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## Table of Contents

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### **16.2 SUBJECT DATA LISTINGS**

- 16.2.1 Discontinued Subjects
- 16.2.2 Protocol Deviations
- 16.2.3 Subjects Excluded From the Efficacy Analysis
- 16.2.4 Demographic Data and Other Baseline Characteristics
- 16.2.5 Compliance and/or Drug Concentration Data
- 16.2.6 Individual Clinical Data (Primary Endpoints)
- 16.2.7 Adverse Event Listings
- 16.2.8 Listing of Individual Laboratory Measurements by Subject
- 16.2.9 Subject disposition

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## **16.2 SUBJECT DATA LISTINGS**

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## **16.2.1 Discontinued Subjects**

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[Listing 16.2.1-1](#)      [Discontinued patients \(FAS, Part 1\)](#)

[Listing 16.2.1-2](#)      [Discontinued patients \(FAS, Part 2\)](#)

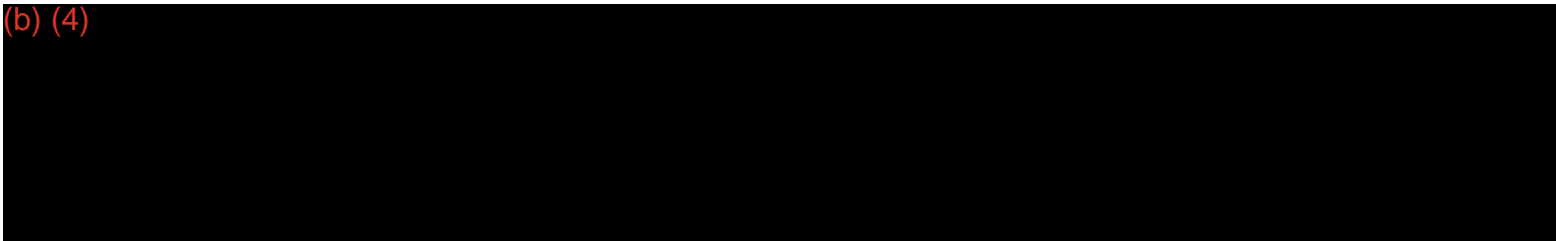
**Listing 16.2.1-1 Discontinued patients (FAS, Part 1)**

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**Listing 16.2.1-2 Discontinued patients (FAS, Part 2)**

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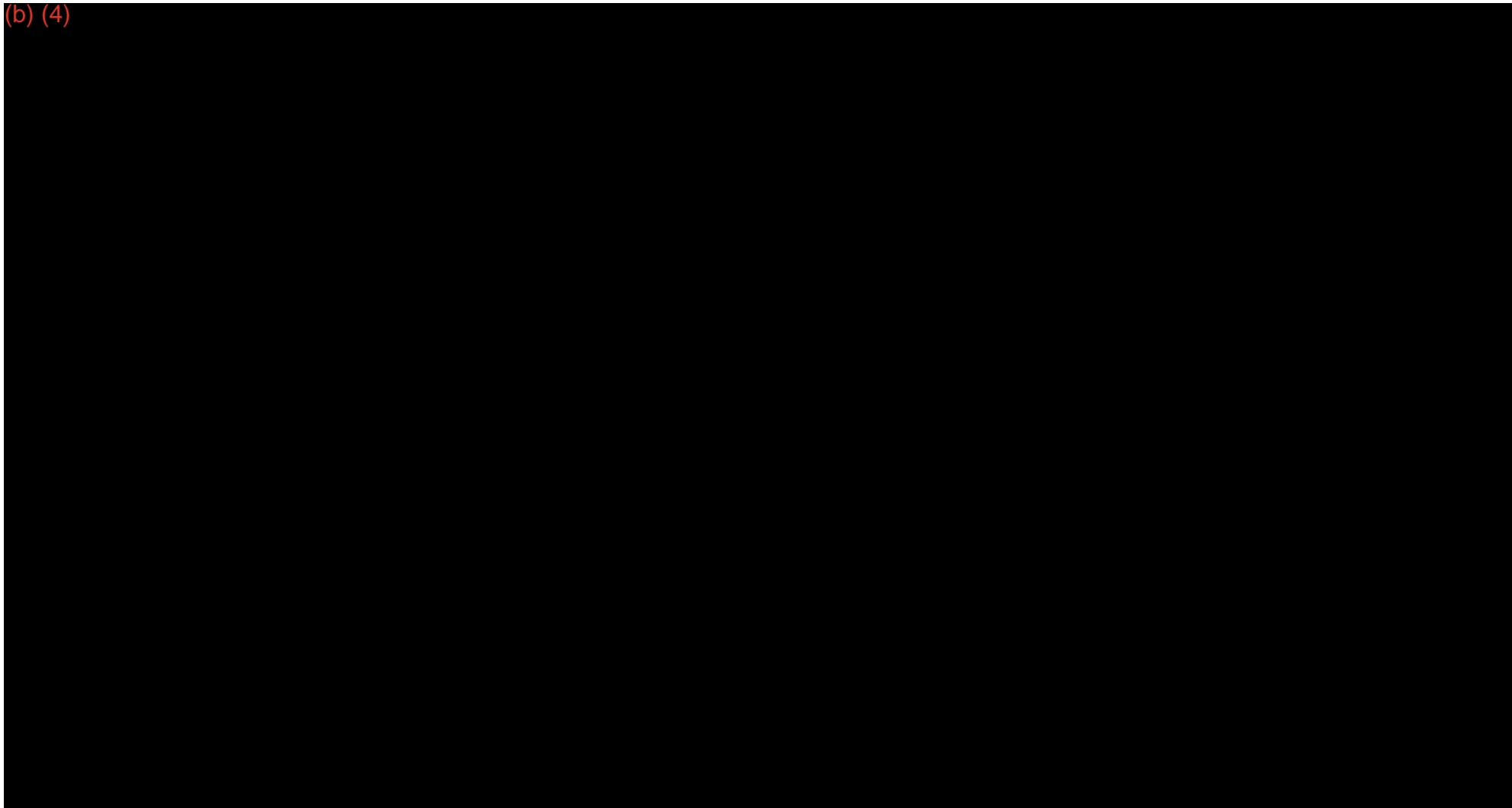
## 16.2.2 Protocol Deviations

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[Listing 16.2.2-1](#)      [Protocol deviations \(FAS, Part 1\)](#)  
[Listing 16.2.2-2](#)      [Protocol deviations \(FAS, Part 2\)](#)

**Listing 16.2.2-1 Protocol deviations (FAS, Part 1)**

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### **16.2.3 Subjects Excluded From the Efficacy Analysis**

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Listing 16.2.3-1	Subjects excluded from PPS (FAS, Part 1)
Listing 16.2.3-2	Subjects excluded from PPS (FAS, Part 2)
Listing 16.2.3-3	Subjects populations (FAS, Part 1)
Listing 16.2.3-4	Subjects populations (FAS, Part 2)
Listing 16.2.3-5	Inclusion/exclusion exceptions (FAS, Part 1)
Listing 16.2.3-6	Inclusion/exclusion exceptions (FAS, Part 2)

**Listing 16.2.3-1 Subjects excluded from PPS (FAS, Part 1)**

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**Listing 16.2.3-2 Subjects excluded from PPS (FAS, Part 2)**

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**Listing 16.2.3-3 Subjects populations (FAS, Part 1)**

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**Listing 16.2.3-5 Inclusion/exclusion exceptions (FAS, Part 1)**

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**Listing 16.2.3-6 Inclusion/exclusion exceptions (FAS, Part 2)**

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## **16.2.4 Demographic Data and Other Baseline Characteristics**

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Listing 16.2.4-1	Demographic data (FAS, Part 1)
Listing 16.2.4-2	Demographic data (FAS, Part 2)
Listing 16.2.4-3	Pregnancy test results (FAS, Part 1)
Listing 16.2.4-4	Pregnancy test results (FAS, Part 2)
Listing 16.2.4-5	Medical history (FAS, Part 1)
Listing 16.2.4-6	Medical history (FAS Part 2)
Listing 16.2.4-7	Medications prior to first dose, indications (FAS, Part 1)
Listing 16.2.4-8	Medications prior to first dose, duration (FAS, Part 1)
Listing 16.2.4-9	Medications prior to first dose, indications (FAS, Part 2)
Listing 16.2.4-10	Medications prior to first dose, duration (FAS, Part 2)
Listing 16.2.4-11	Baseline symptoms, duration (FAS, Part 1)
Listing 16.2.4-12	Baseline symptoms, coding and severity (FAS, Part 1)
Listing 16.2.4-13	Baseline symptoms, duration (FAS, Part 2)
Listing 16.2.4-14	Baseline symptoms, coding and severity (FAS, Part 2)

**Listing 16.2.4-1 Demographic data (FAS, Part 1)**

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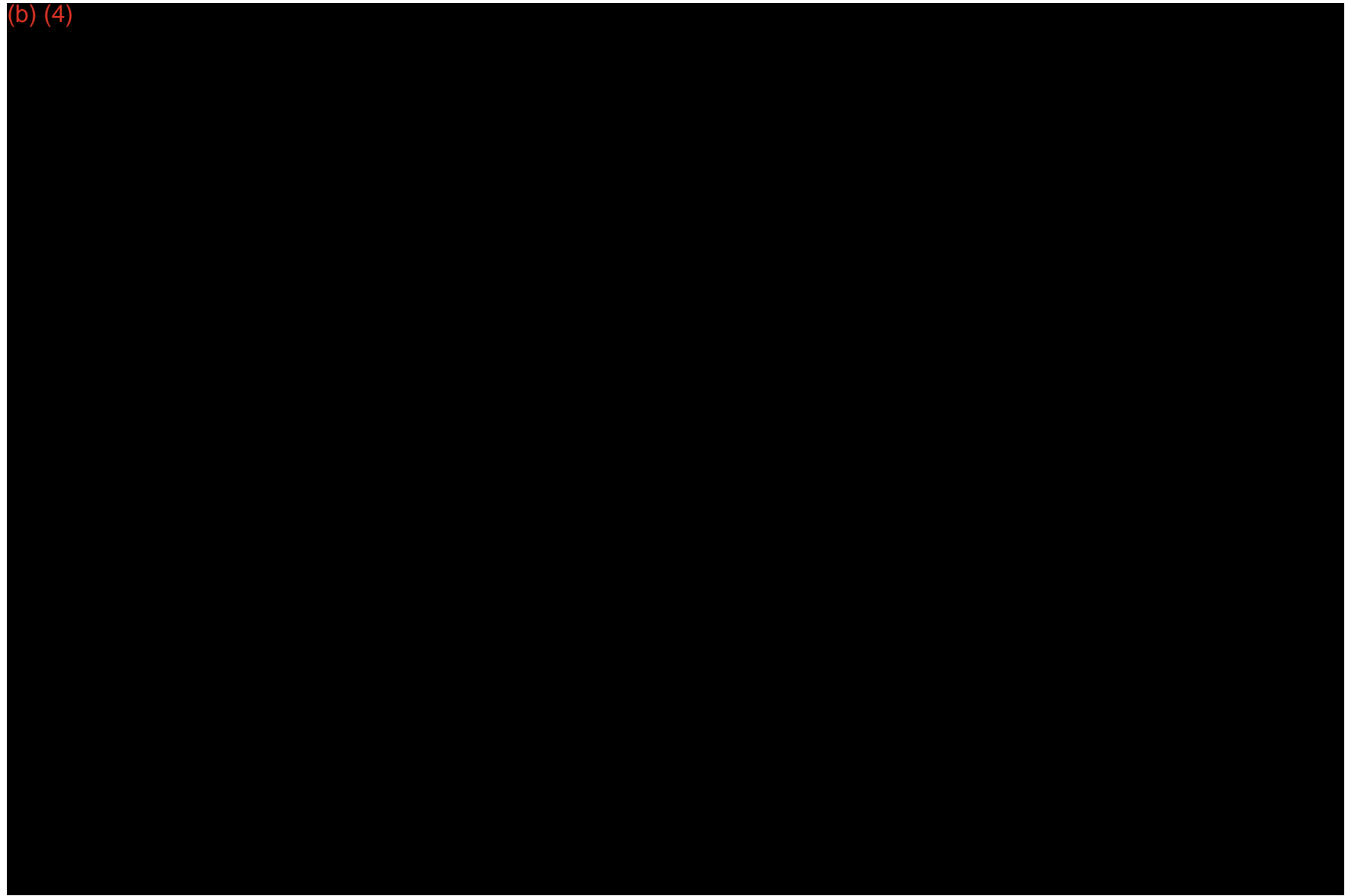


**Listing 16.2.4-2 Demographic data (FAS, Part 2)**

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**Listing 16.2.4-3    Pregnancy test results (FAS, Part 1)**

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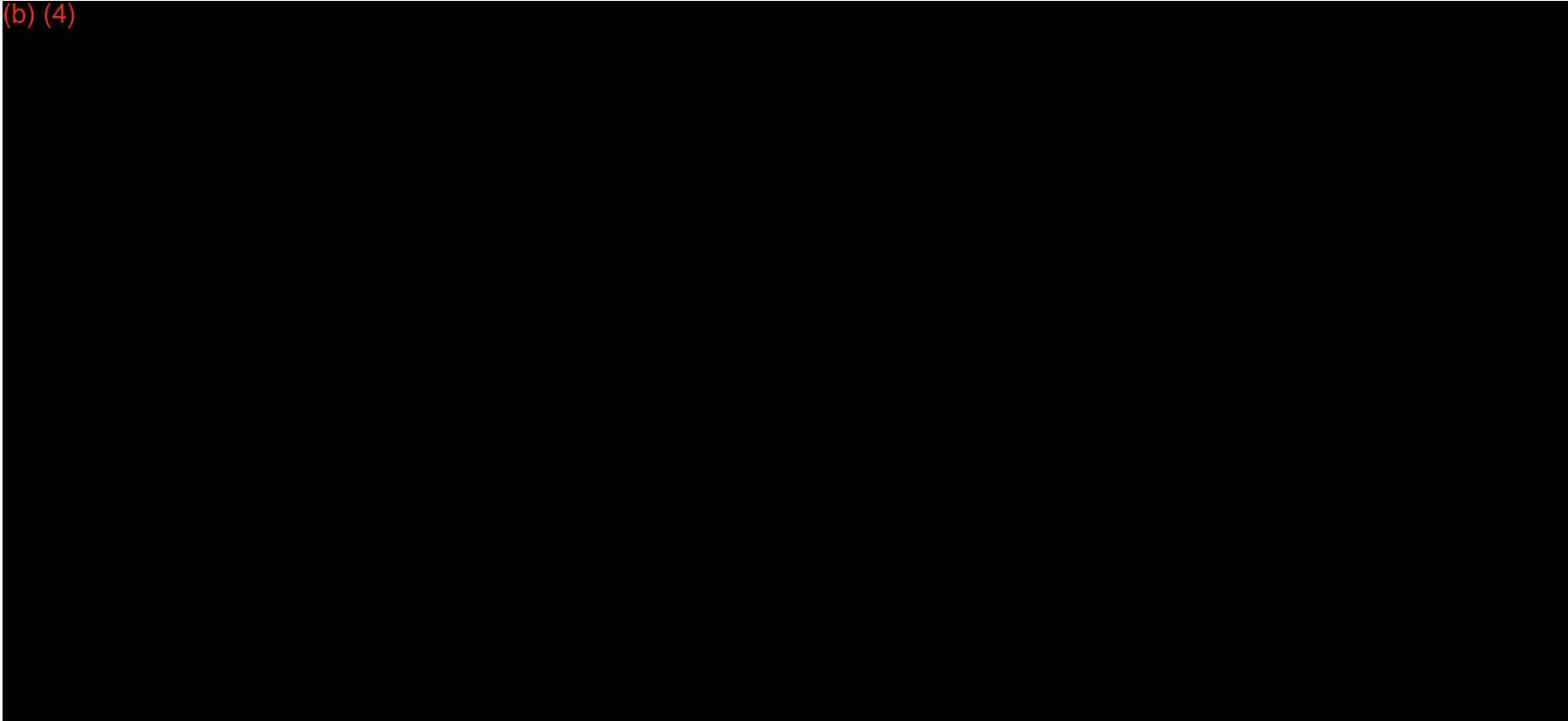


**Listing 16.2.4-4    Pregnancy test results (FAS, Part 2)**

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**Listing 16.2.4-5 Medical history (FAS, Part 1)**

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**Listing 16.2.4-7 Medications prior to first dose, indications (FAS, Part 1)**

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**Listing 16.2.4-8 Medications prior to first dose, duration (FAS, Part 1)**

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**Listing 16.2.4-9 Medications prior to first dose, indications (FAS, Part 2)**

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**Listing 16.2.4-10 Medications prior to first dose, duration (FAS, Part 2)**

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**Listing 16.2.4-11 Baseline symptoms, duration (FAS, Part 1)**

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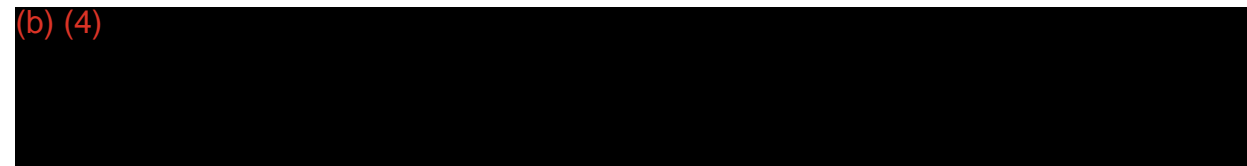
**Listing 16.2.4-12 Baseline symptoms, coding and severity (FAS, Part 1)**

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**Listing 16.2.4-13 Baseline symptoms, duration (FAS, Part 2)**

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**Listing 16.2.4-14 Baseline symptoms, coding and severity (FAS, Part 2)**

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## **16.2.5 Compliance and/or Drug Concentration Data**

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Listing 16.2.5-1	Exposure to study product (FAS, Part 1)
Listing 16.2.5-2	Exposure to study product (FAS, Part 2)
Listing 16.2.5-3	Concomitant medications, indications (FAS, Part 1)
Listing 16.2.5-4	Concomitant medications, durations (FAS, Part 1)
Listing 16.2.5-5	Concomitant medications, indications (FAS, Part 2)
Listing 16.2.5-6	Concomitant medications, durations (FAS, Part 2)

**Listing 16.2.5-1 Exposure to study product (FAS, Part 1)**

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**Listing 16.2.5-2 Exposure to study product (FAS, Part 2)**

