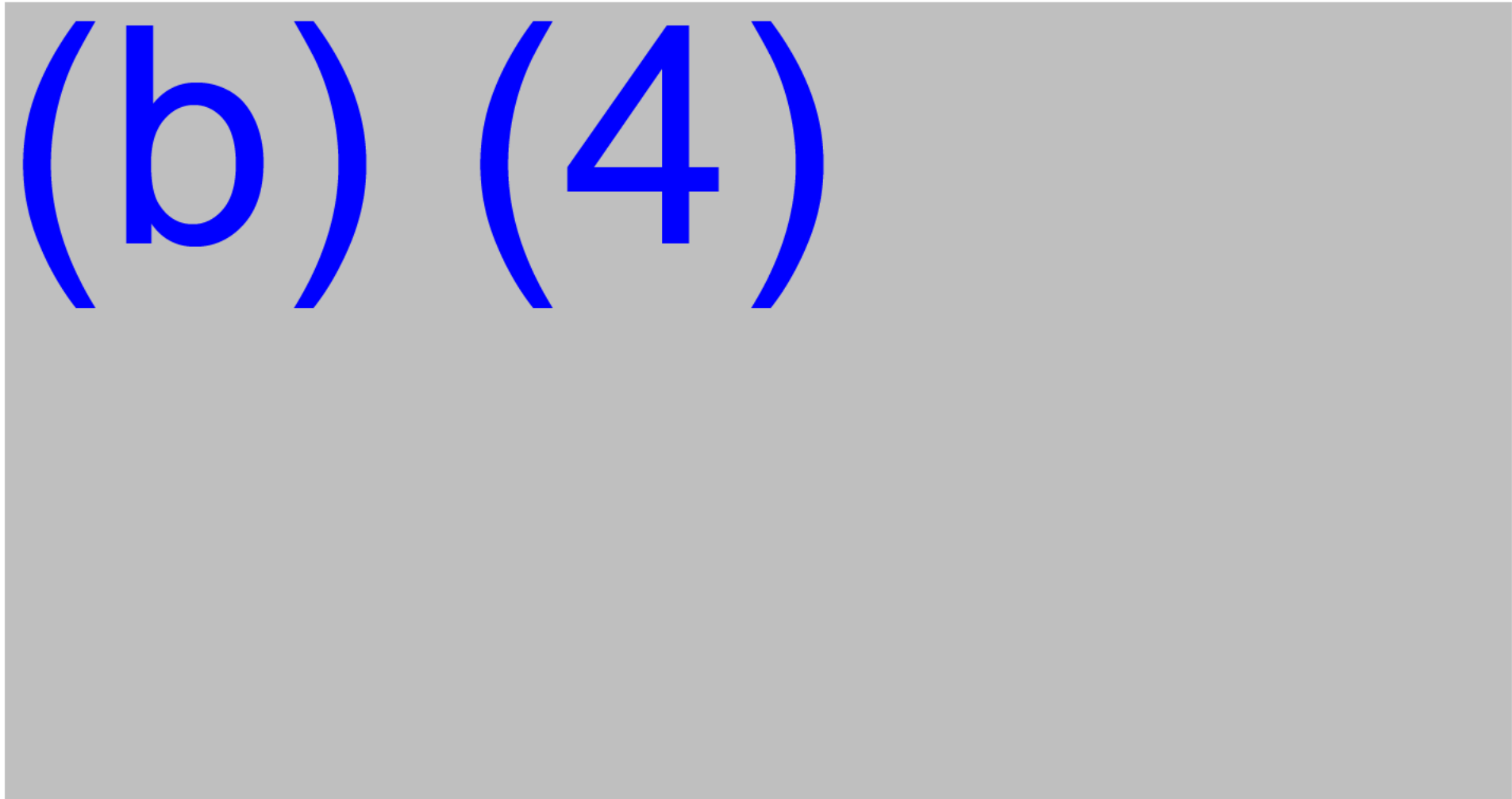
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Appendix 16.2.7

Listing 16.2.7-1 Adverse events

Listing 16.2.7-2 Serious adverse events

Listing 16.2.7-1 Adverse events (Full analysis set)

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Listing 16.2.7-1 Adverse events (Full analysis set)

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Listing 16.2.7-2 Serious adverse events (Full analysis set)

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Appendix 16.2.8

Listing 16.2.8-1 Safety laboratory measurements

Listing 16.2.8-2 Other laboratory measurements

Listing 16.2.8-1 Safety laboratory measurements (Full analysis set)

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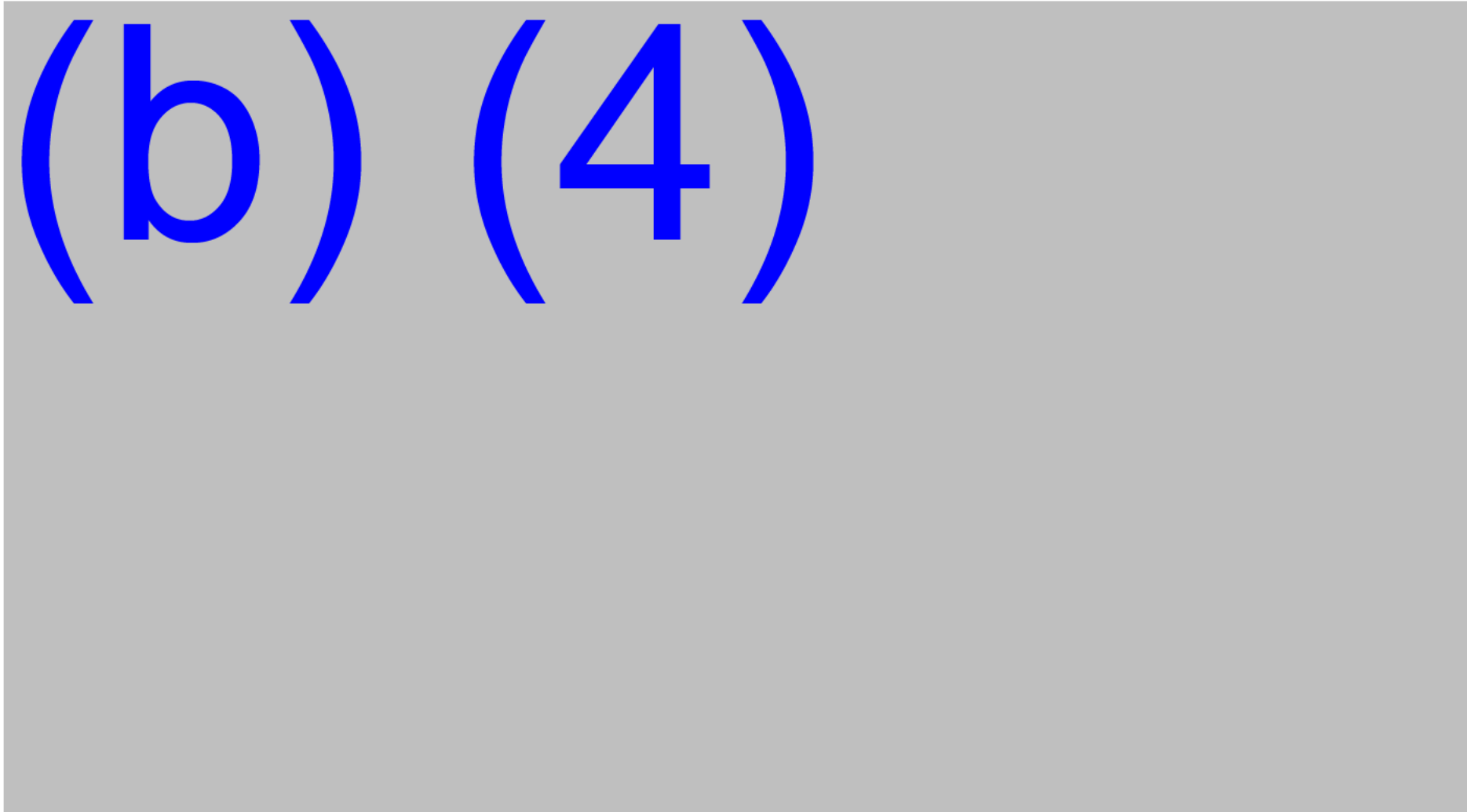
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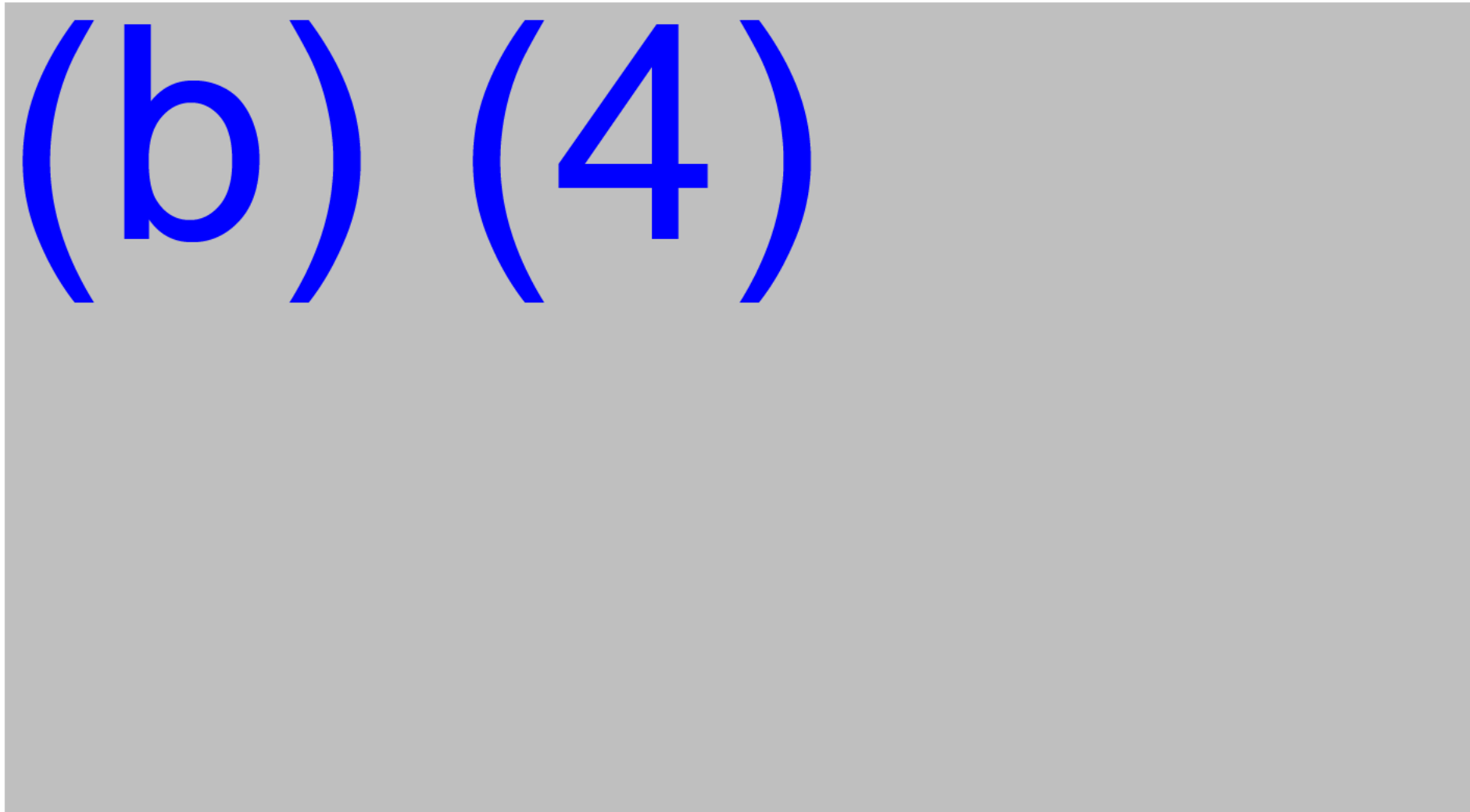
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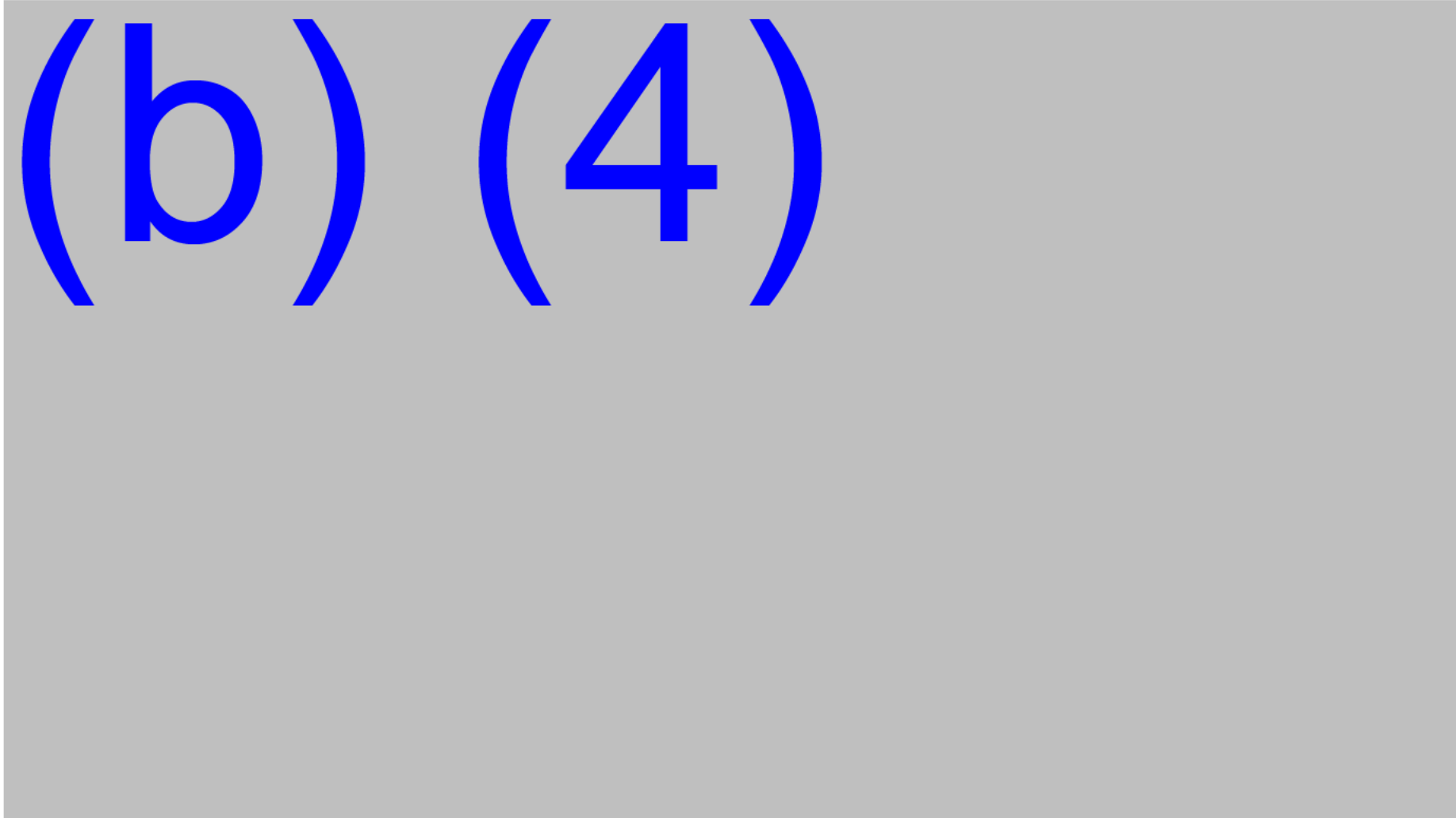
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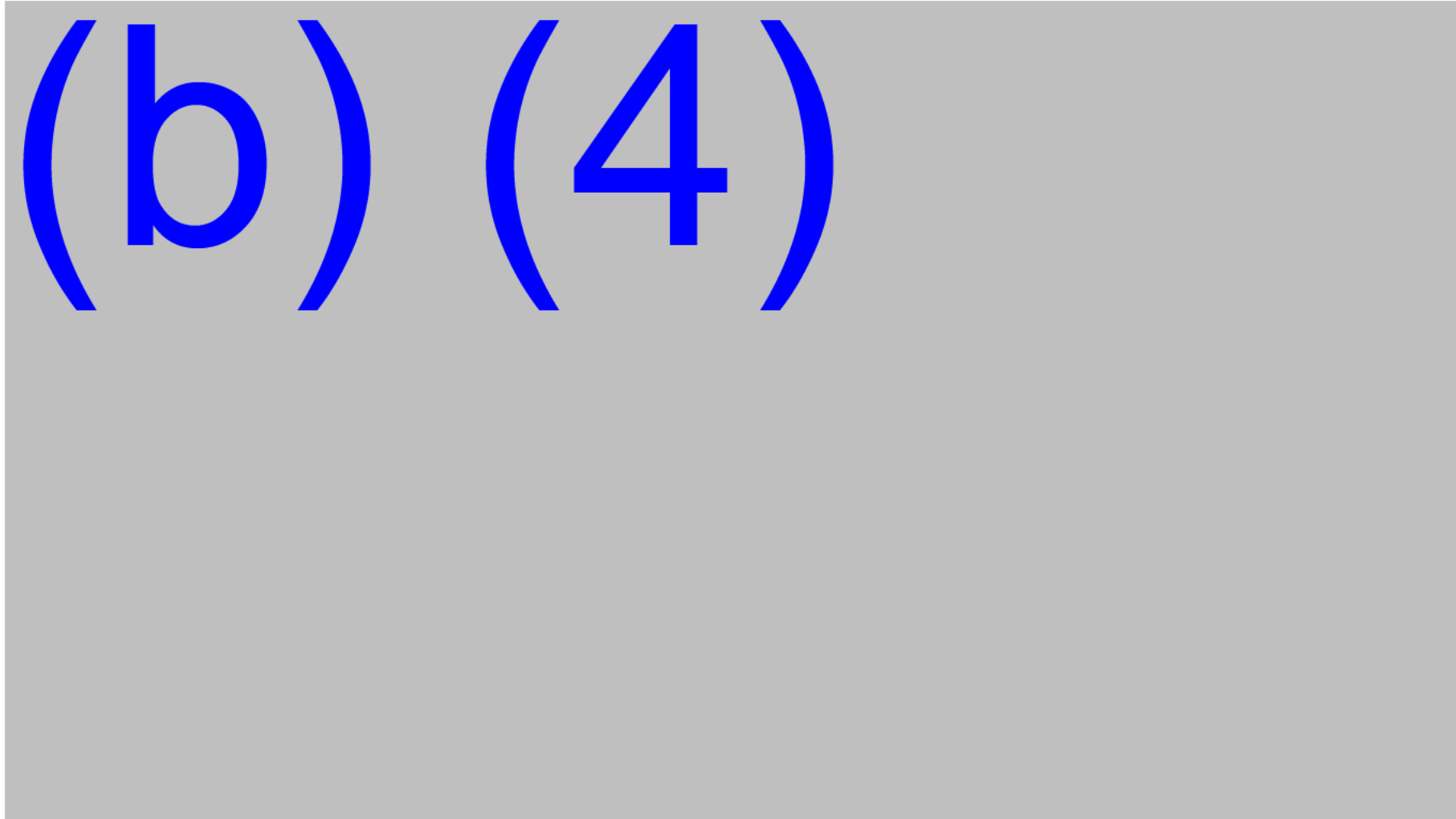
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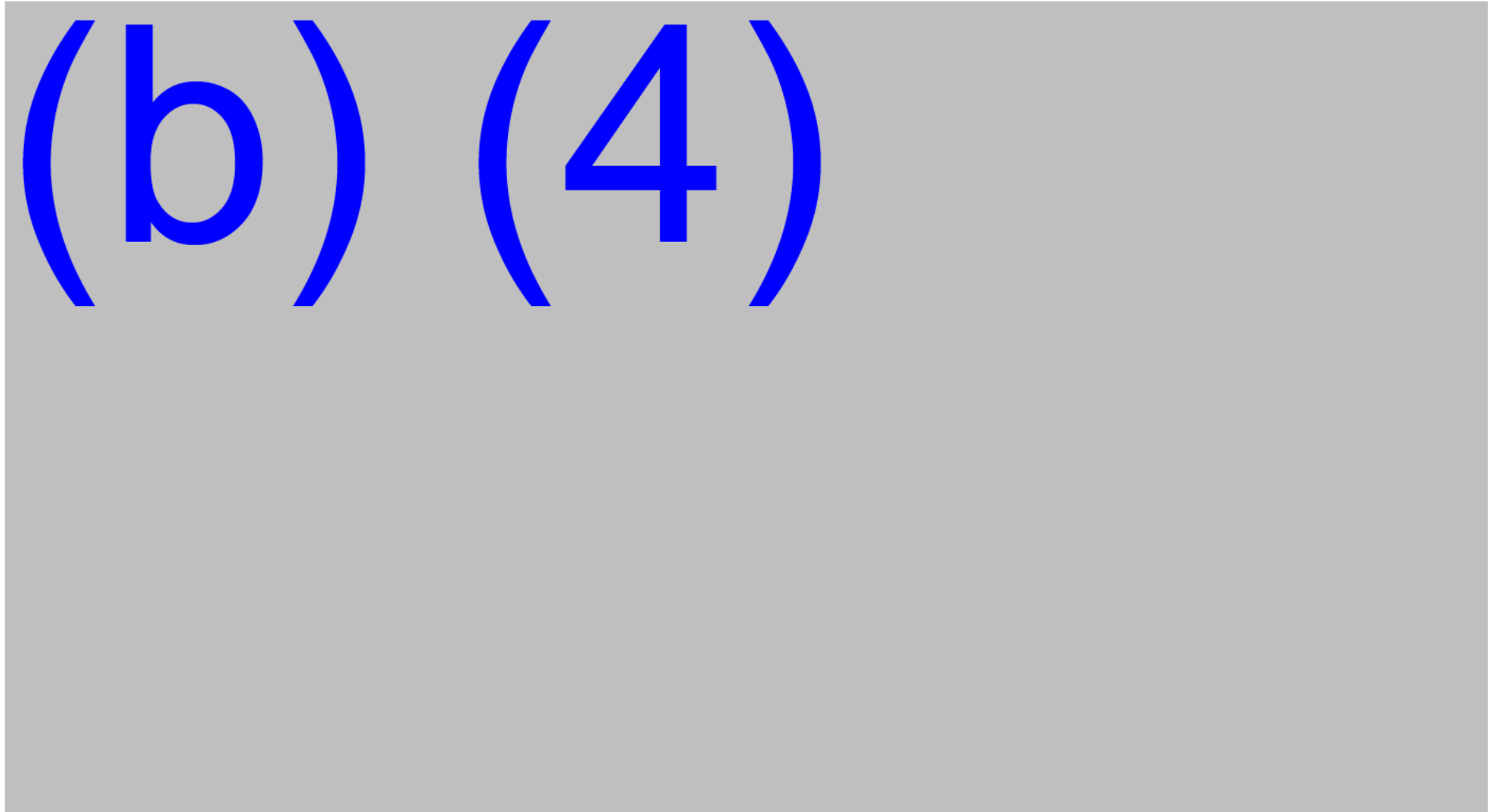
Listing 16.2.8-1 Safety laboratory measurements (Full analysis set)