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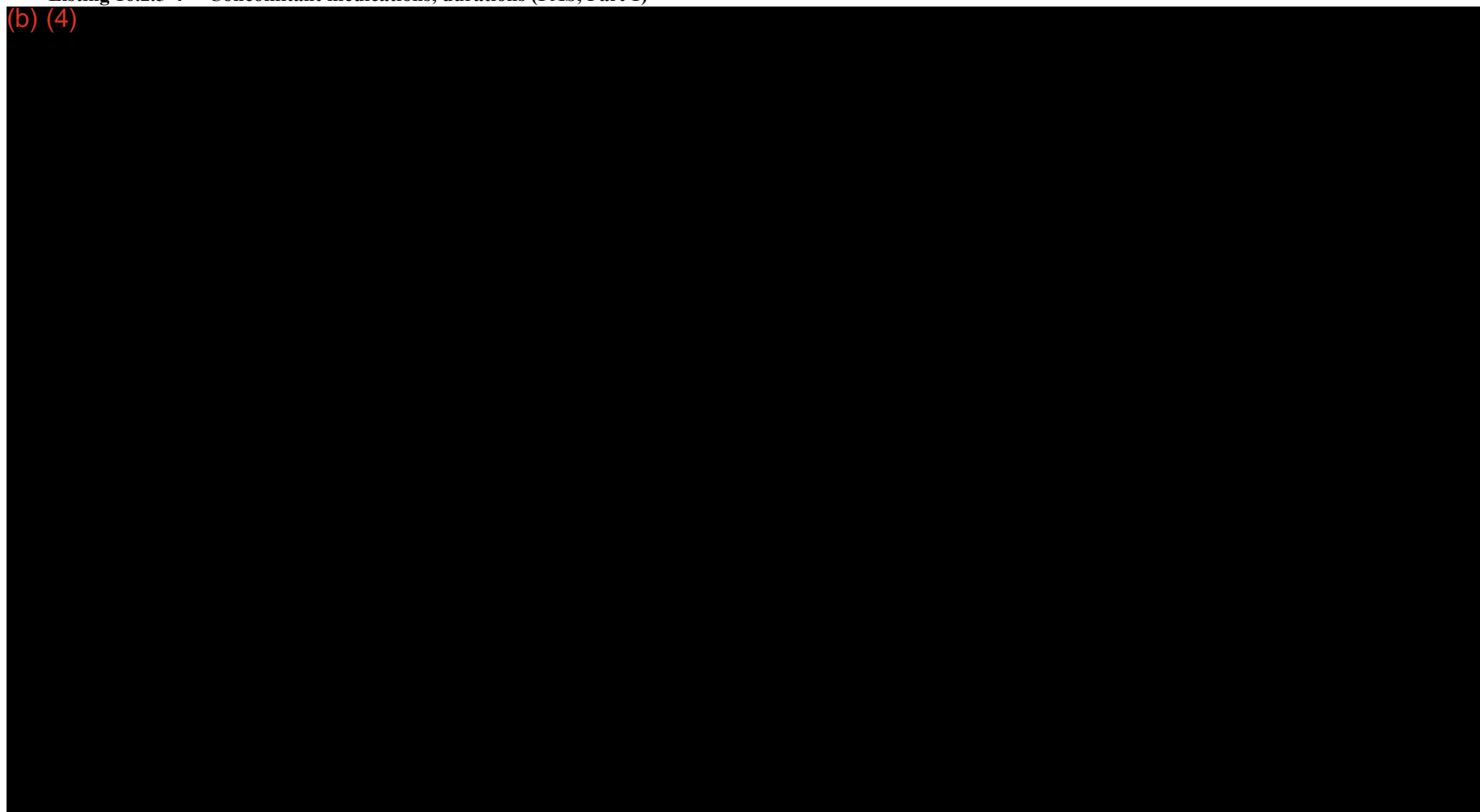
**Listing 16.2.5-3 Concomitant medications, indications (FAS, Part 1)**

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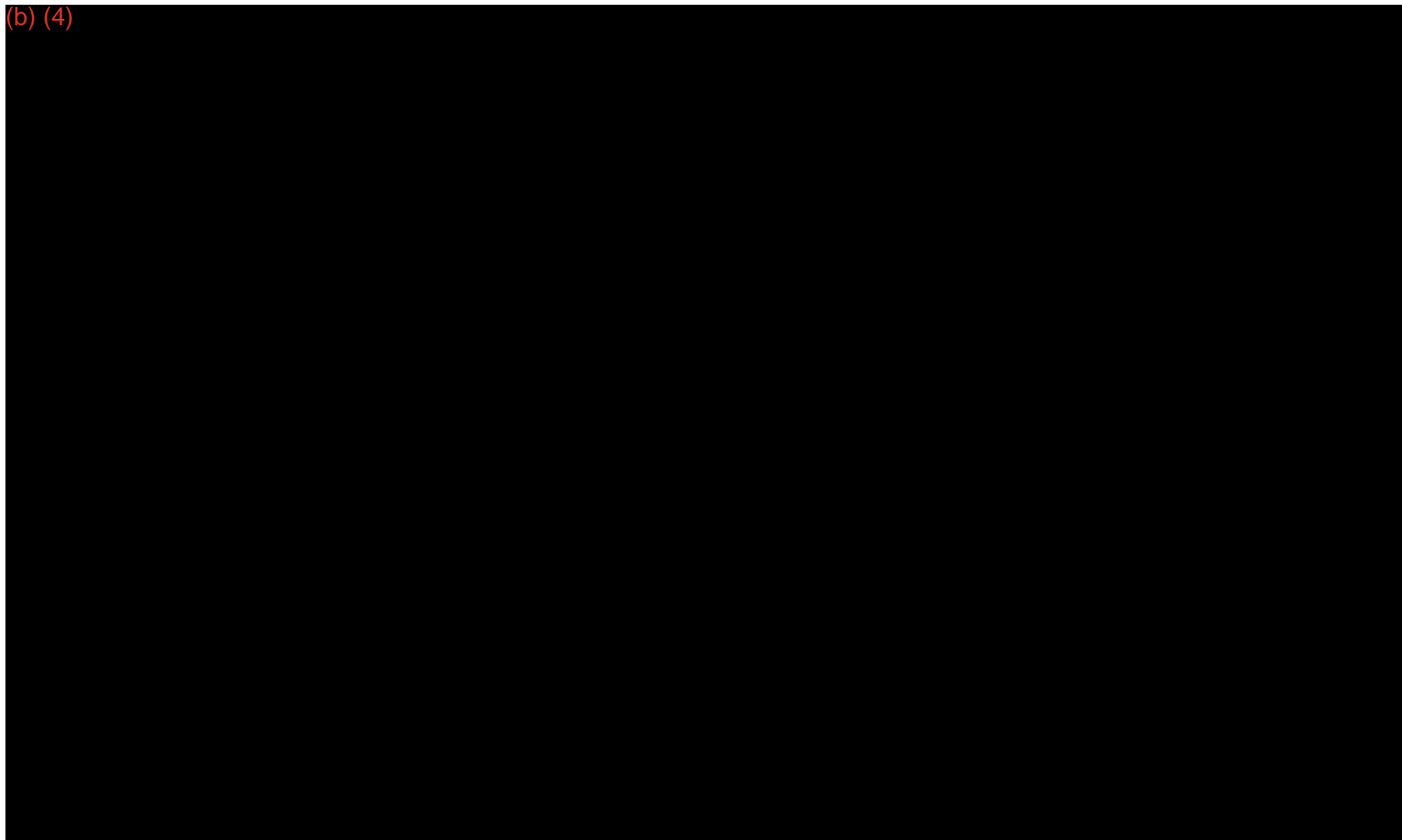
**Listing 16.2.5-4 Concomitant medications, durations (FAS, Part 1)**

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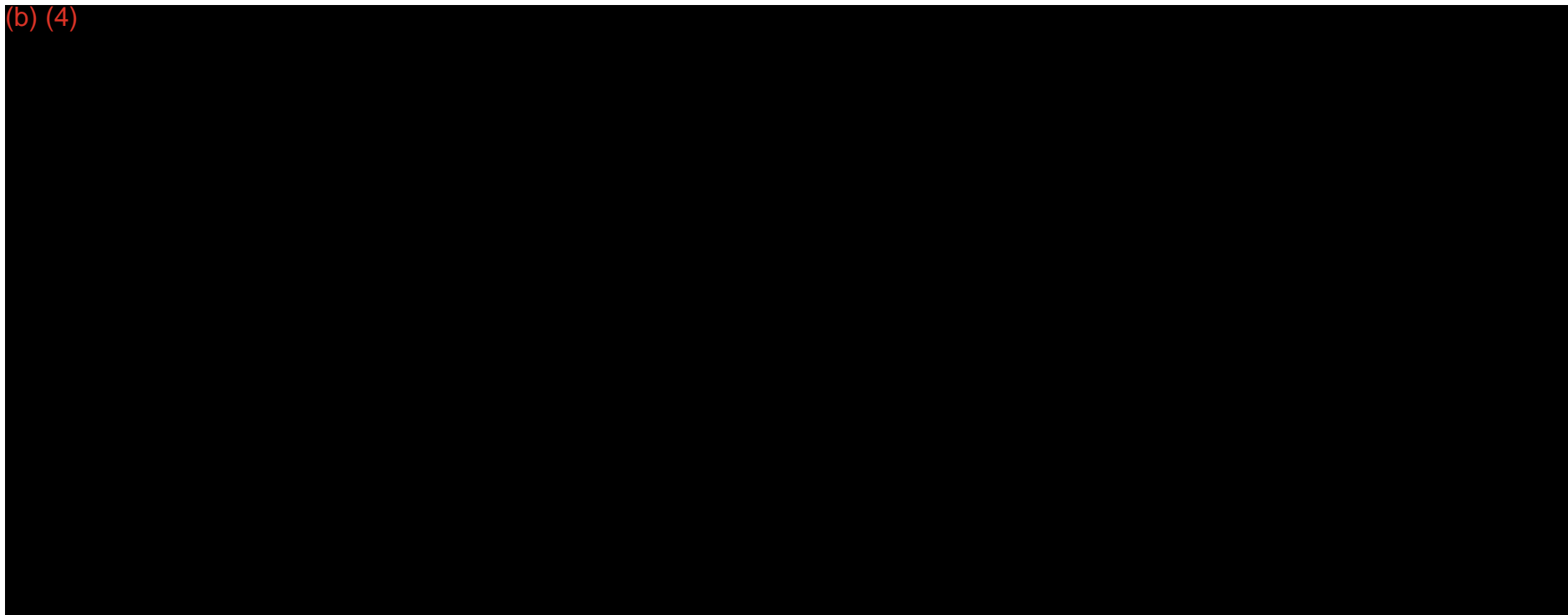


**Listing 16.2.5-5 Concomitant medications, indications (FAS, Part 2)**

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**Listing 16.2.5-6 Concomitant medications, durations (FAS, Part 2)**

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## 16.2.6 Individual Clinical Data (Primary Endpoints)

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Listing 16.2.6-1	Saliva status at screening (FAS, Part 1)
Listing 16.2.6-2	Saliva and oral mucosa status (FAS, Part 2)
Listing 16.2.6-3	Physical examination (FAS, Part 1)
Listing 16.2.6-4	Physical examination (FAS, Part 2)
Listing 16.2.6-5	Dental plaque acidogenicity (FAS, Part 1)
Listing 16.2.6-6	Dental plaque acidogenicity (pH) site 1 (FAS, Part 2)
Listing 16.2.6-7	Dental plaque acidogenicity (pH) site 2 (FAS, Part 2)
Listing 16.2.6-8	Dental plaque acidogenicity (pH) mean of site 1 and site 2 (FAS, Part 2)
Listing 16.2.6-9	Plaque amount (Silness-Löe) T16 (FAS, Part 2)
Listing 16.2.6-10	Plaque amount (Silness-Löe) T21 (FAS, Part 2)
Listing 16.2.6-11	Plaque amount (Silness-Löe) T24 (FAS, Part 2)
Listing 16.2.6-12	Plaque amount (Silness-Löe) T36 (FAS, Part 2)
Listing 16.2.6-13	Plaque amount (Silness-Löe) T41 (FAS, Part 2)
Listing 16.2.6-14	Plaque amount (Silness-Löe) T44 (FAS, Part 2)
Listing 16.2.6-15	Plaque amount (Silness-Löe) mean of all sites (Part 2)
Listing 16.2.6-16	Oral microflora (FAS, Part 2)

**Listing 16.2.6-1 Saliva status at screening (FAS, Part 1)**

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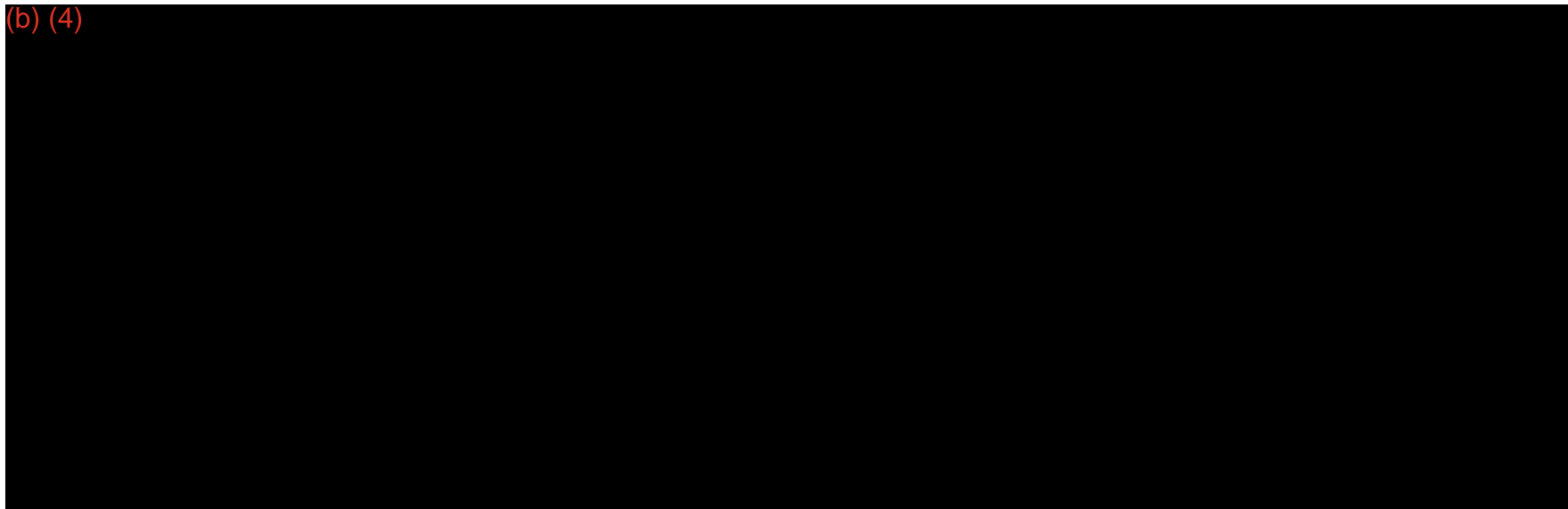




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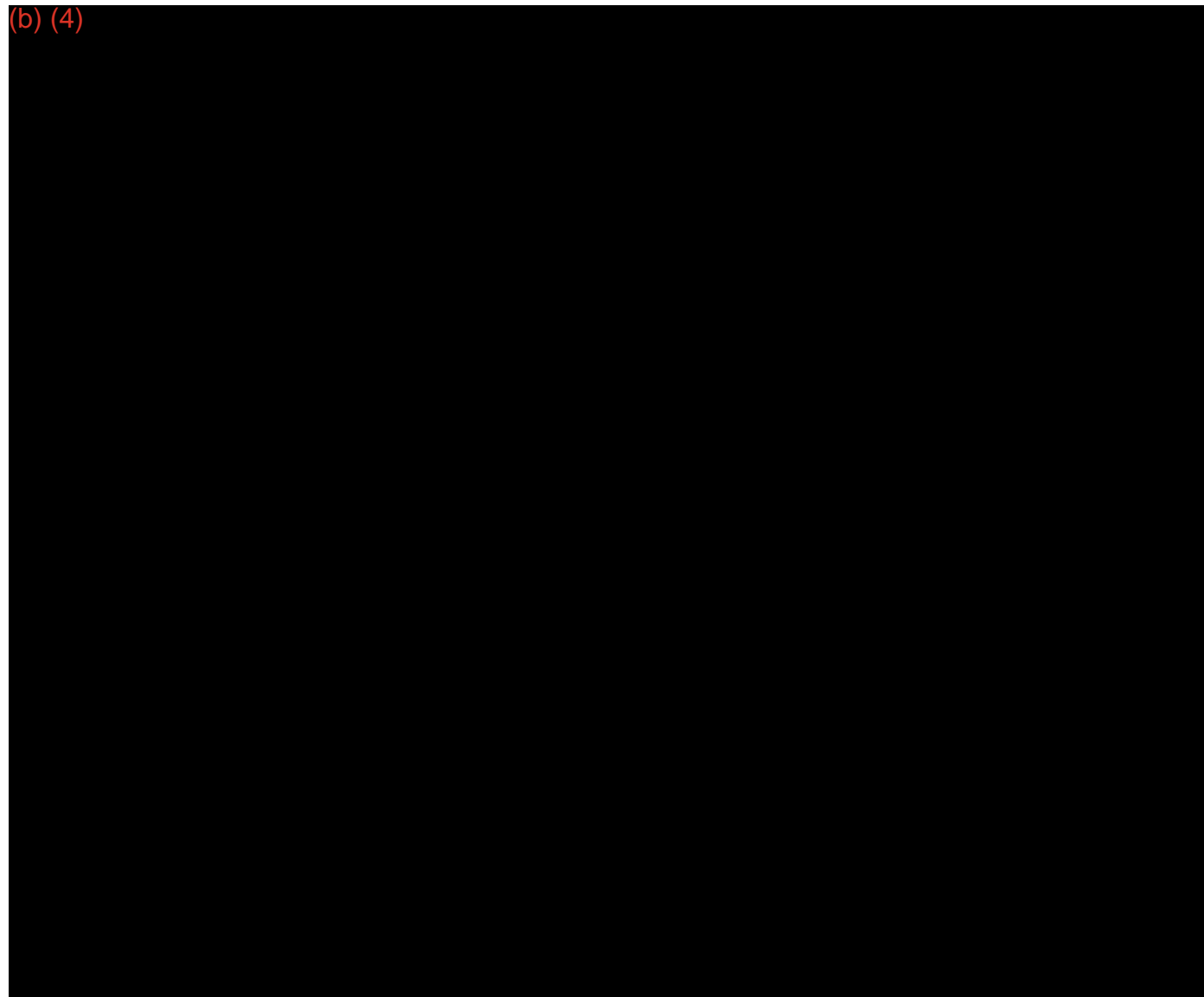


**Listing 16.2.6-2 Saliva and oral mucosa status (FAS, Part 2)**

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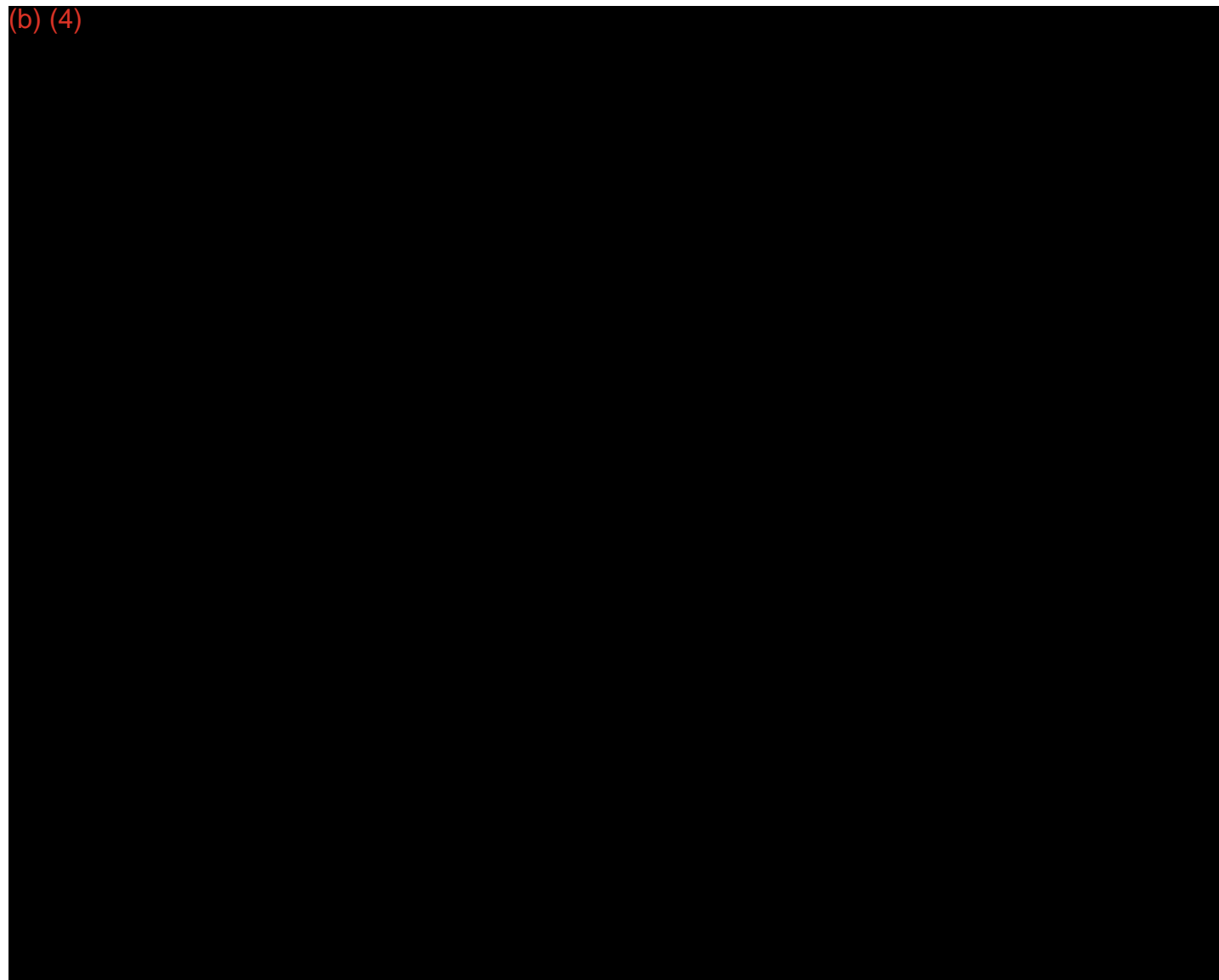
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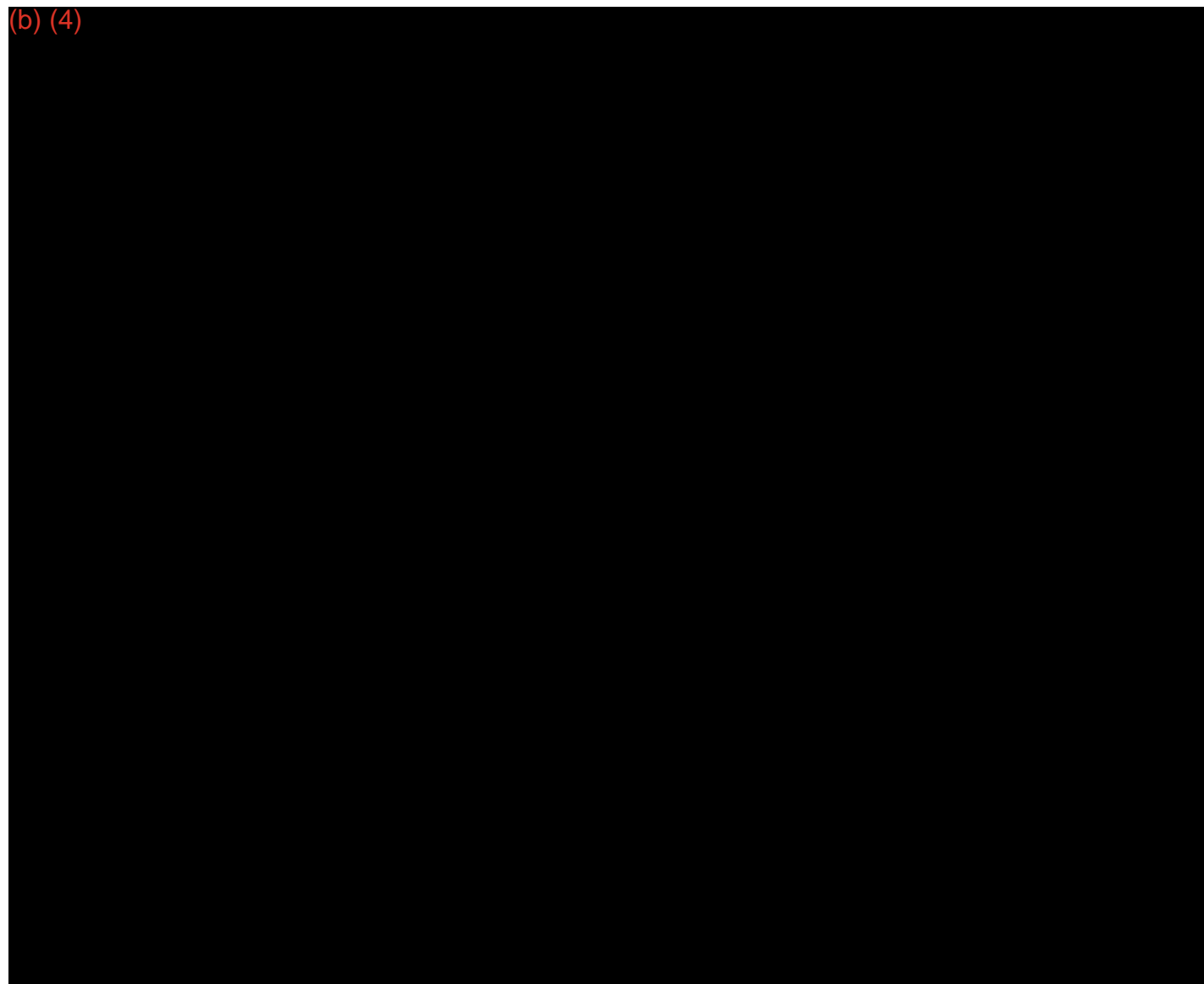
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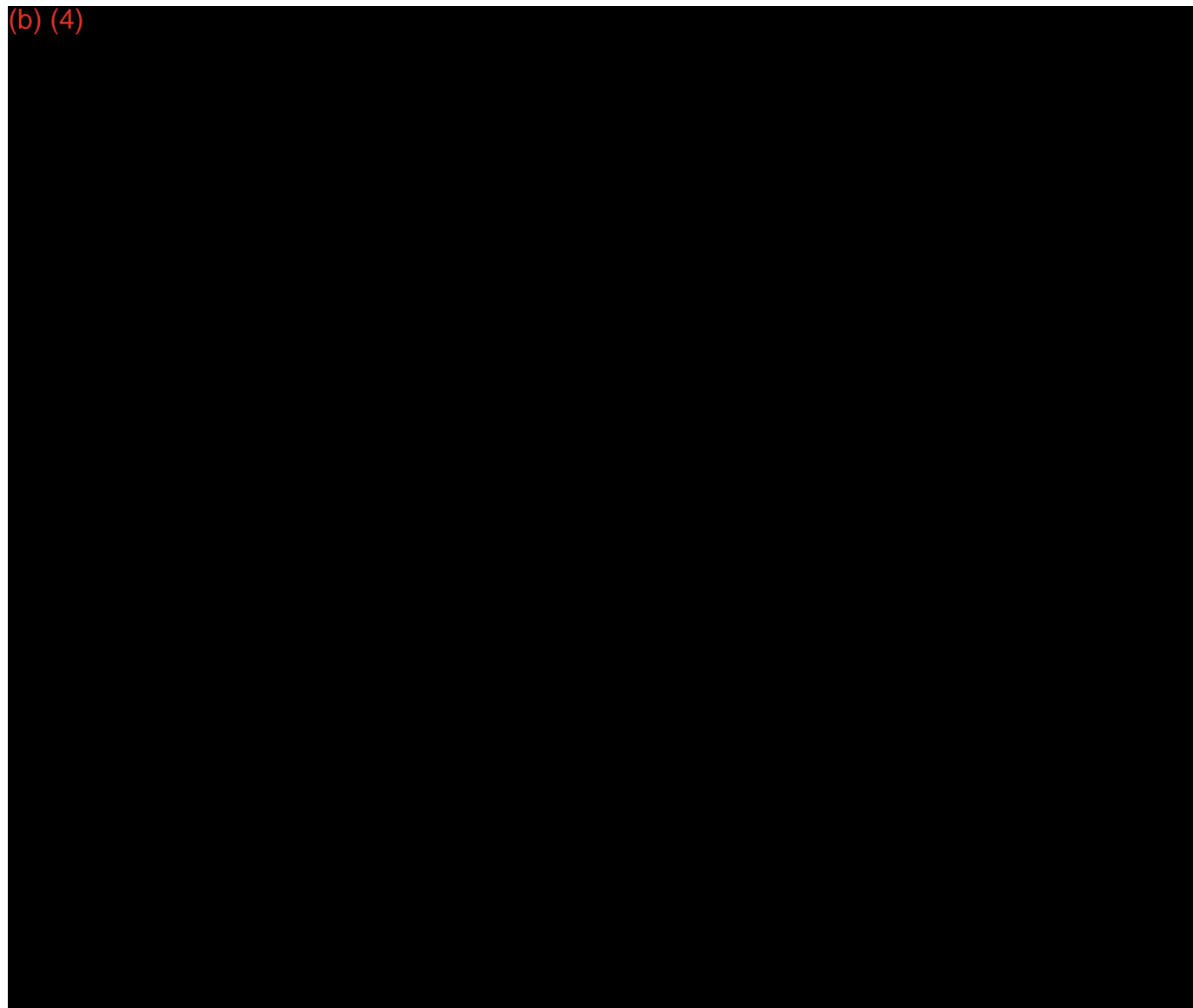