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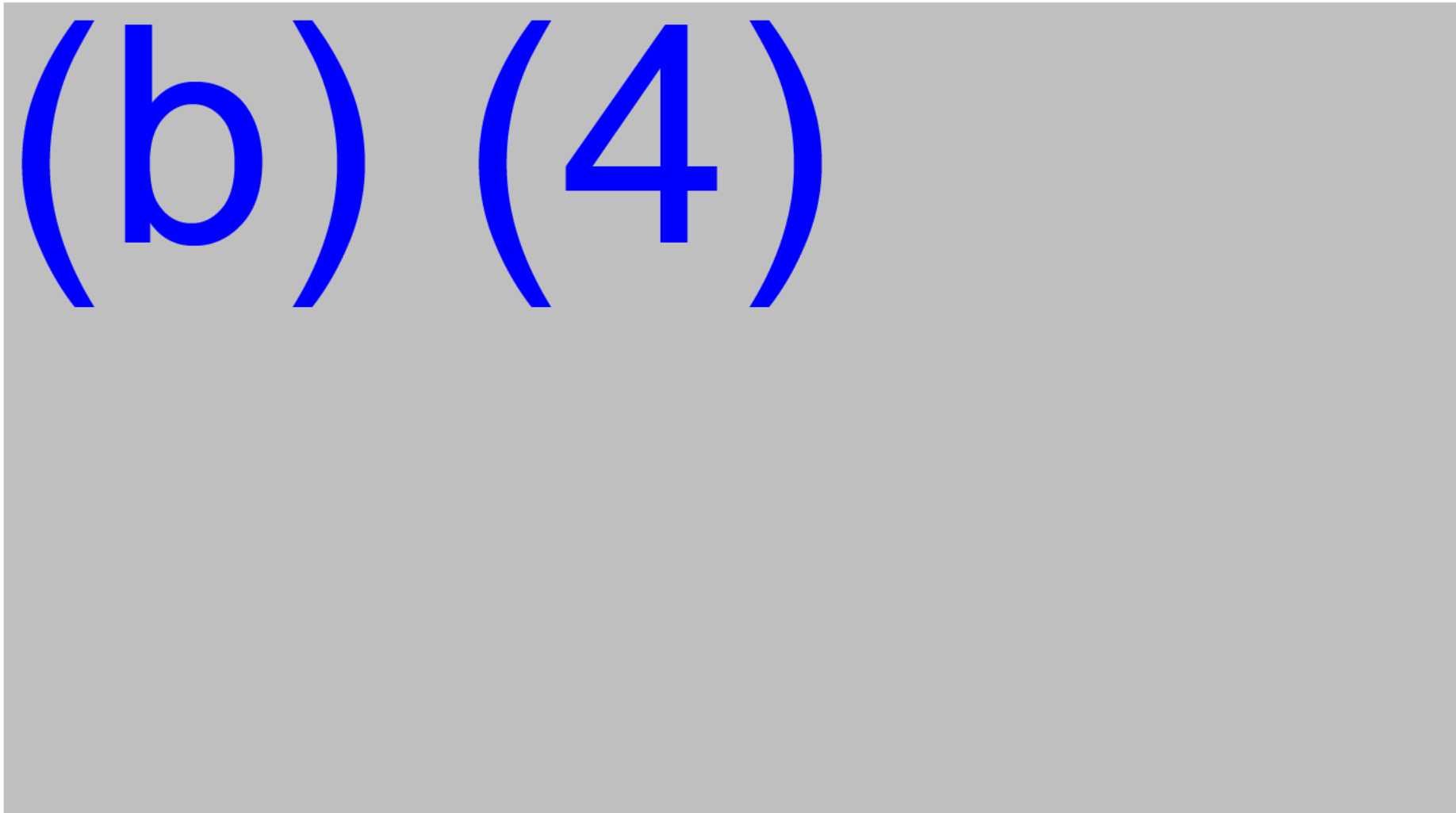
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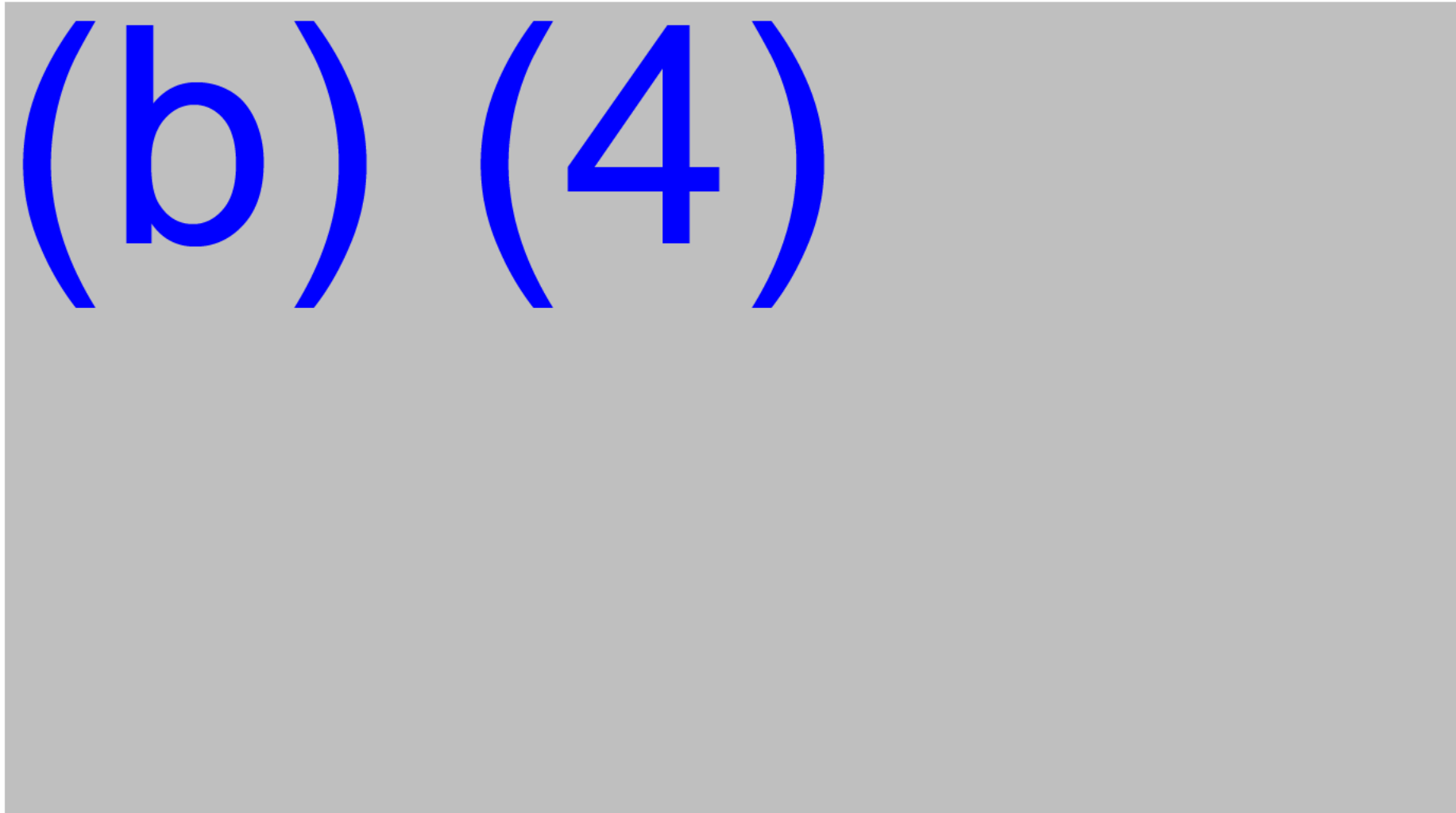
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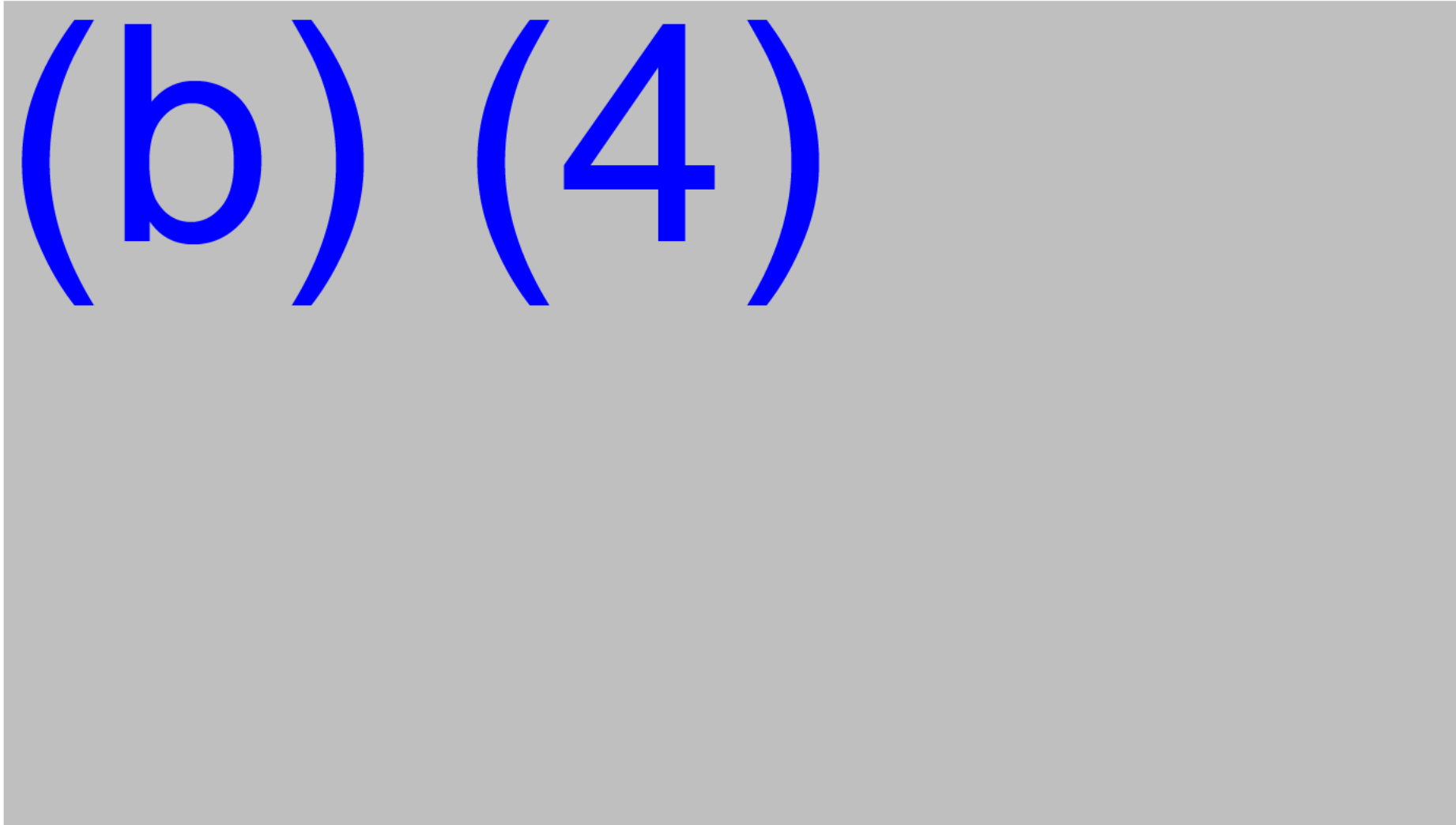
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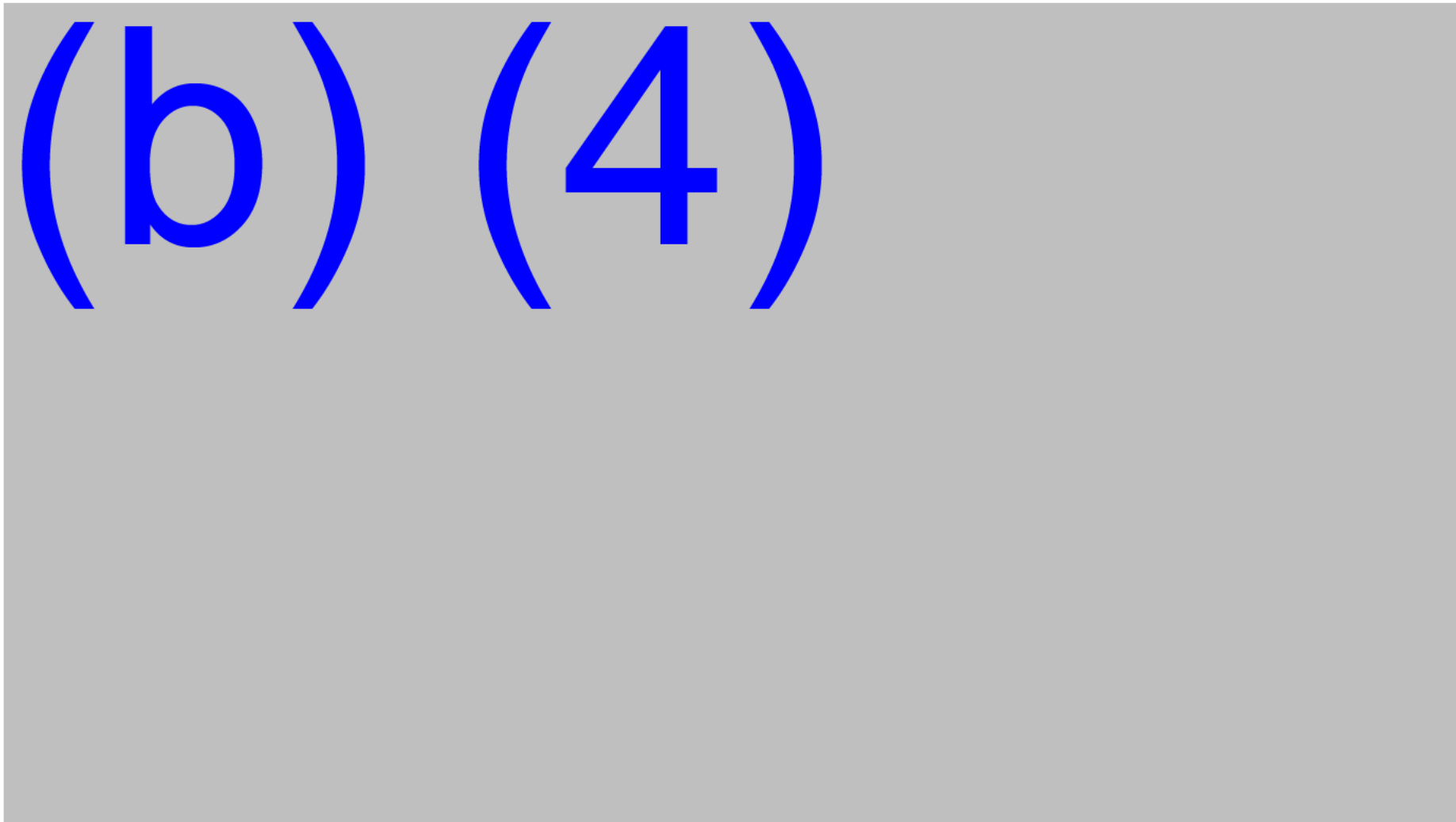
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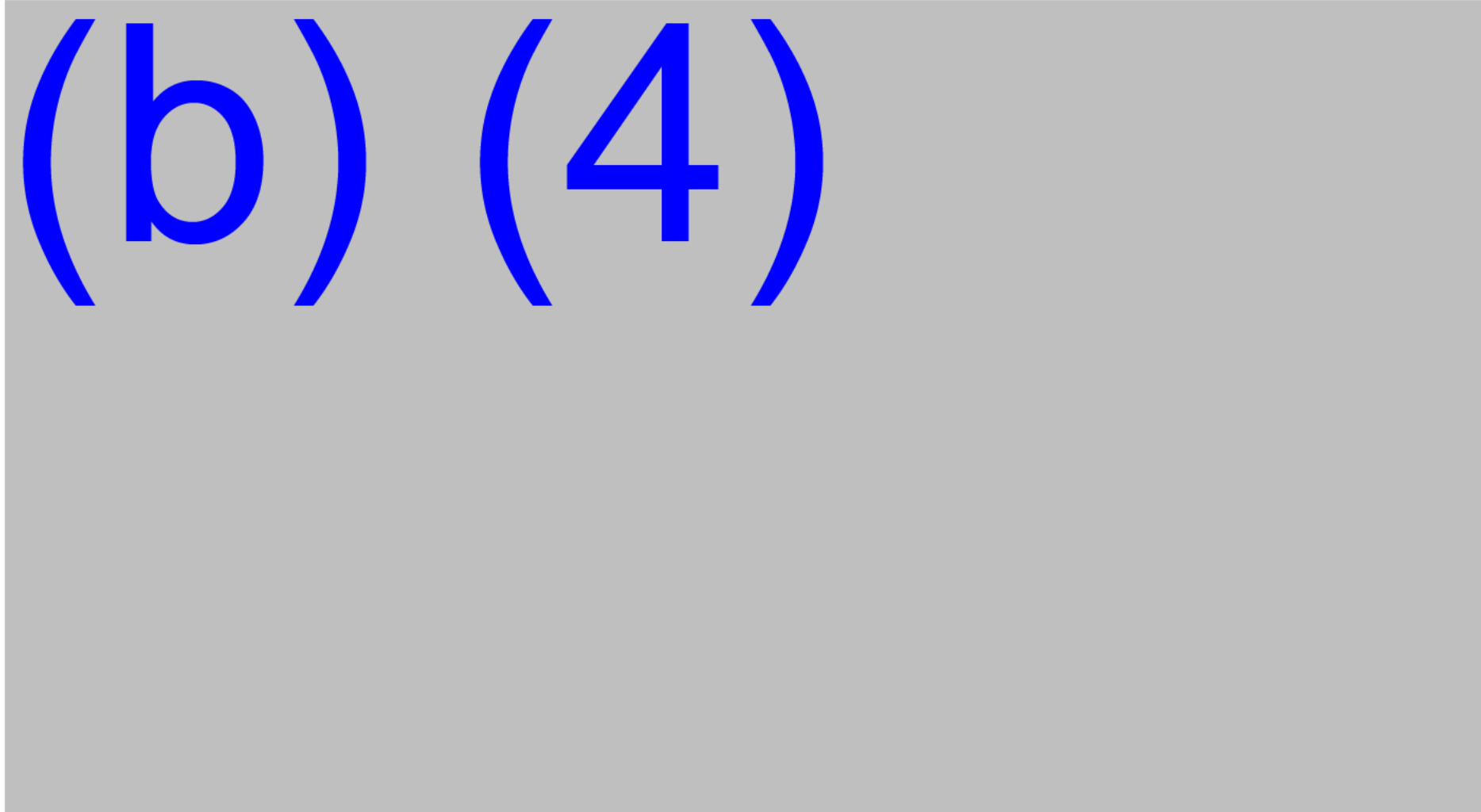
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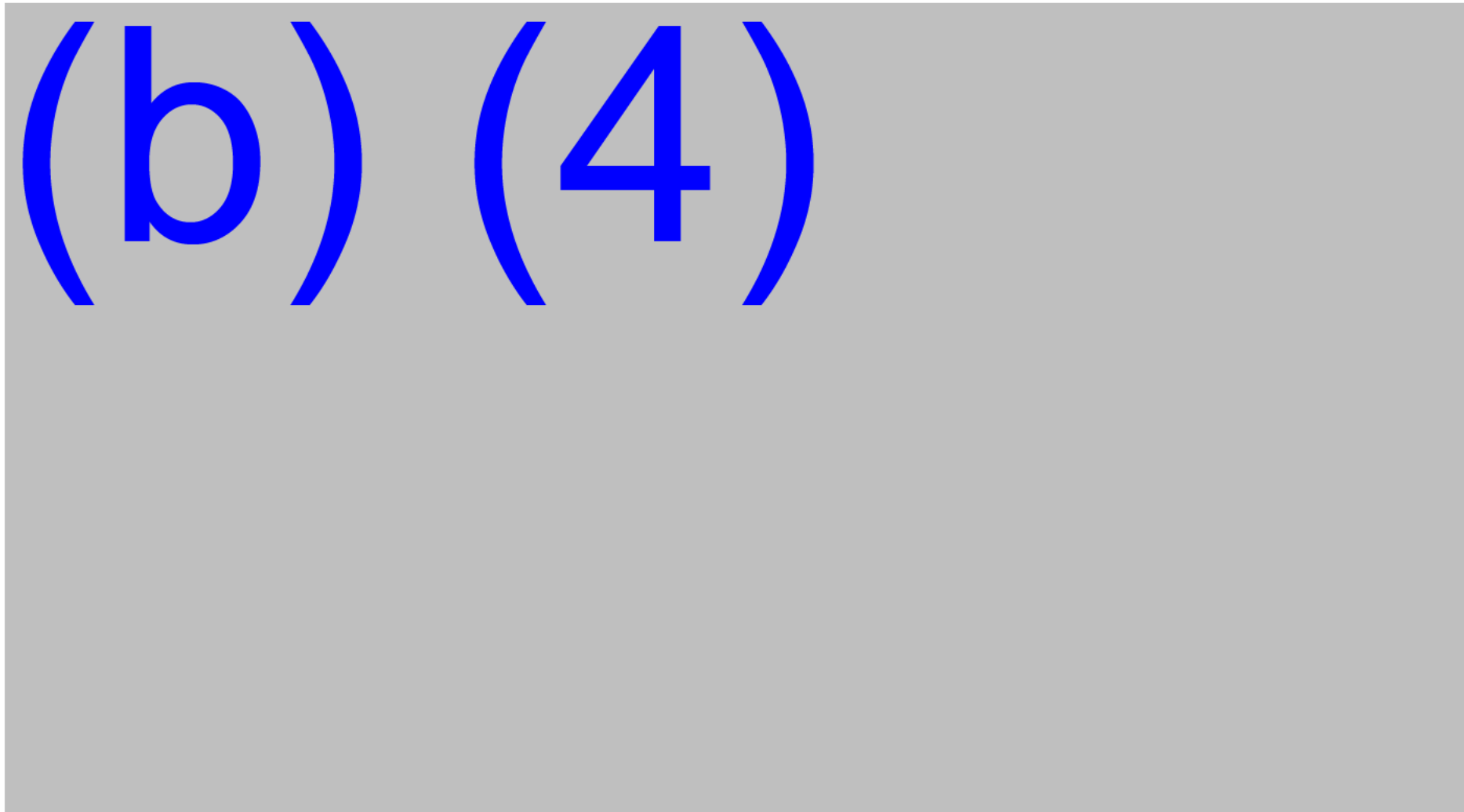
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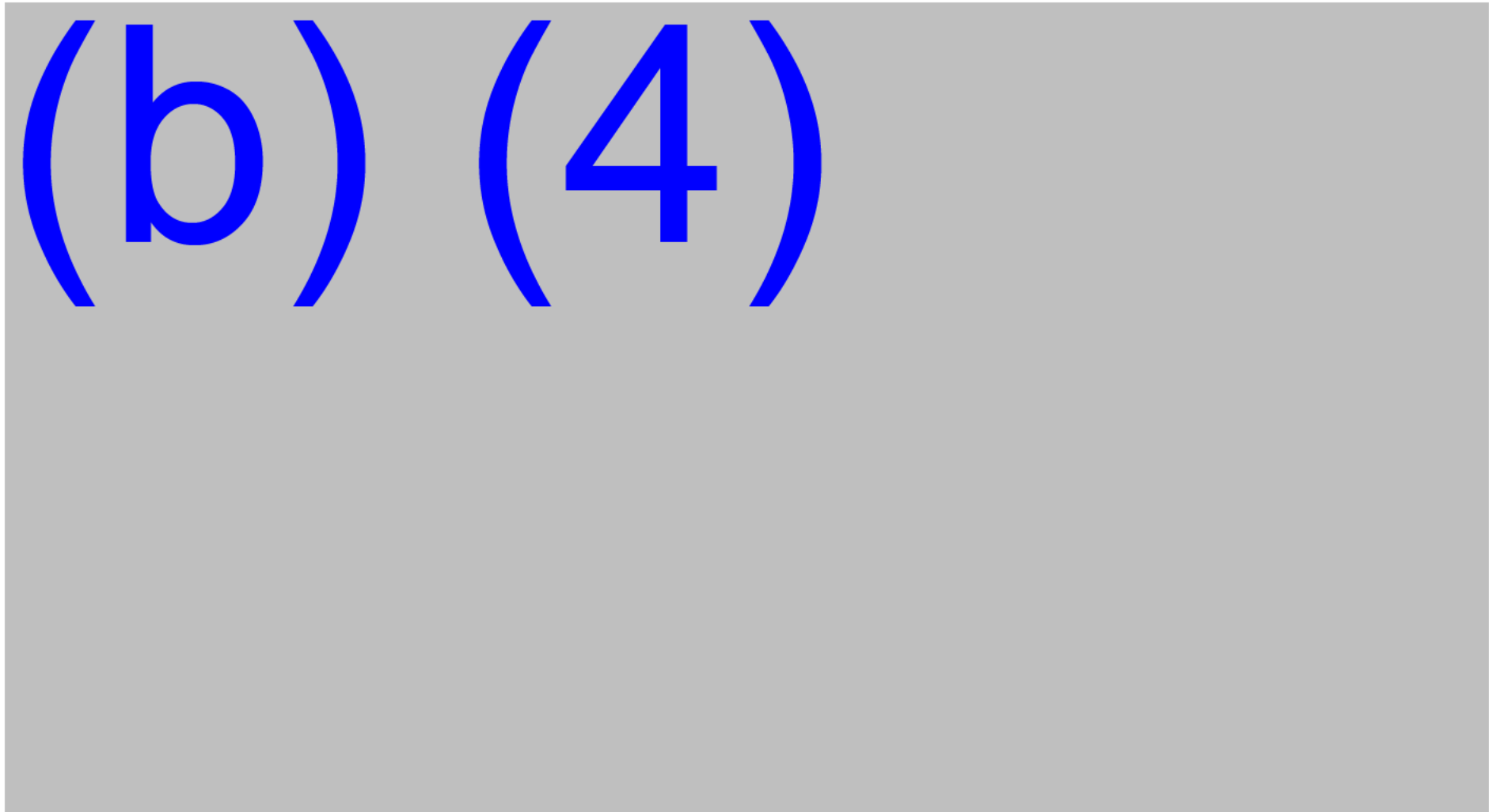
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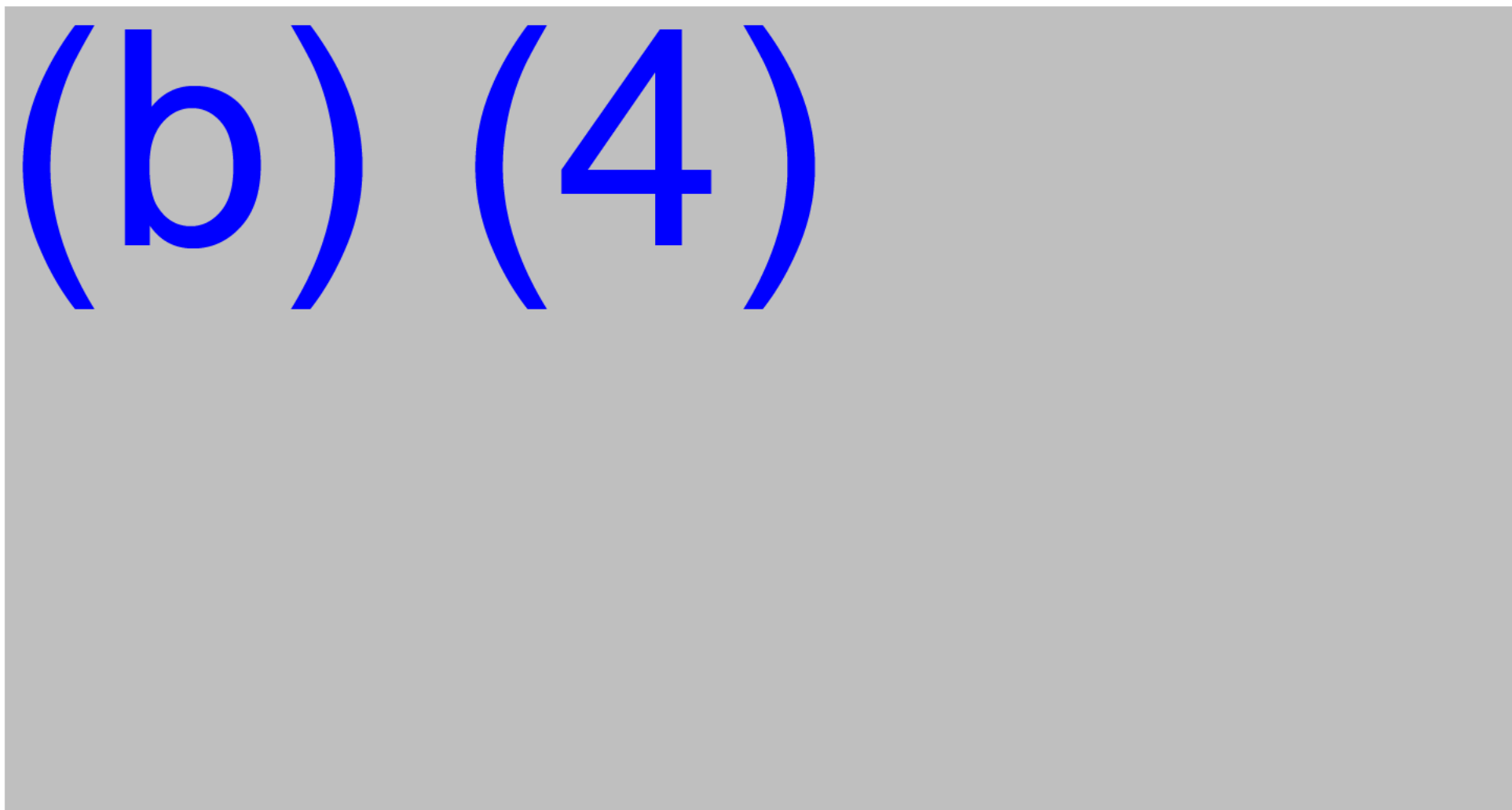
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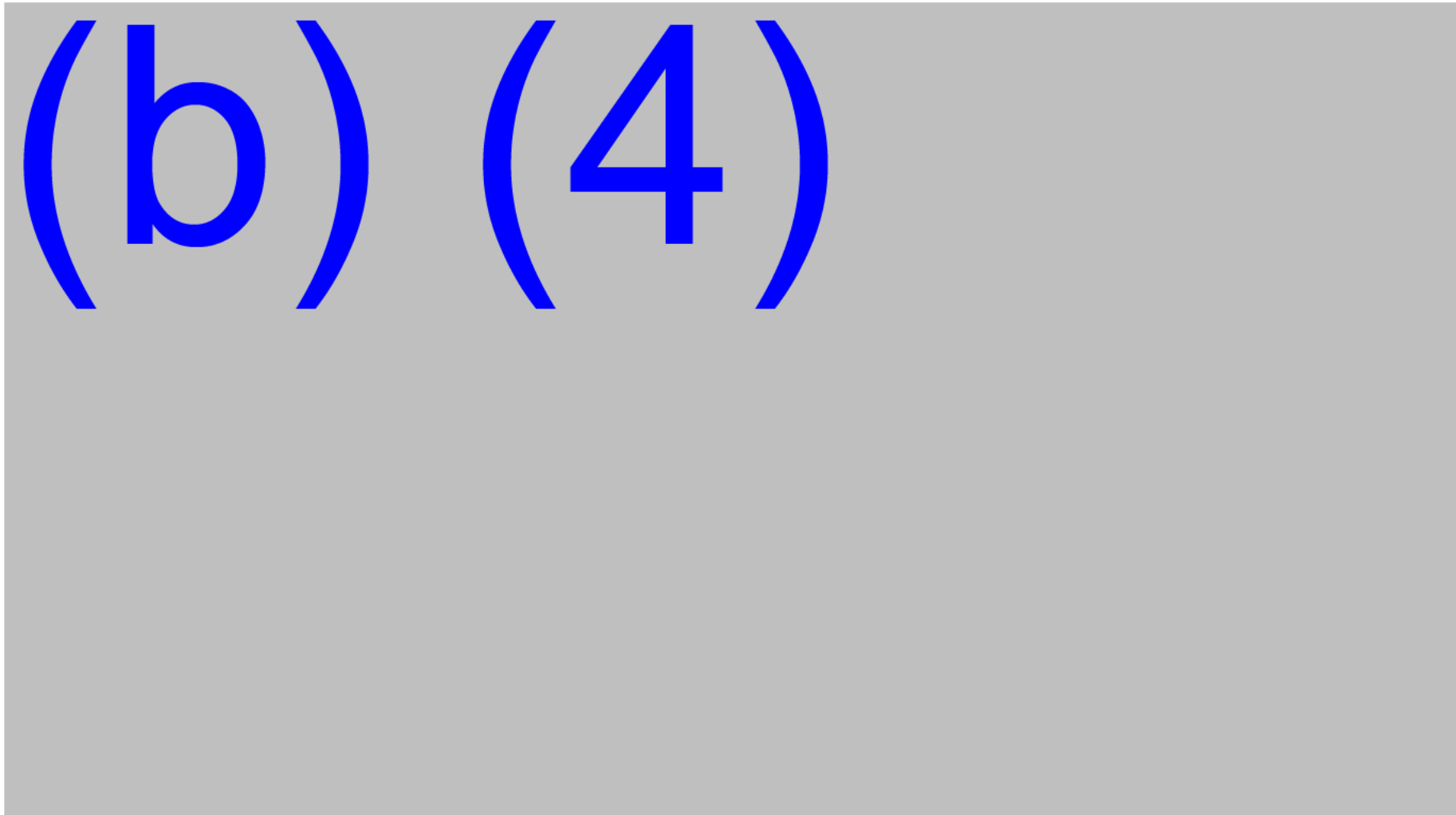
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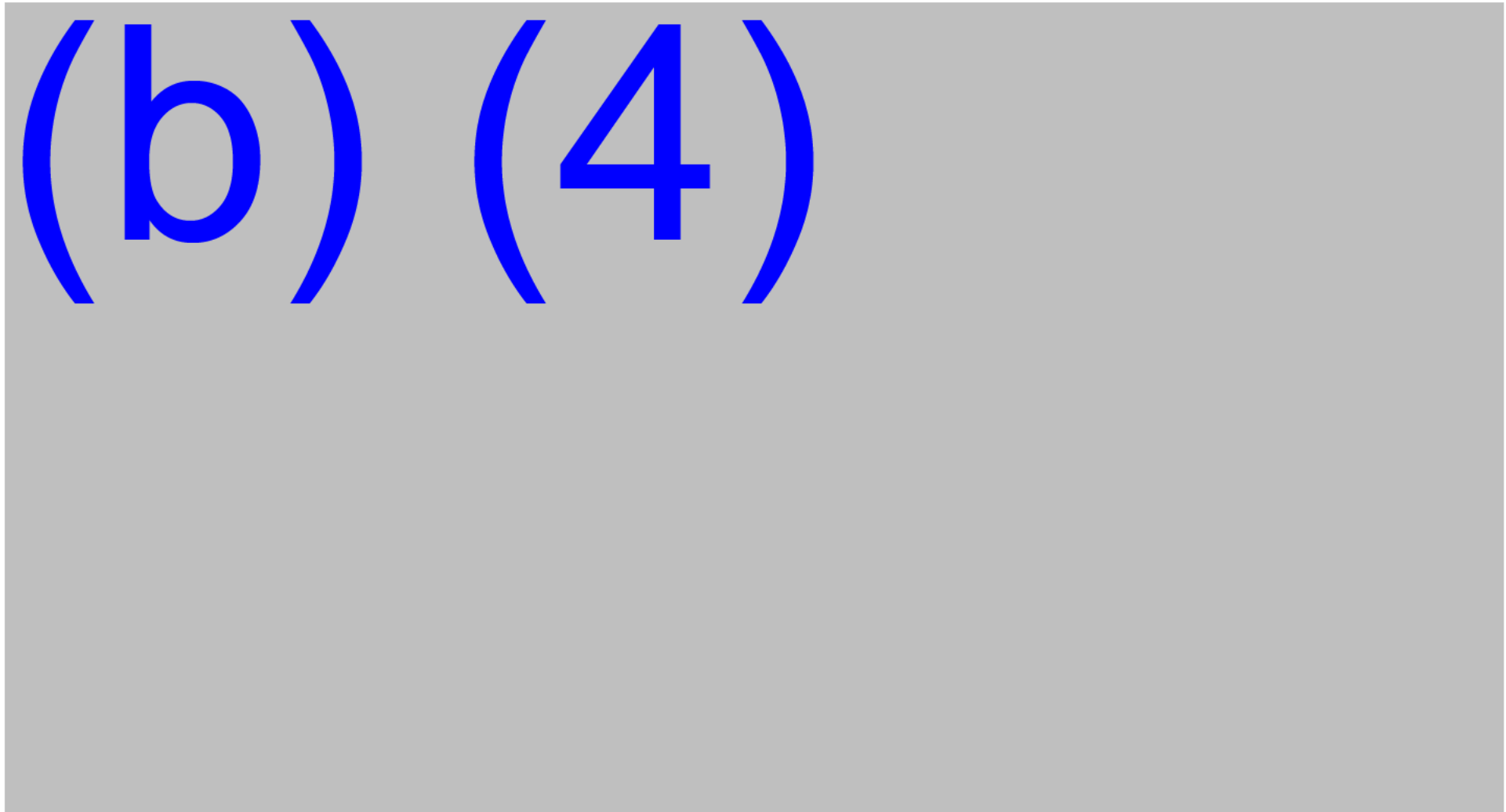
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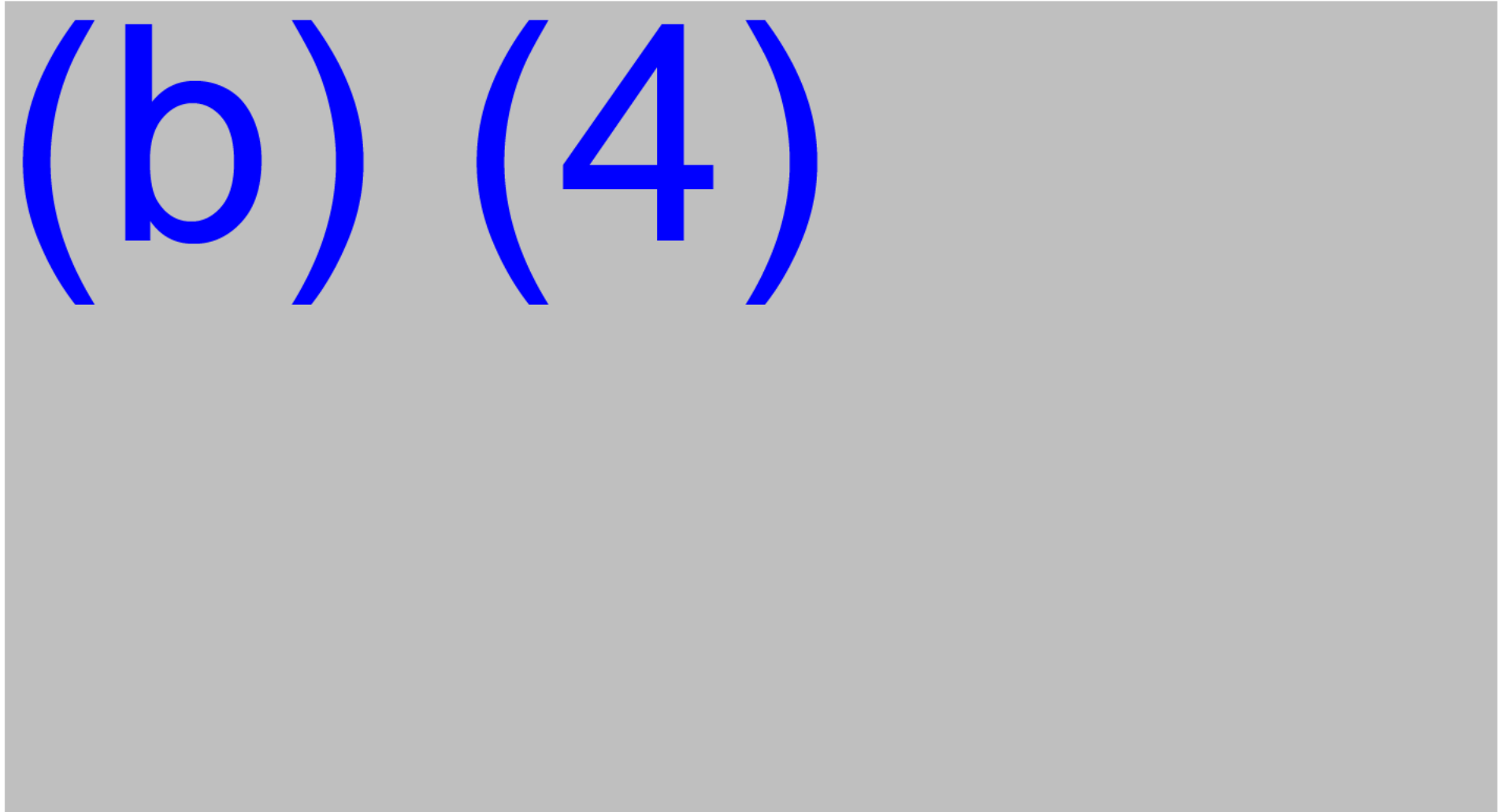
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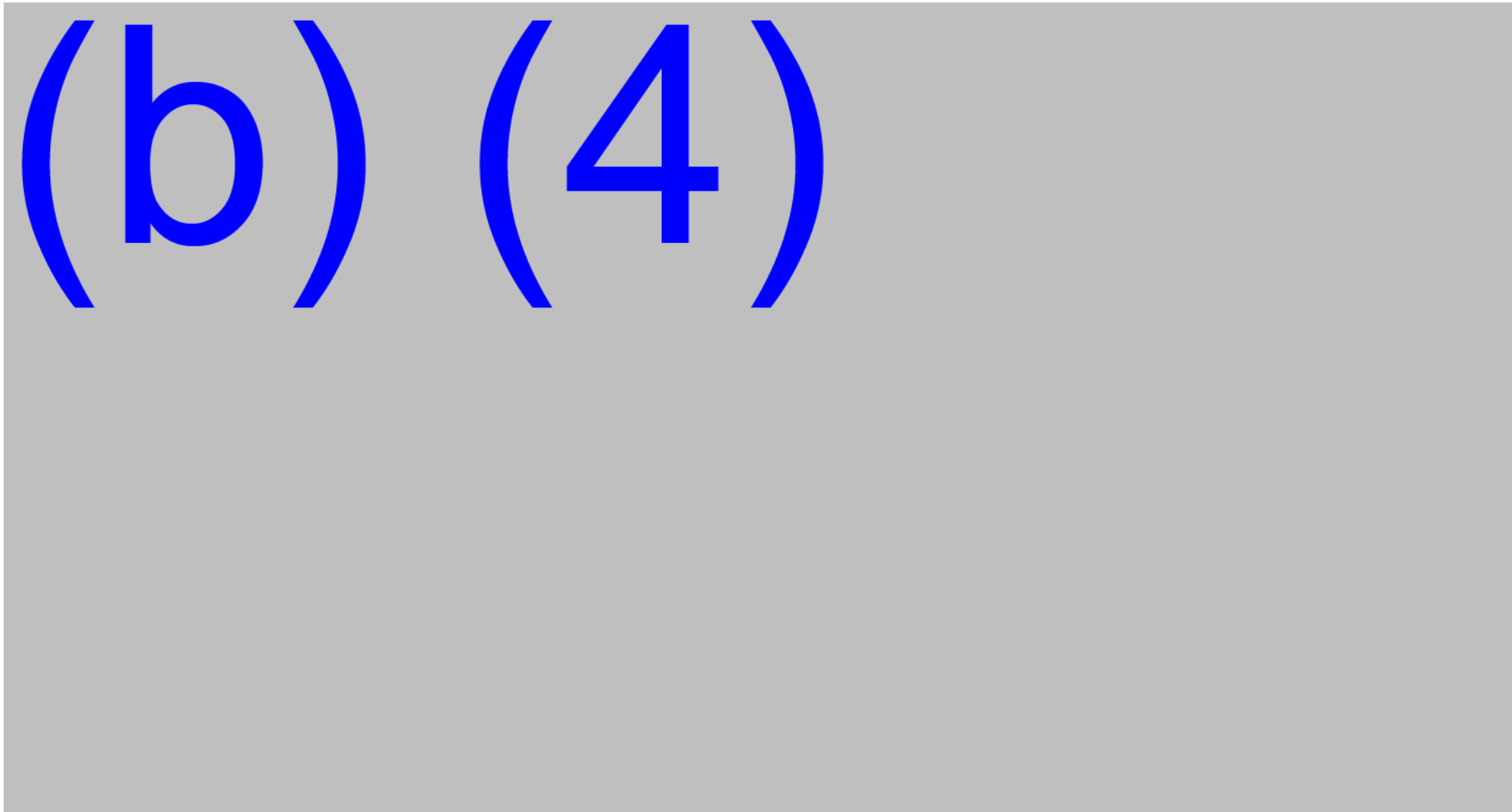
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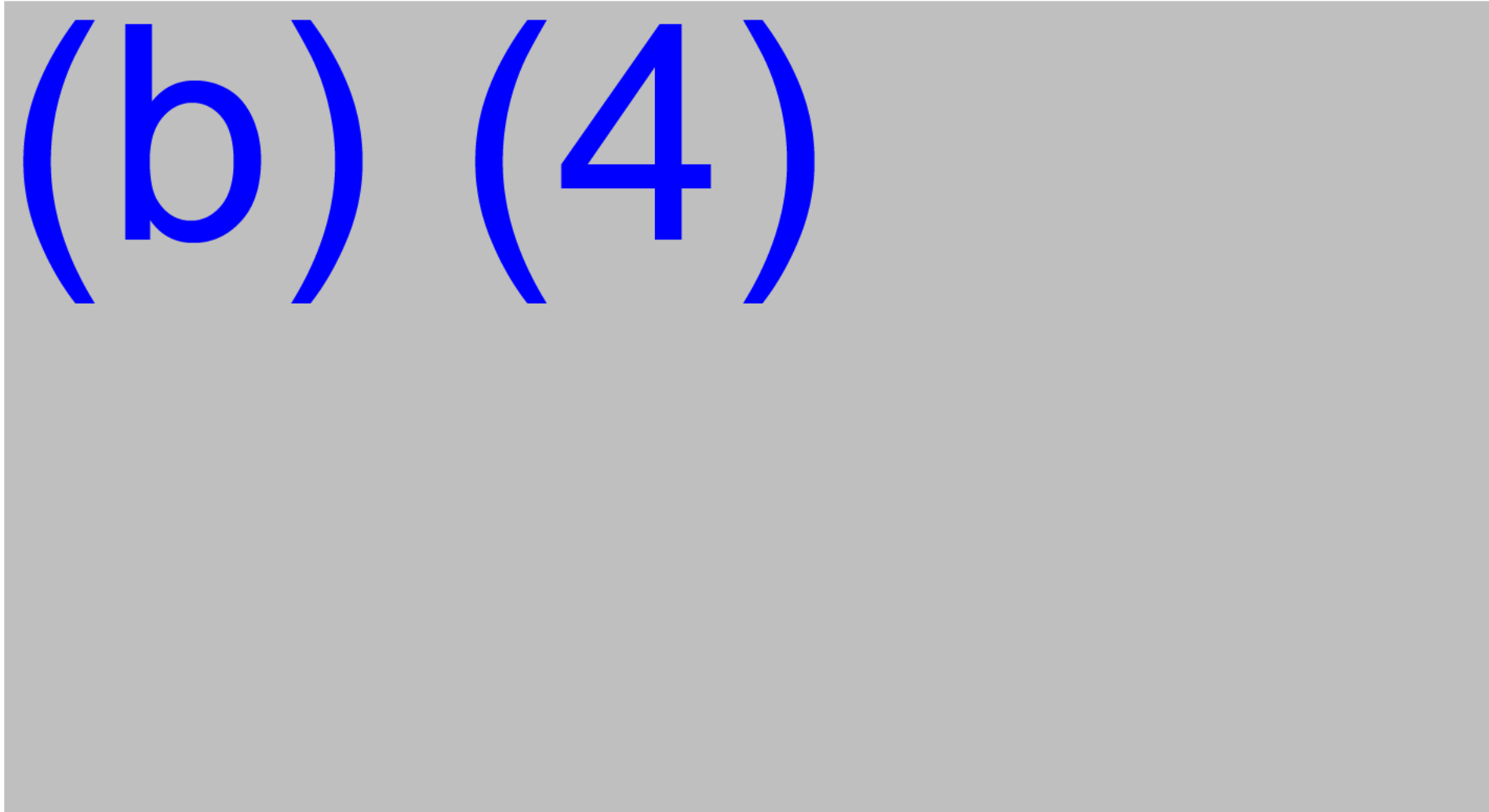
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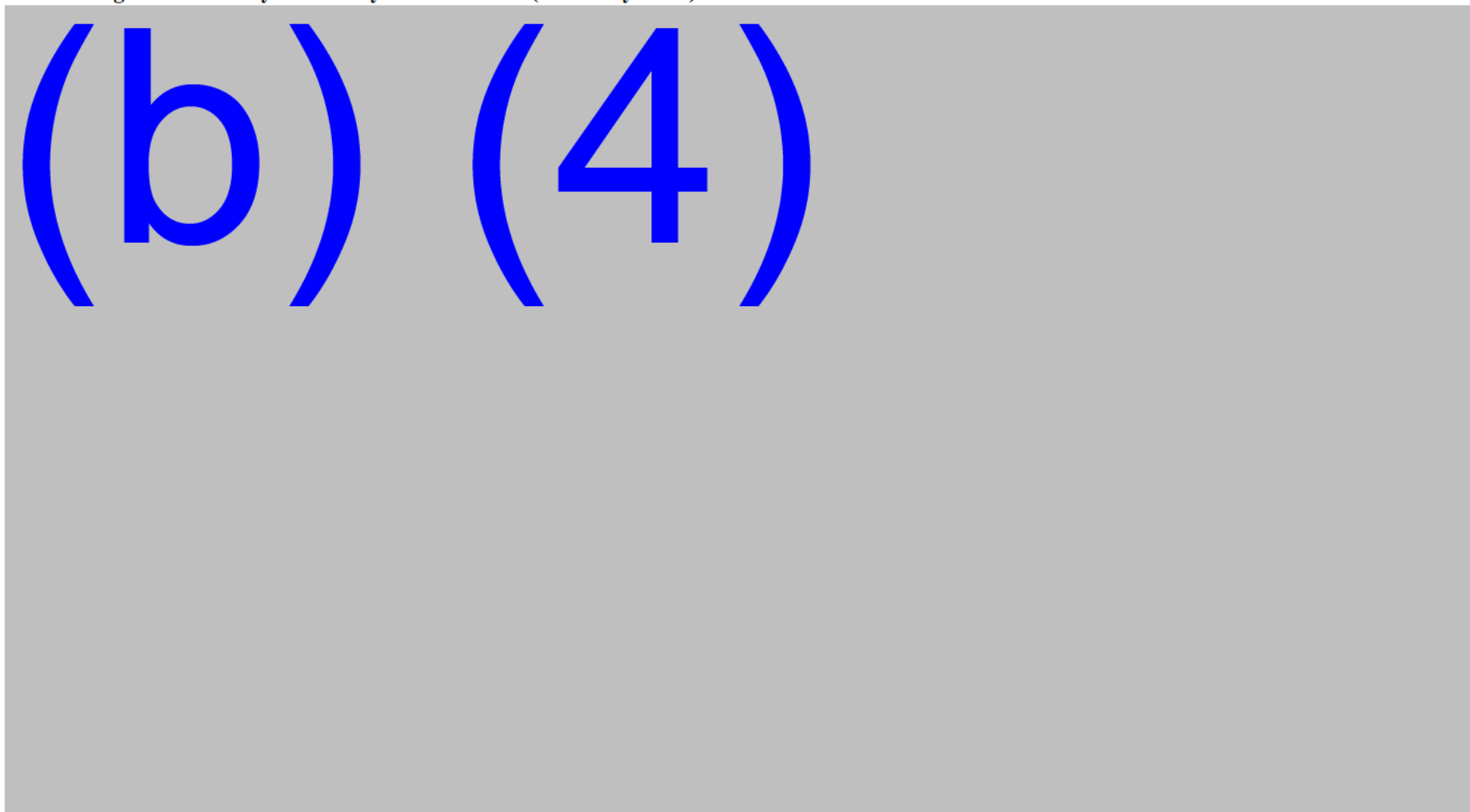
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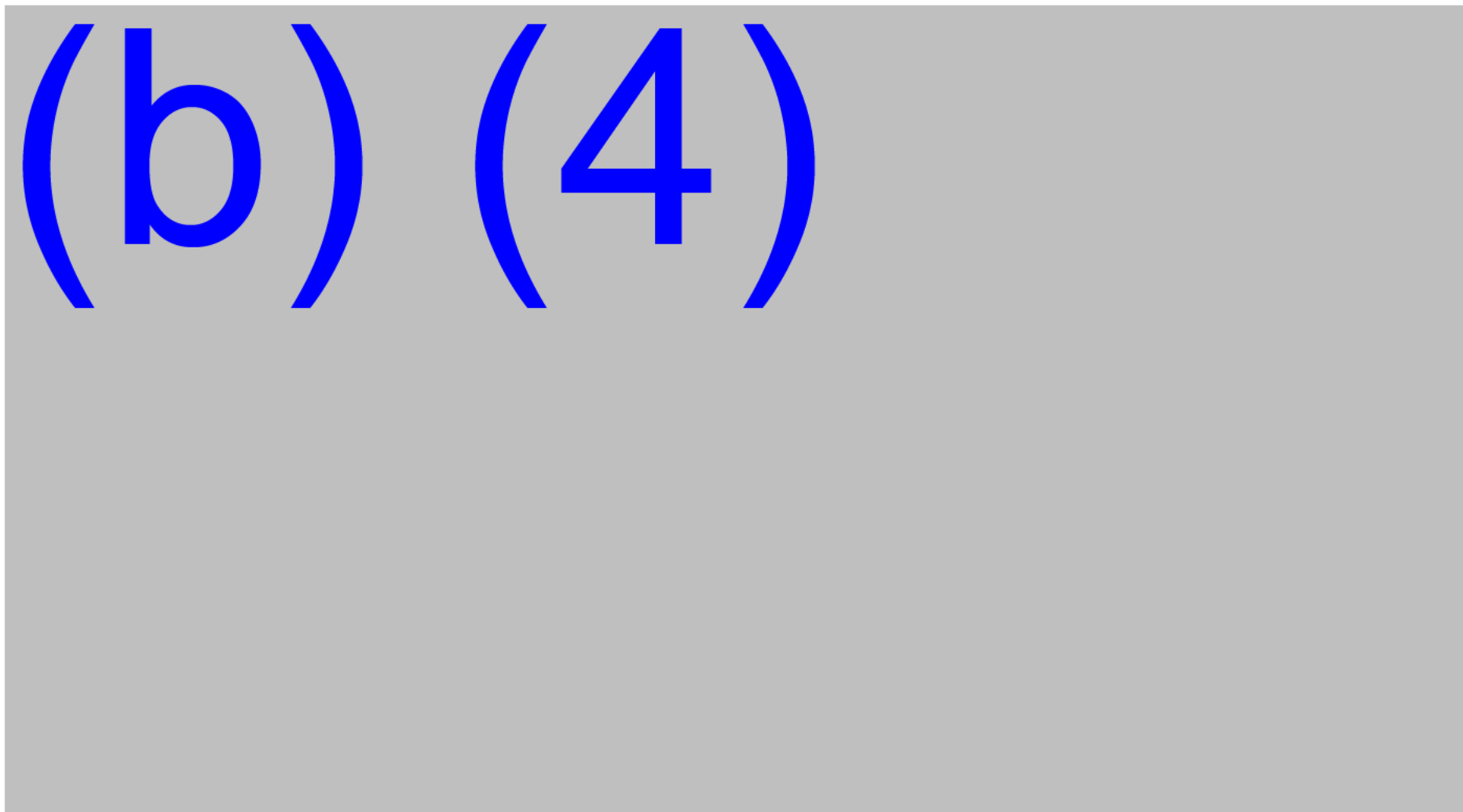
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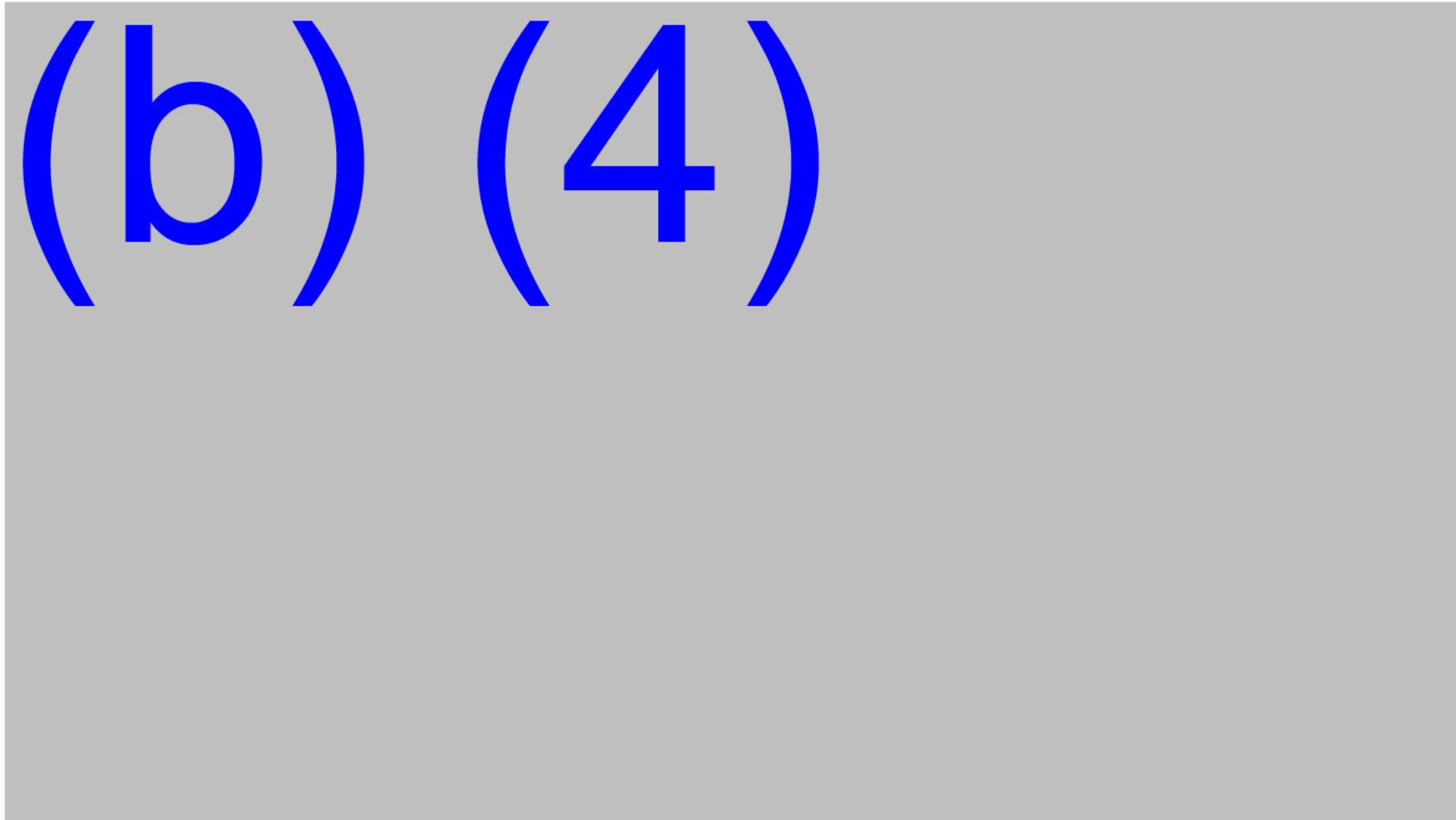
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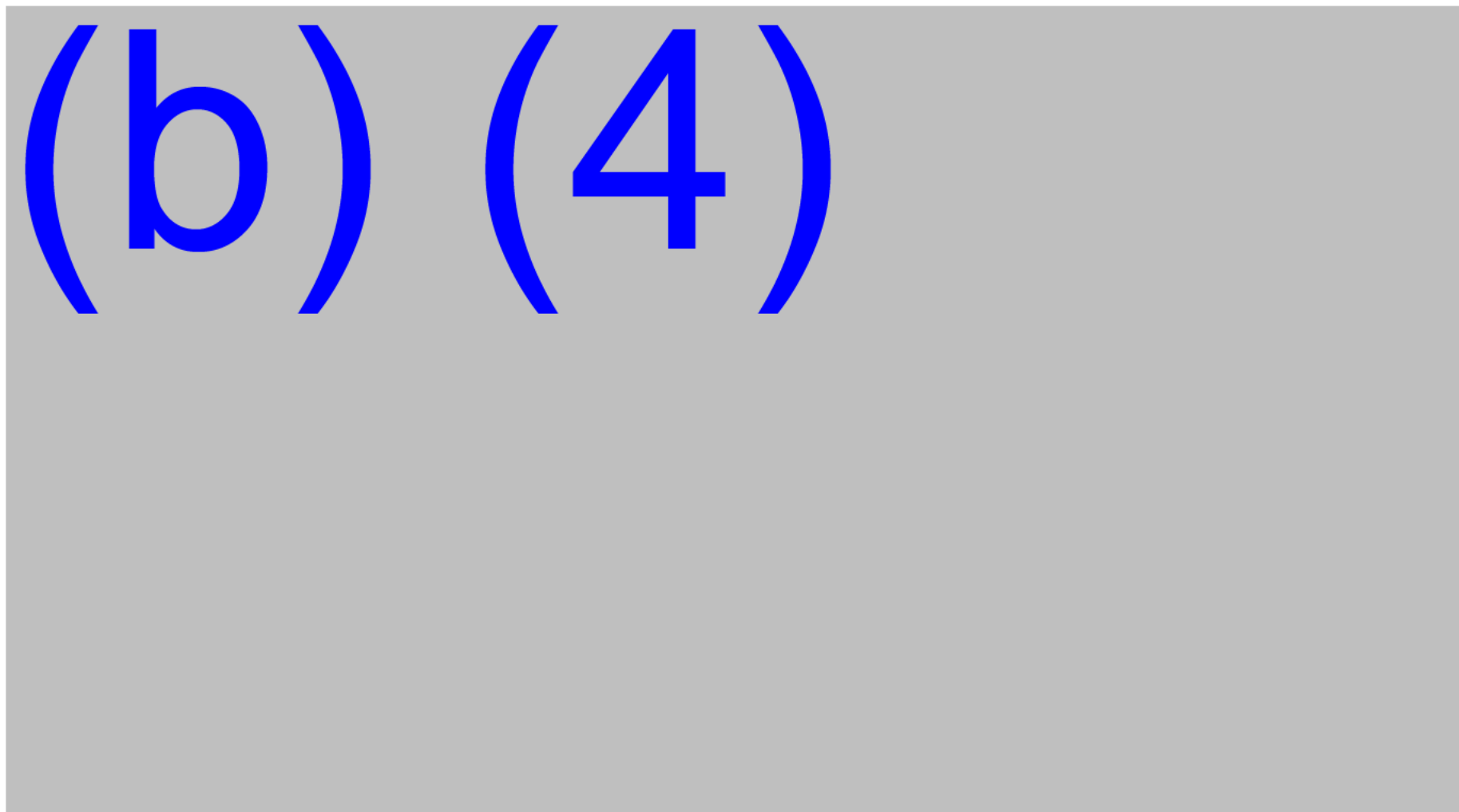
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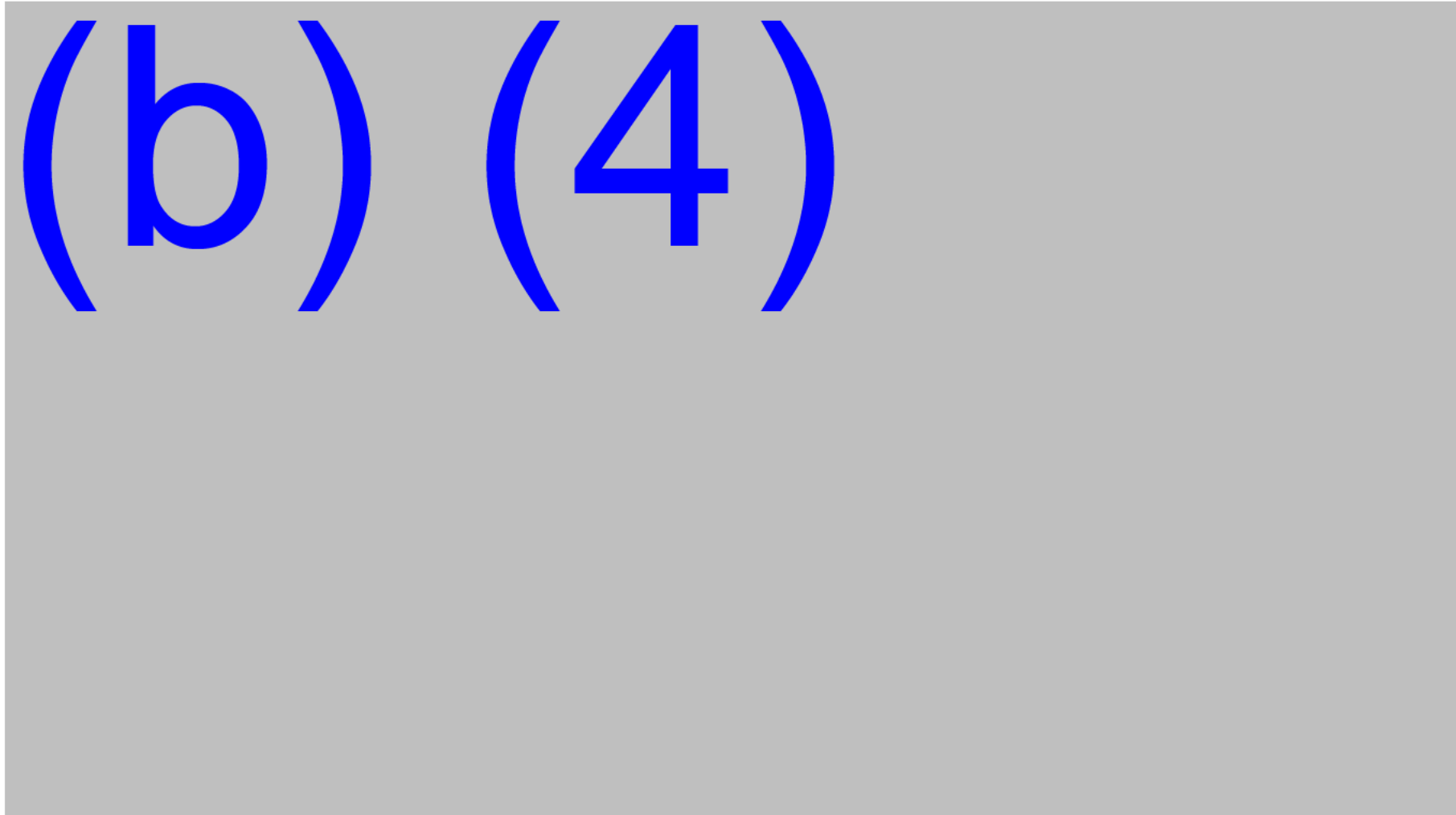
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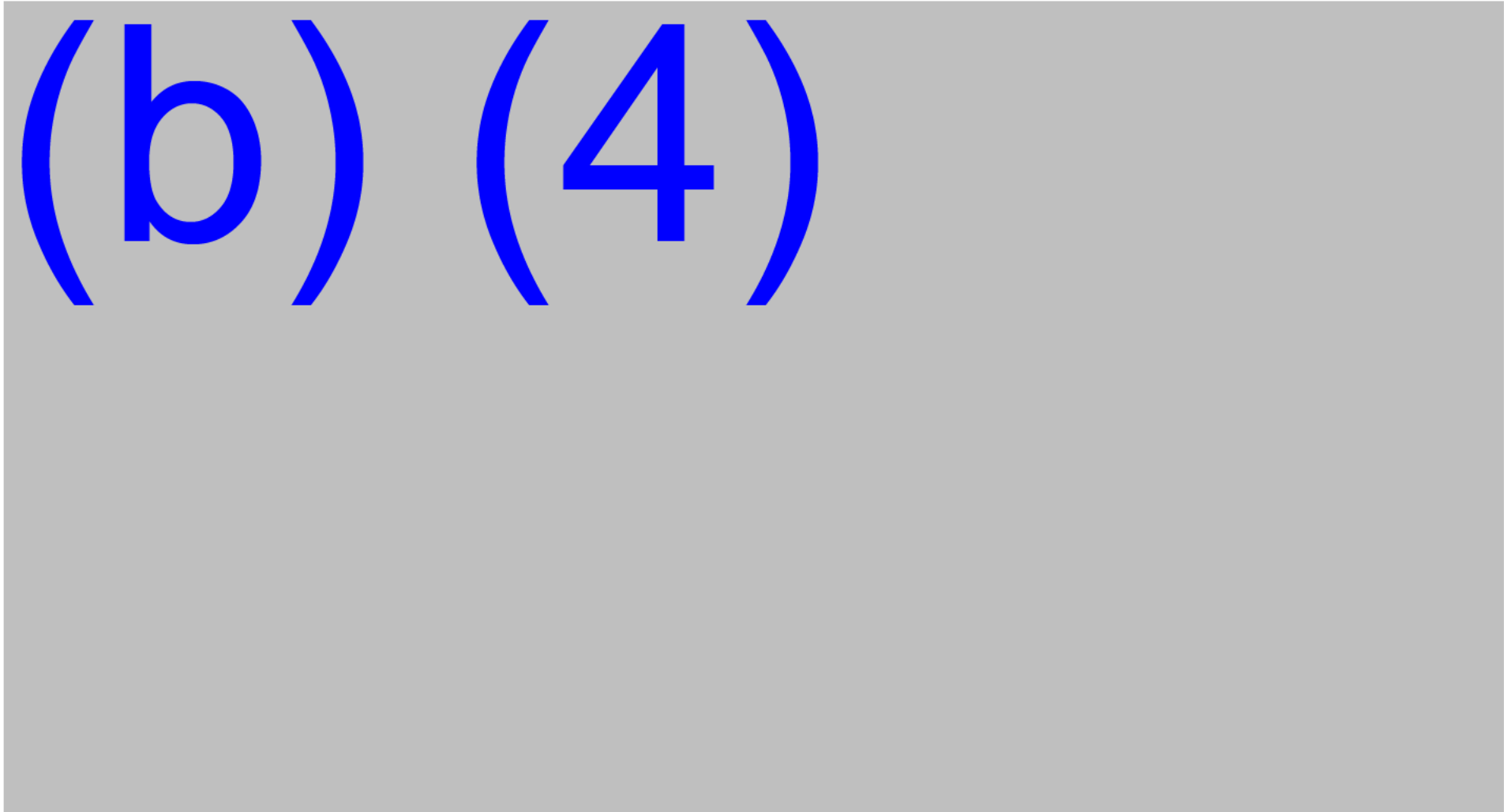
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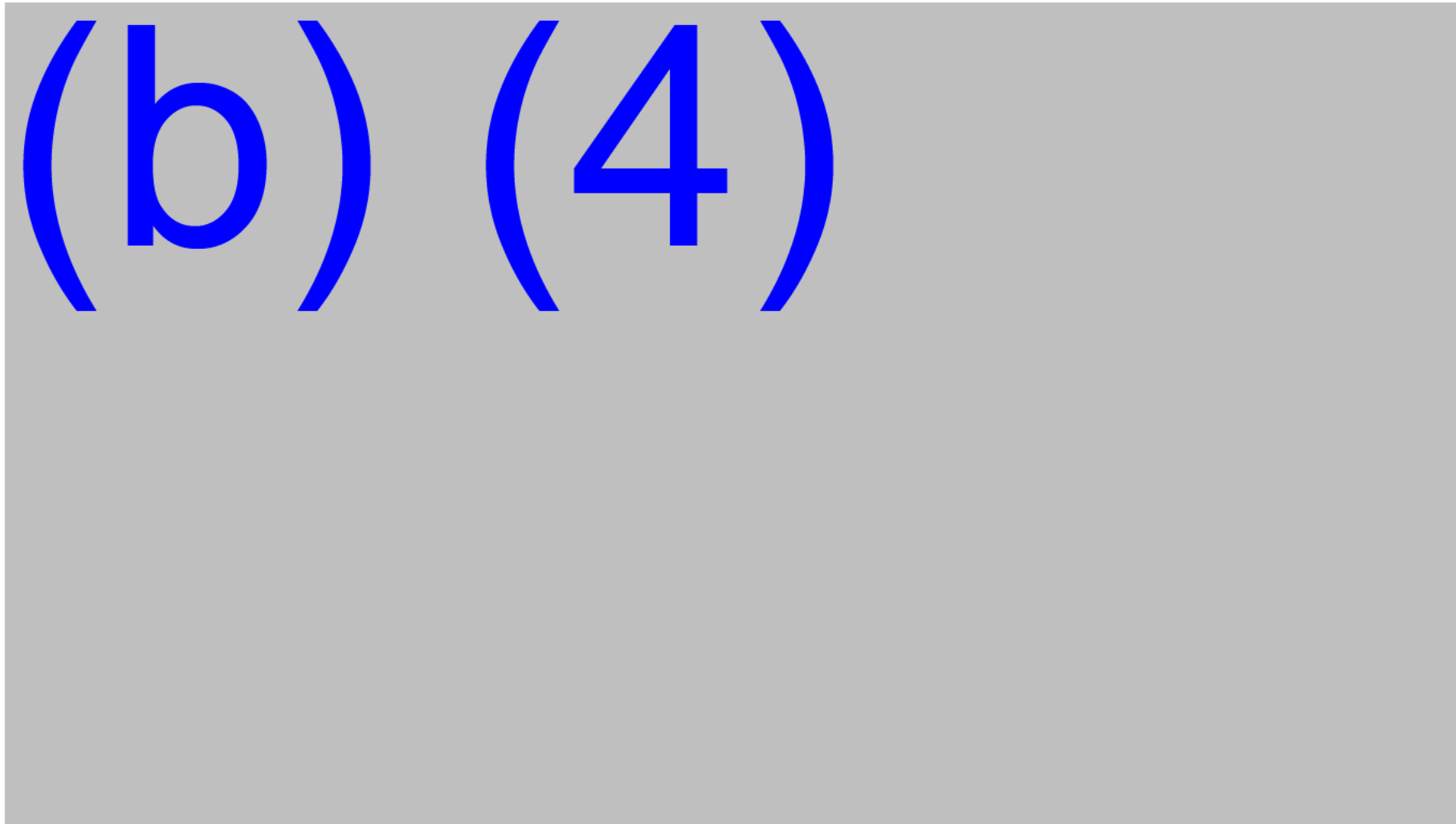
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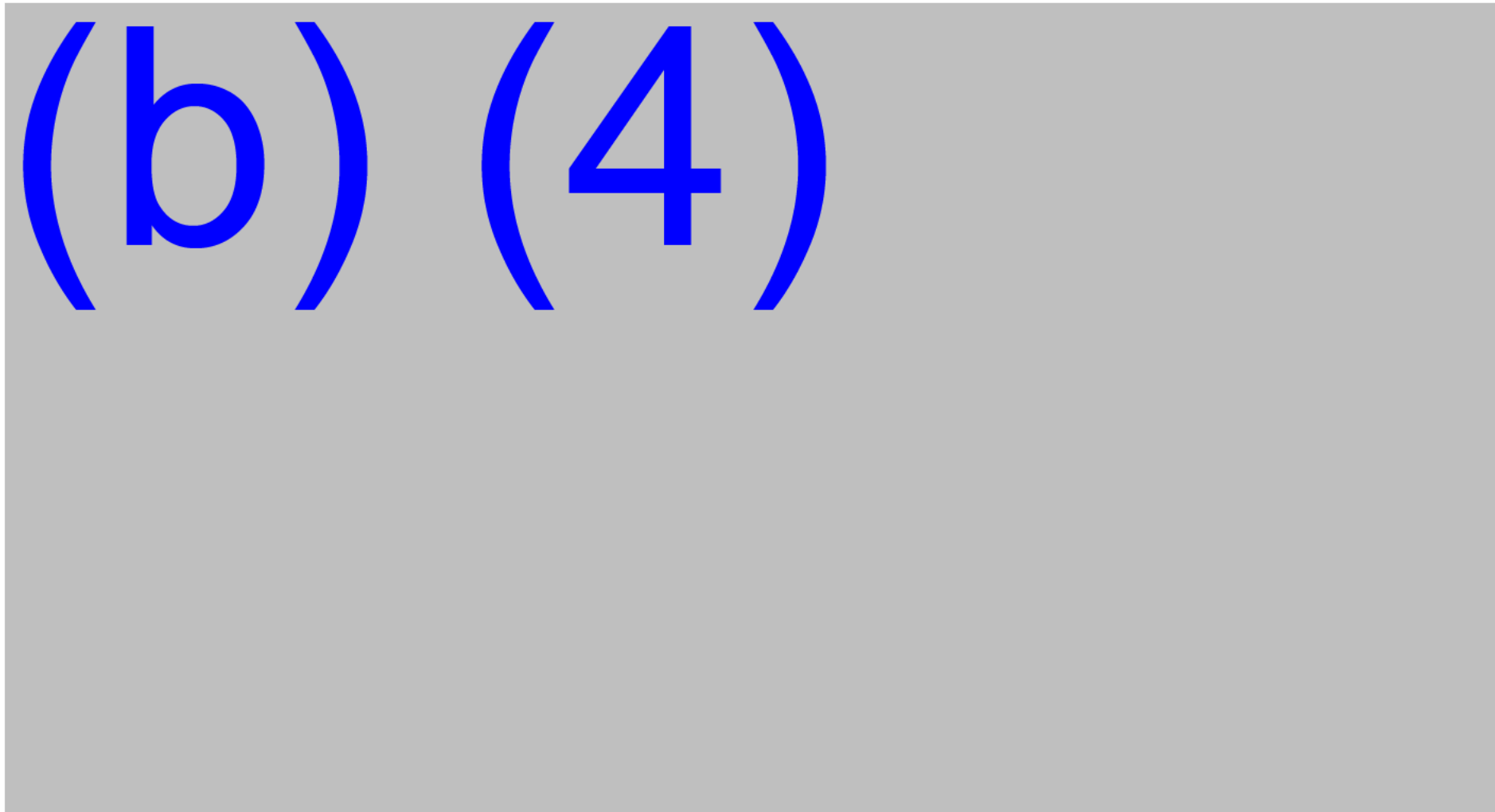
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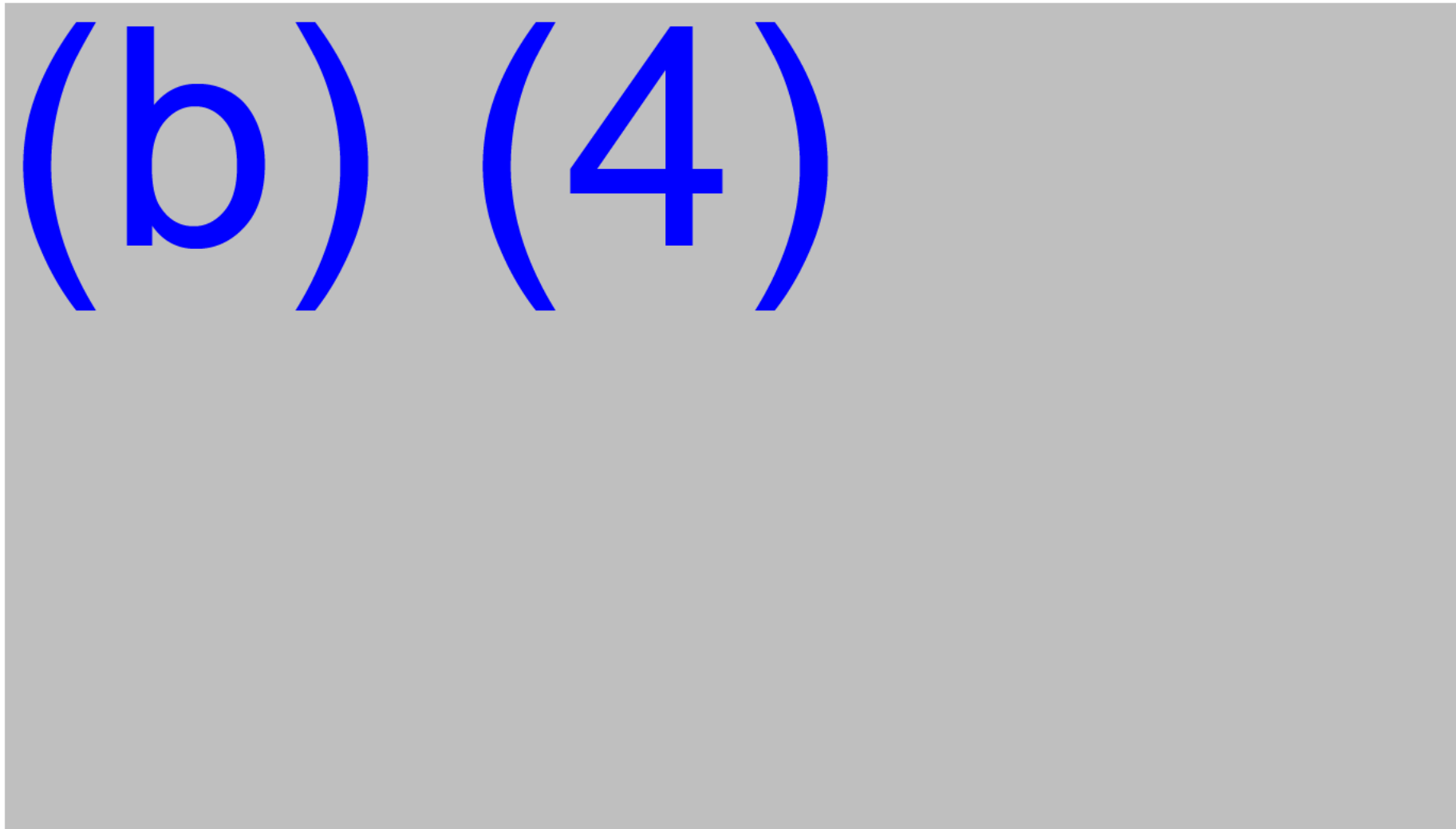
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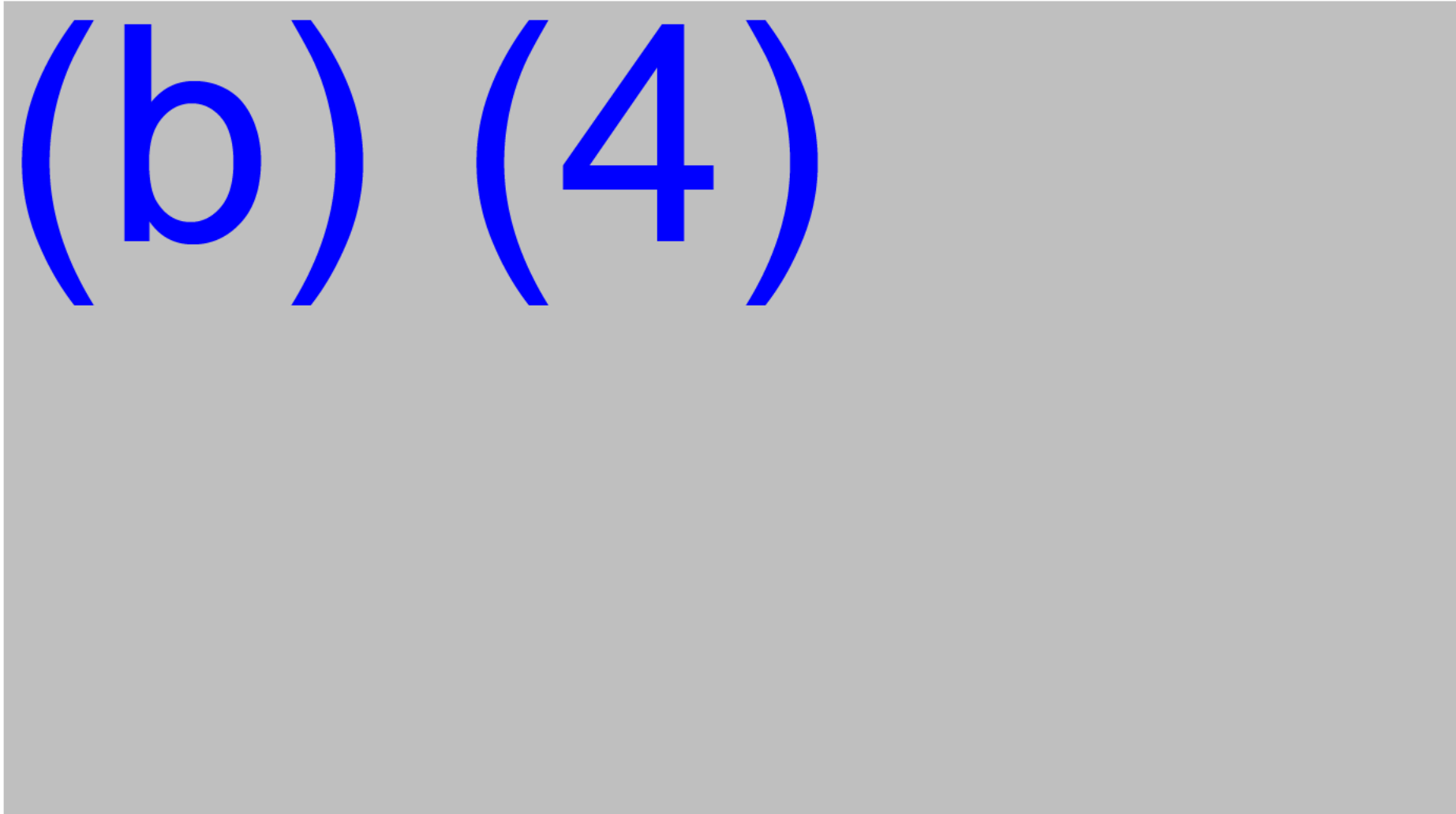
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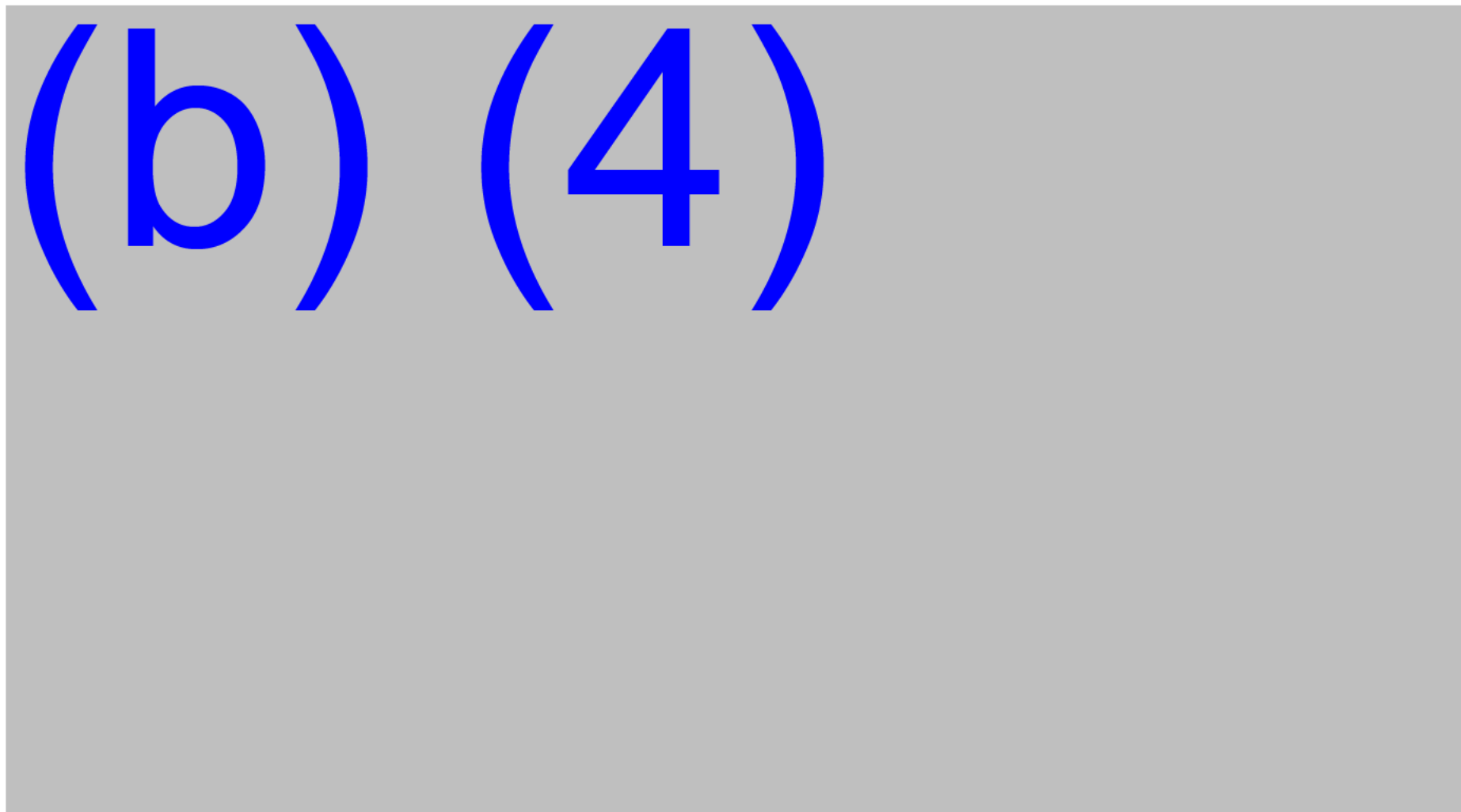
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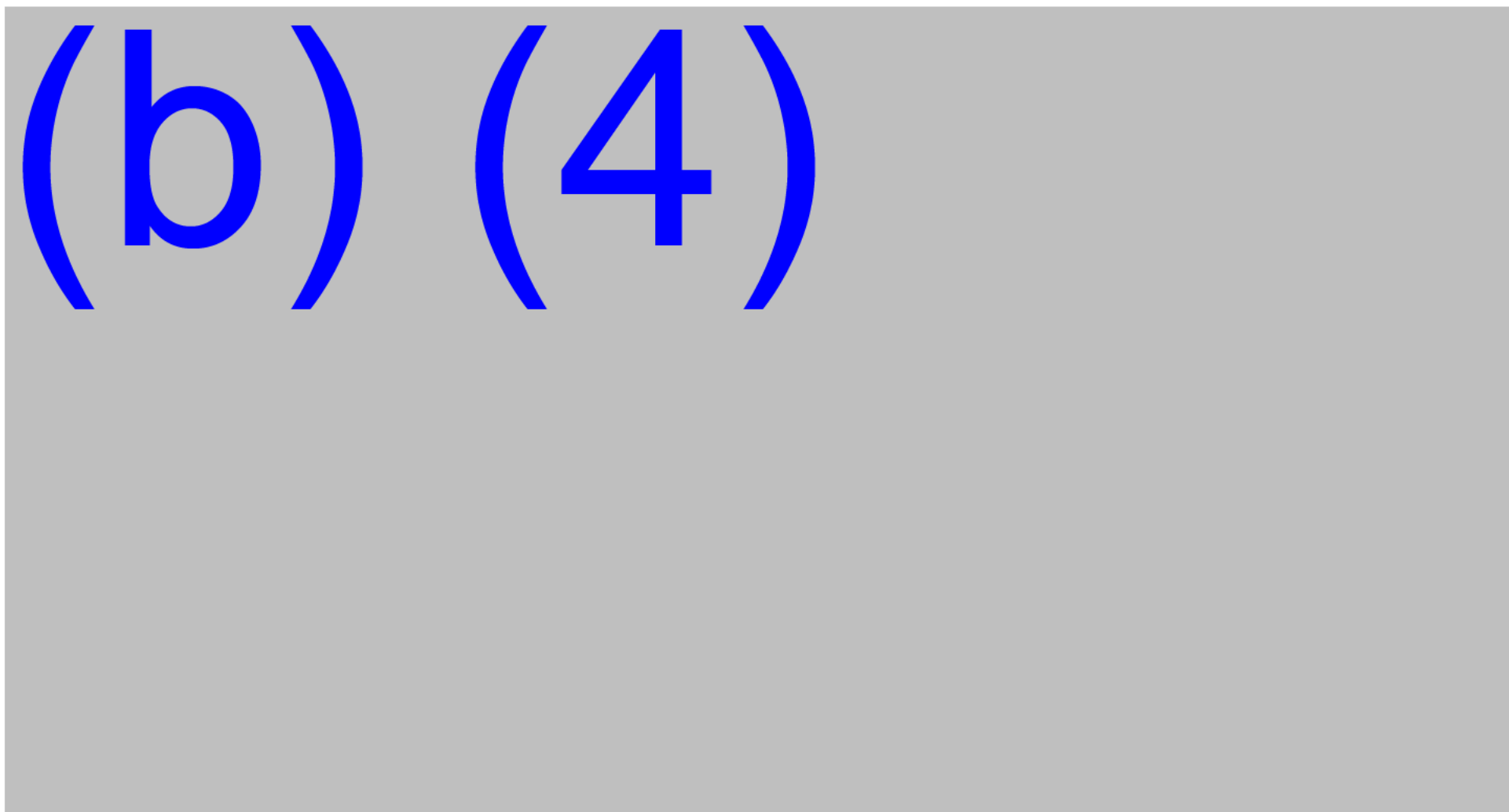
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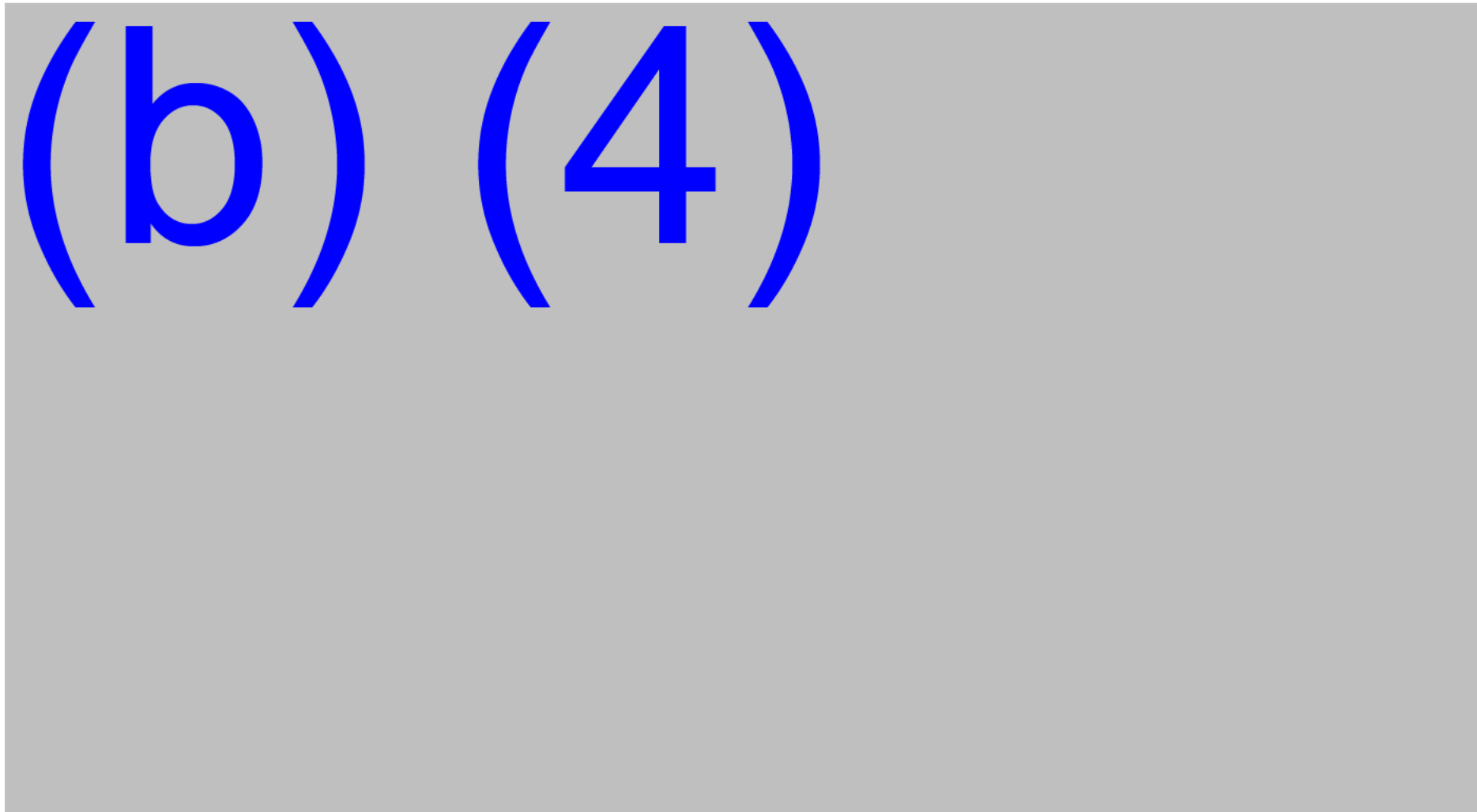
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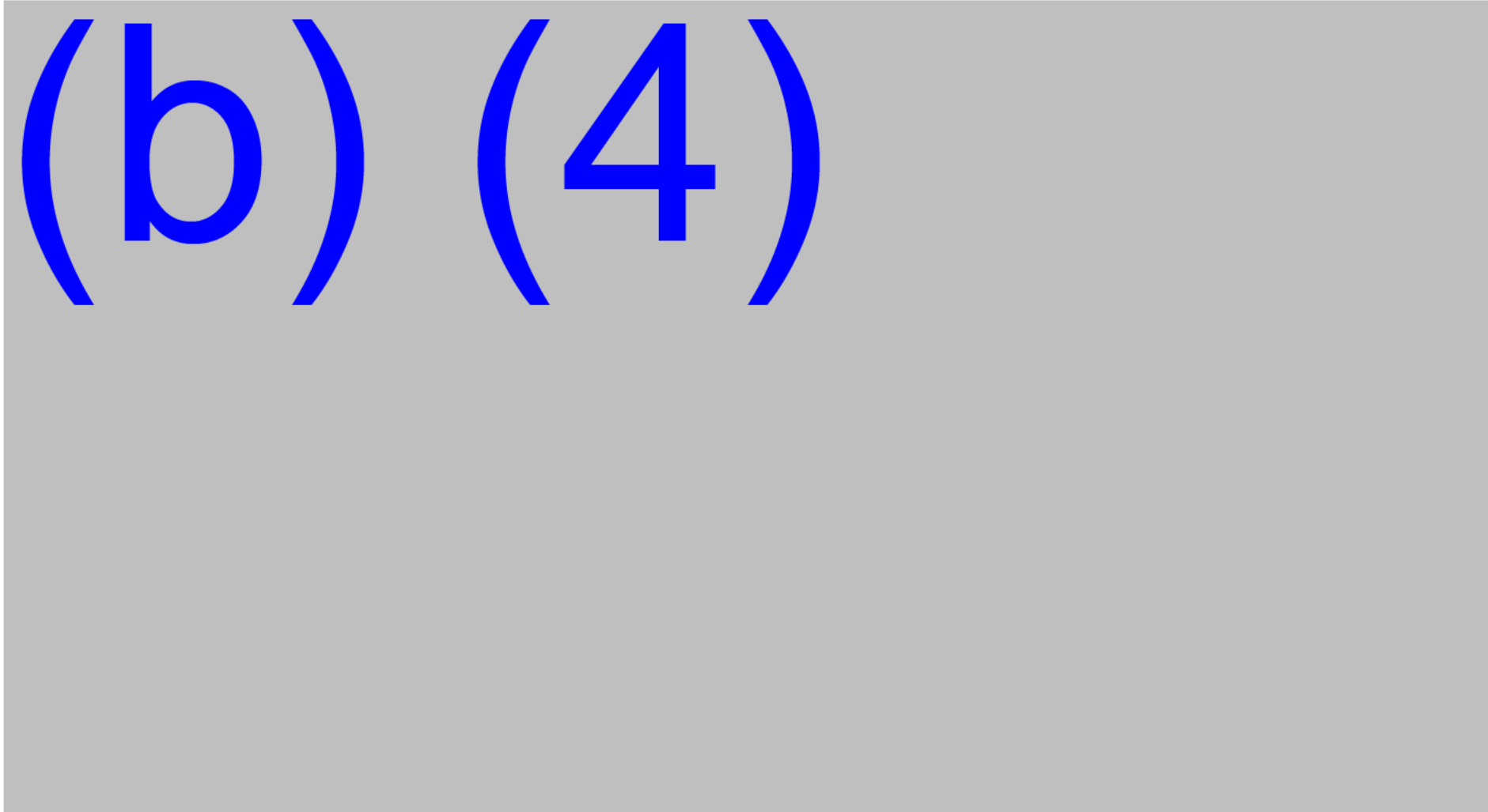
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Listing 16.2.8-2 Other laboratory measurements (Full analysis set)