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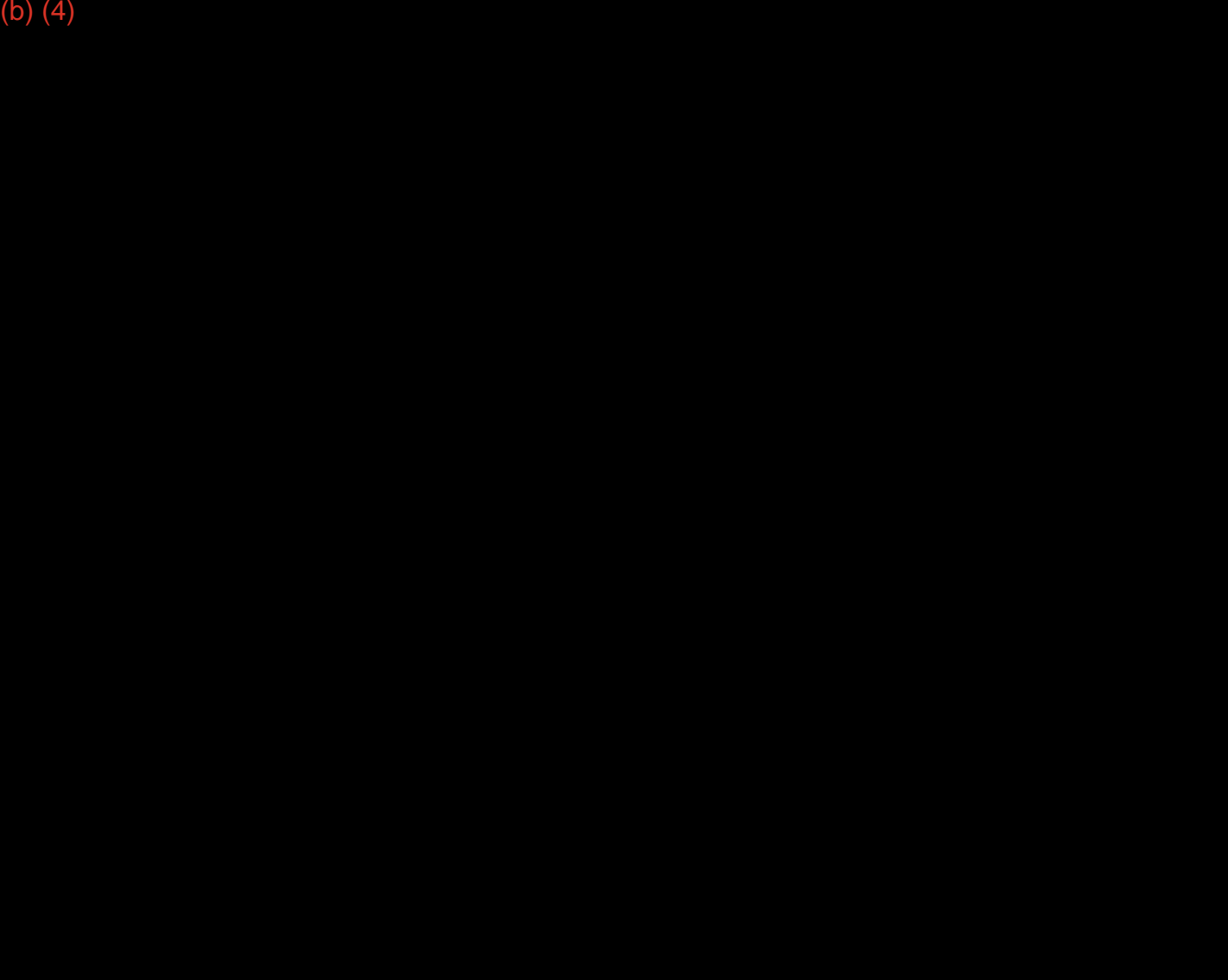
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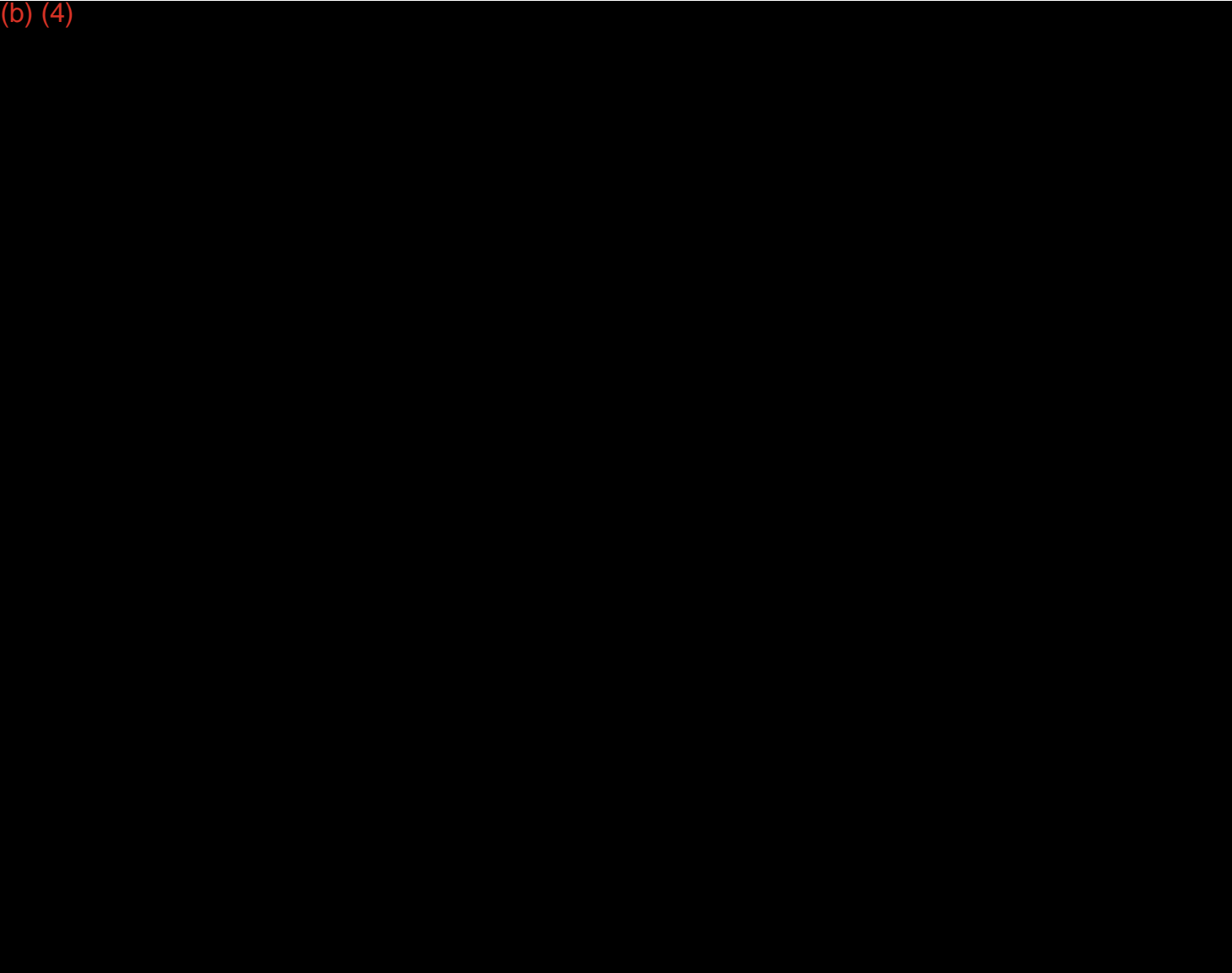
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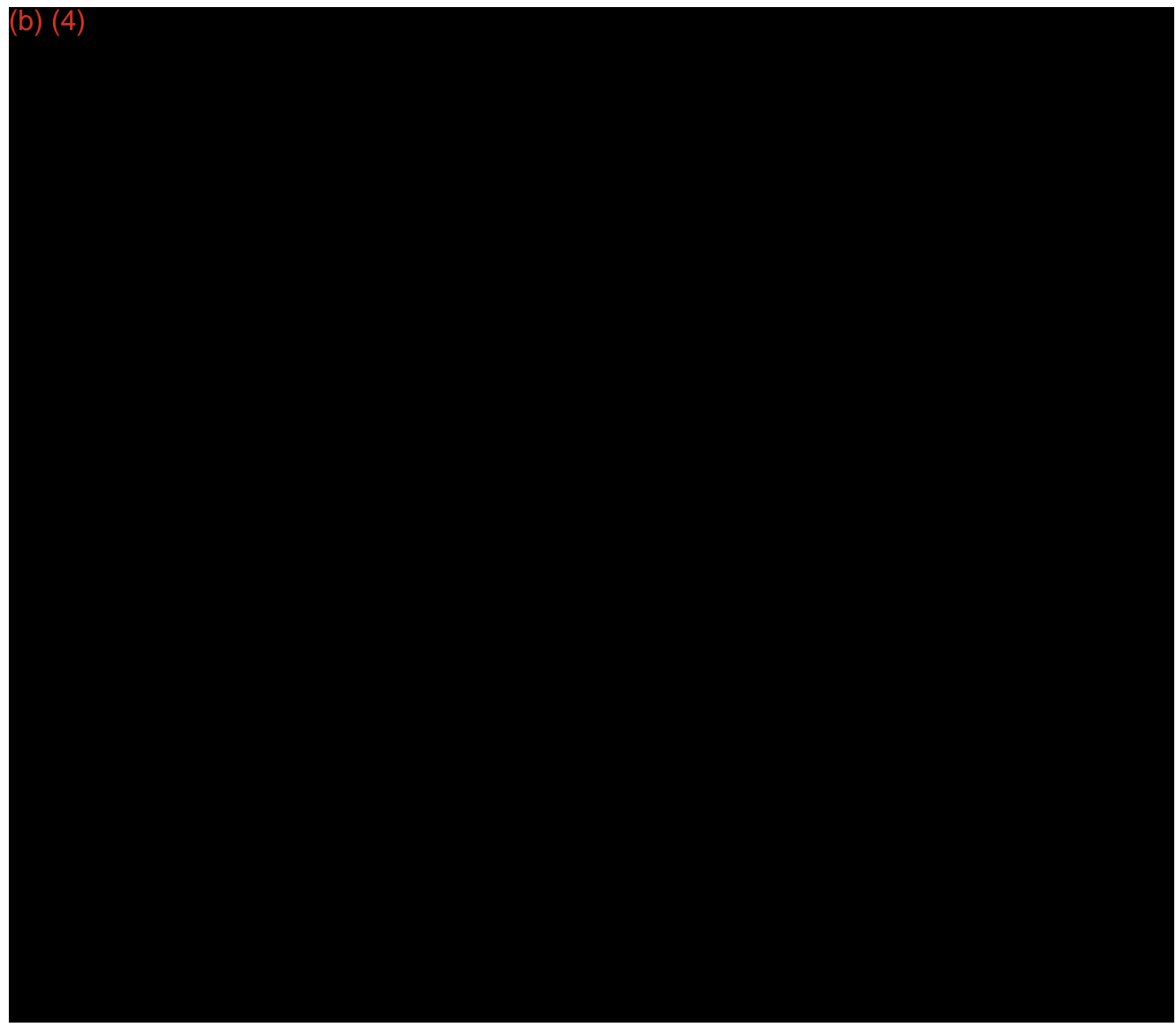
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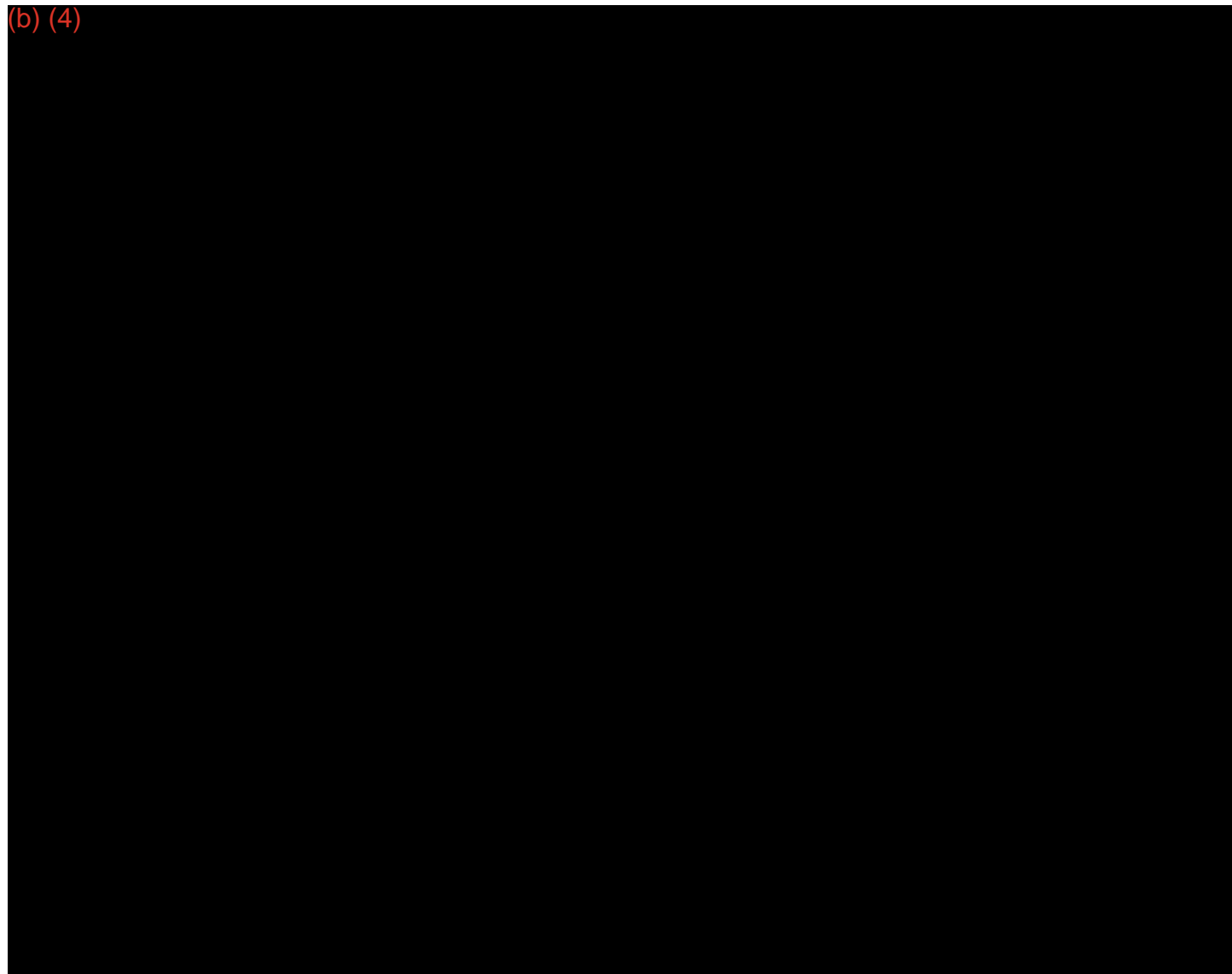
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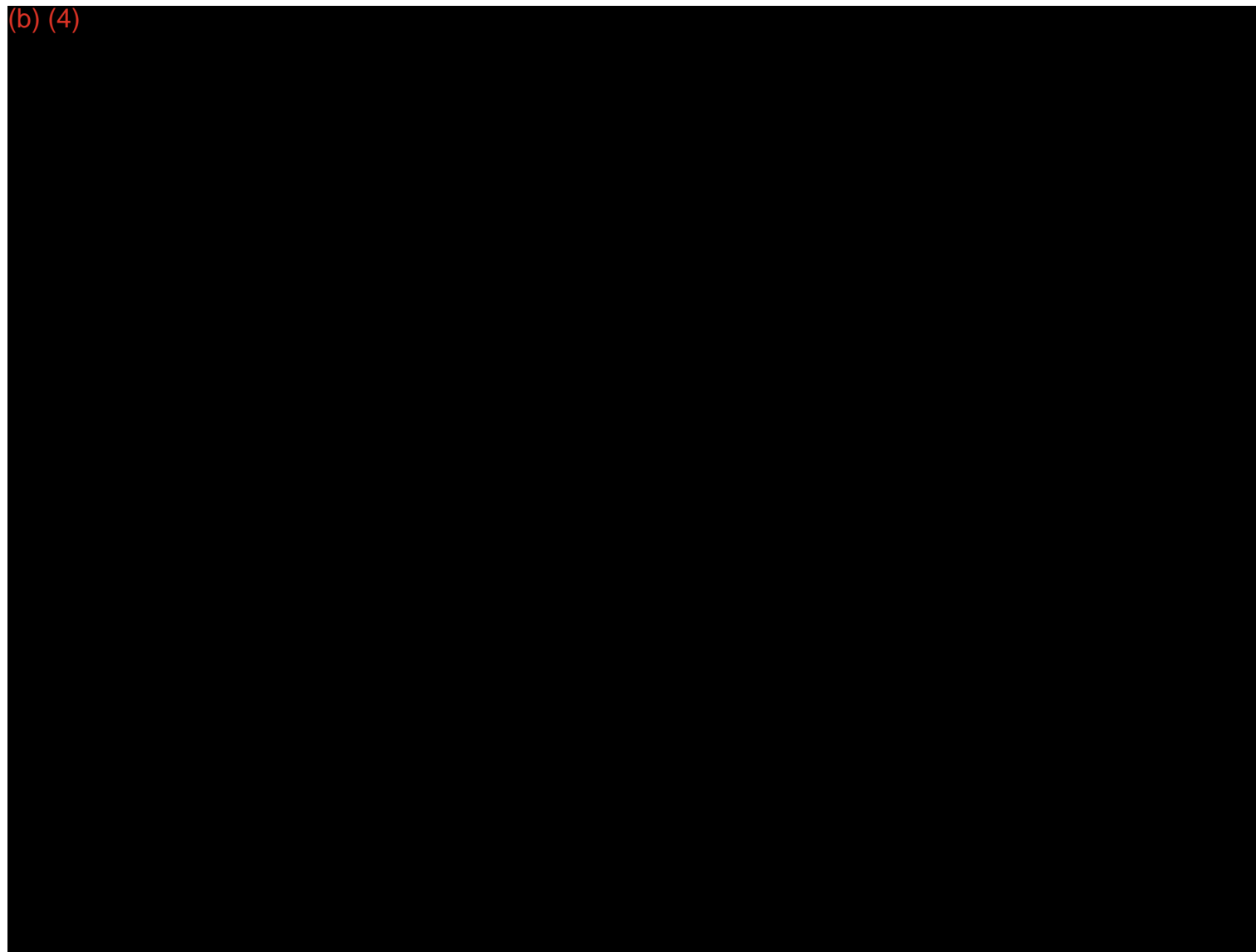
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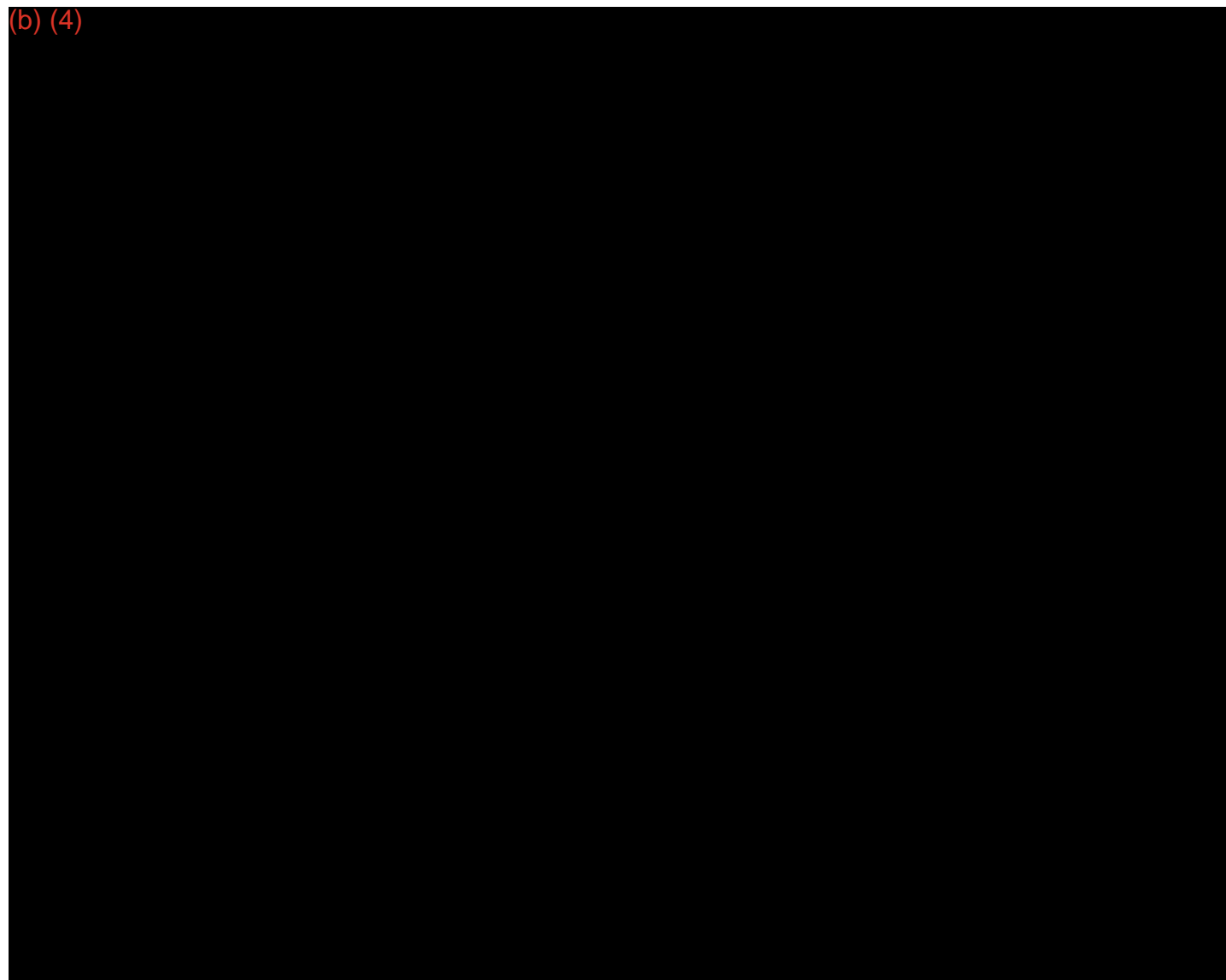
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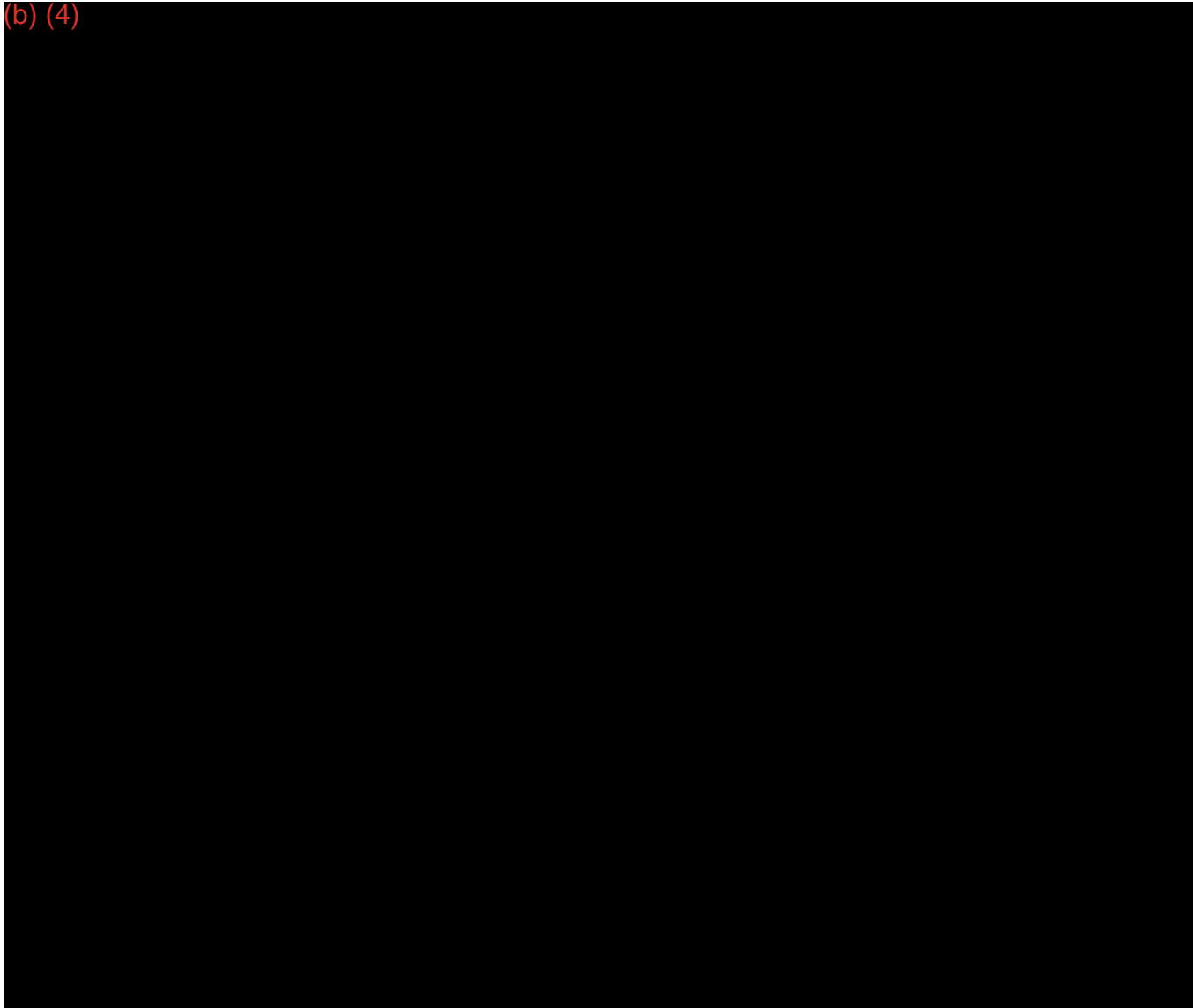


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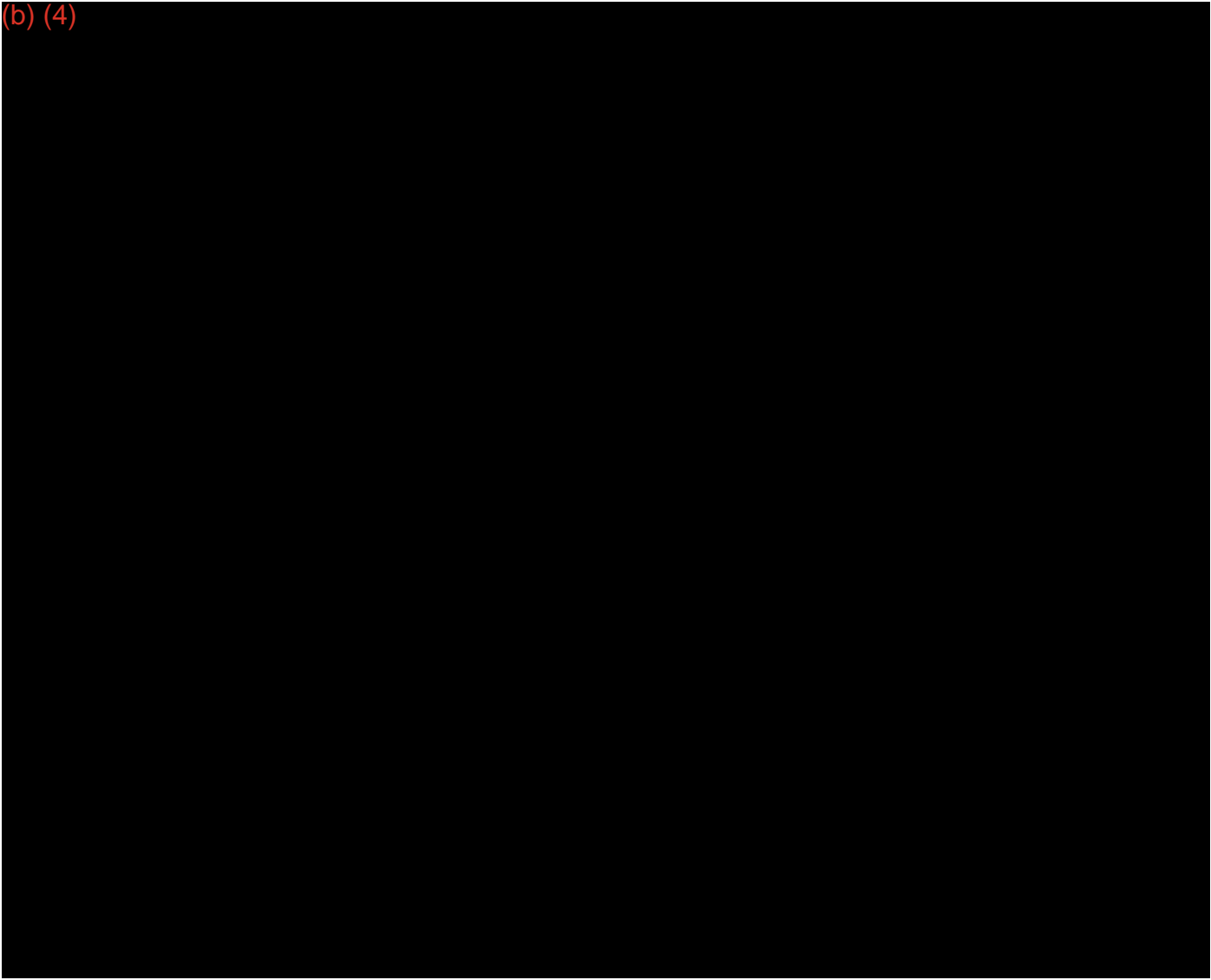
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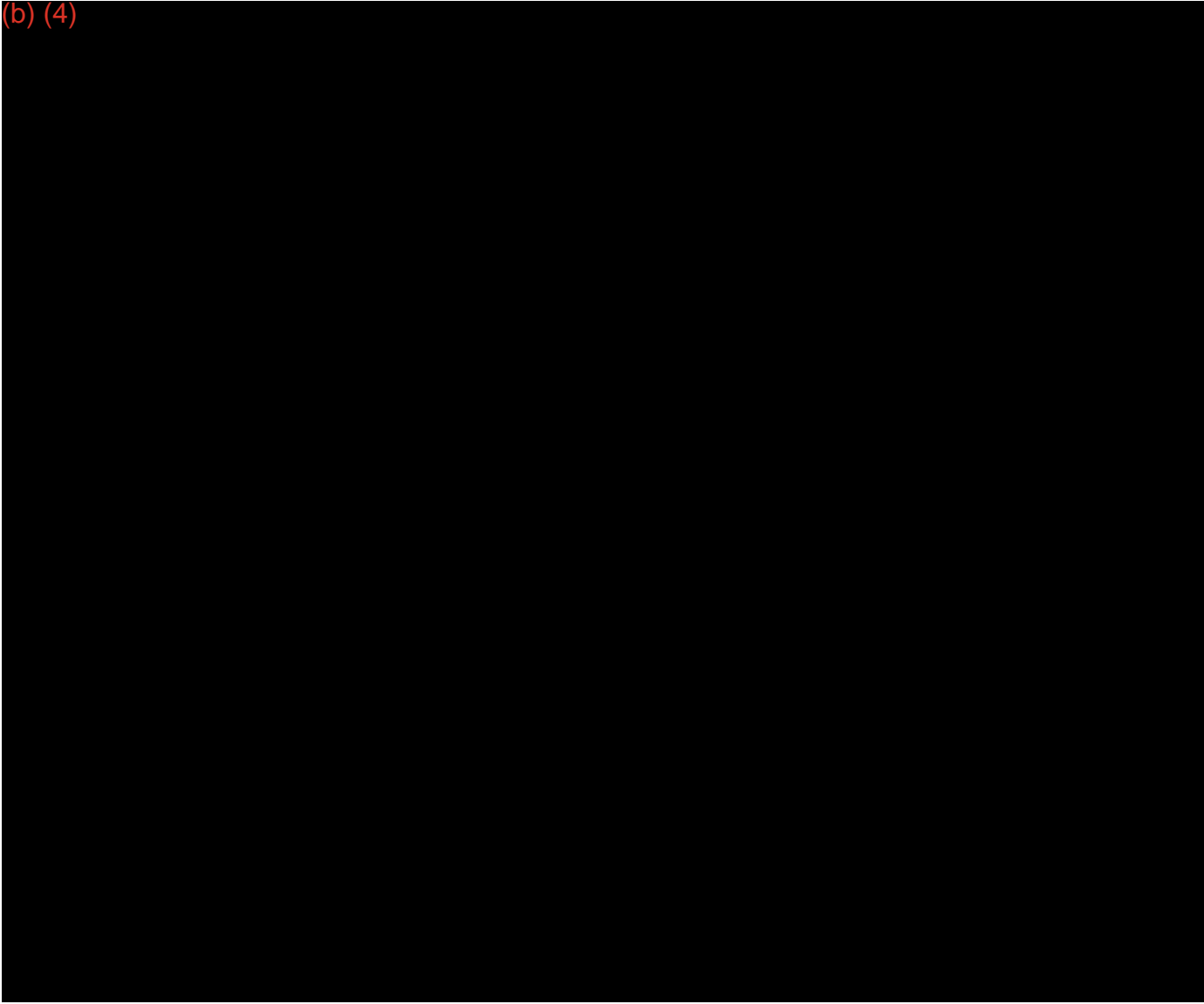
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**Listing 16.2.6-3 Physical examination (FAS, Part 1)**