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Listing 16.2.8-2 Other laboratory measurements (Full analysis set)



Listing 16.2.8-2 Other laboratory measurements (Full analysis set)

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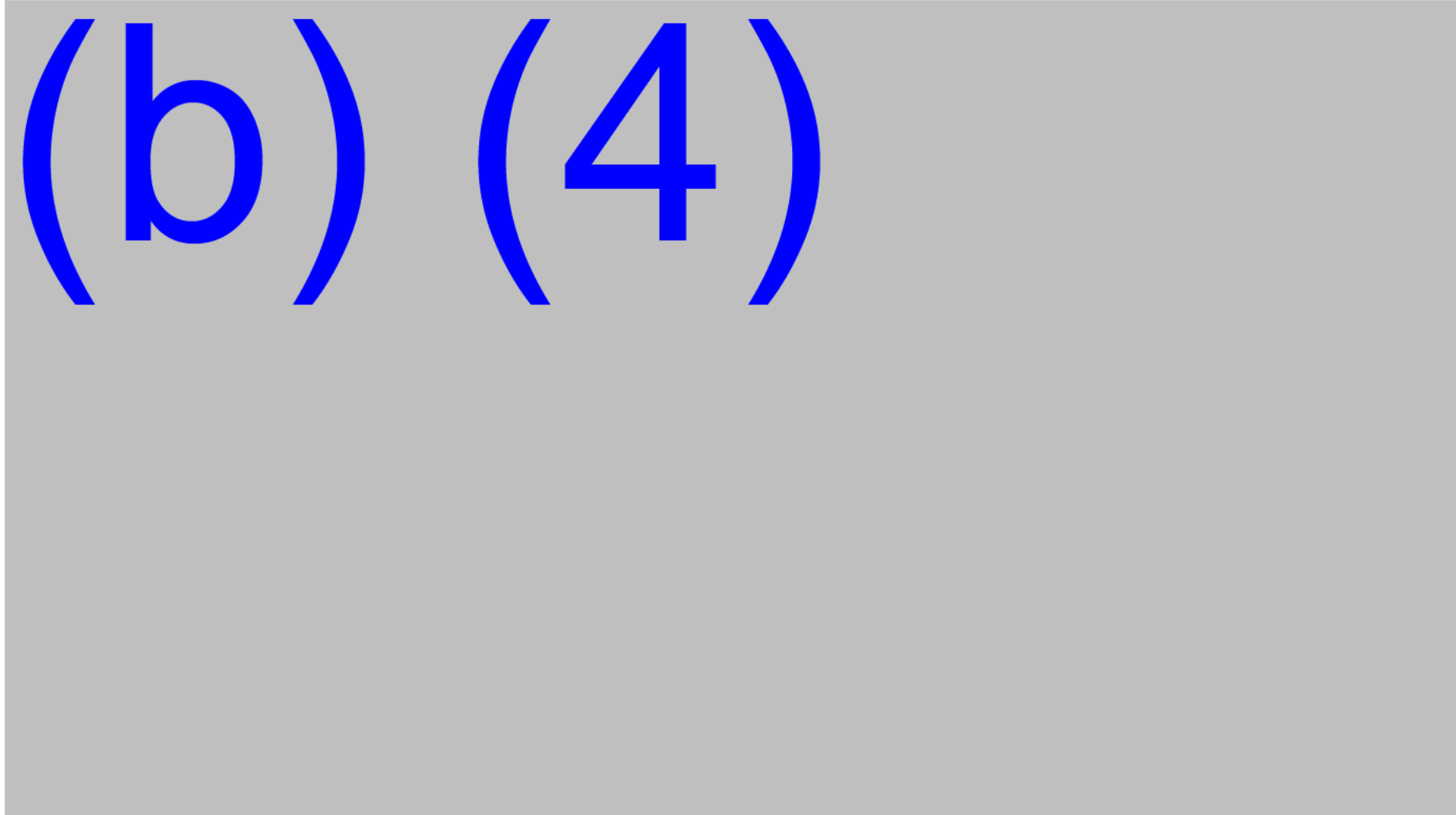
Listing 16.2.8-2 Other laboratory measurements (Full analysis set)

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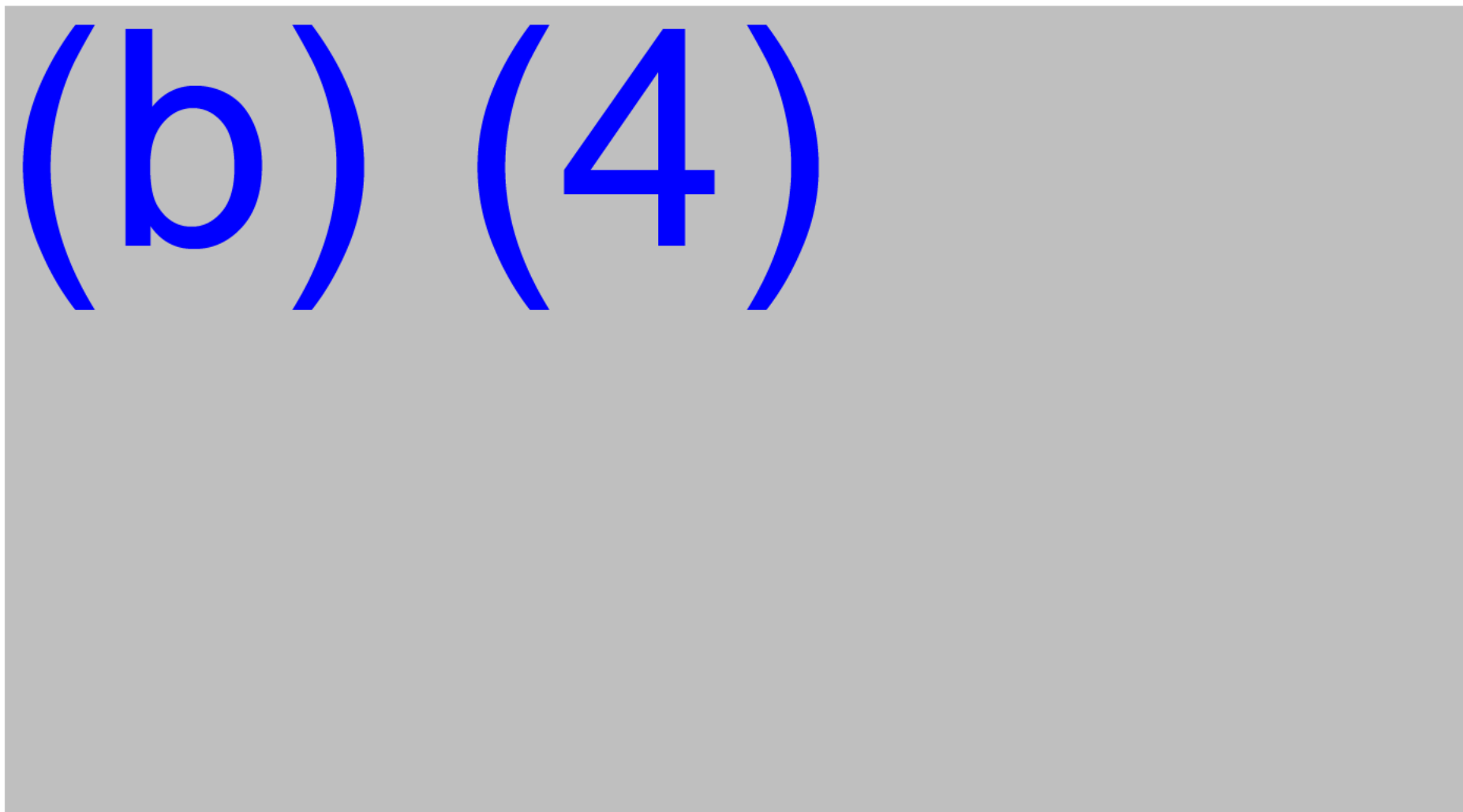
Listing 16.2.8-2 Other laboratory measurements (Full analysis set)

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Listing 16.2.8-2 Other laboratory measurements (Full analysis set)



Listing 16.2.8-2 Other laboratory measurements (Full analysis set)



Listing 16.2.8-2 Other laboratory measurements (Full analysis set)

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Listing 16.2.8-2 Other laboratory measurements (Full analysis set)

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Appendix 16.2.9

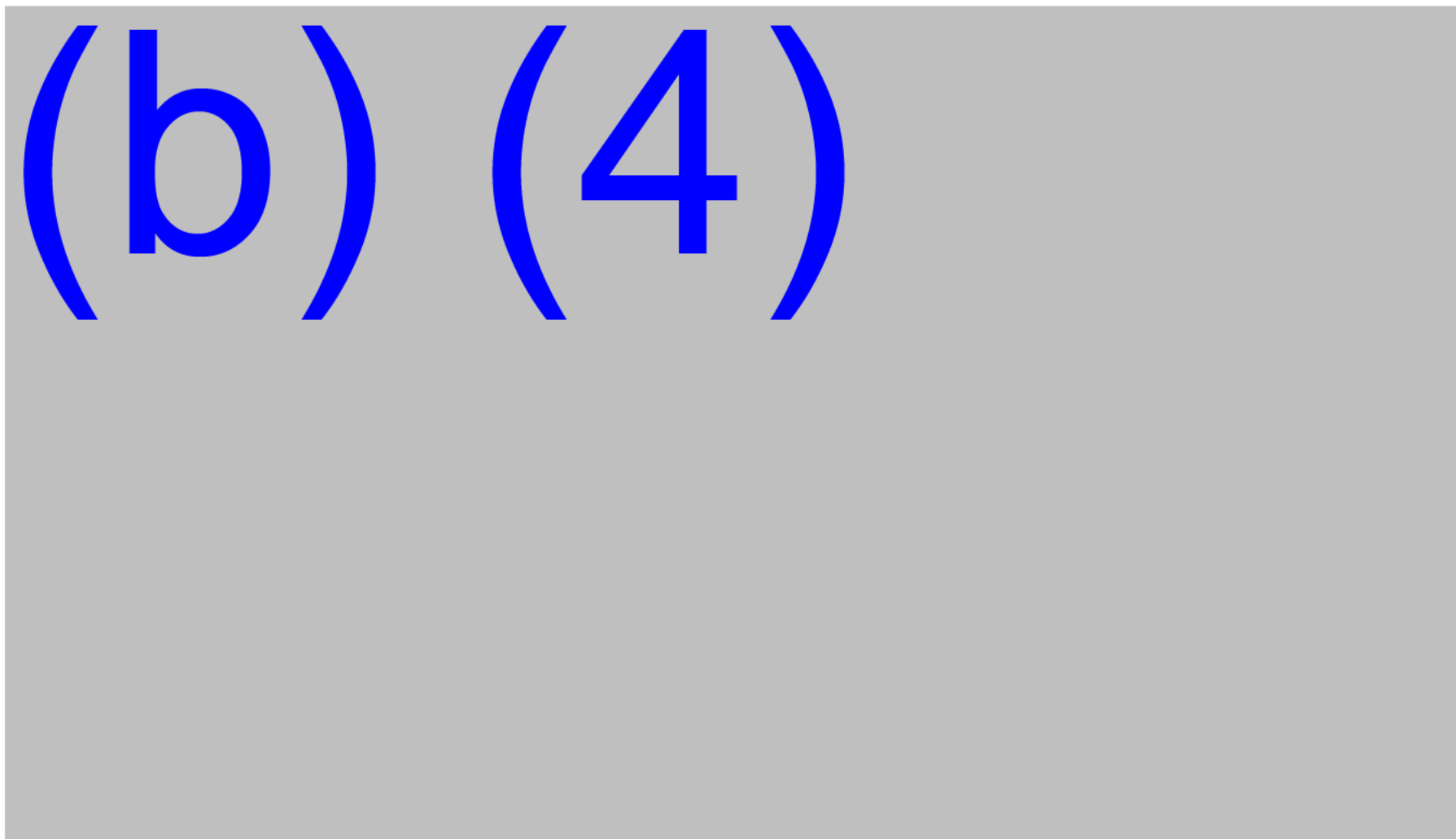
Listing 16.2.9-1 Vital signs

Listing 16.2.9-2 ECG

Listing 16.2.9-3 Physical examinations

Listing 16.2.9-4 Lung function assessed using spirometry

Listing 16.2.9-1 Vital signs (Full analysis set)



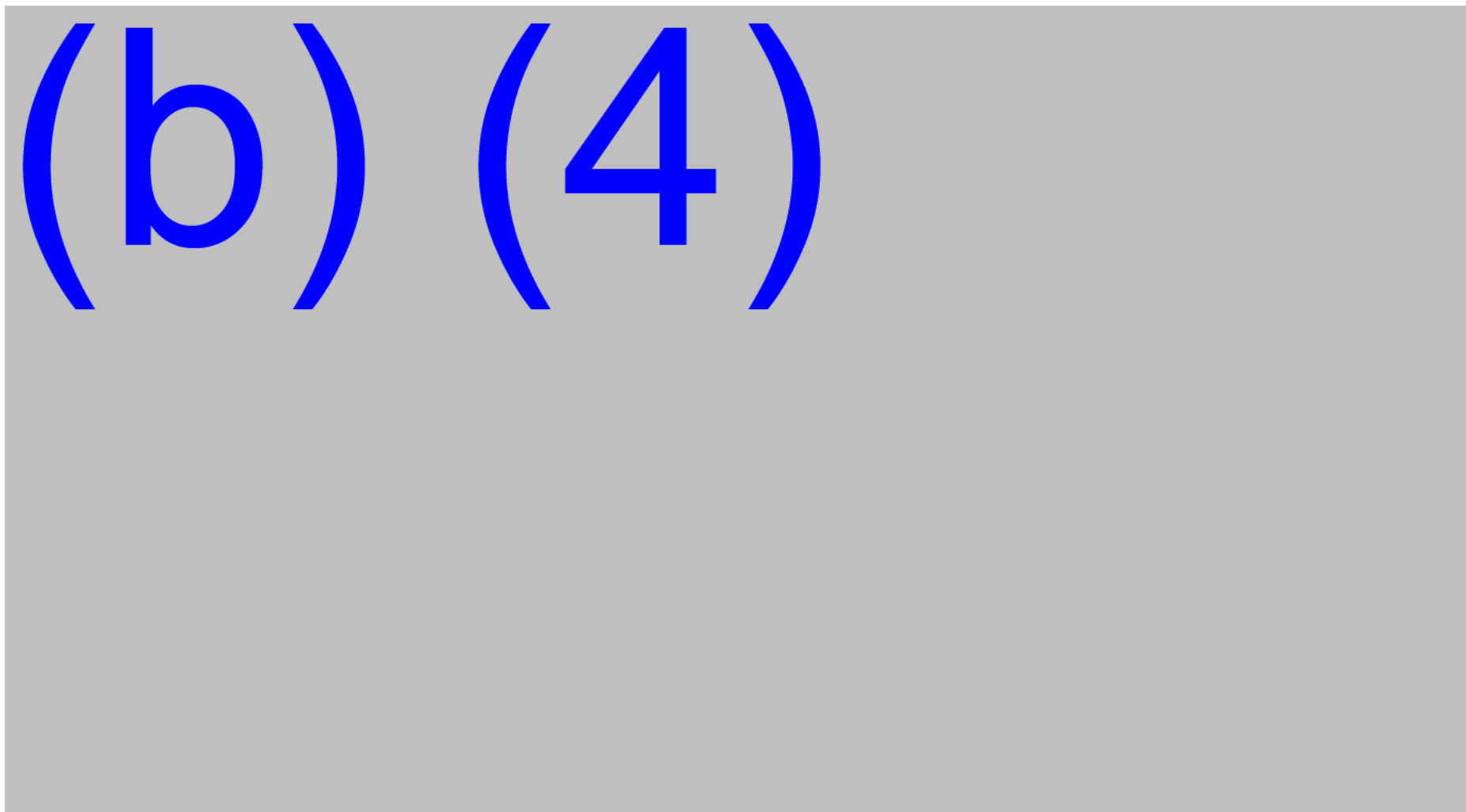
Listing 16.2.9-1 Vital signs (Full analysis set)