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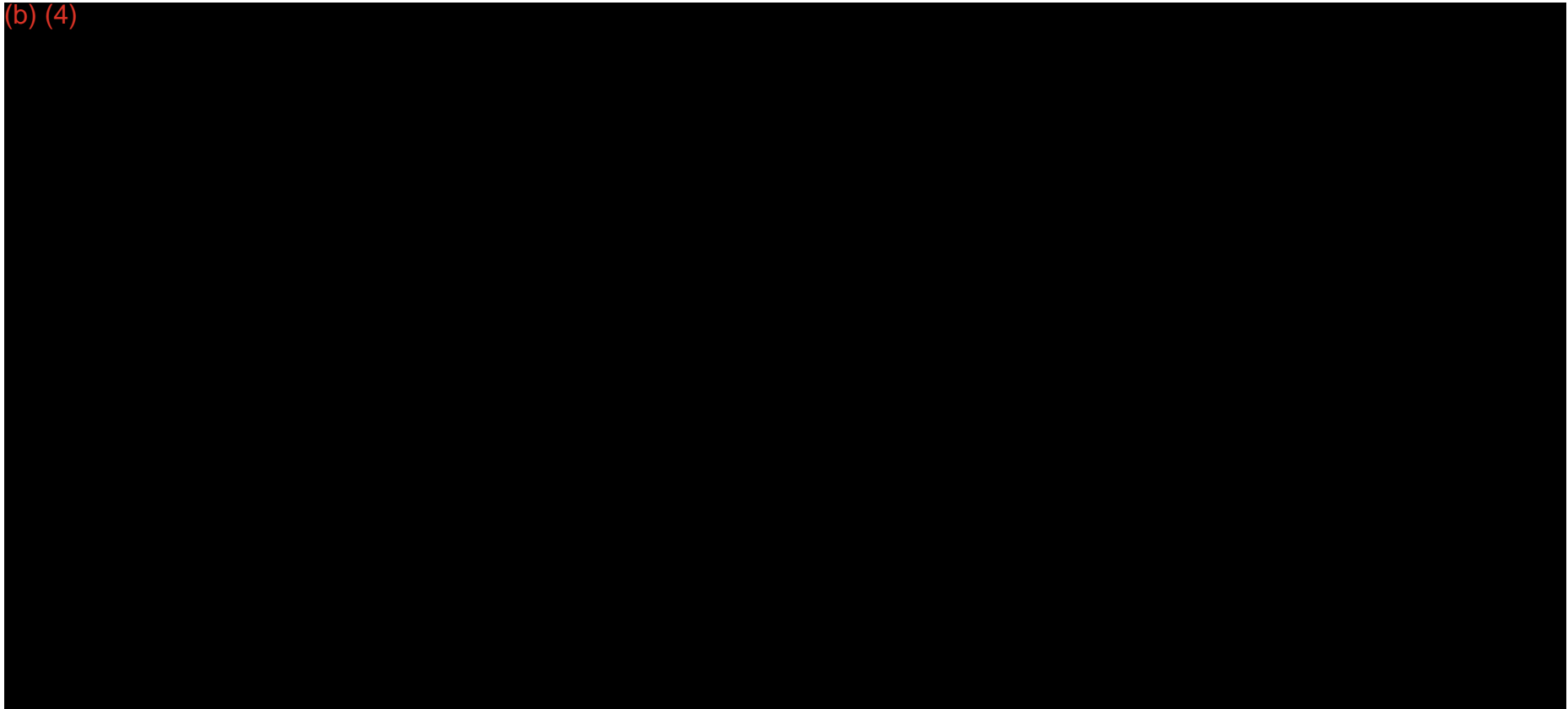
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**Listing 16.2.6-4 Physical examination (FAS, Part 2)**

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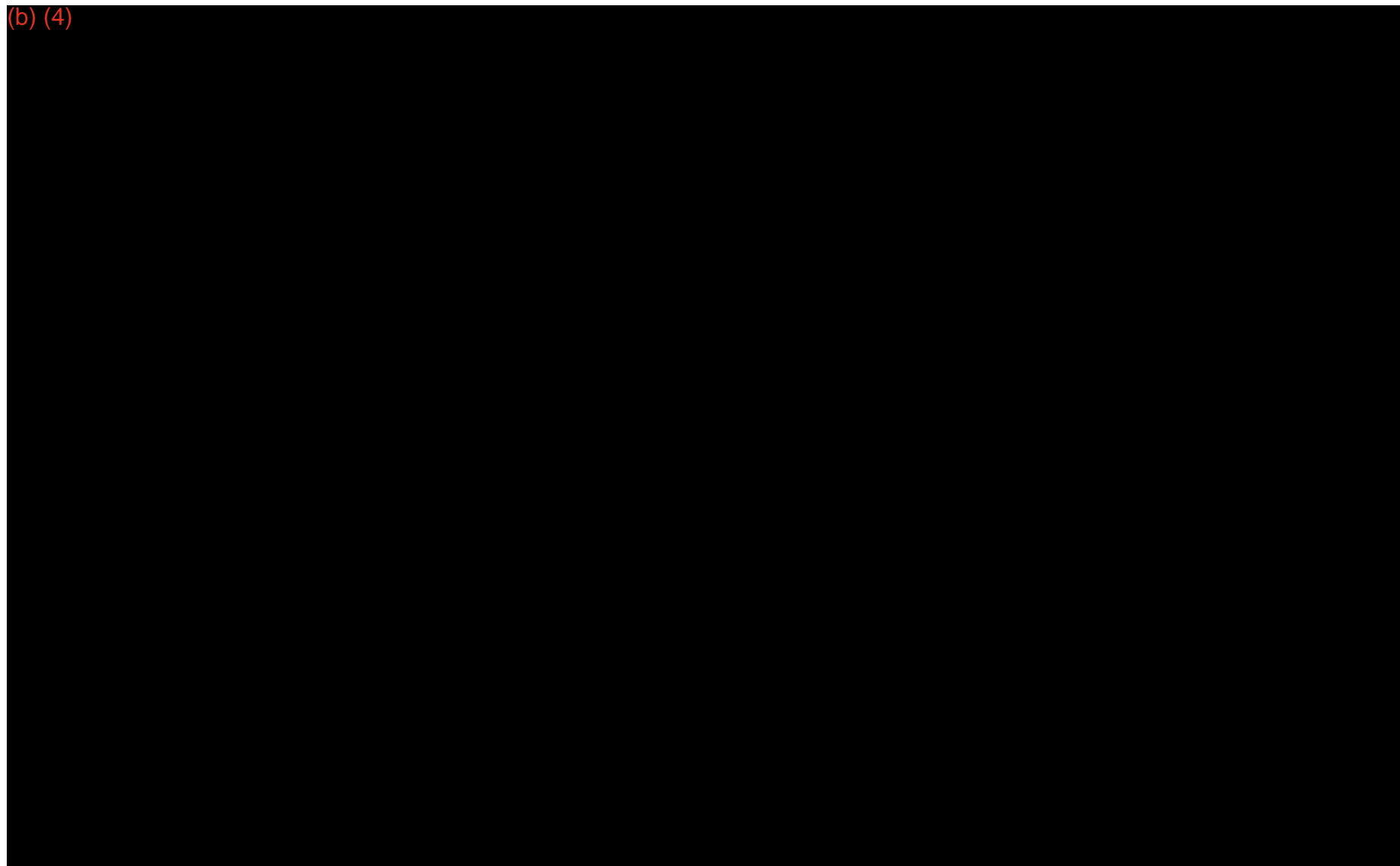




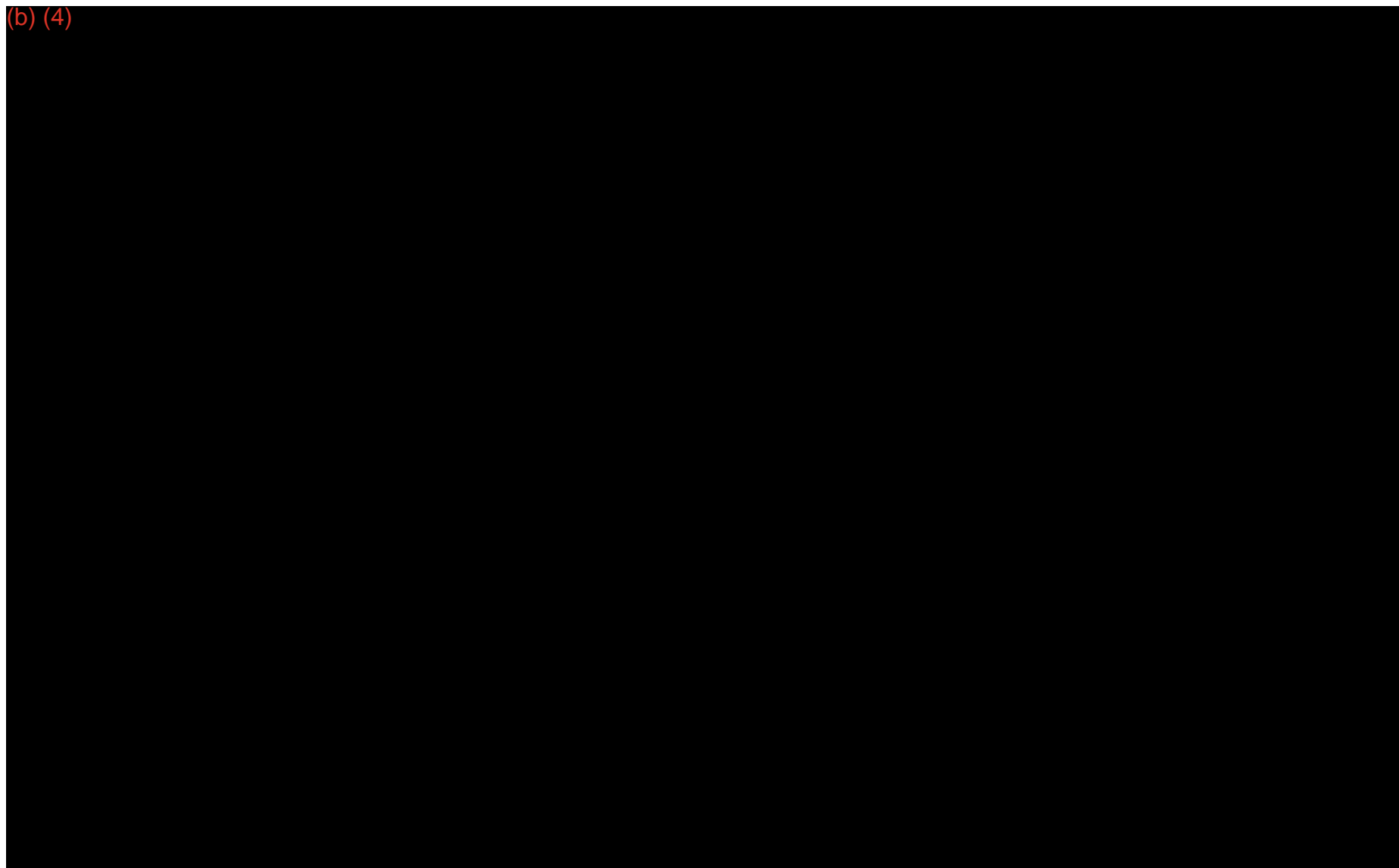
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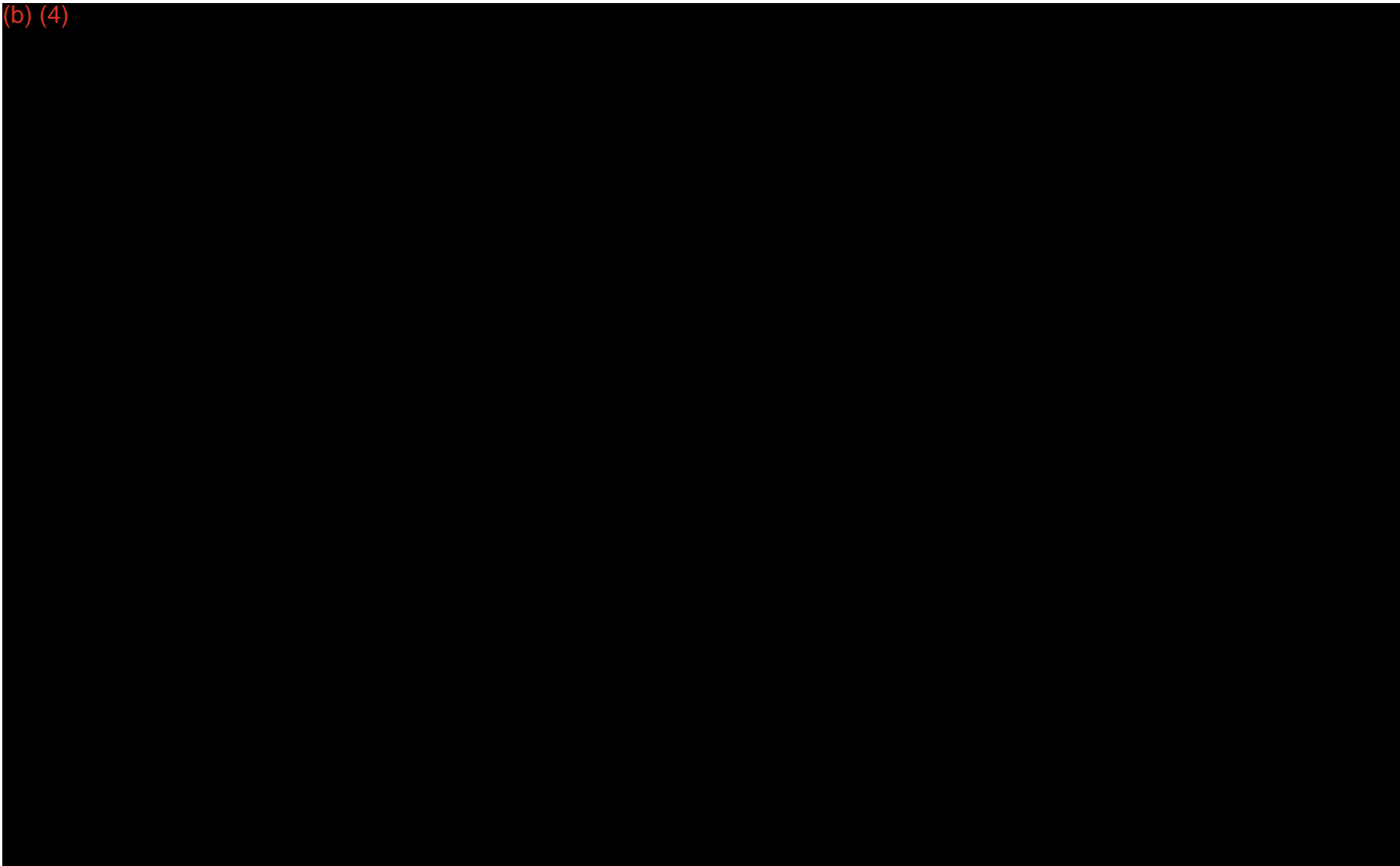
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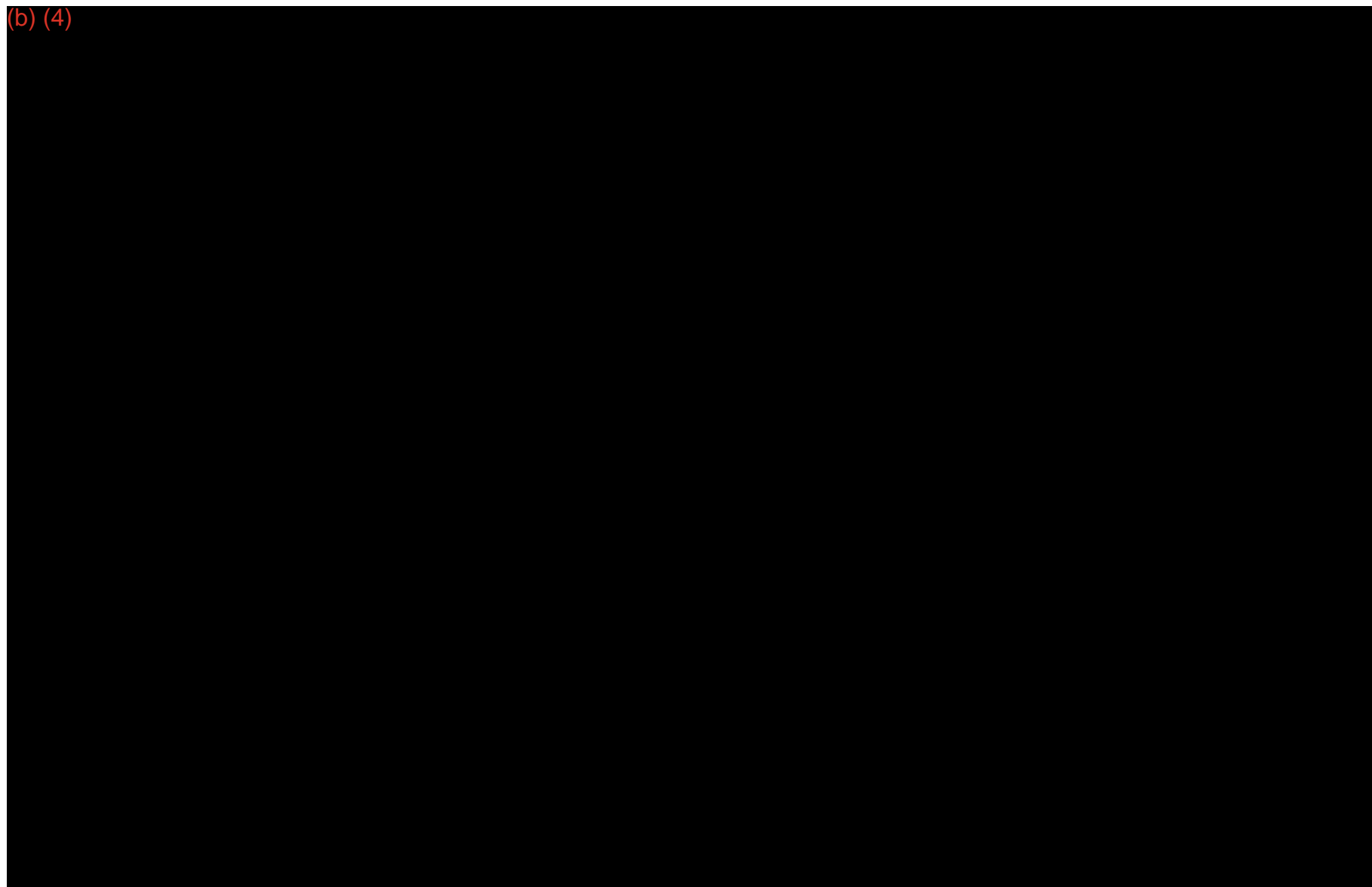
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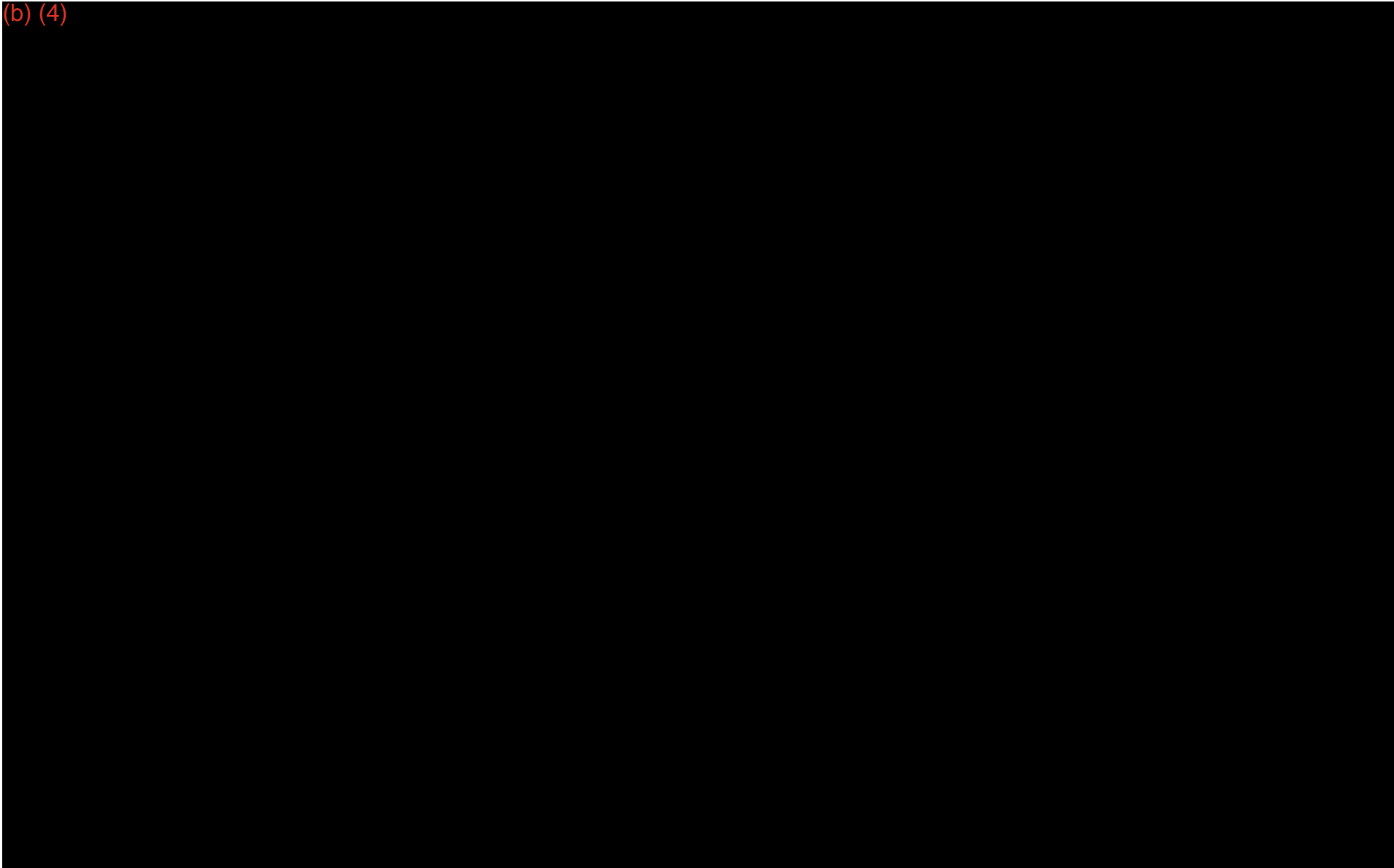
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**Listing 16.2.6-5 Dental plaque acidogenicity (FAS, Part 1)**

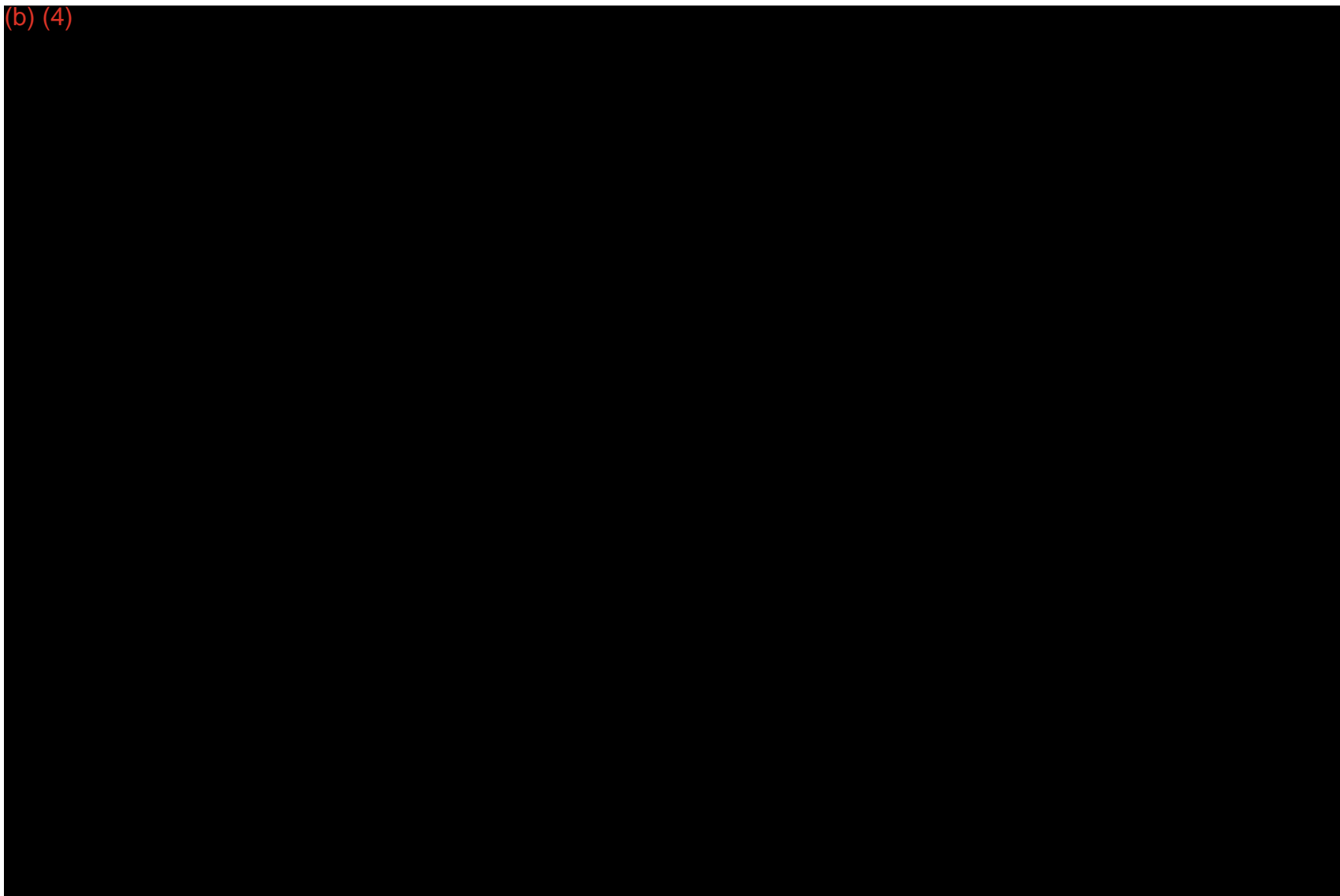
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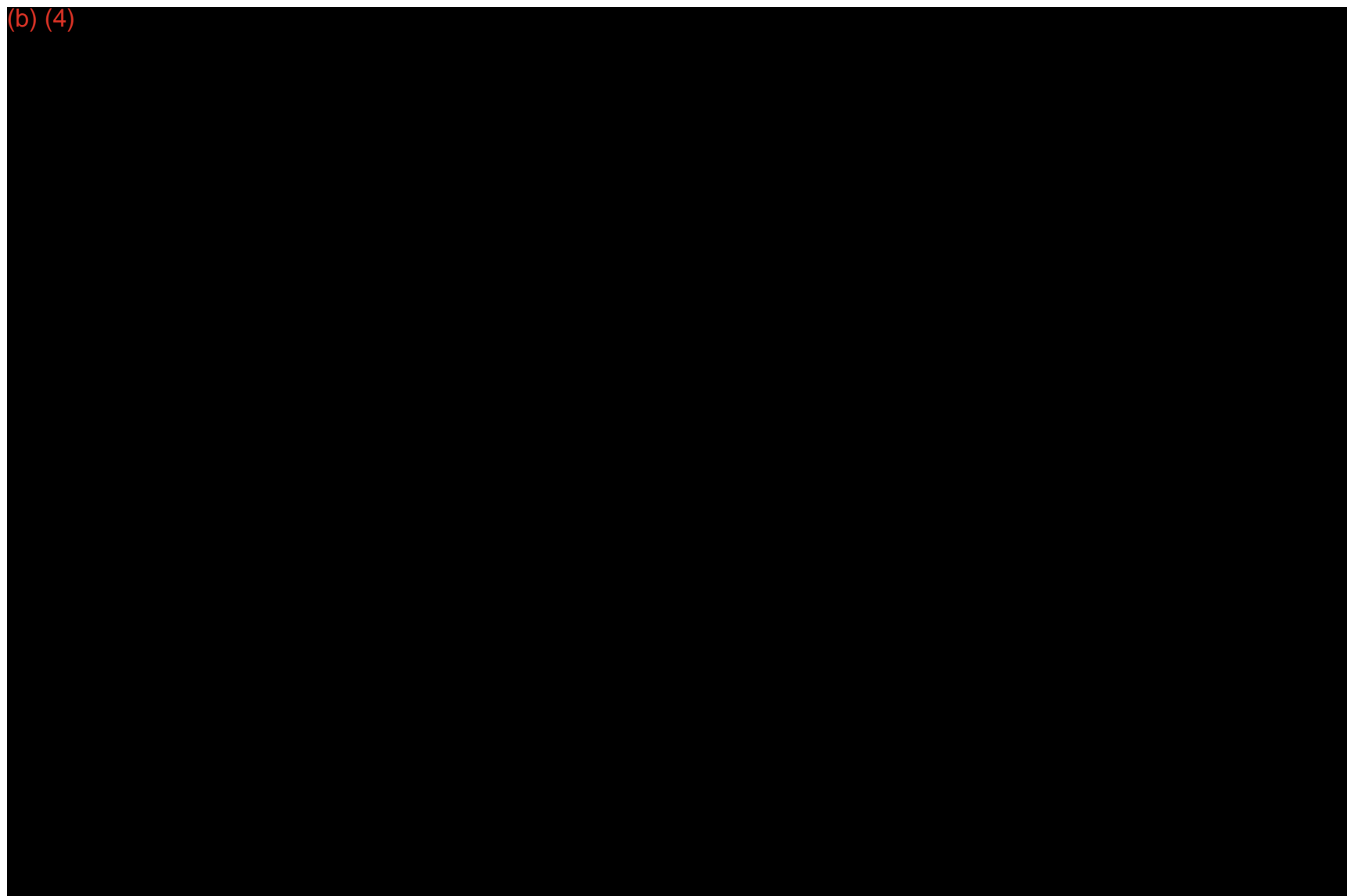




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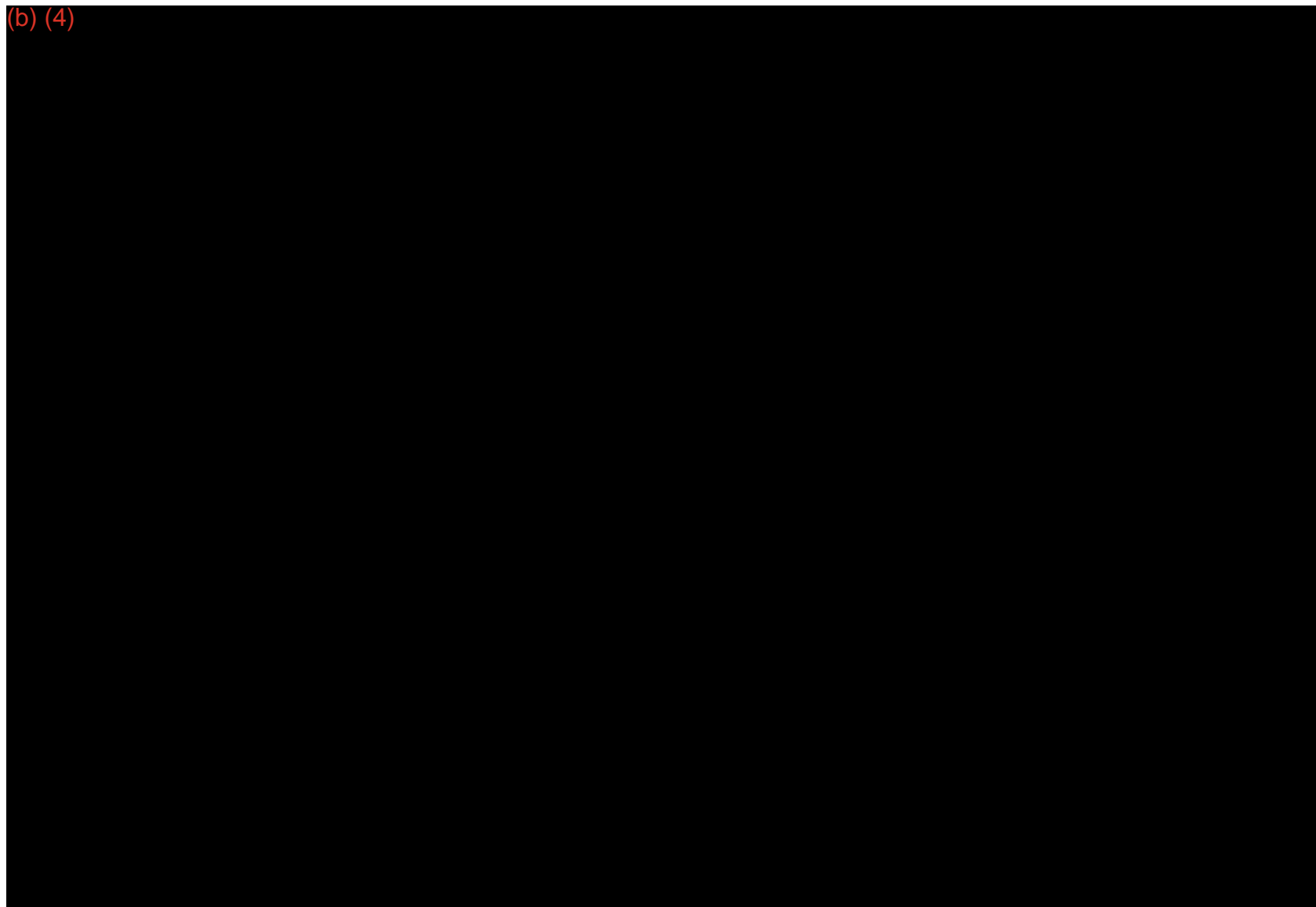