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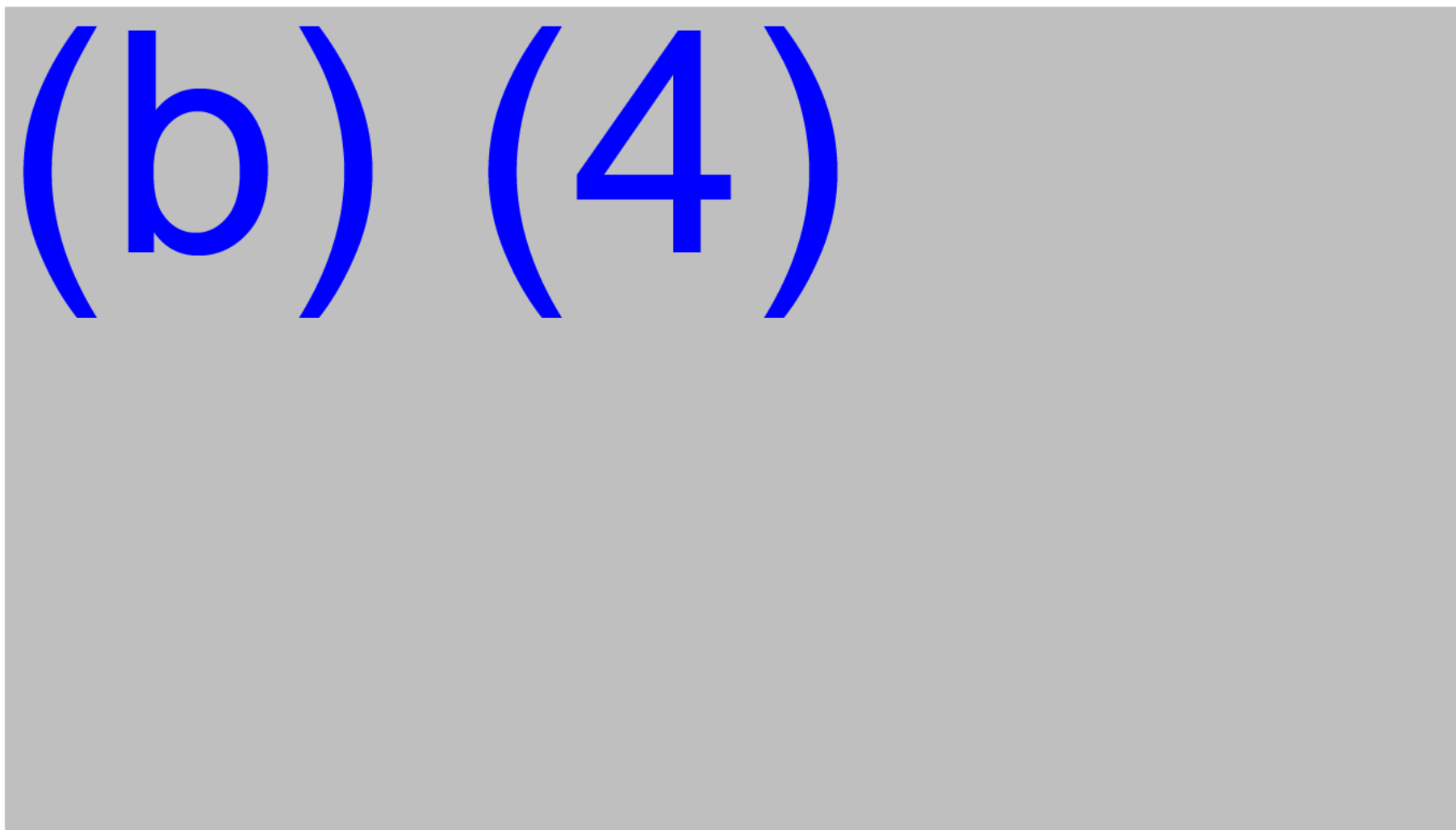
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Listing 16.2.9-1 Vital signs (Full analysis set)

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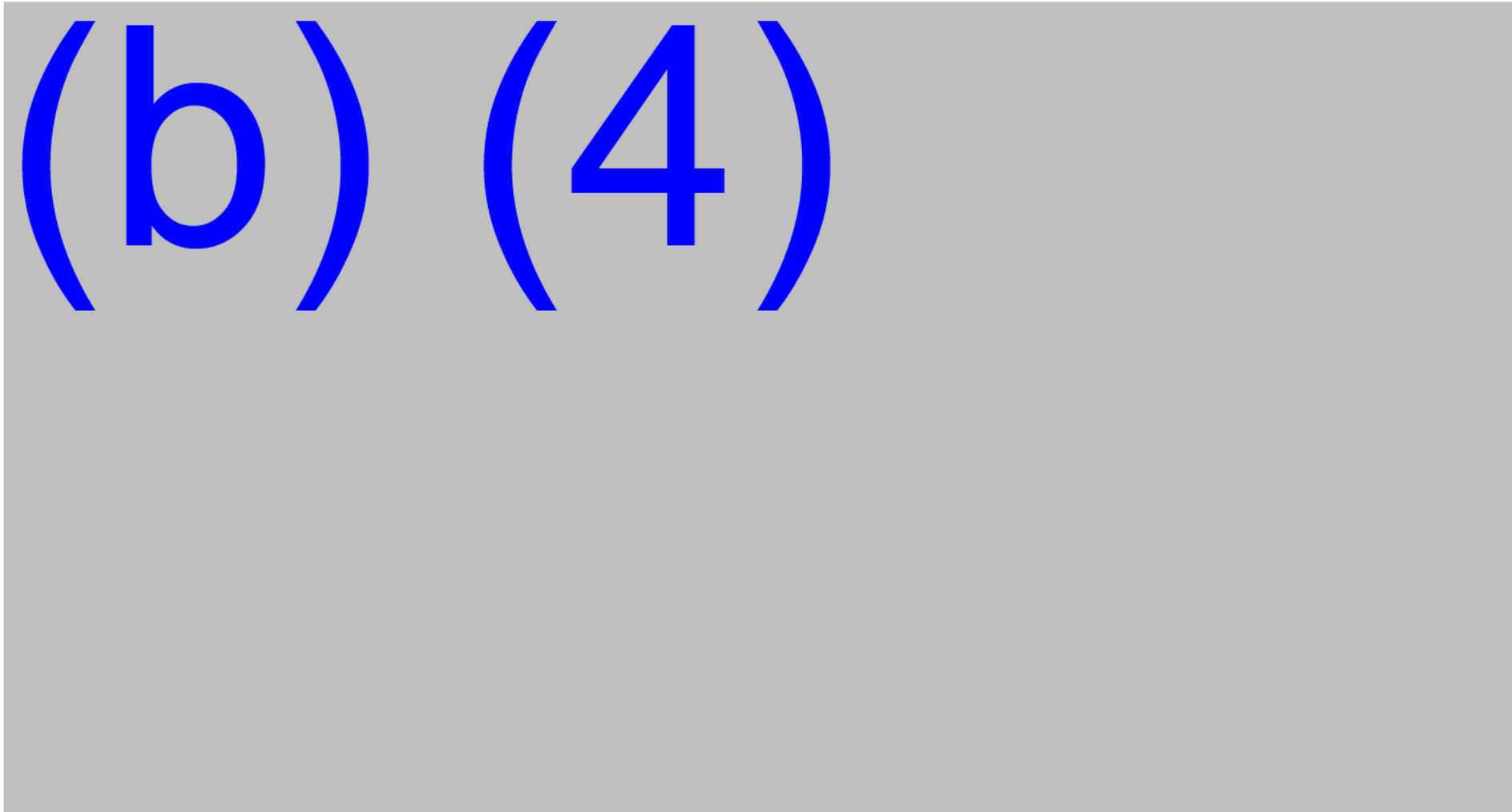
Listing 16.2.9-1 Vital signs (Full analysis set)



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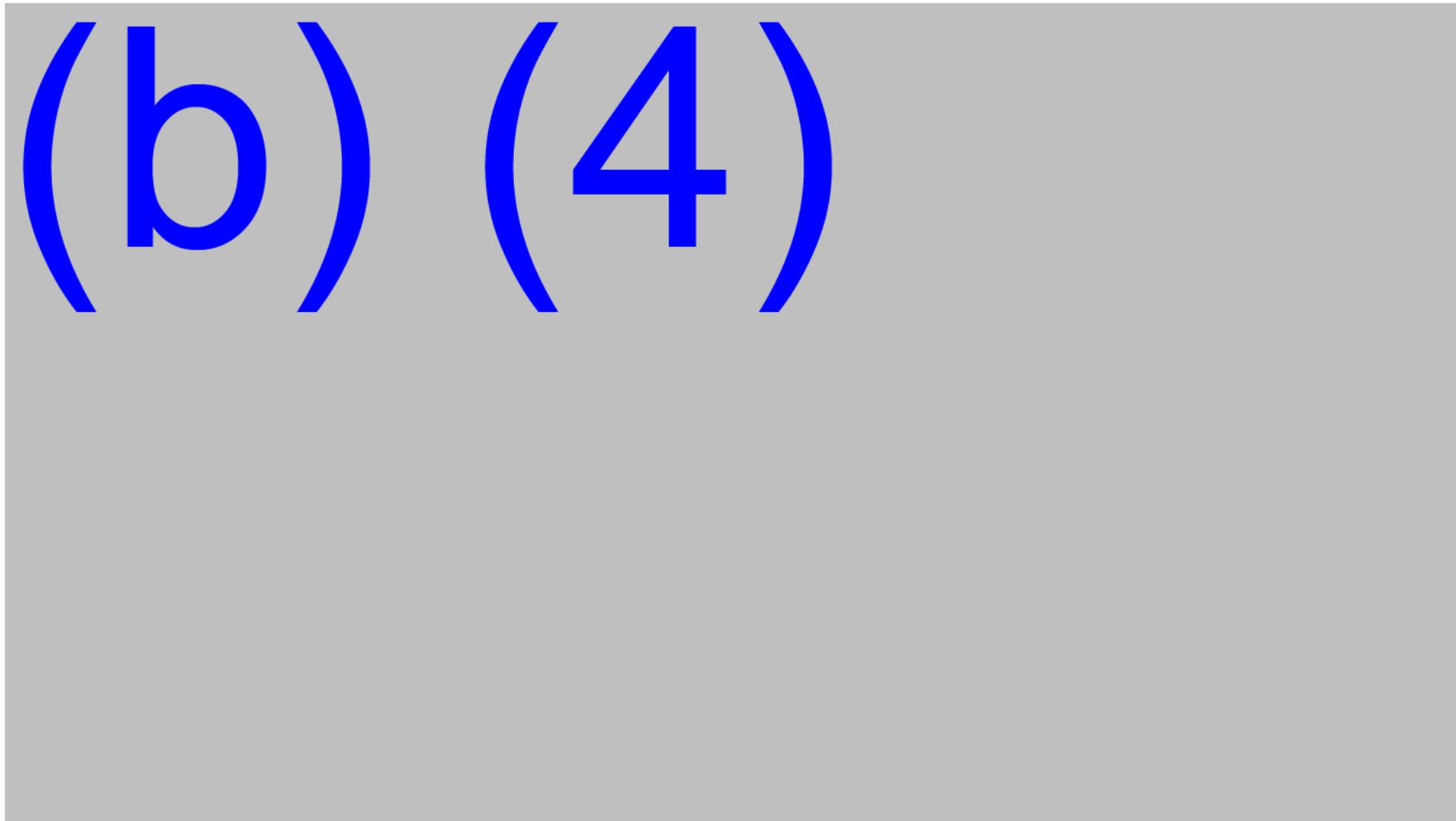
Listing 16.2.9-1 Vital signs (Full analysis set)



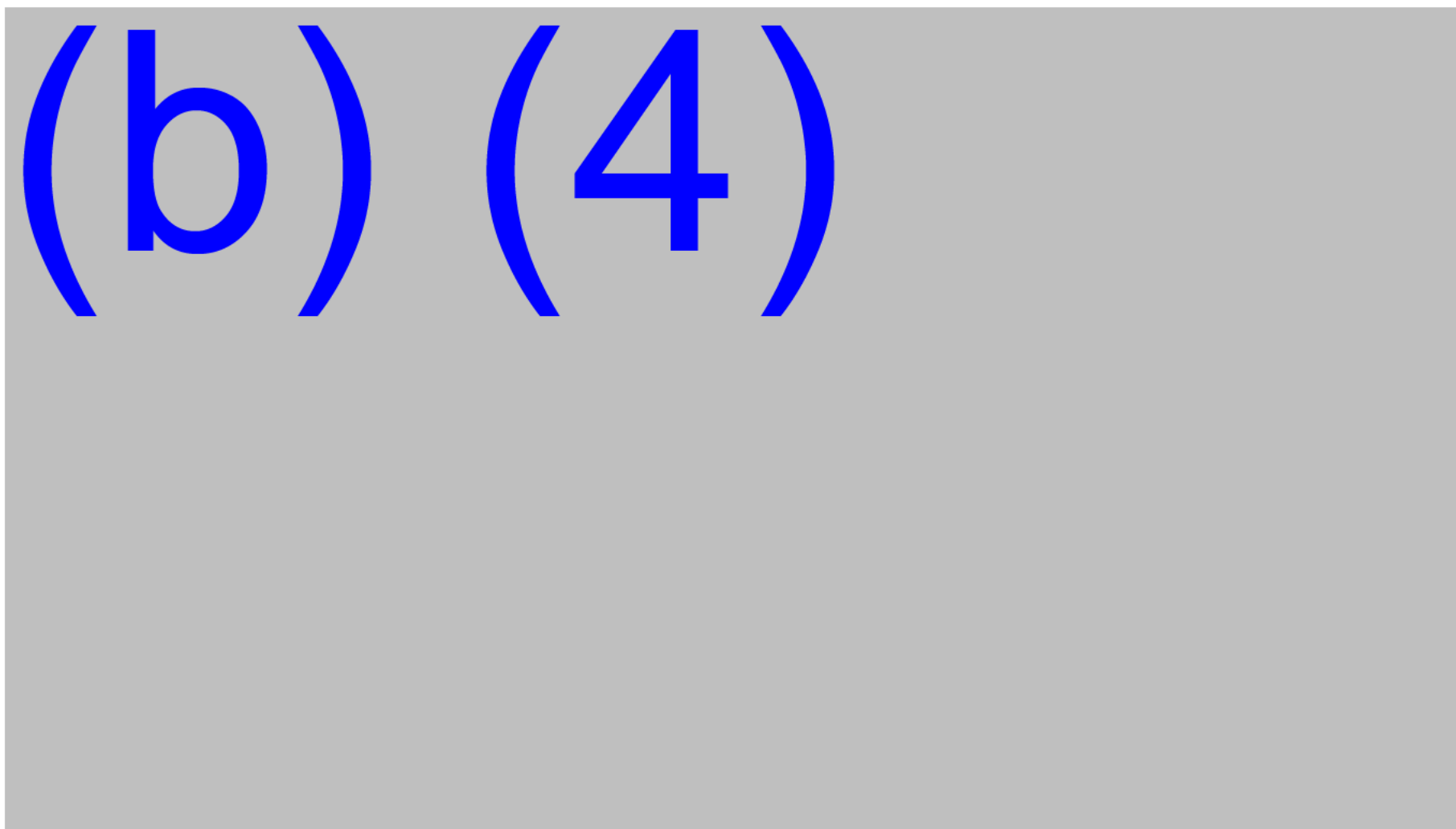
Listing 16.2.9-1 Vital signs (Full analysis set)

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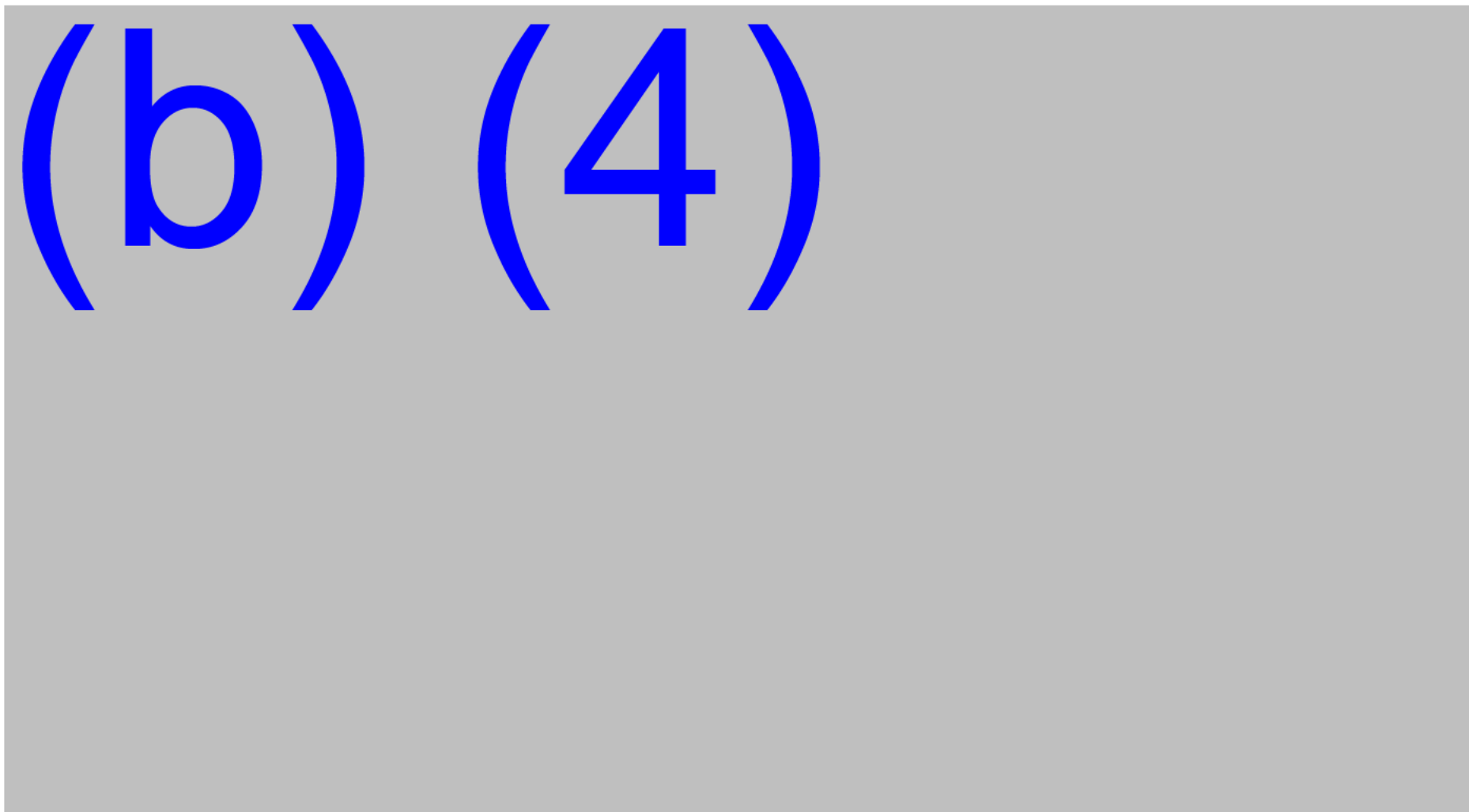
Listing 16.2.9-1 Vital signs (Full analysis set)

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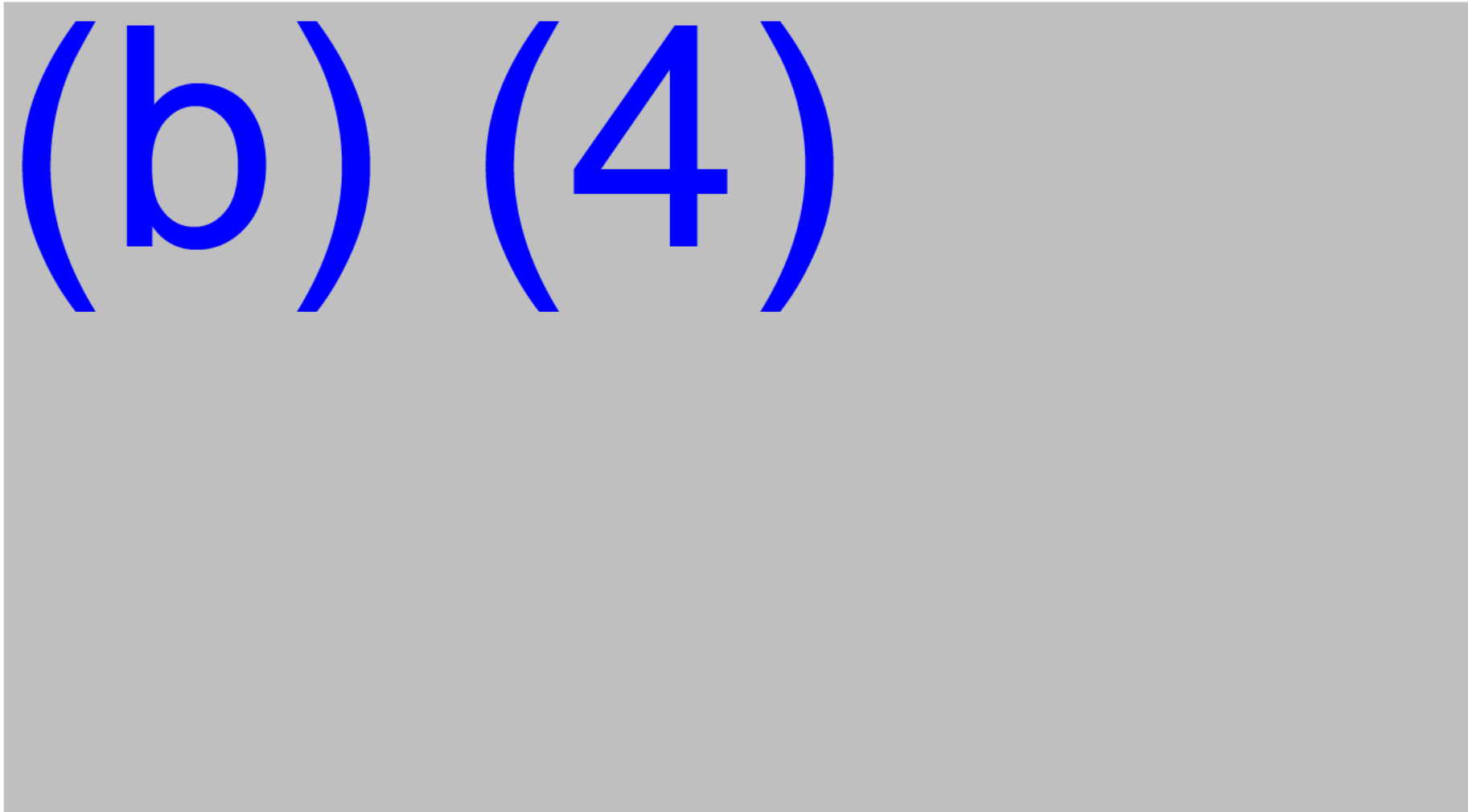
Listing 16.2.9-1 Vital signs (Full analysis set)

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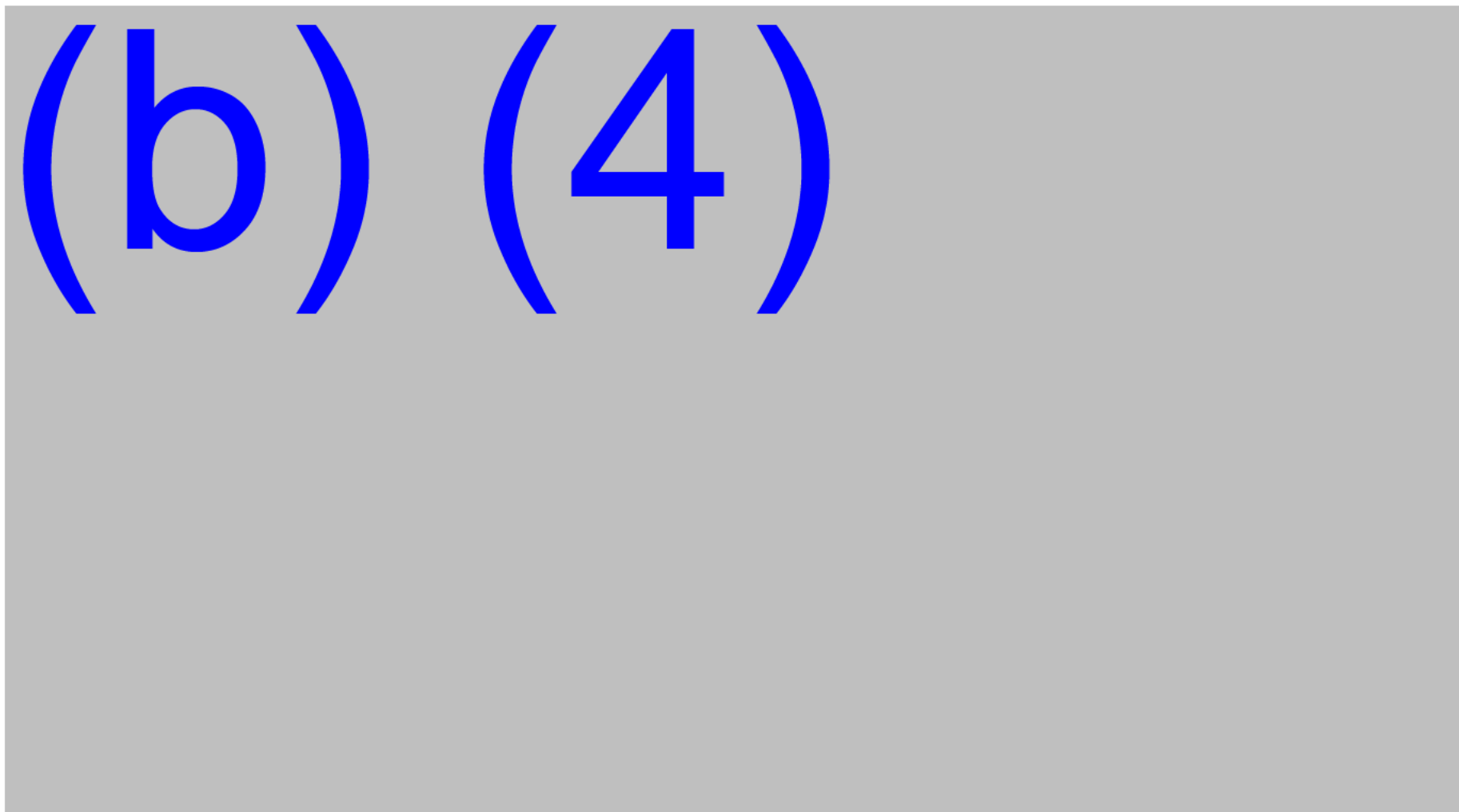
Listing 16.2.9-1 Vital signs (Full analysis set)

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Listing 16.2.9-2 ECG (Full analysis set)



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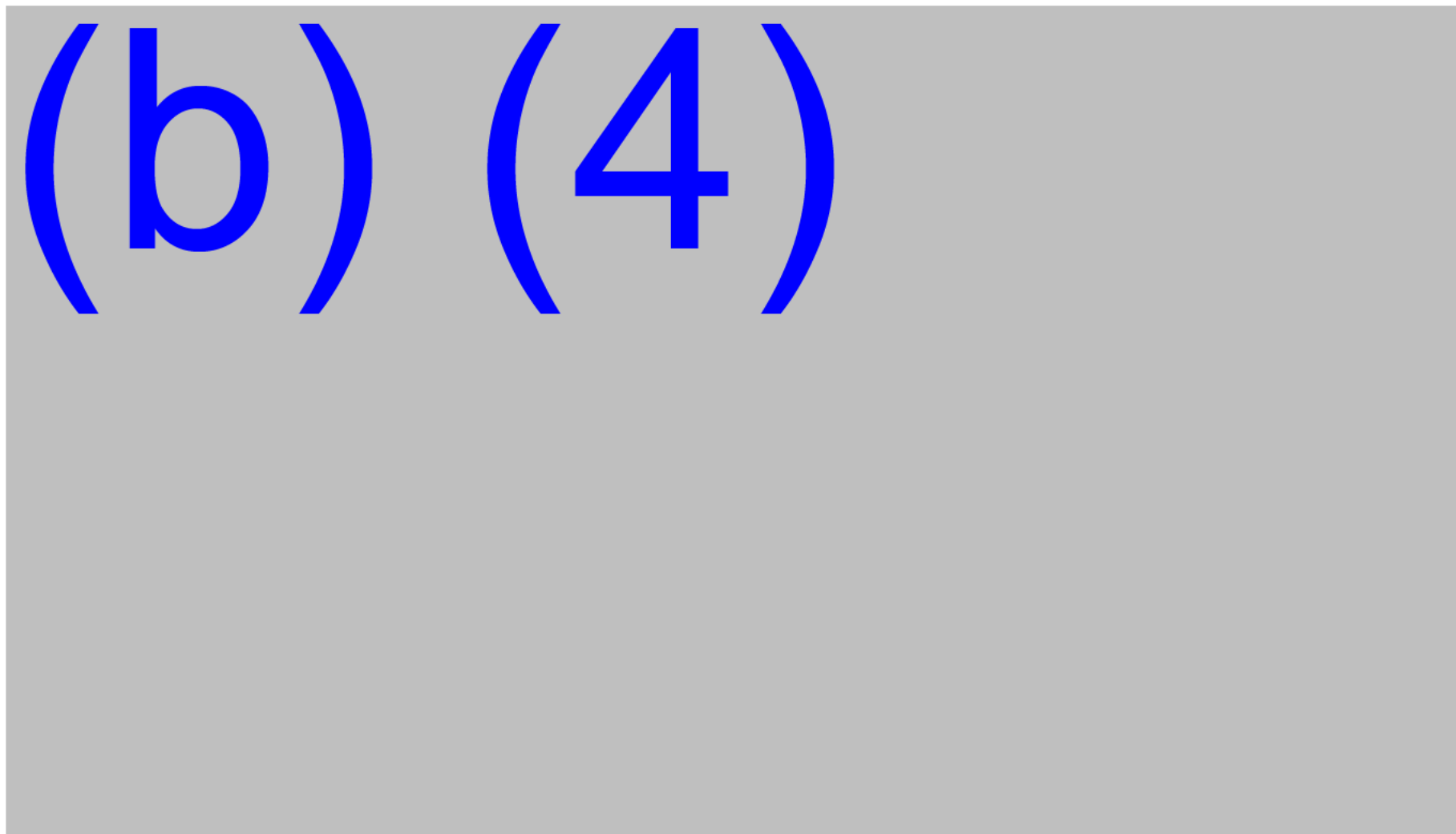
Listing 16.2.9-2 ECG (Full analysis set)

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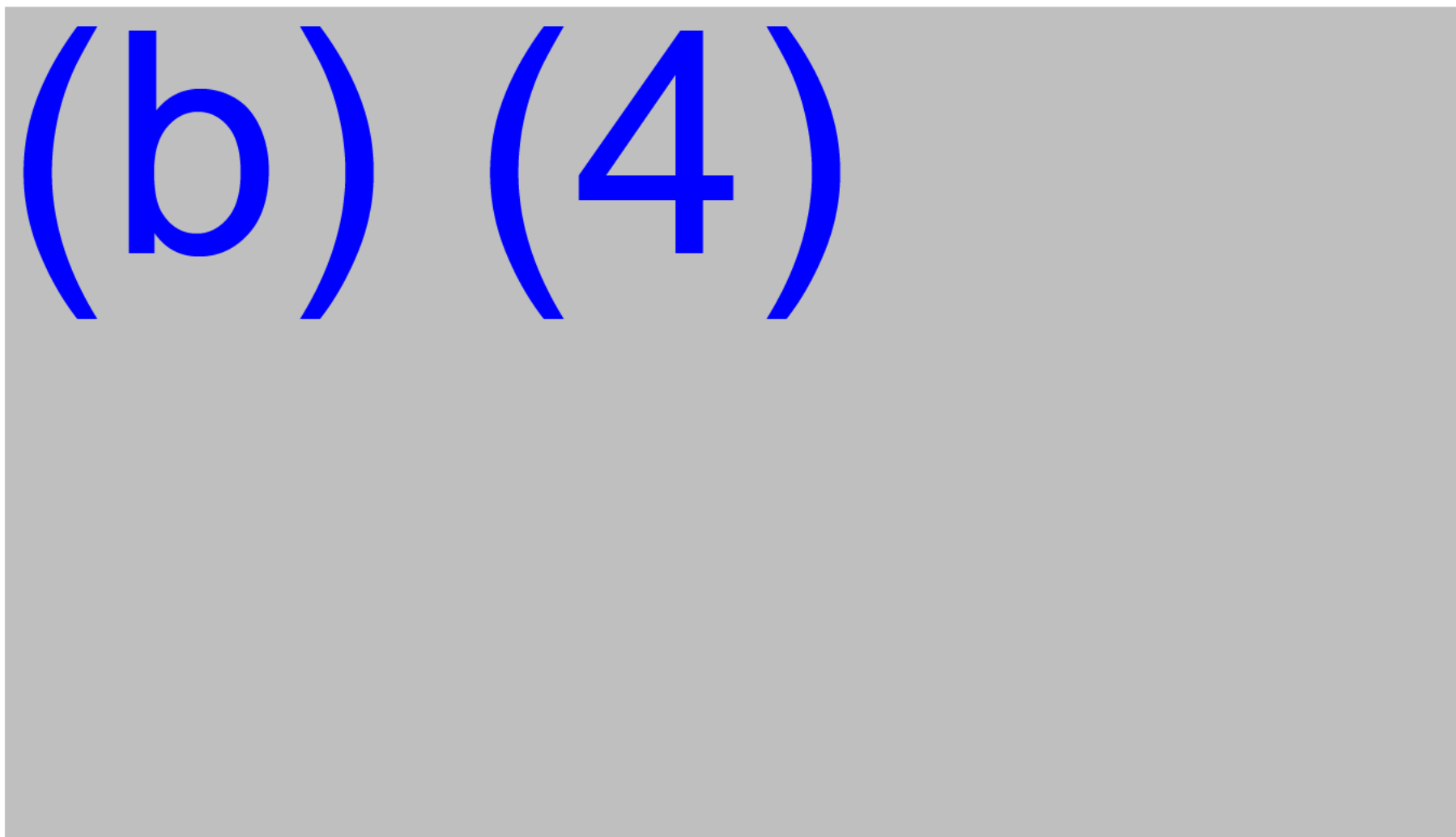
Listing 16.2.9-2 ECG (Full analysis set)