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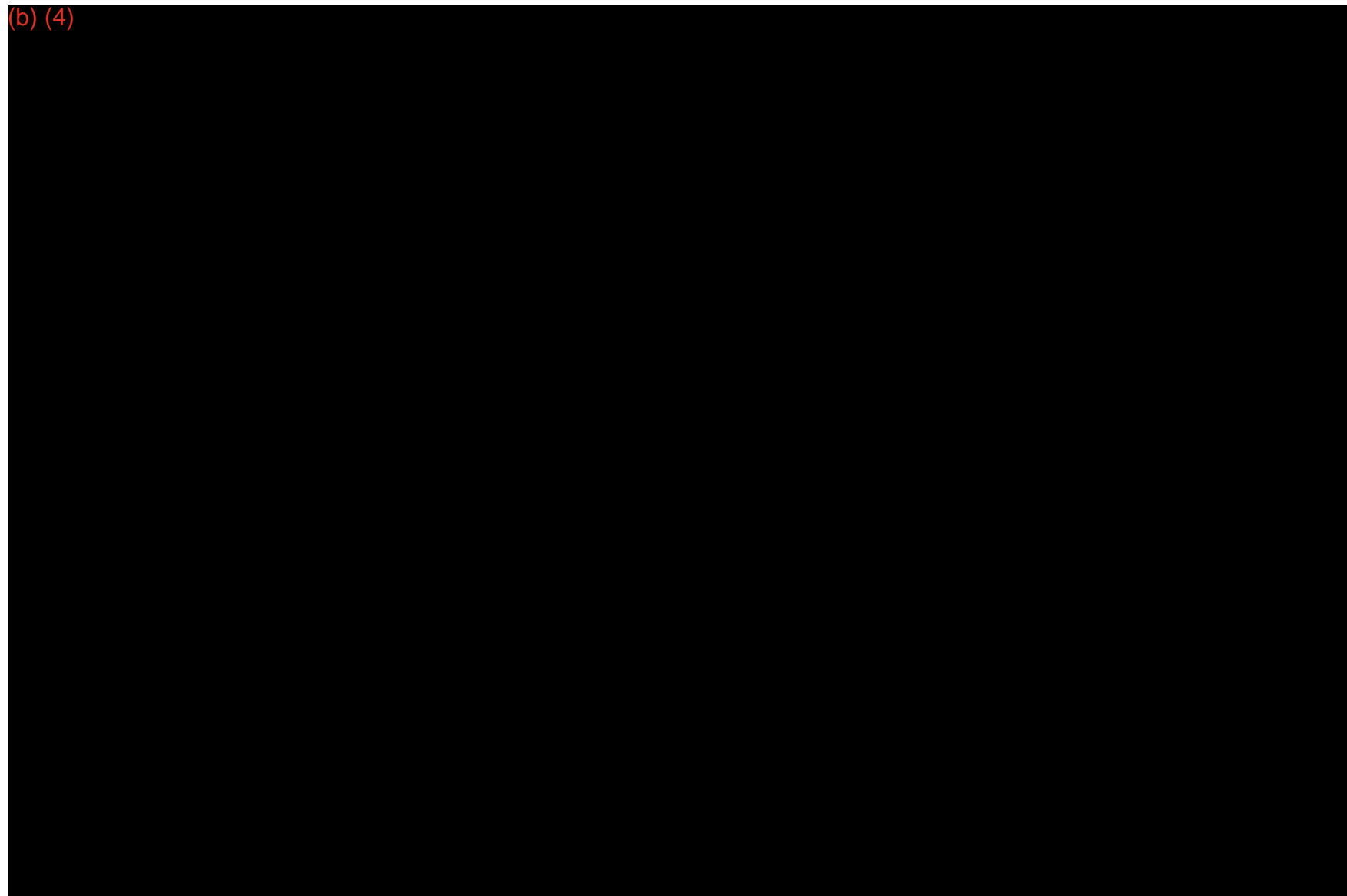
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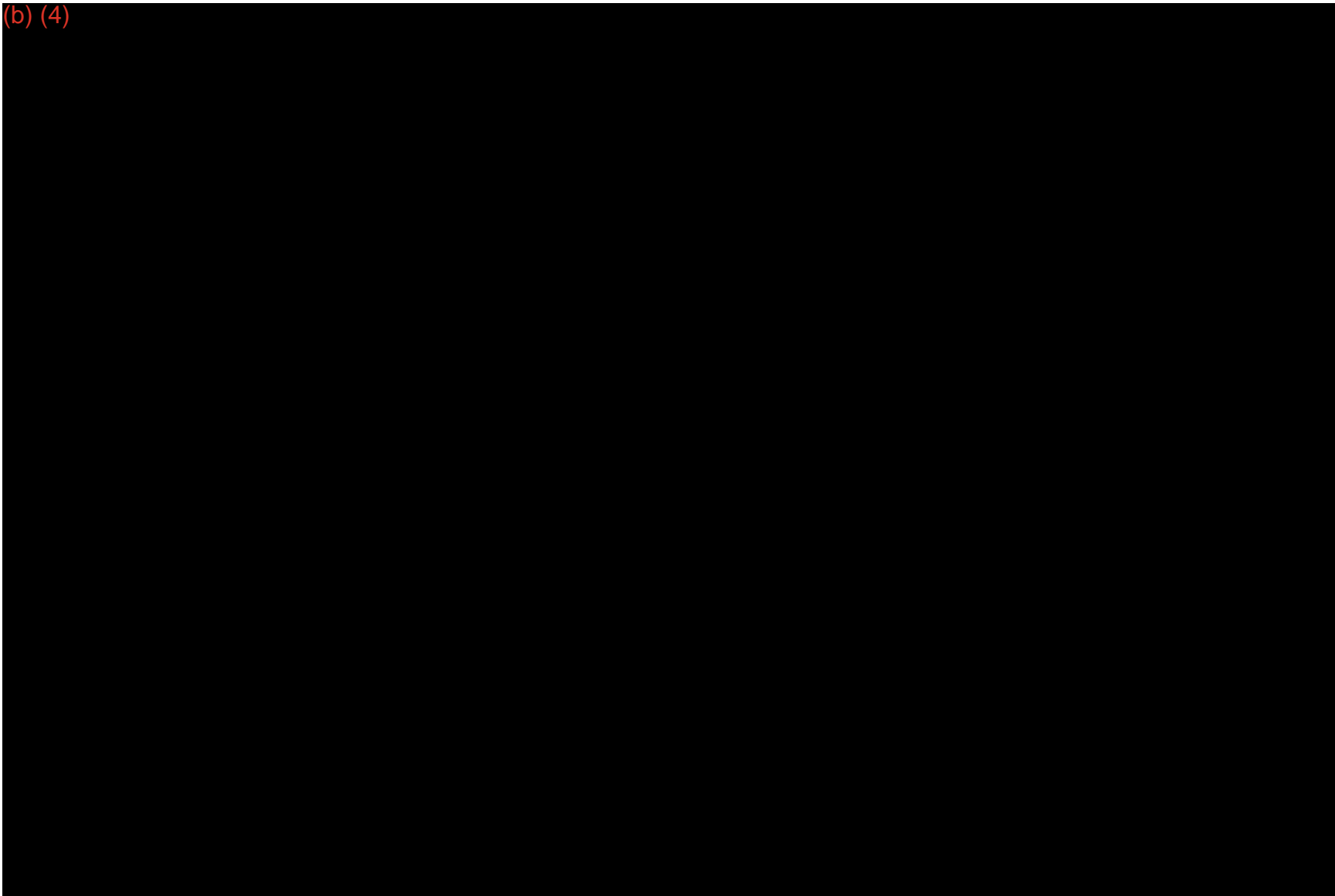


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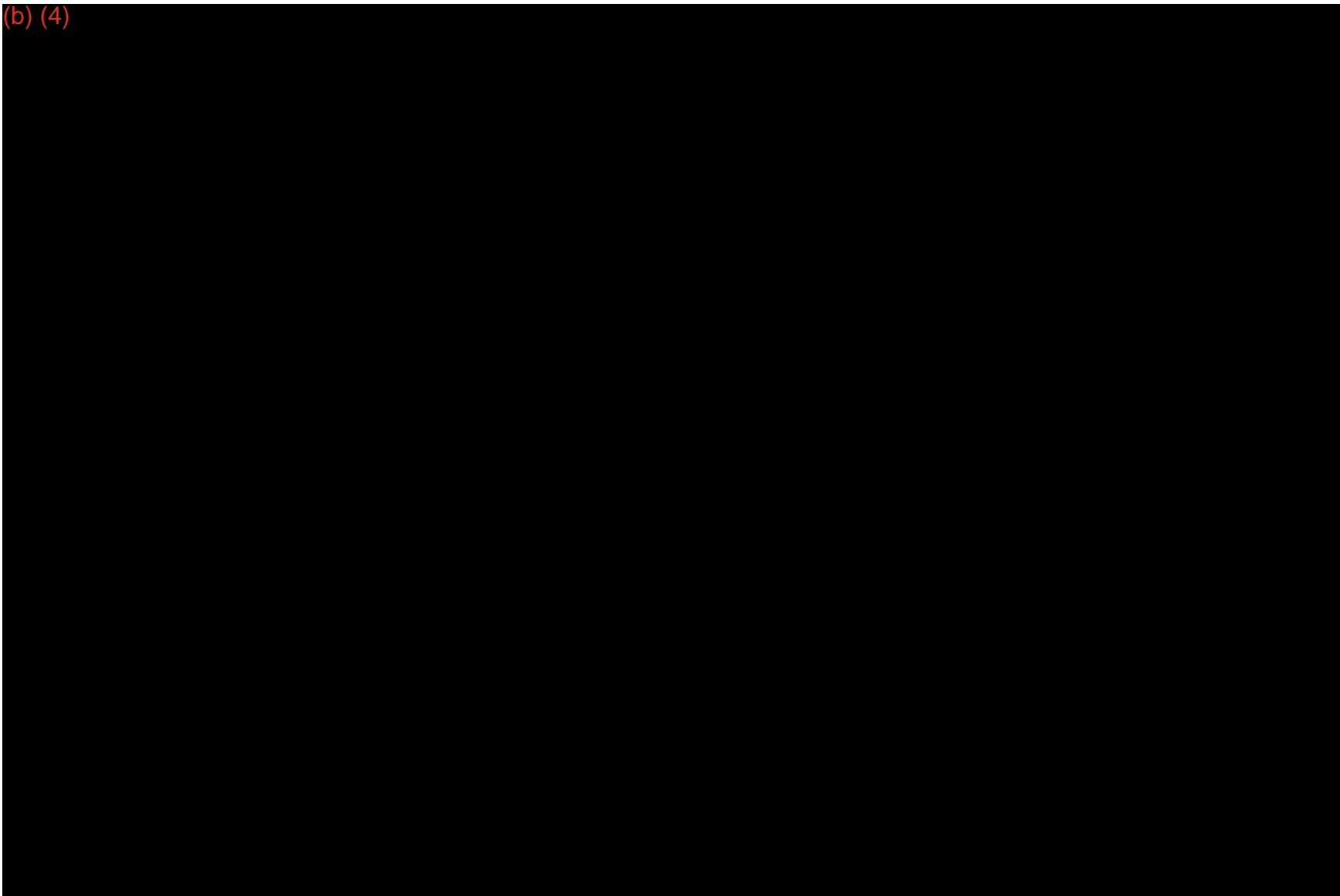
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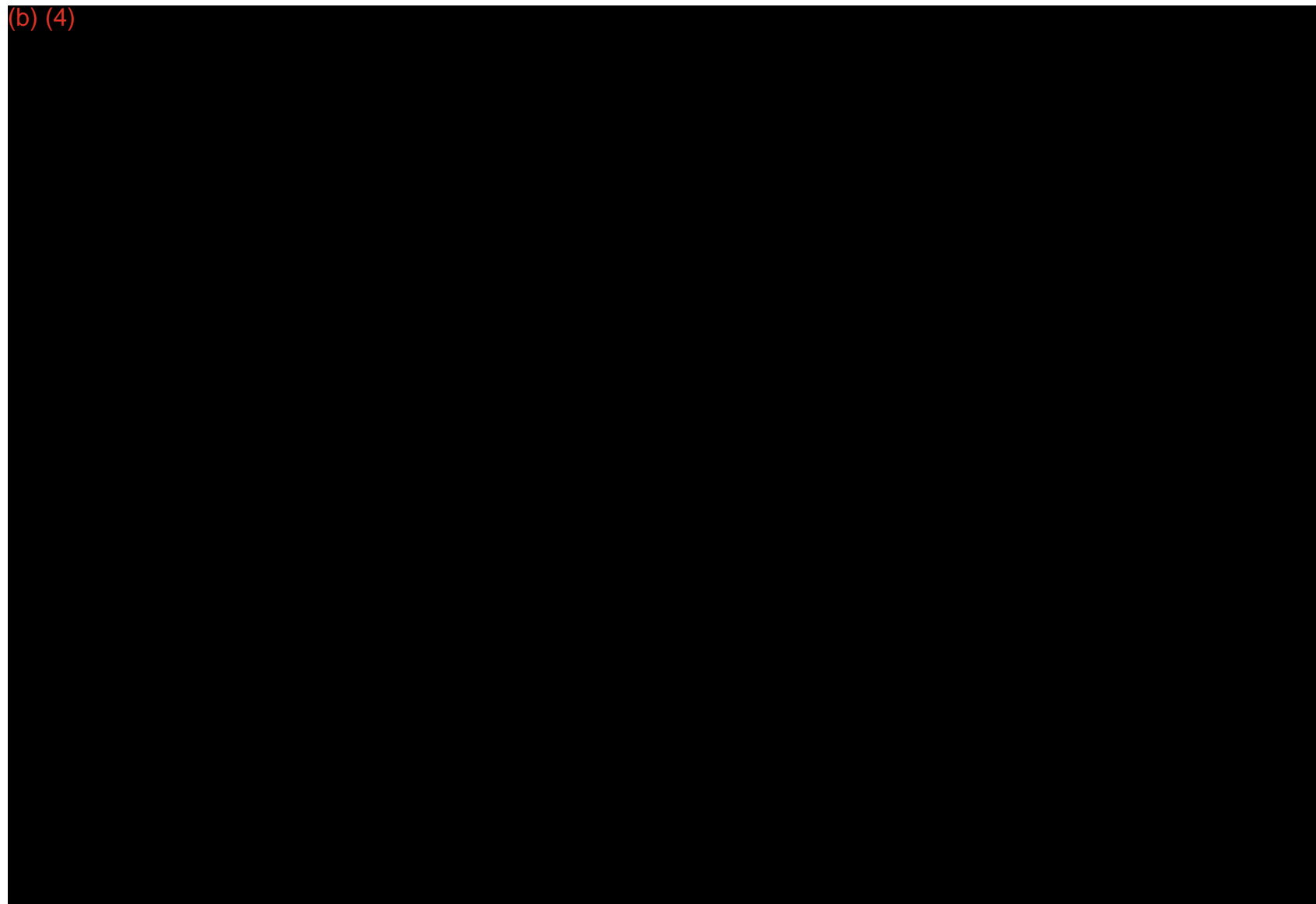
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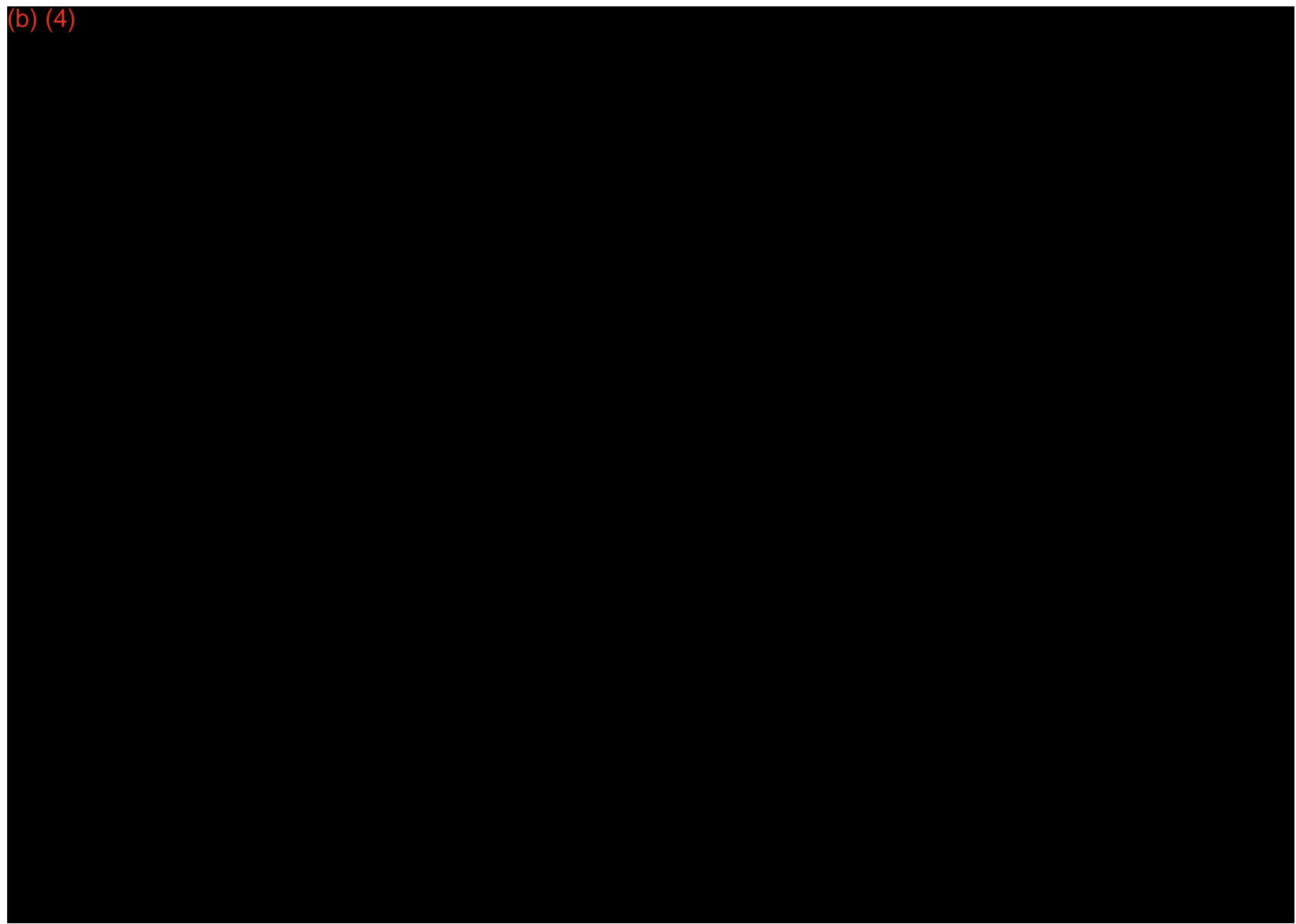
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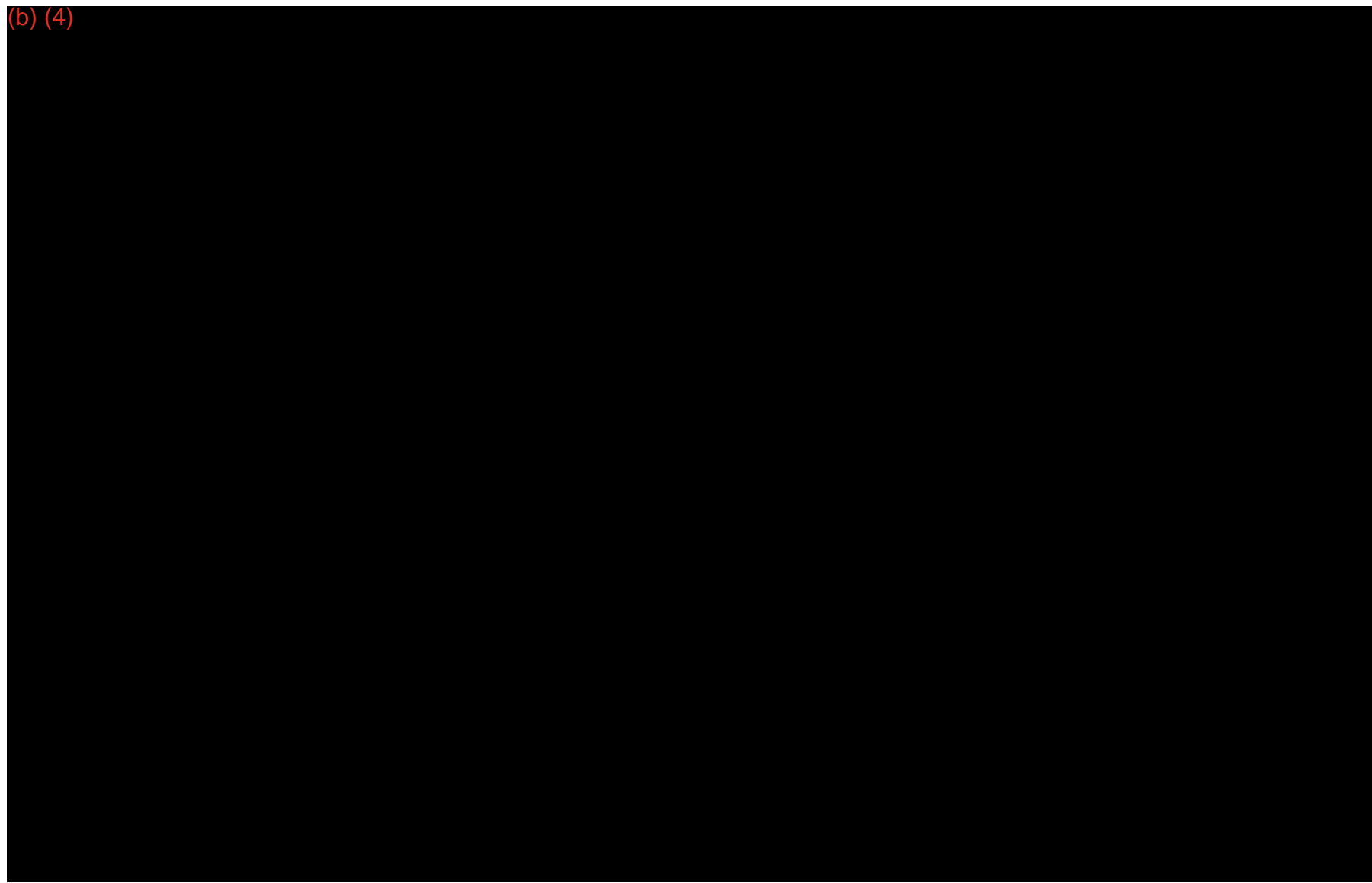
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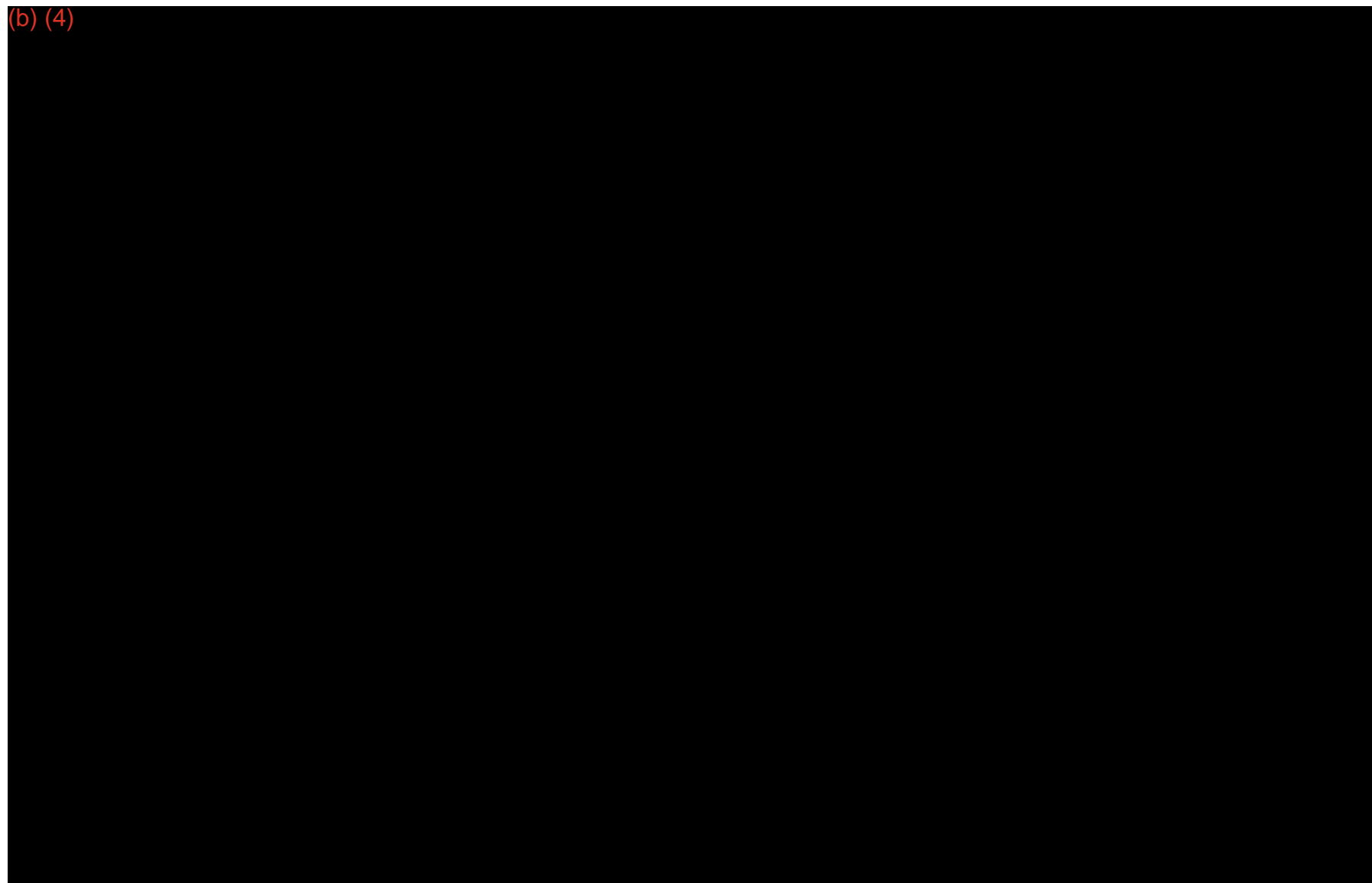
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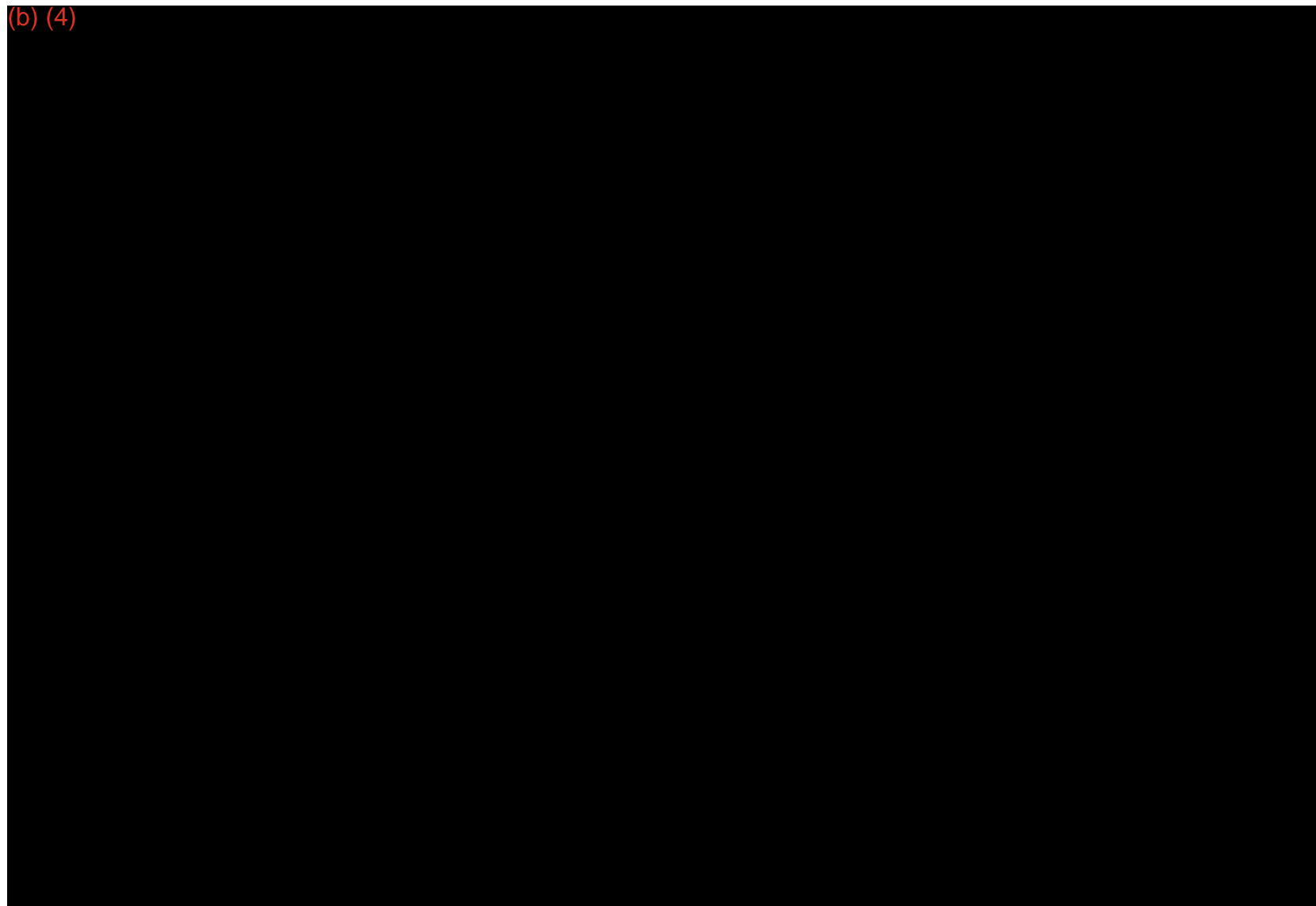
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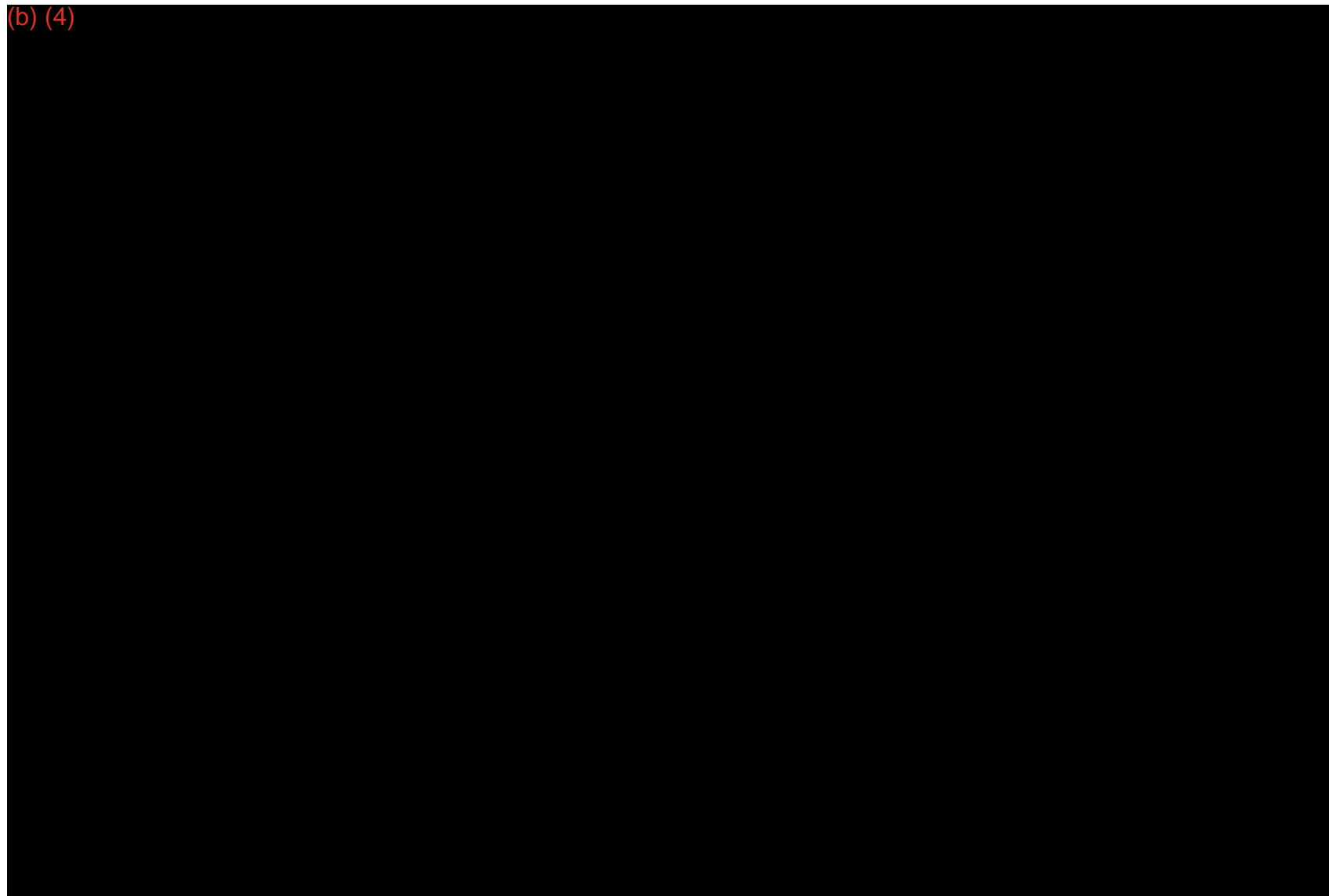