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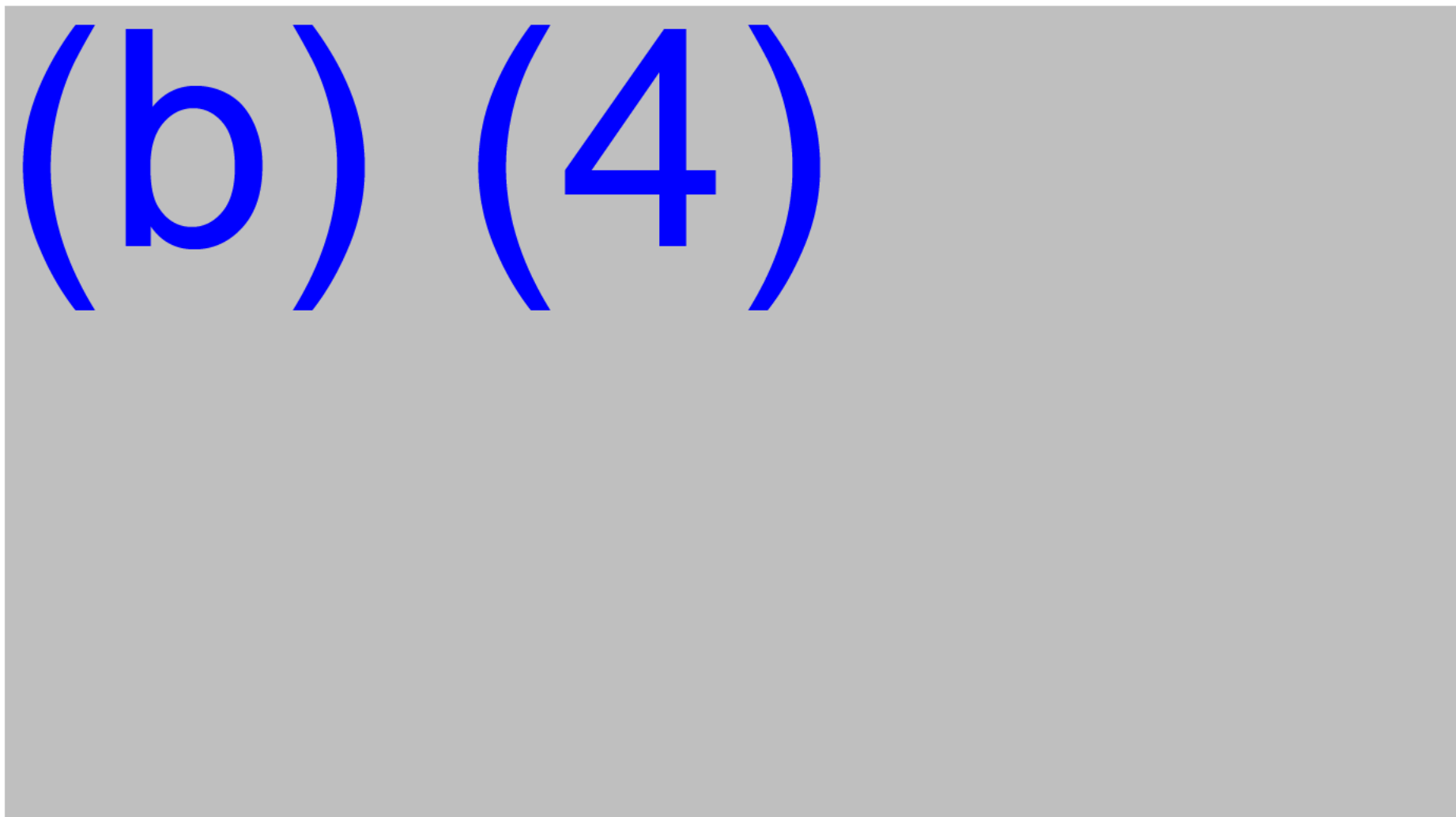
Listing 16.2.9-2 ECG (Full analysis set)

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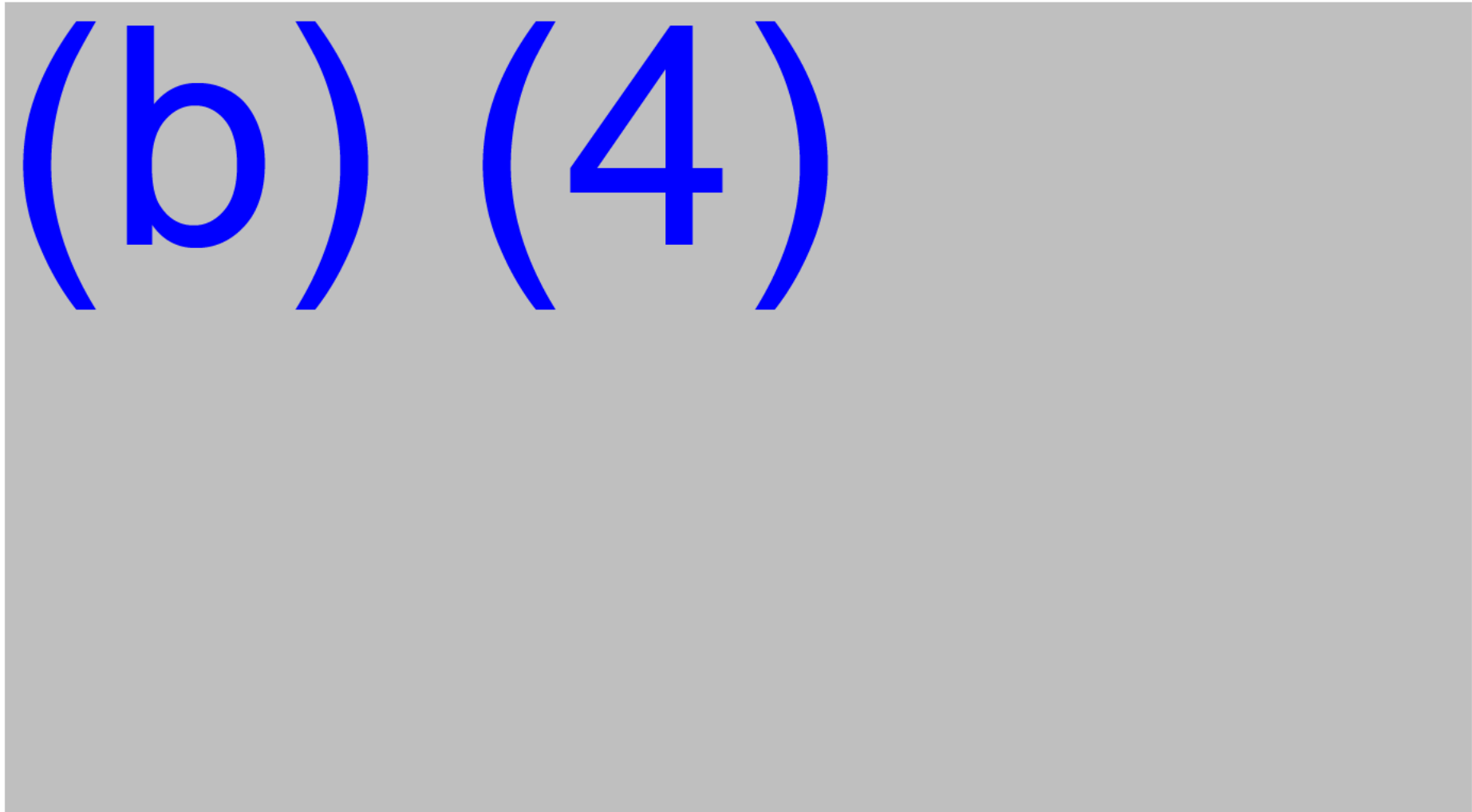
Listing 16.2.9-2 ECG (Full analysis set)

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Listing 16.2.9-2 ECG (Full analysis set)

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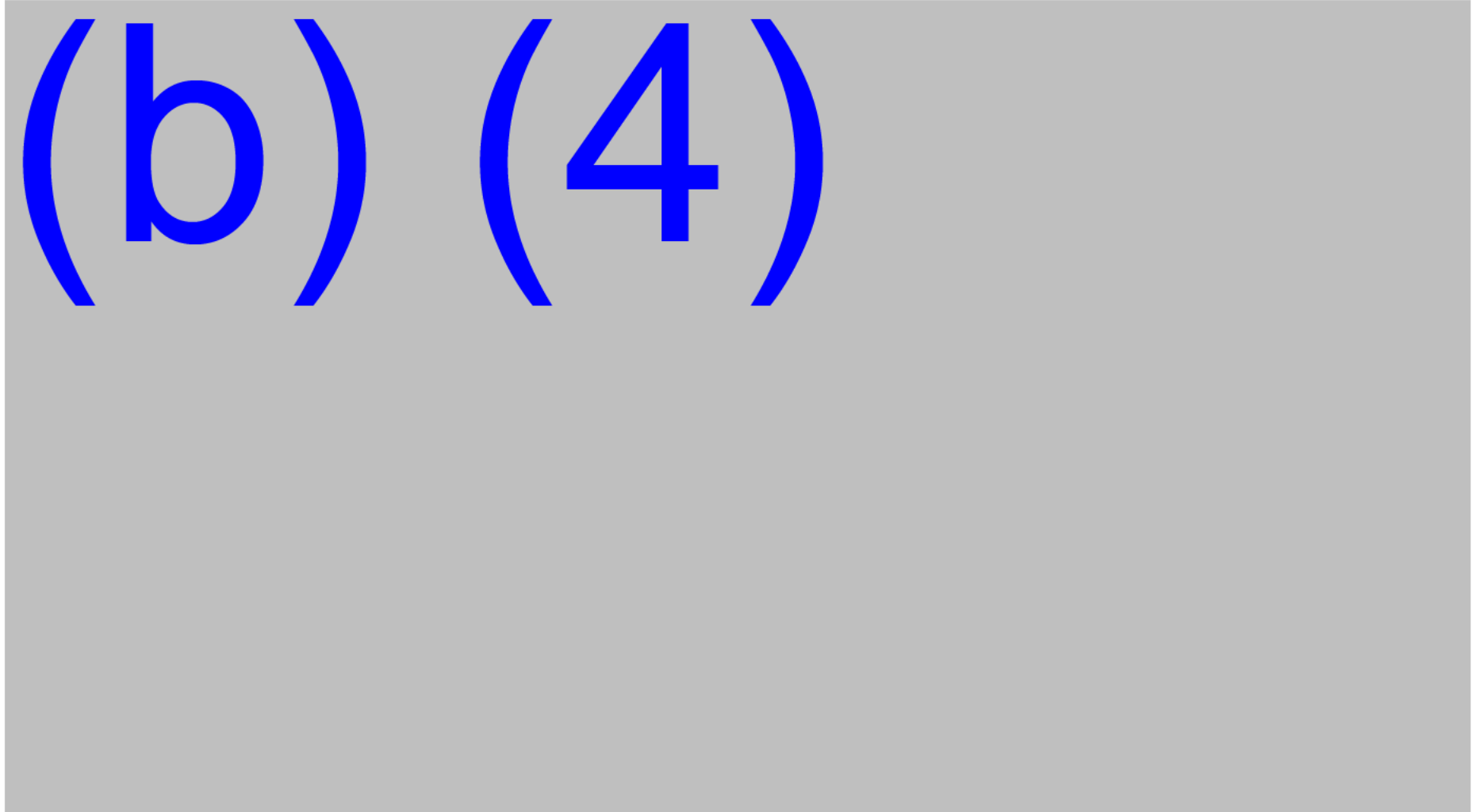
Listing 16.2.9-2 ECG (Full analysis set)

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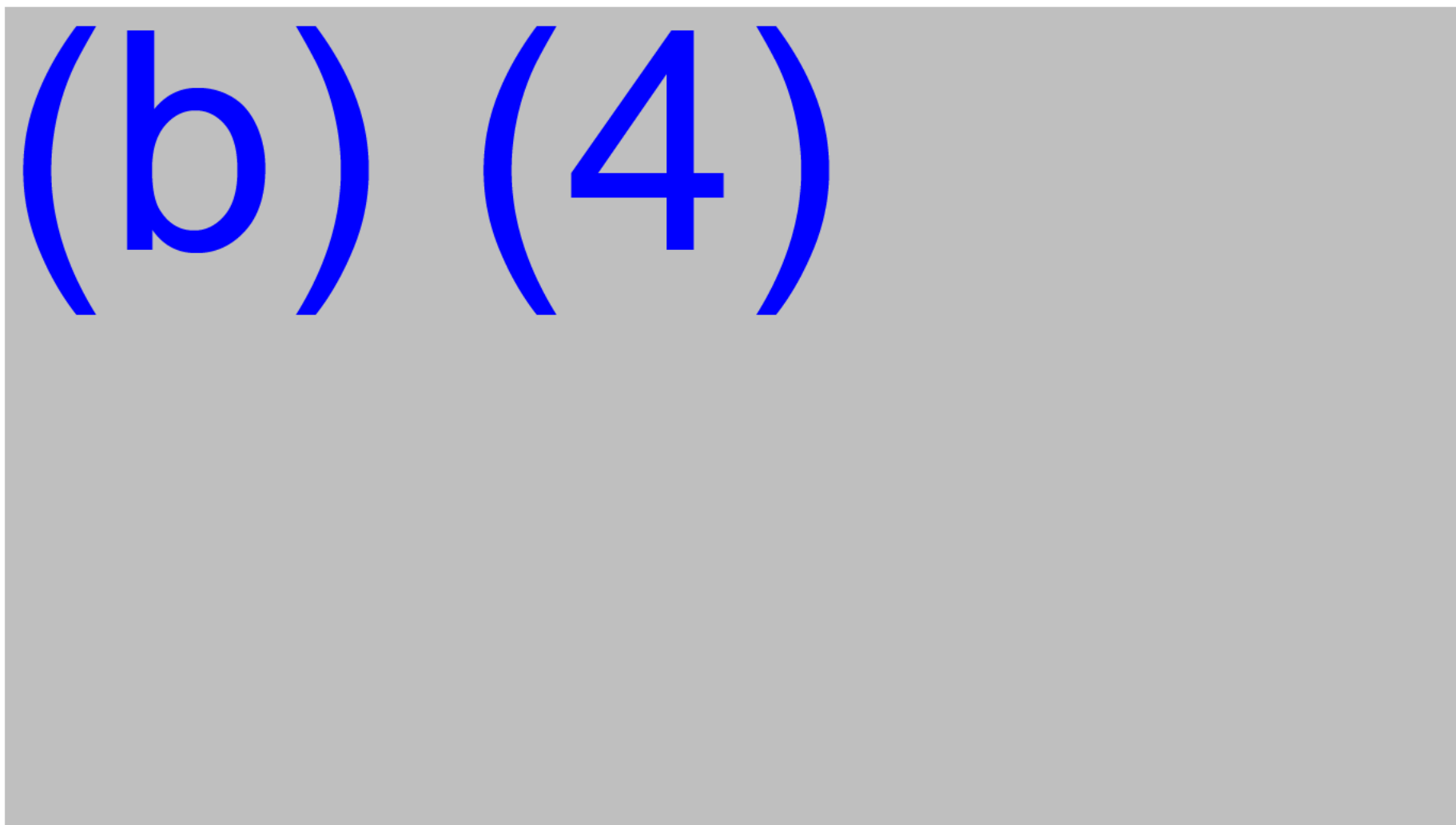
Listing 16.2.9-2 ECG (Full analysis set)

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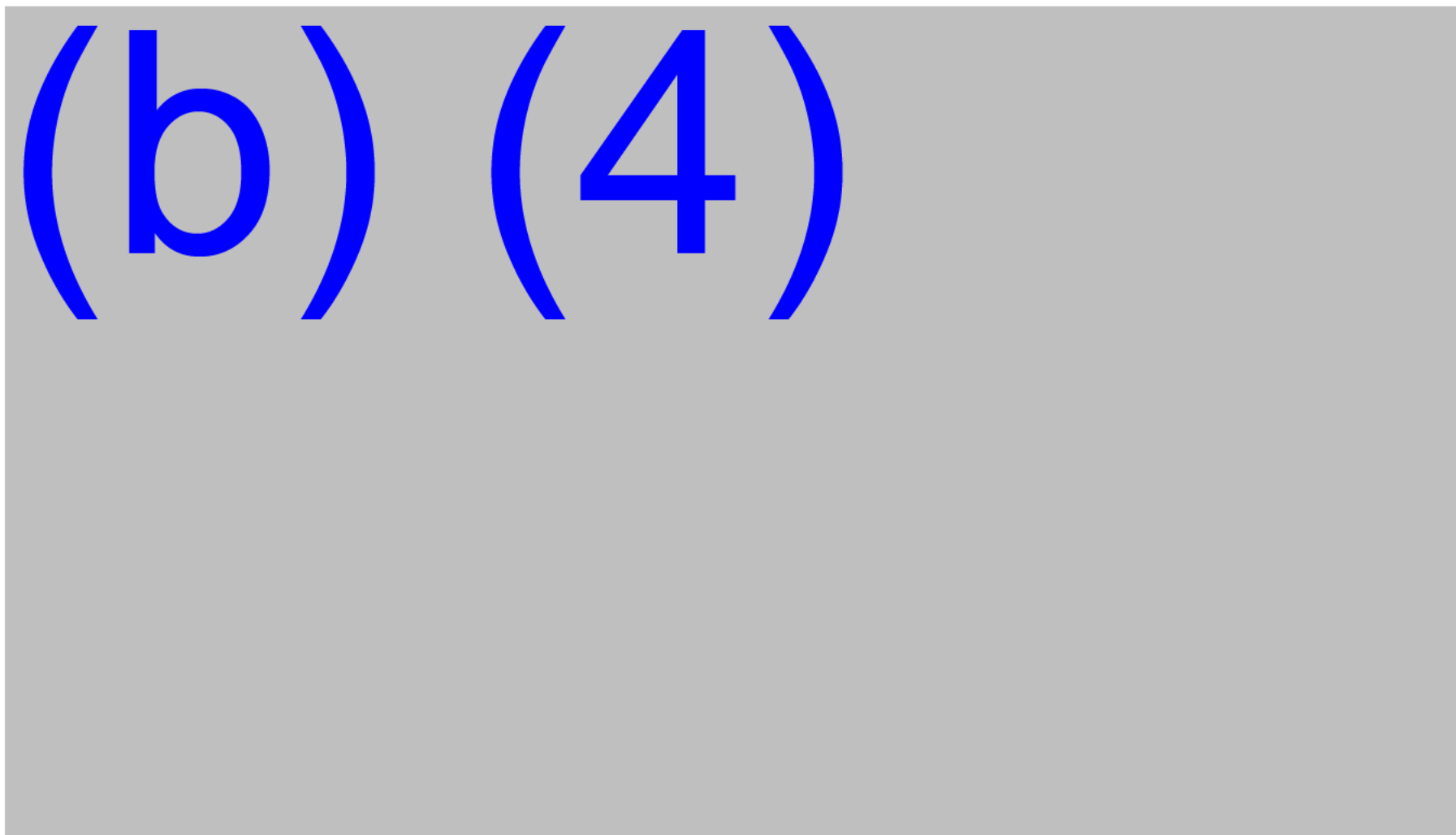
Listing 16.2.9-2 ECG (Full analysis set)

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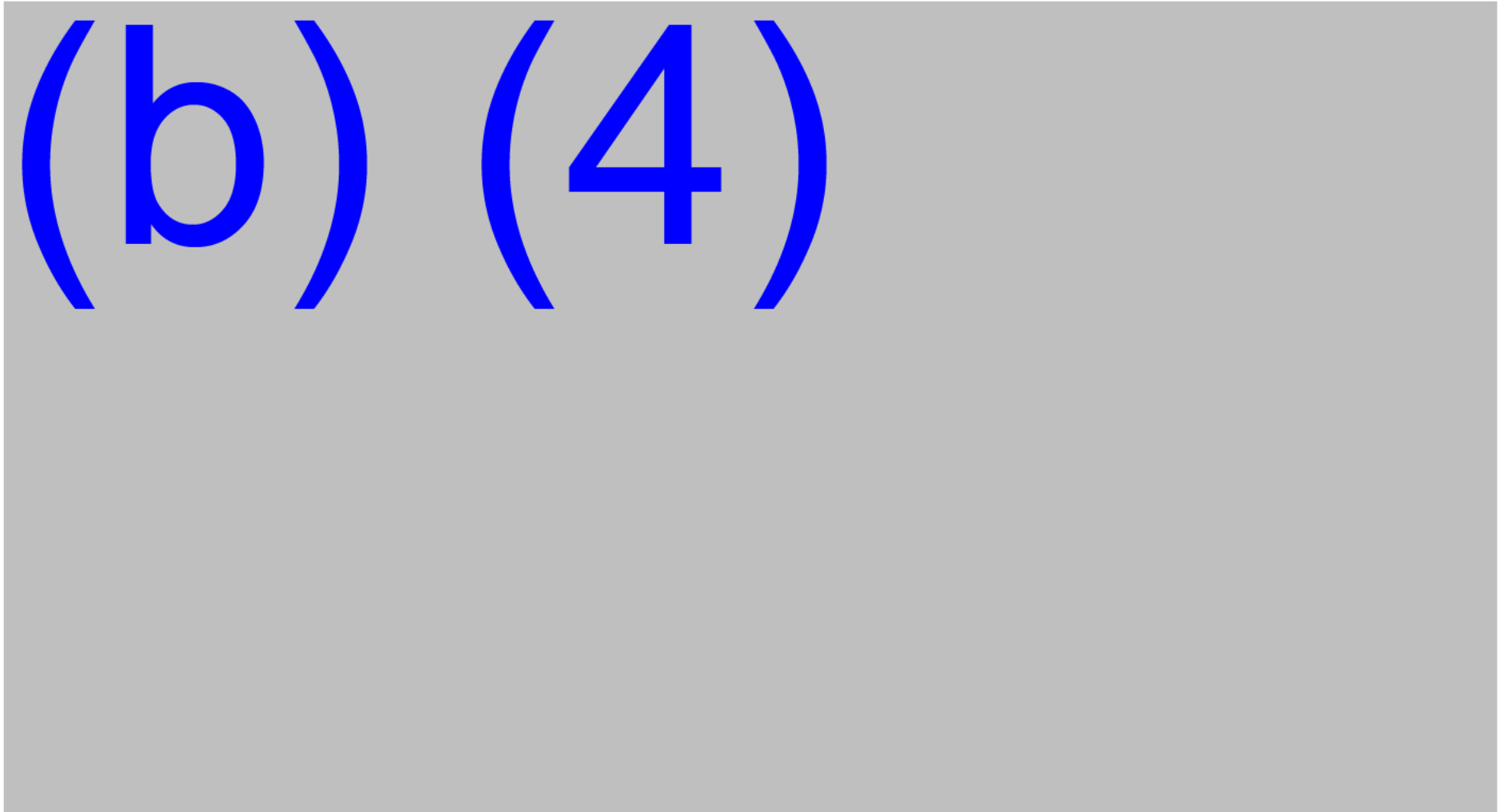
Listing 16.2.9-2 ECG (Full analysis set)

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Listing 16.2.9-3 Physical examinations (Full analysis set)

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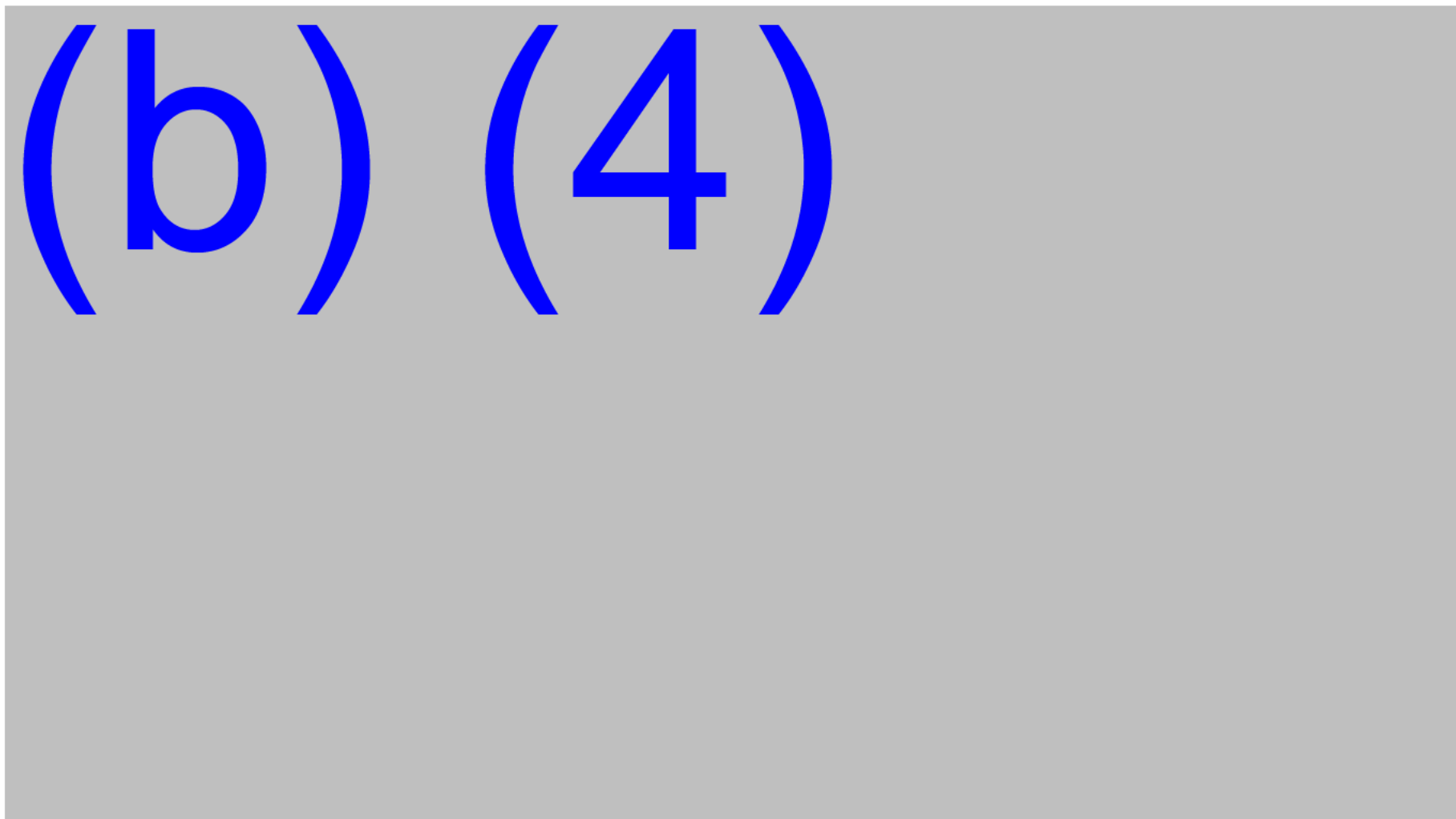
Listing 16.2.9-3 Physical examinations (Full analysis set)

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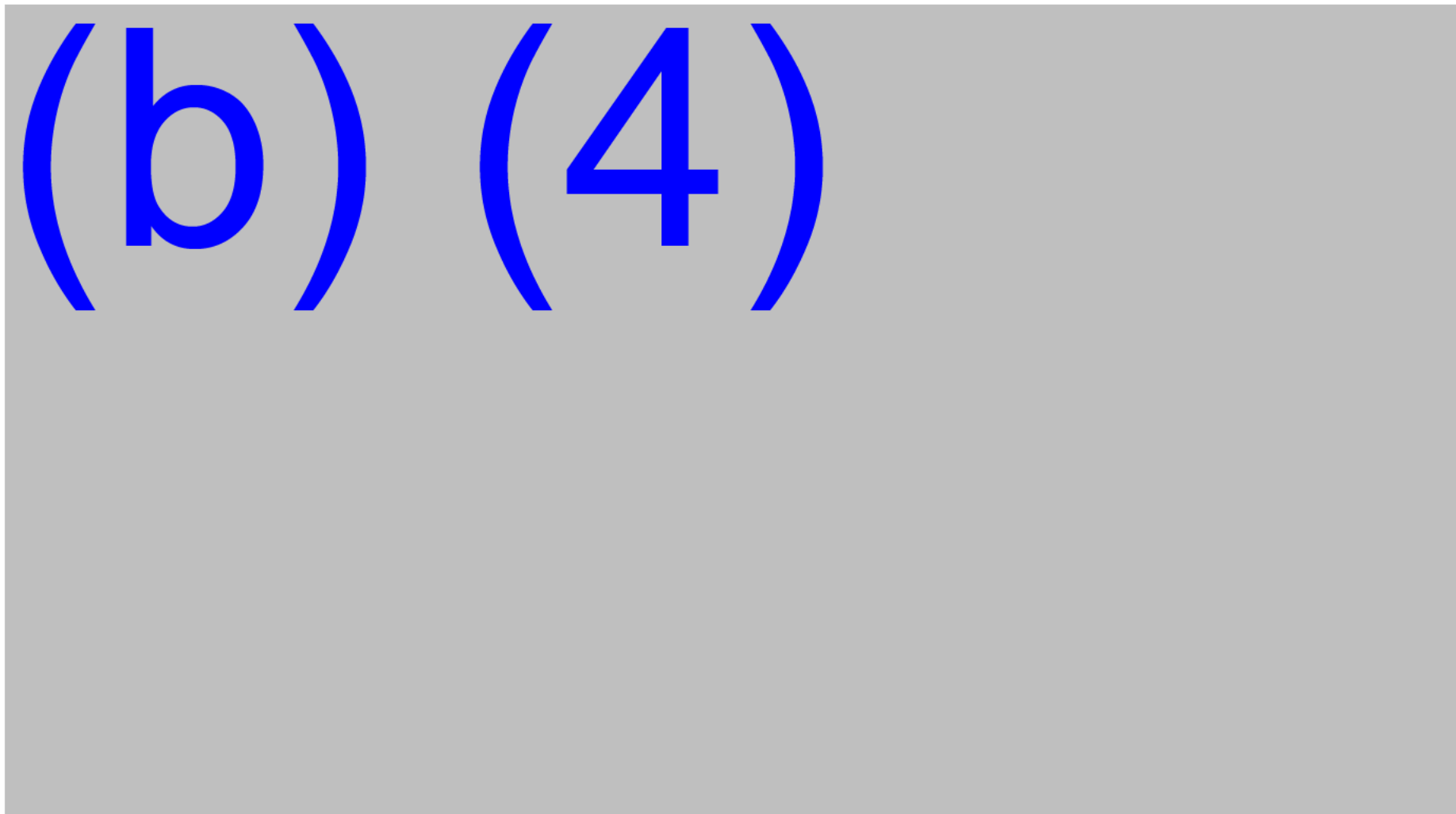
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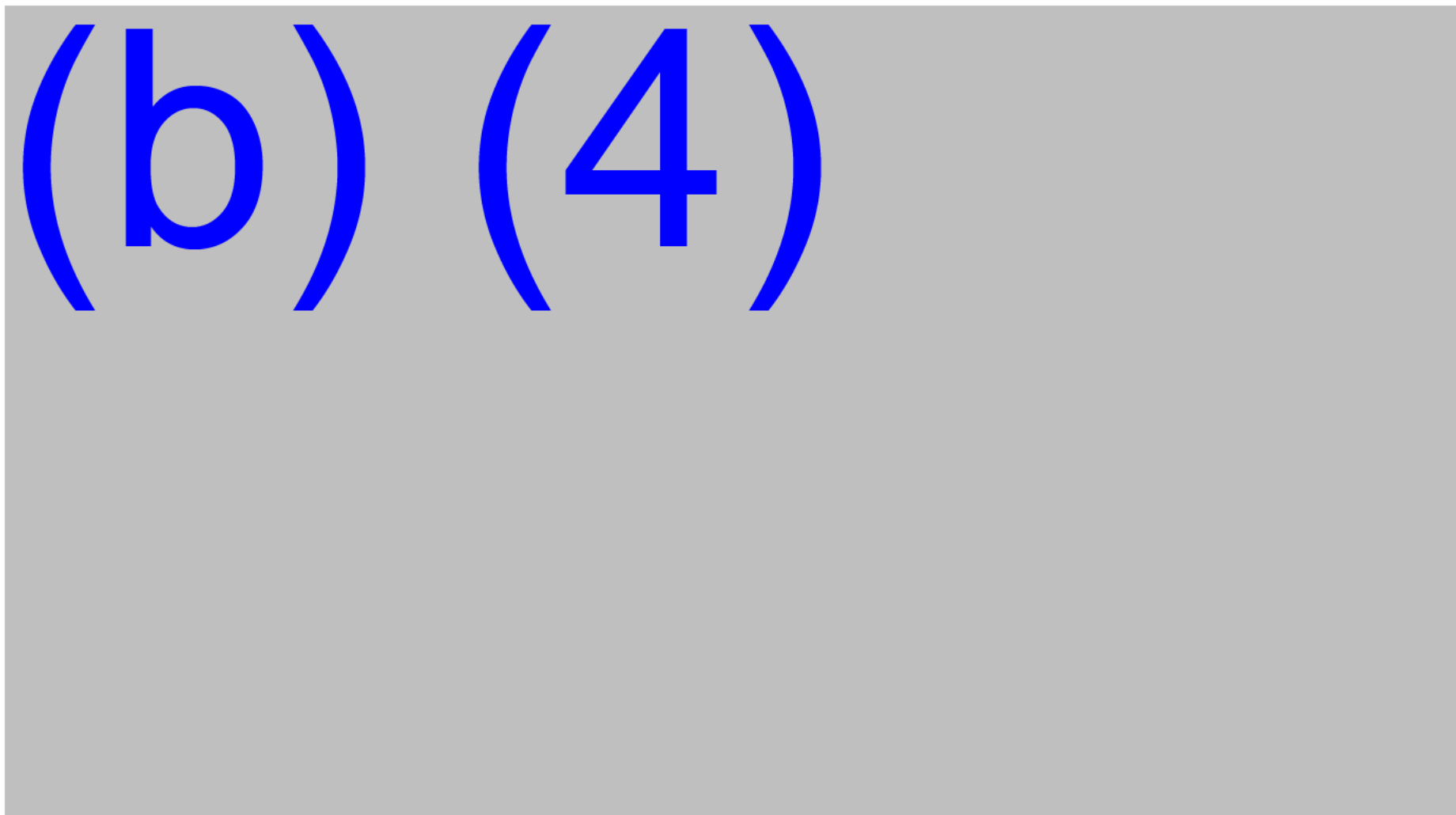
Listing 16.2.9-3 Physical examinations (Full analysis set)

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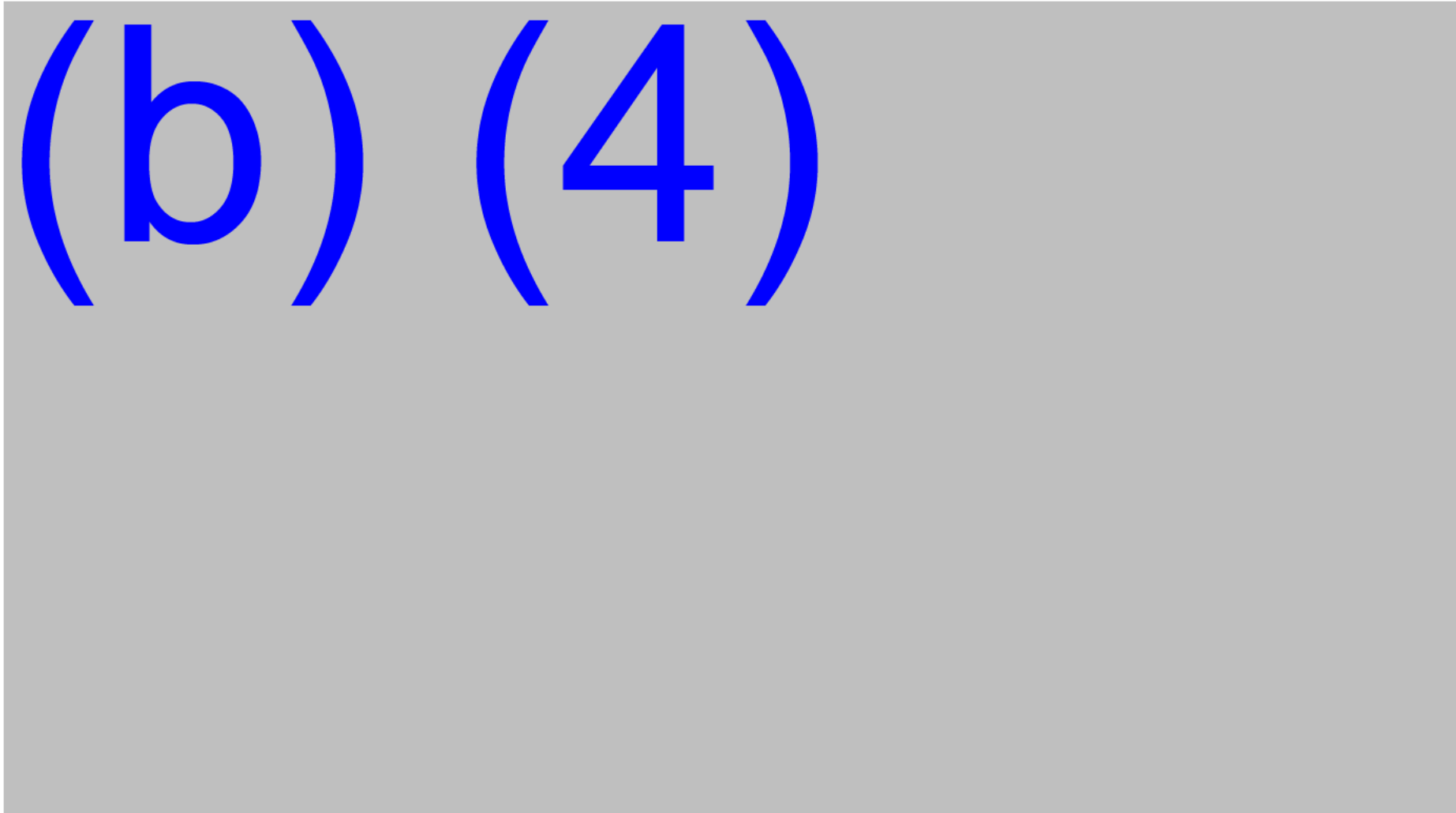
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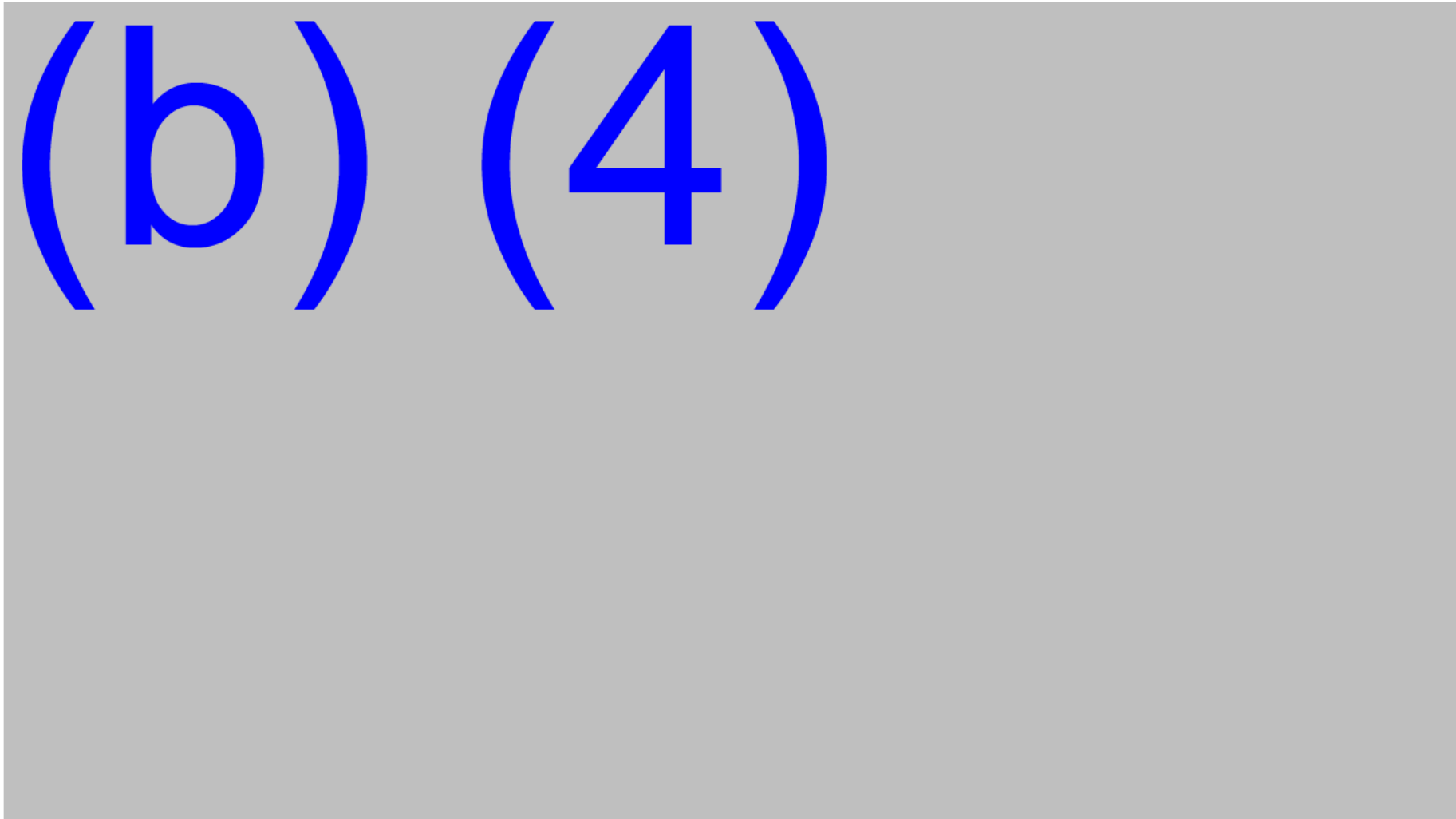
Listing 16.2.9-3 Physical examinations (Full analysis set)

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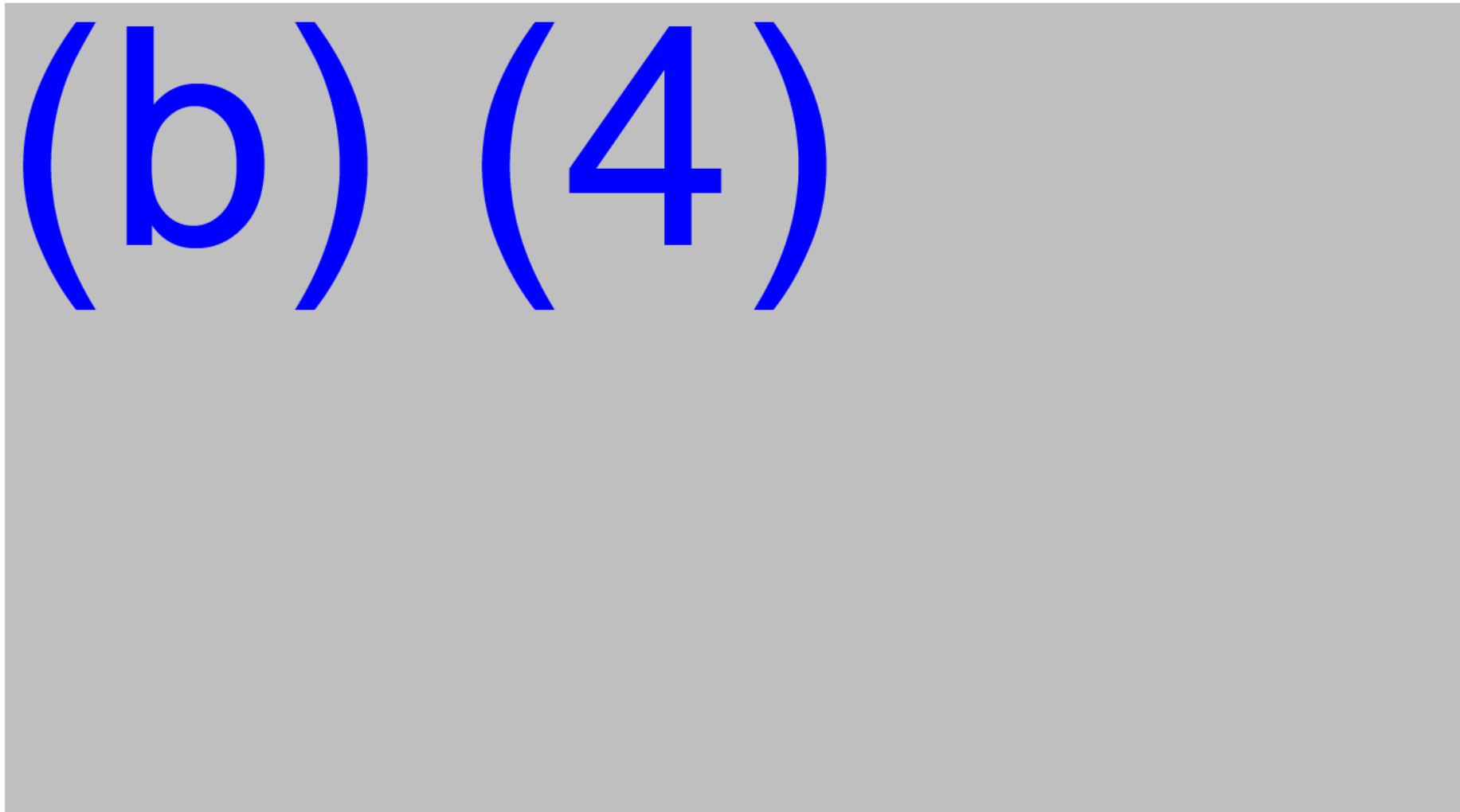
Listing 16.2.9-3 Physical examinations (Full analysis set)

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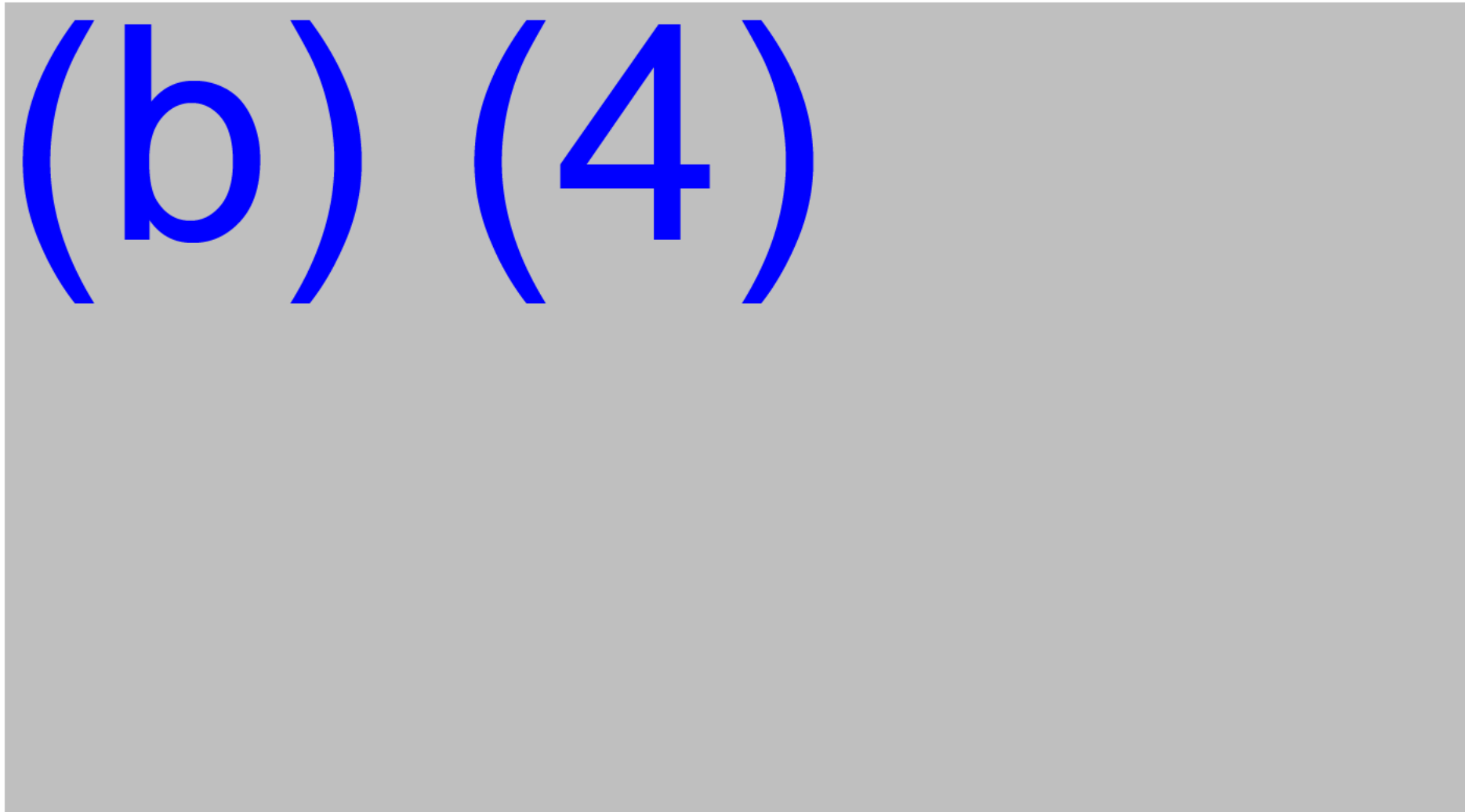
Listing 16.2.9-3 Physical examinations (Full analysis set)

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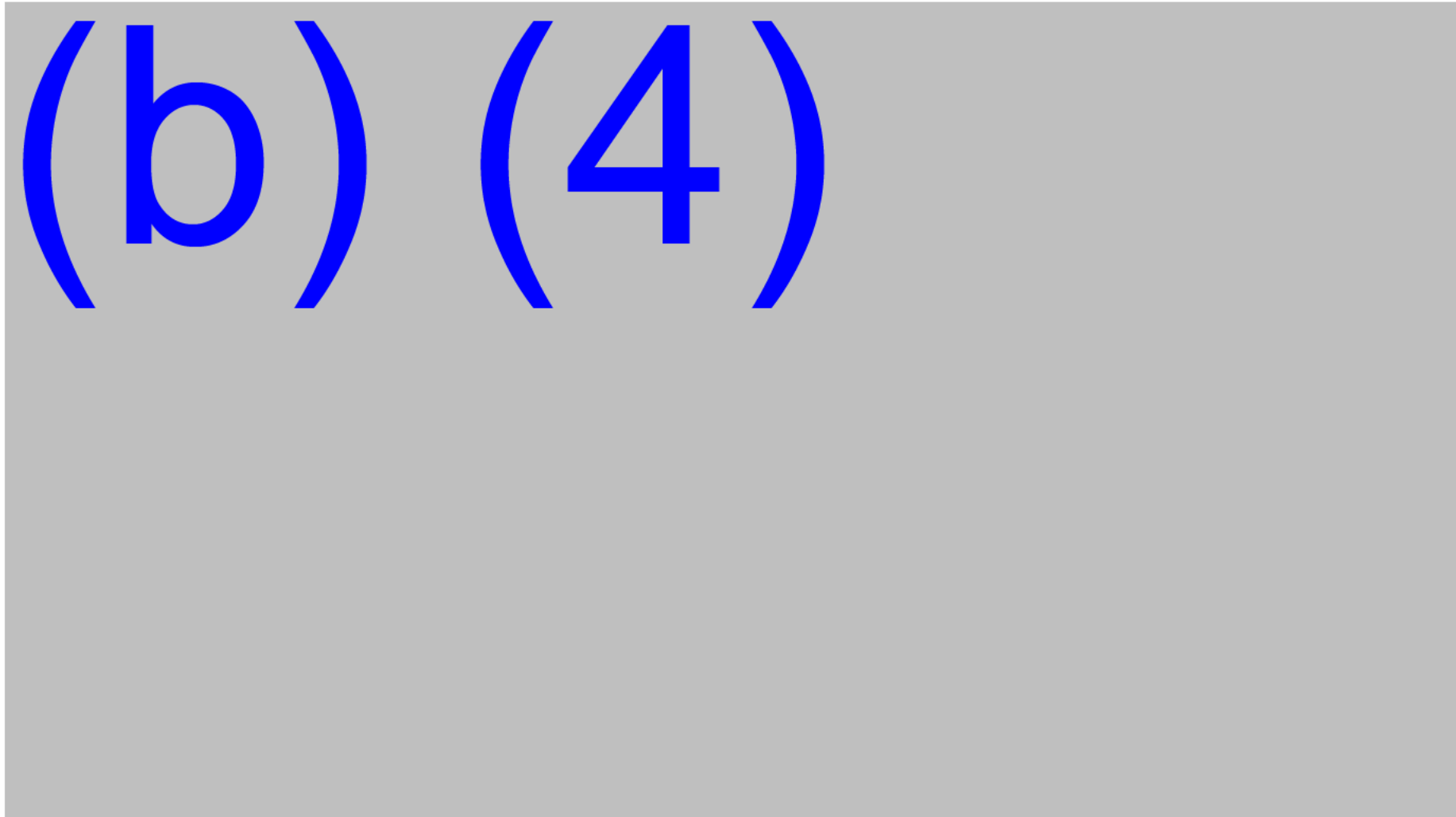
Listing 16.2.9-3 Physical examinations (Full analysis set)

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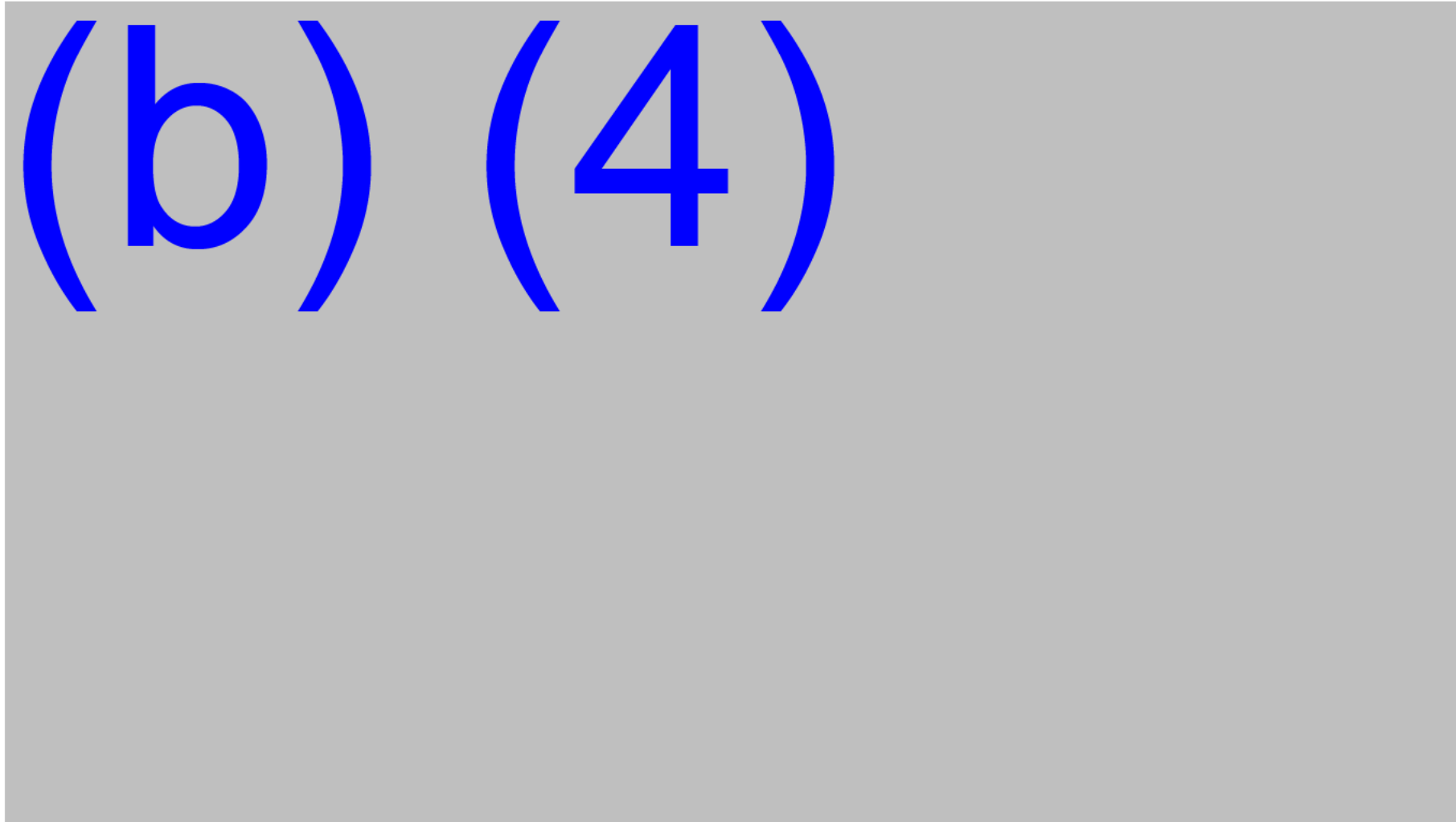
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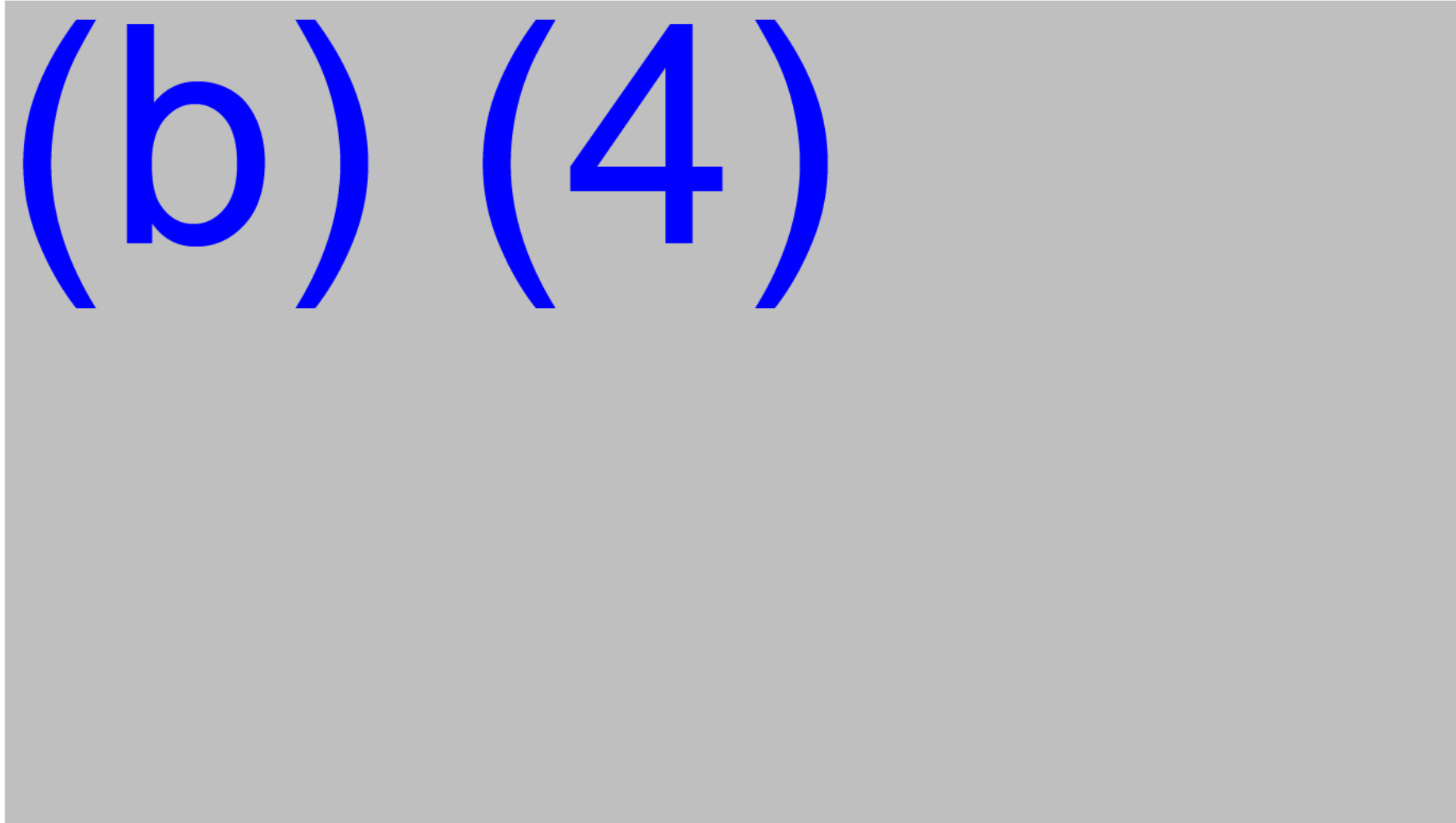
Listing 16.2.9-3 Physical examinations (Full analysis set)

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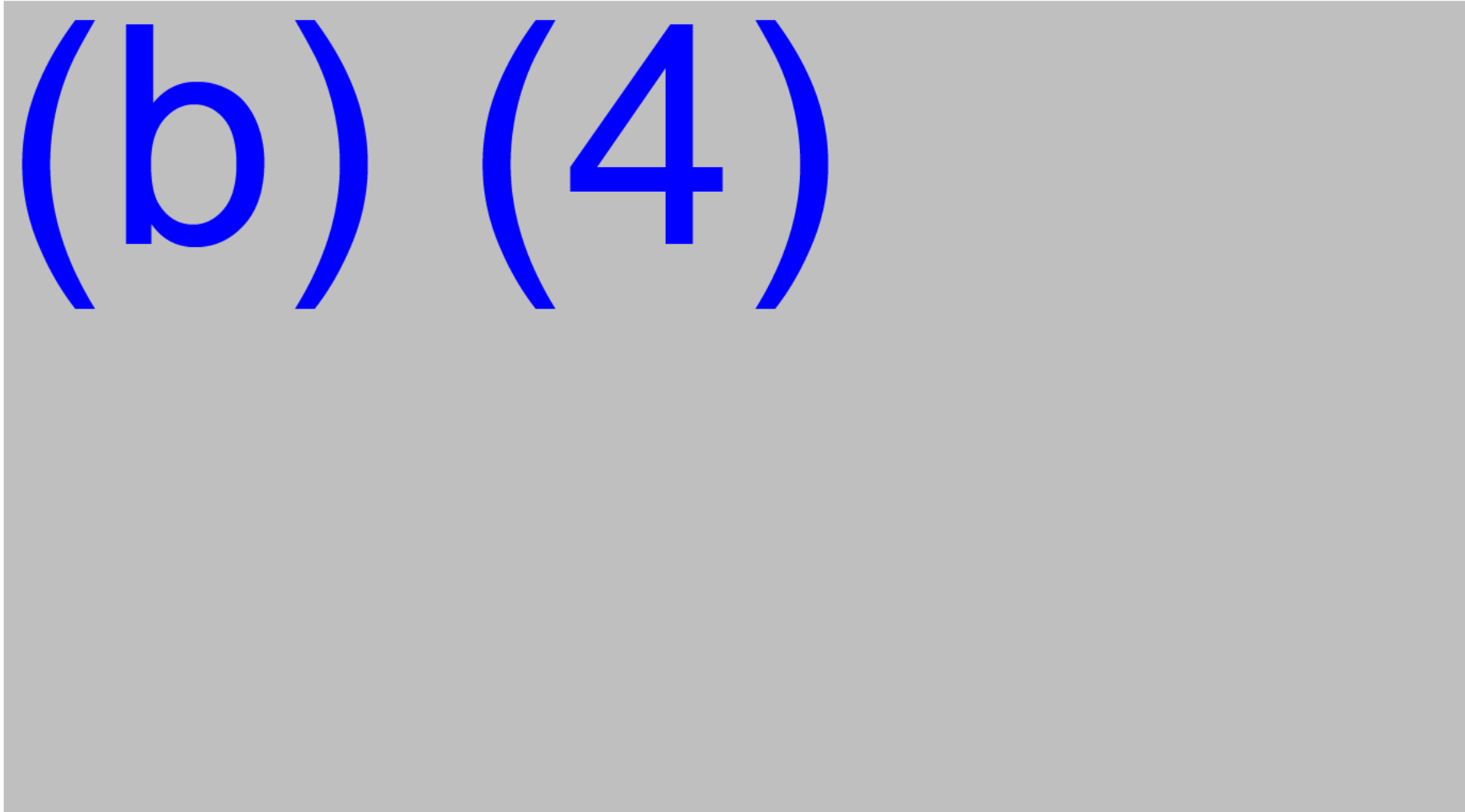
Listing 16.2.9-3 Physical examinations (Full analysis set)

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Listing 16.2.9-3 Physical examinations (Full analysis set)



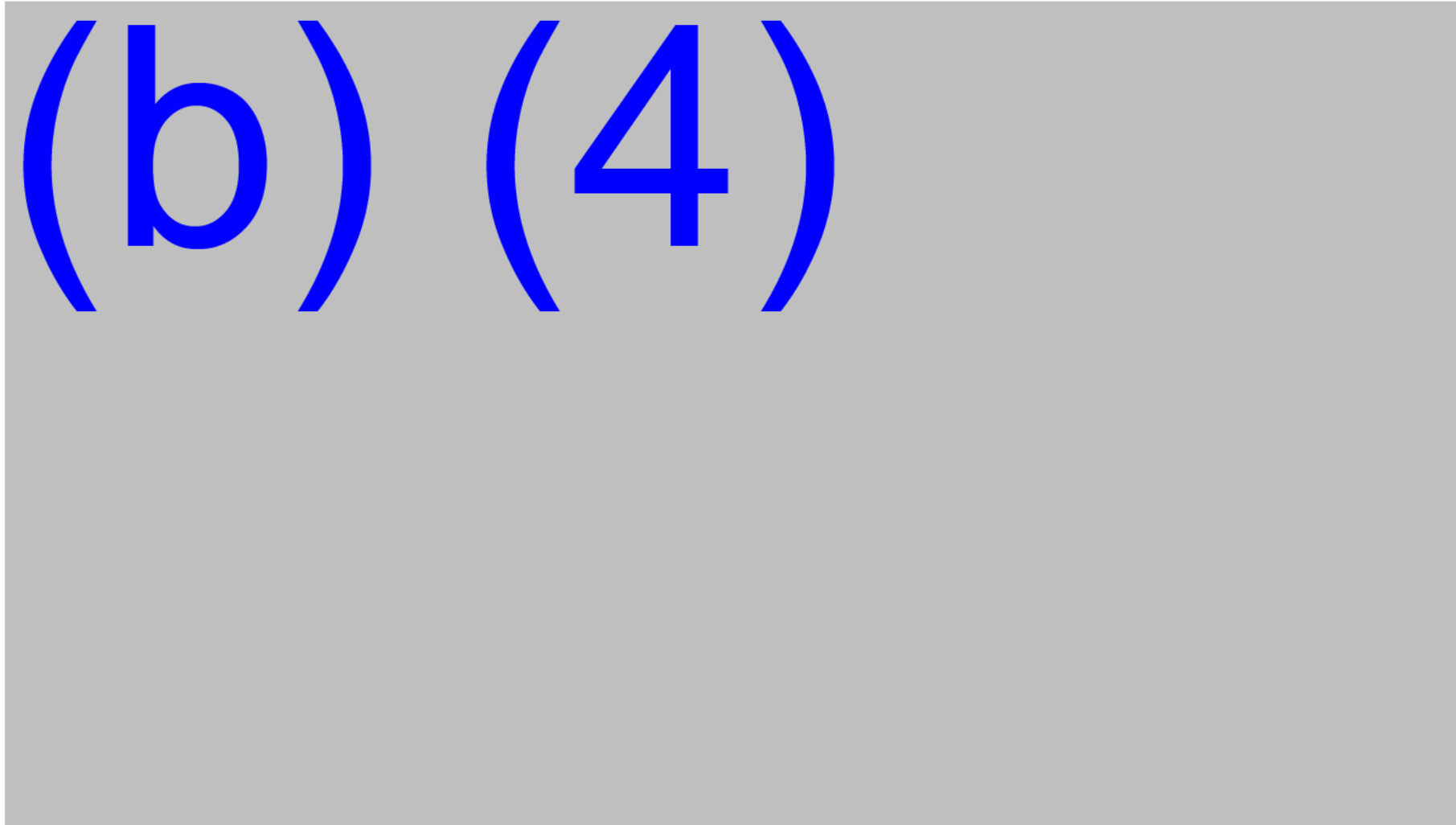
Listing 16.2.9-3 Physical examinations (Full analysis set)

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Listing 16.2.9-3 Physical examinations (Full analysis set)

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Listing 16.2.9-3 Physical examinations (Full analysis set)

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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

(b) (4)

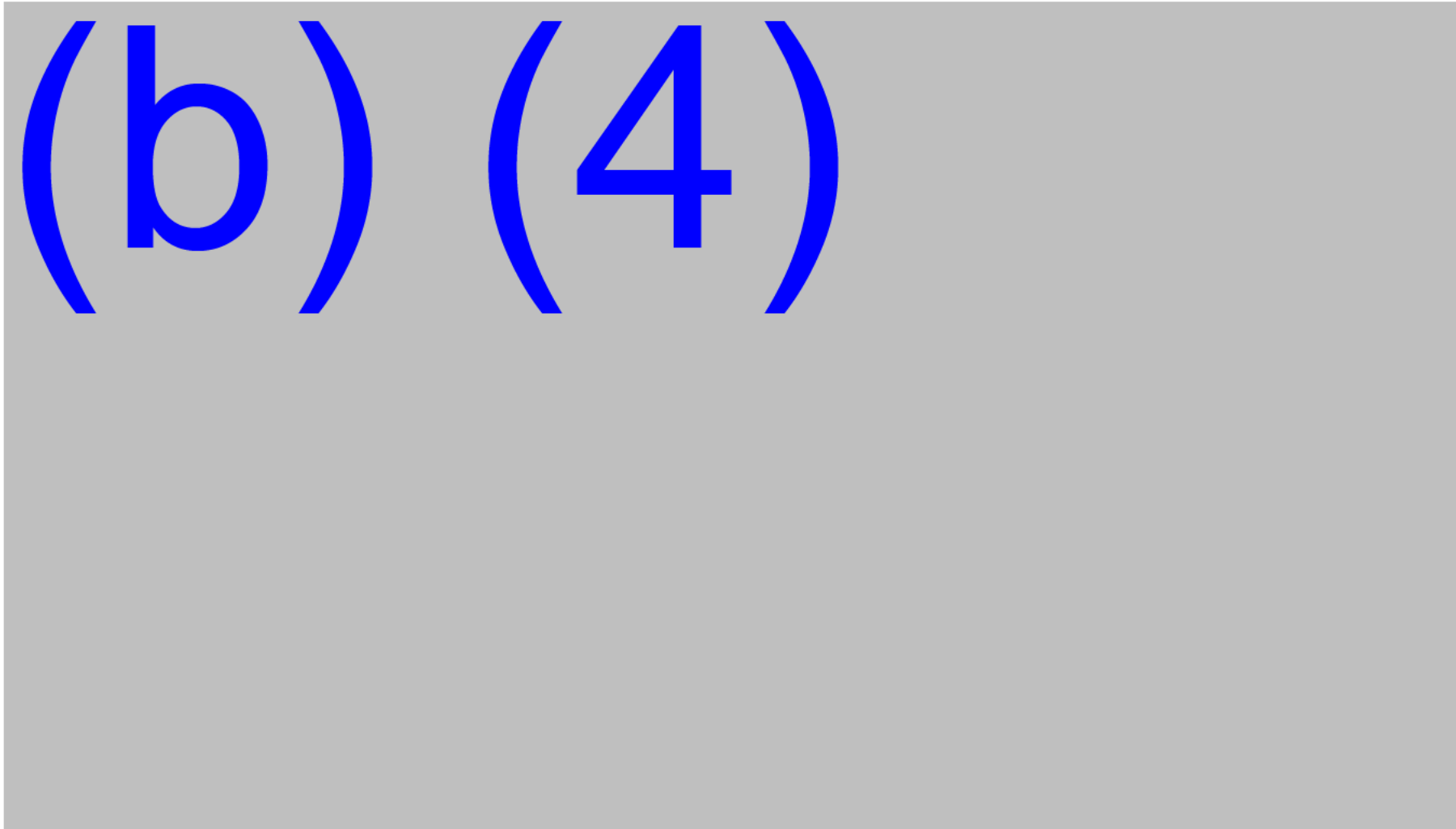
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)



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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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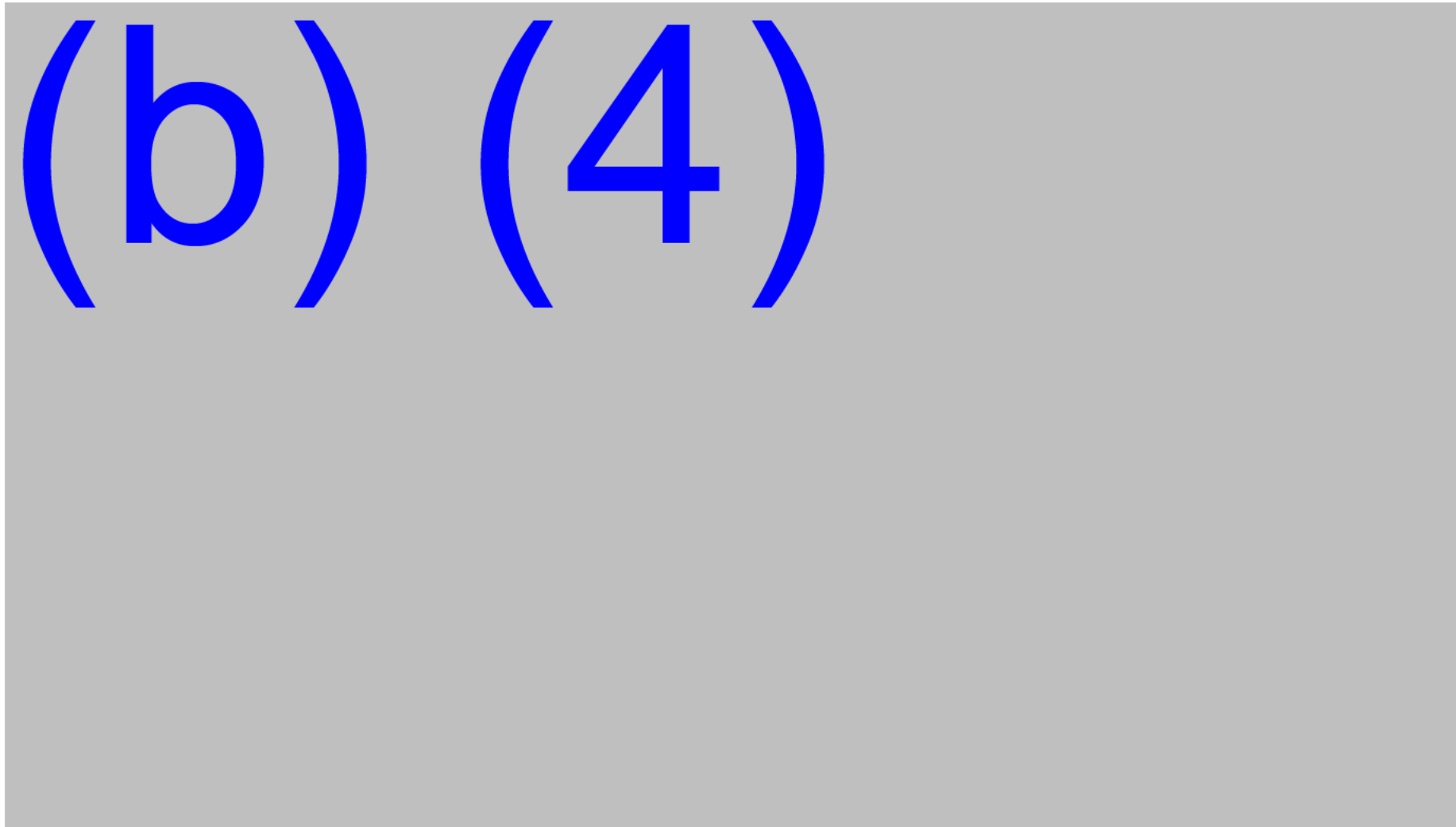
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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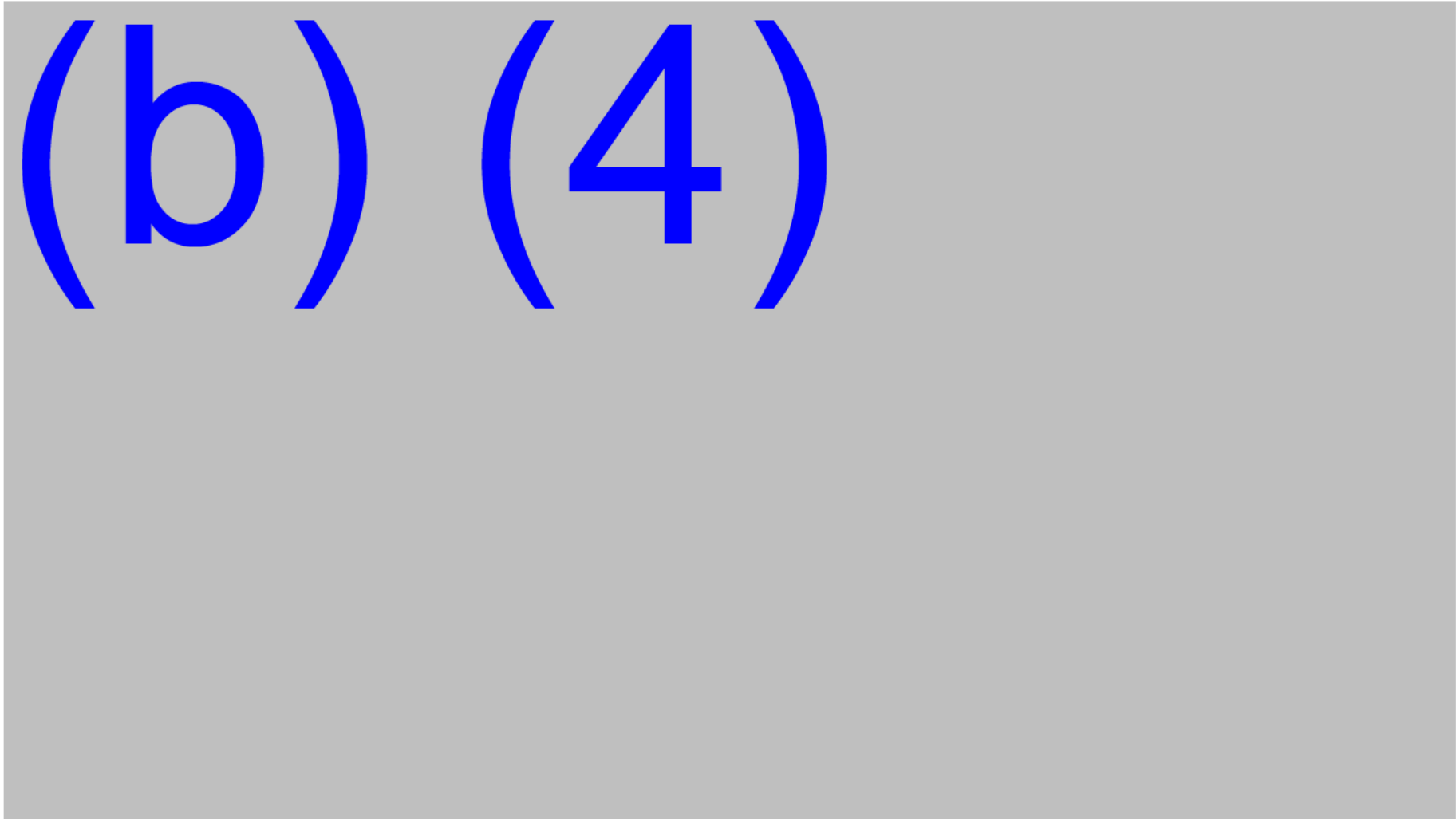
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

(b) (4)

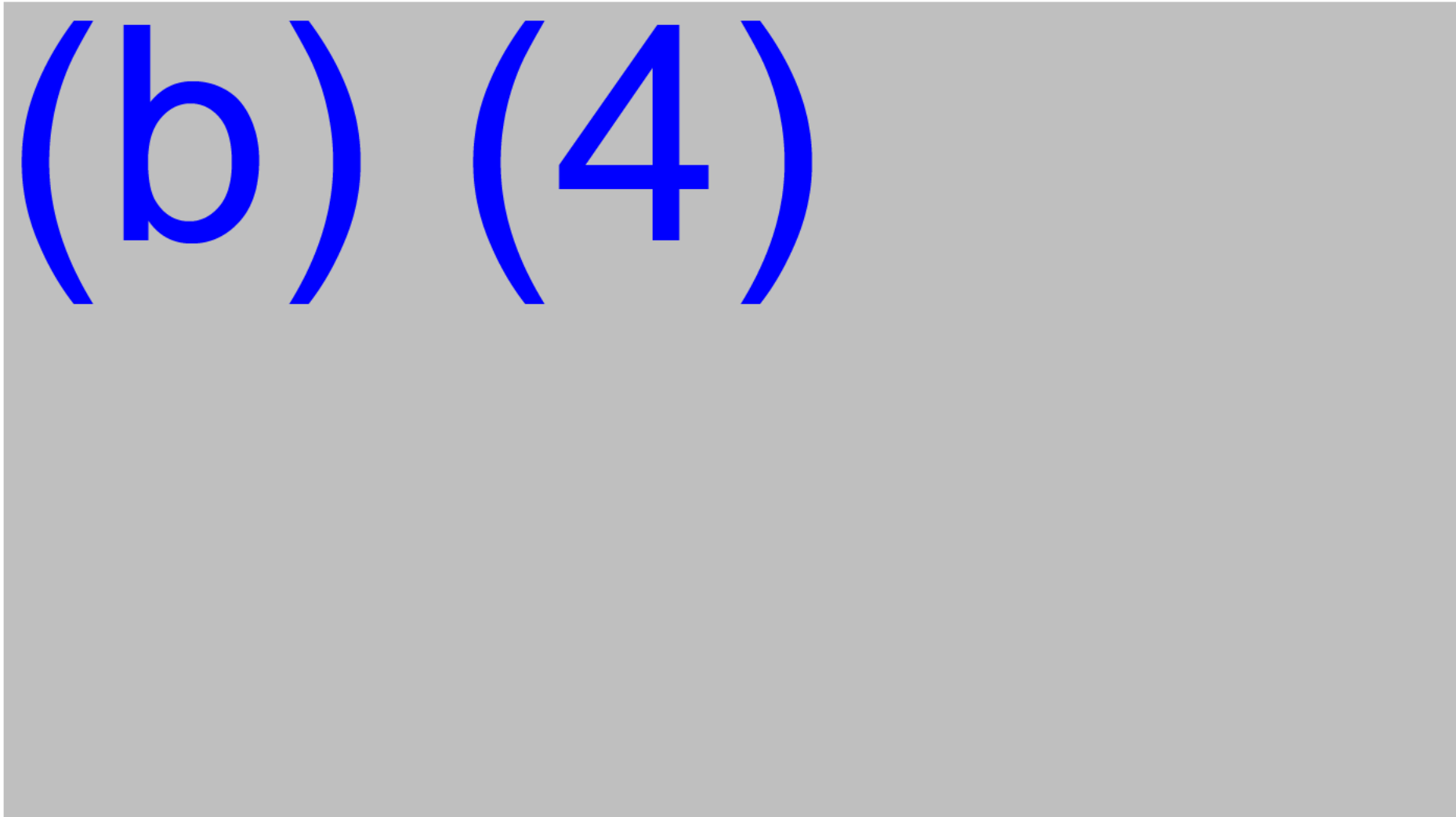
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)



Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)



Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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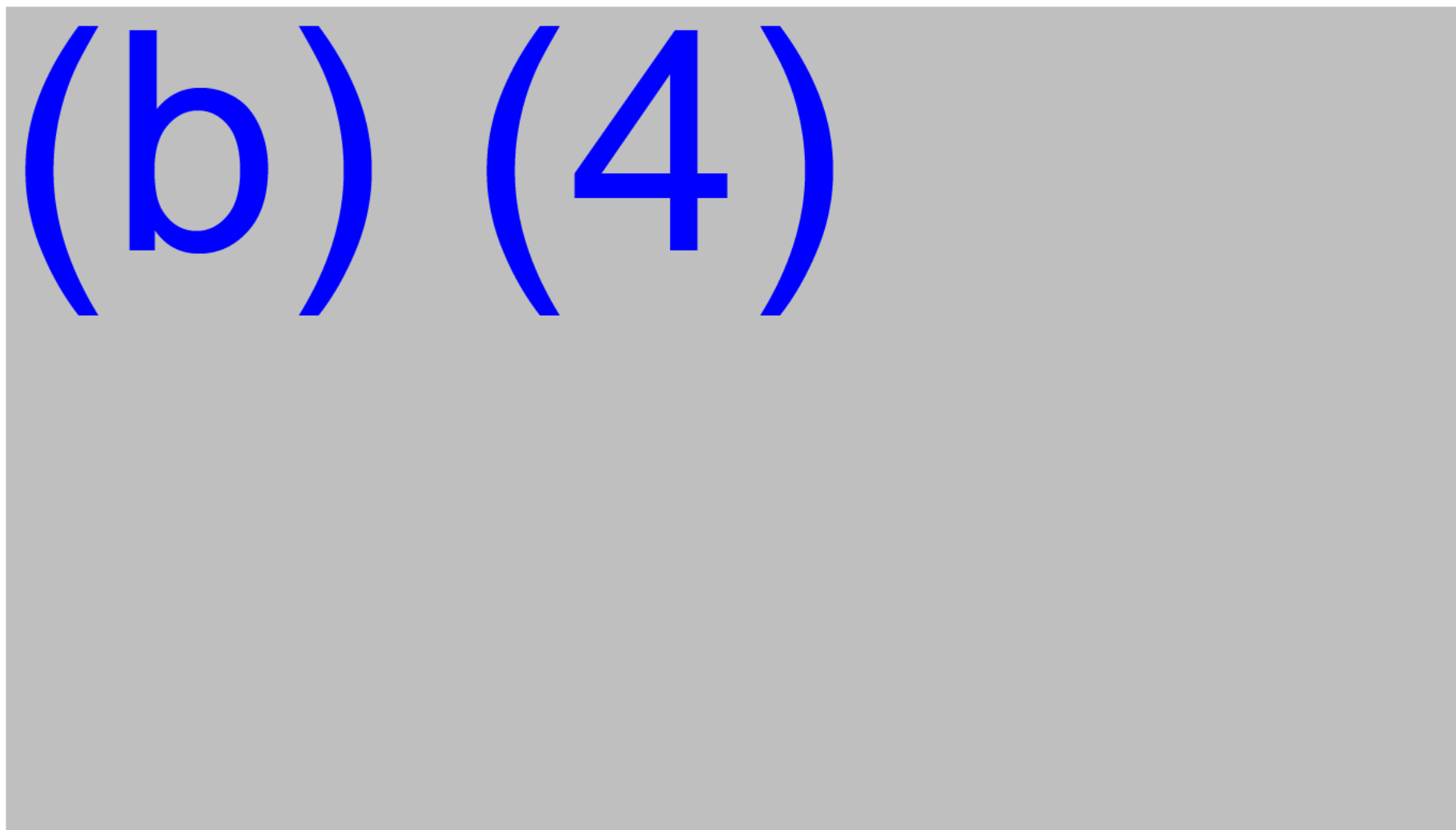
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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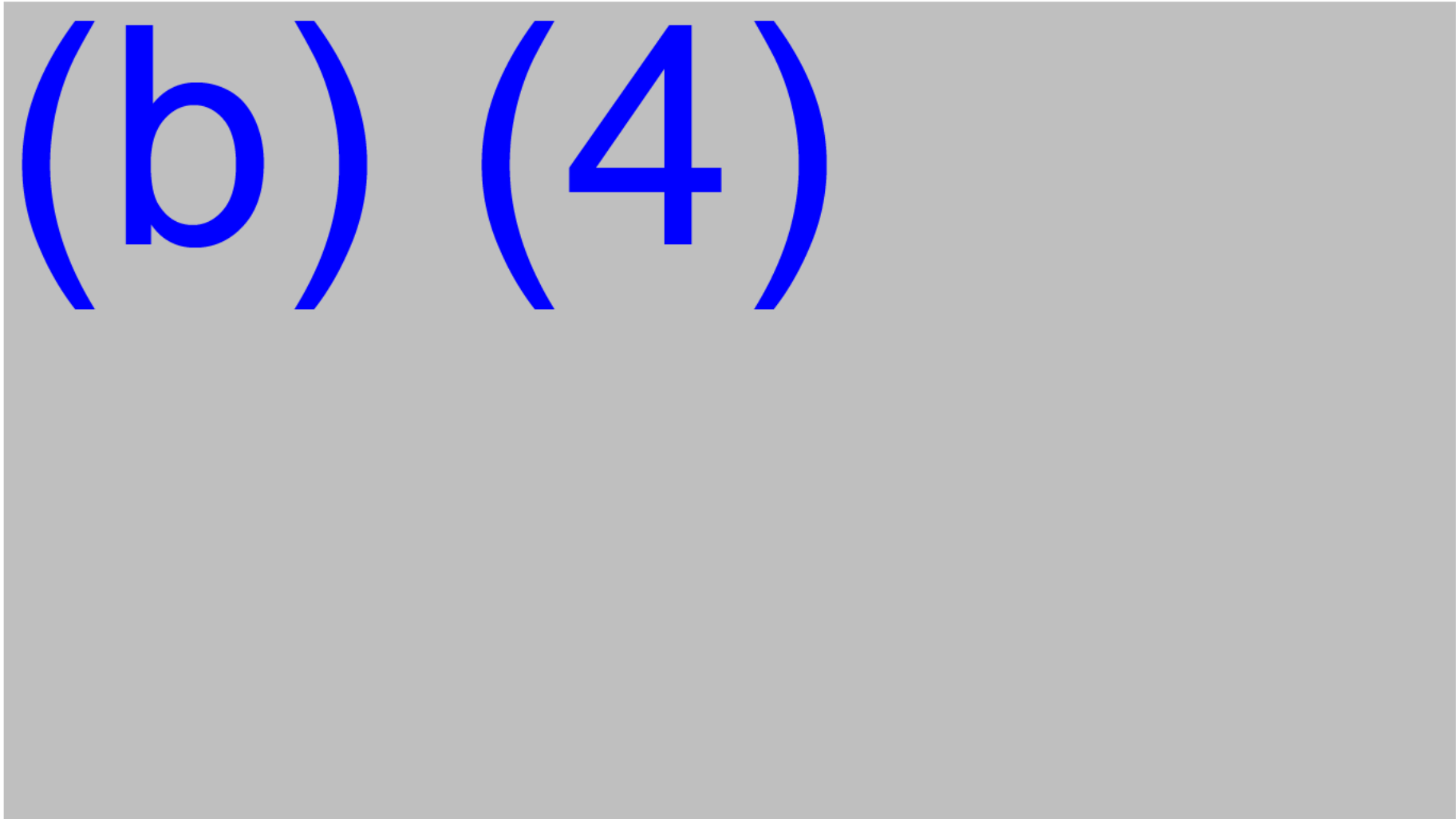
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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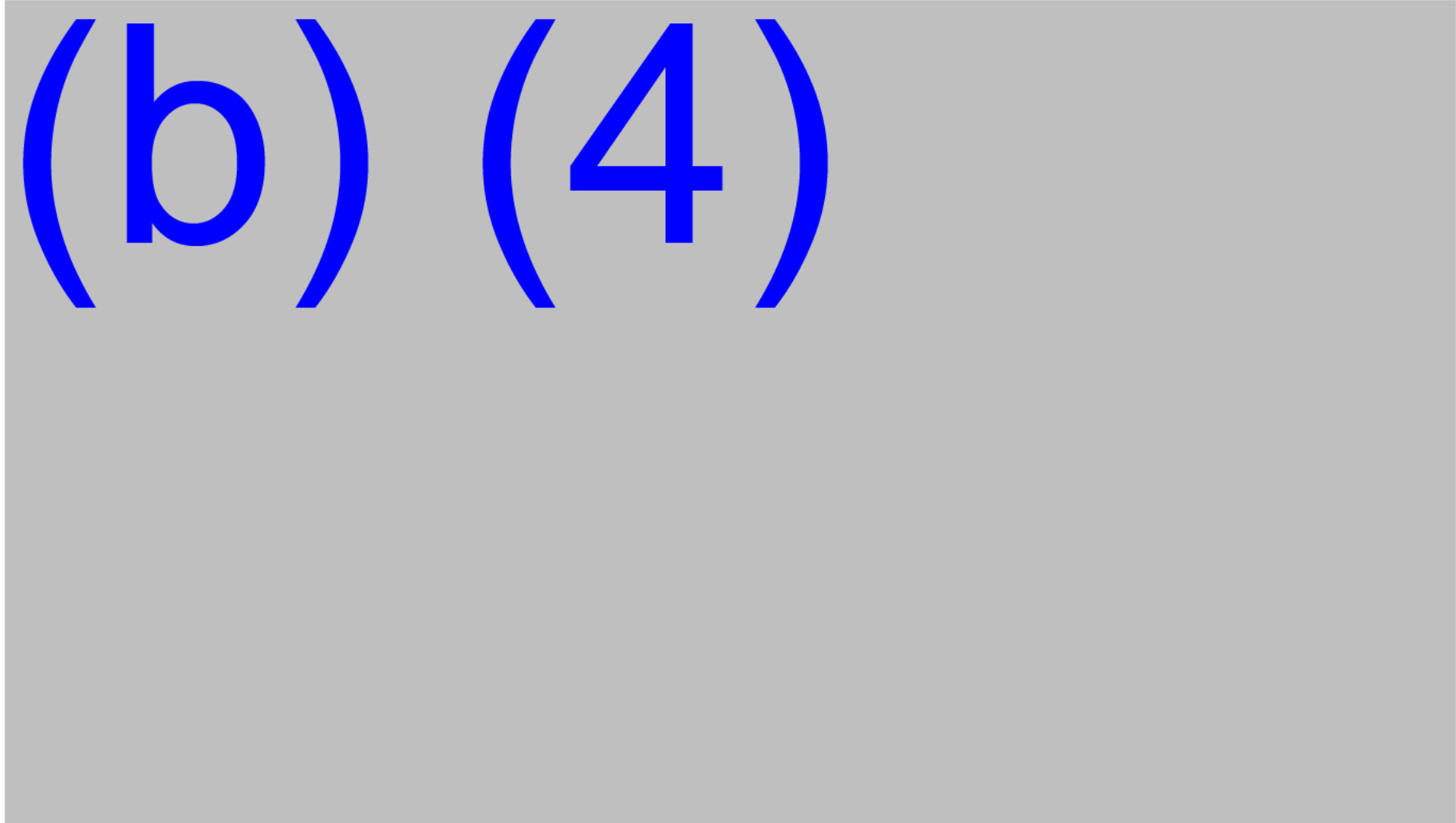
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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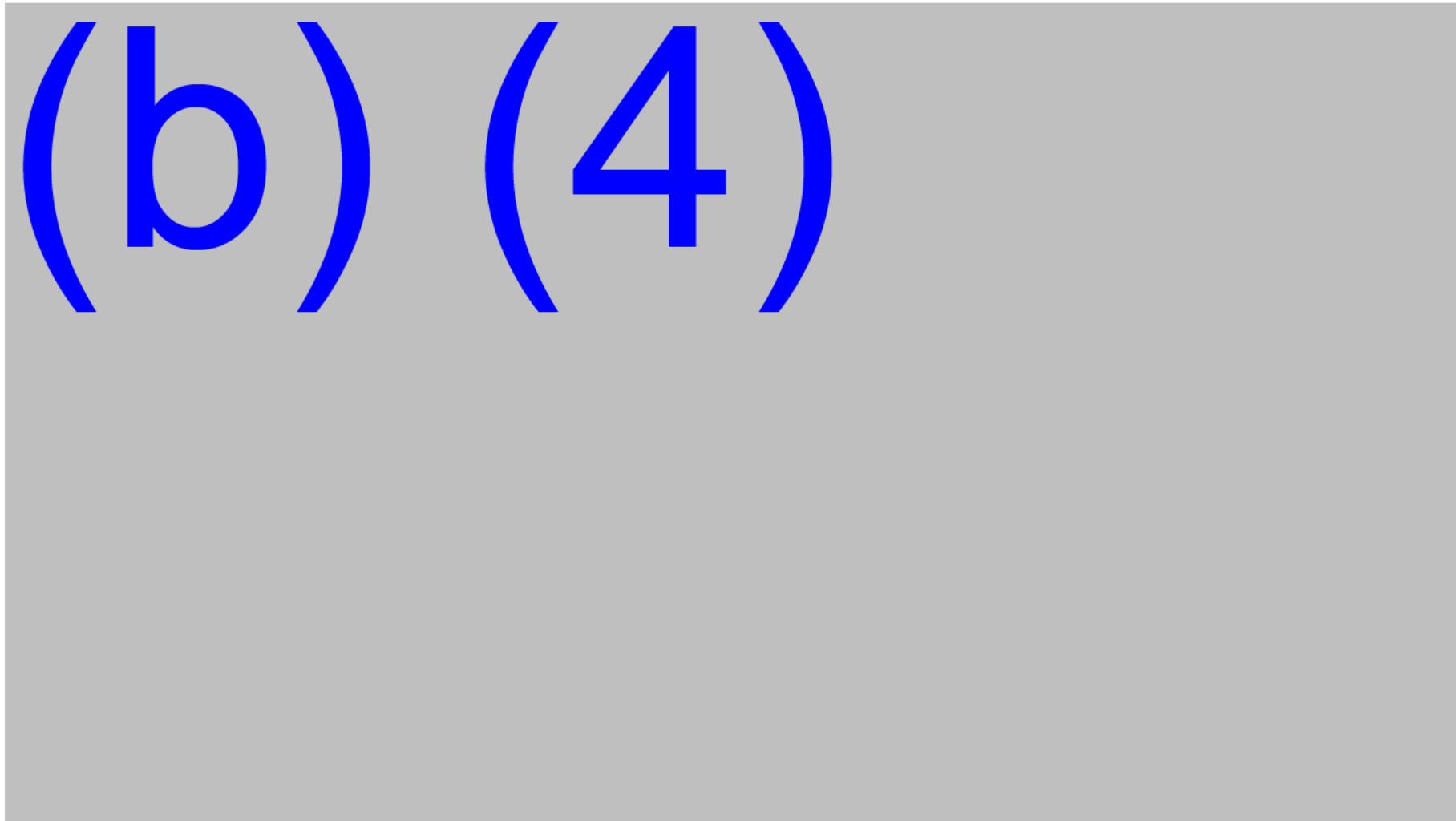
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)



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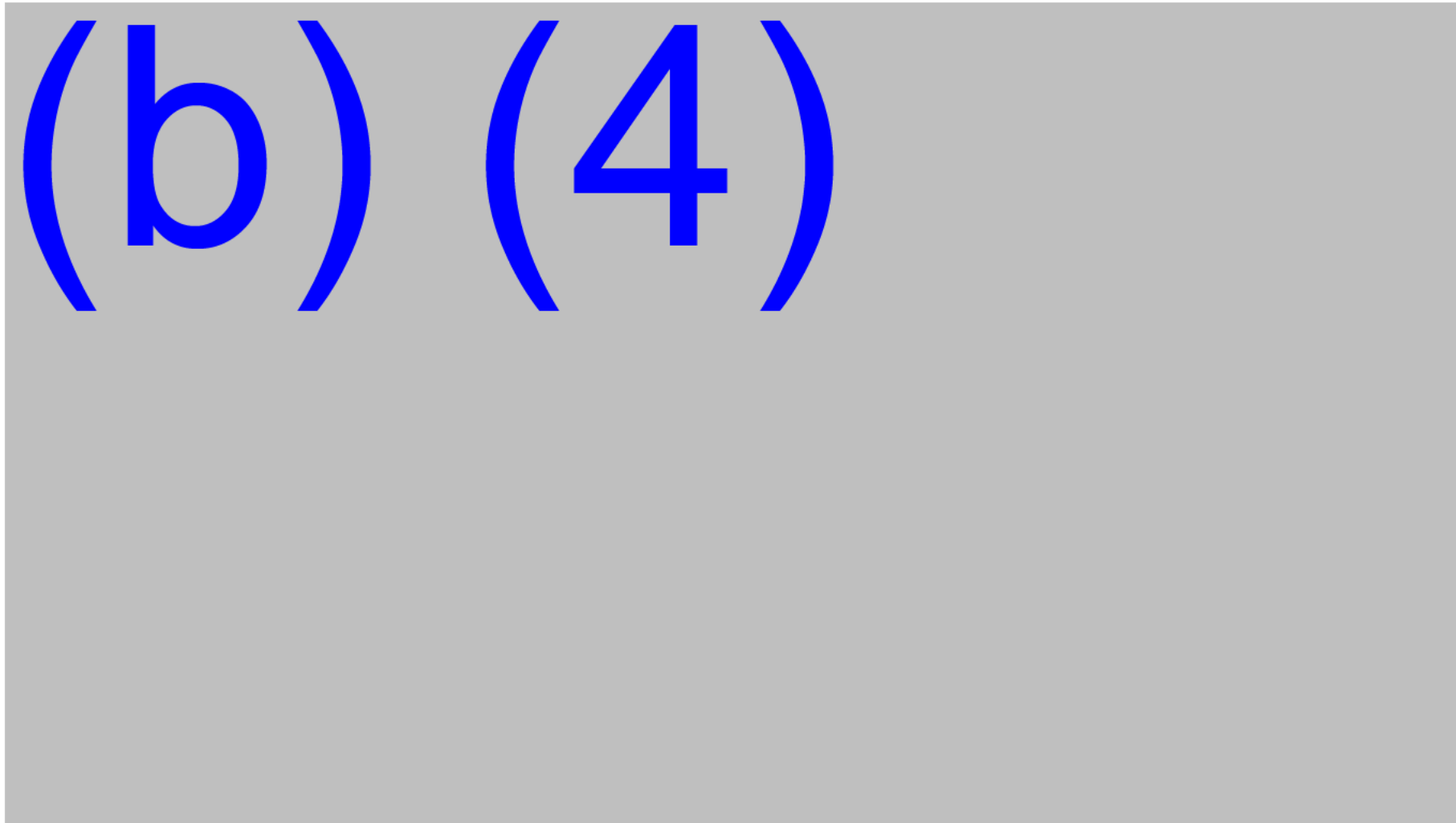
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)

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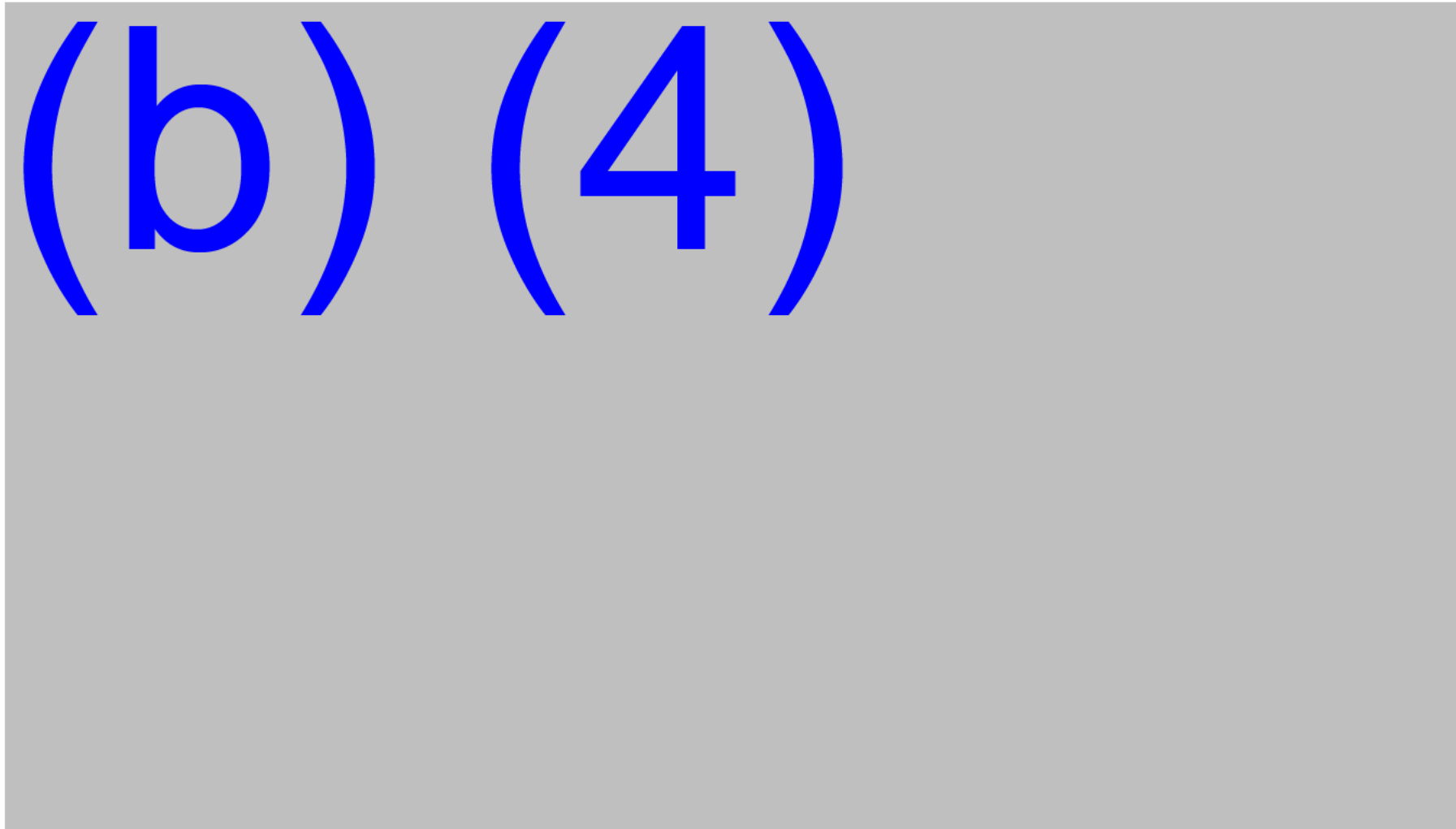
Listing 16.2.9-4 Lung function assessed using spirometry (Full analysis set)



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