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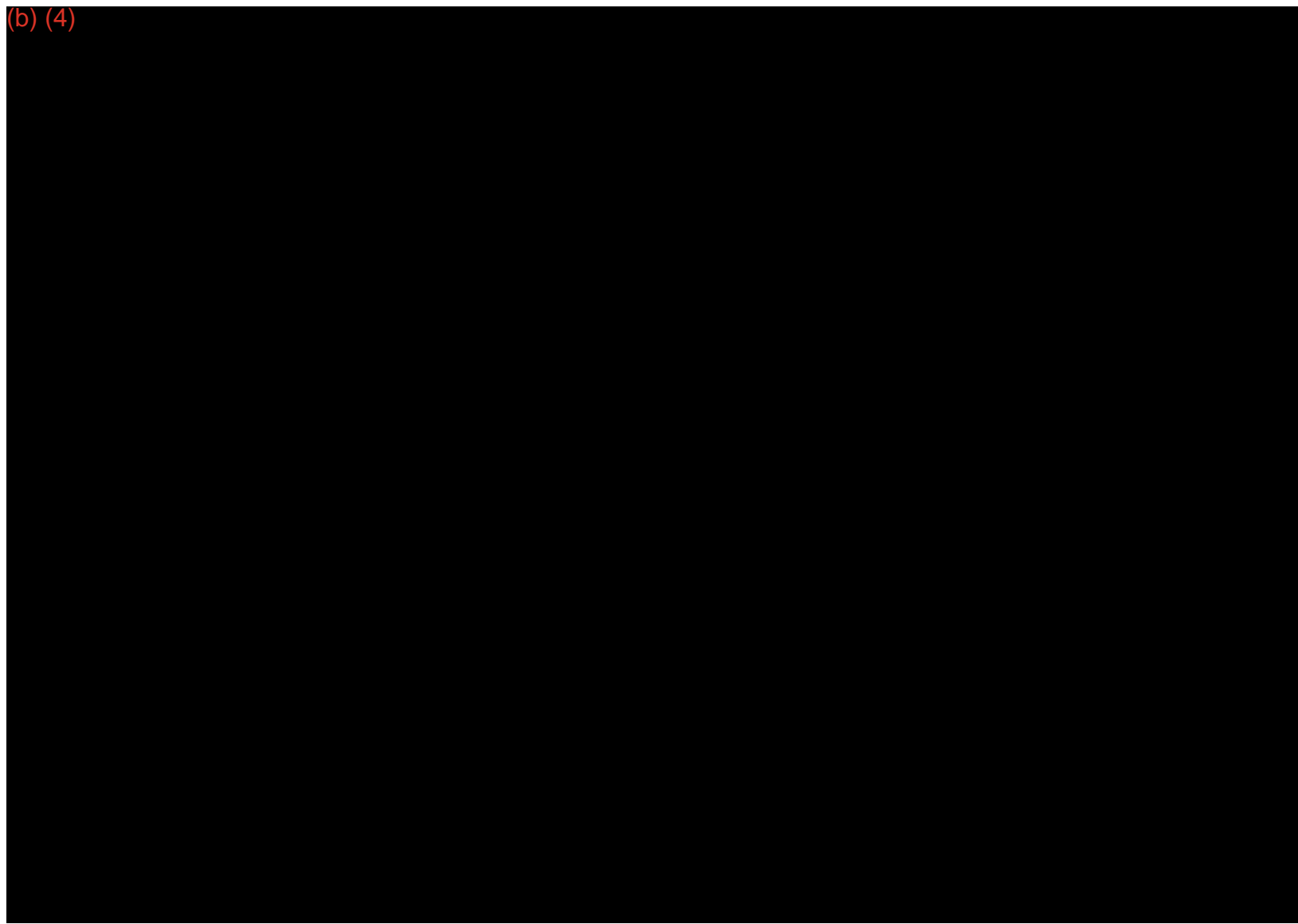




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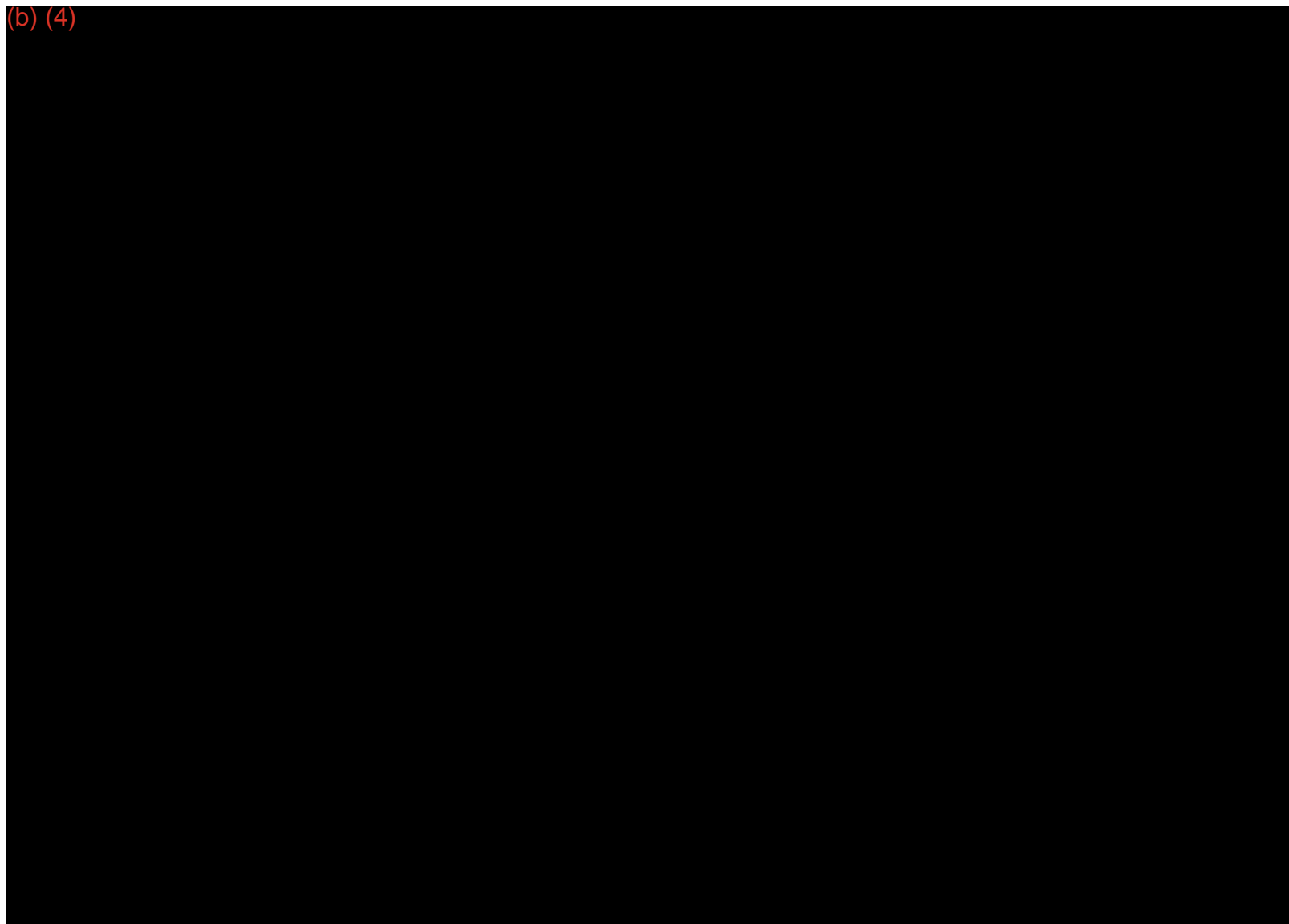
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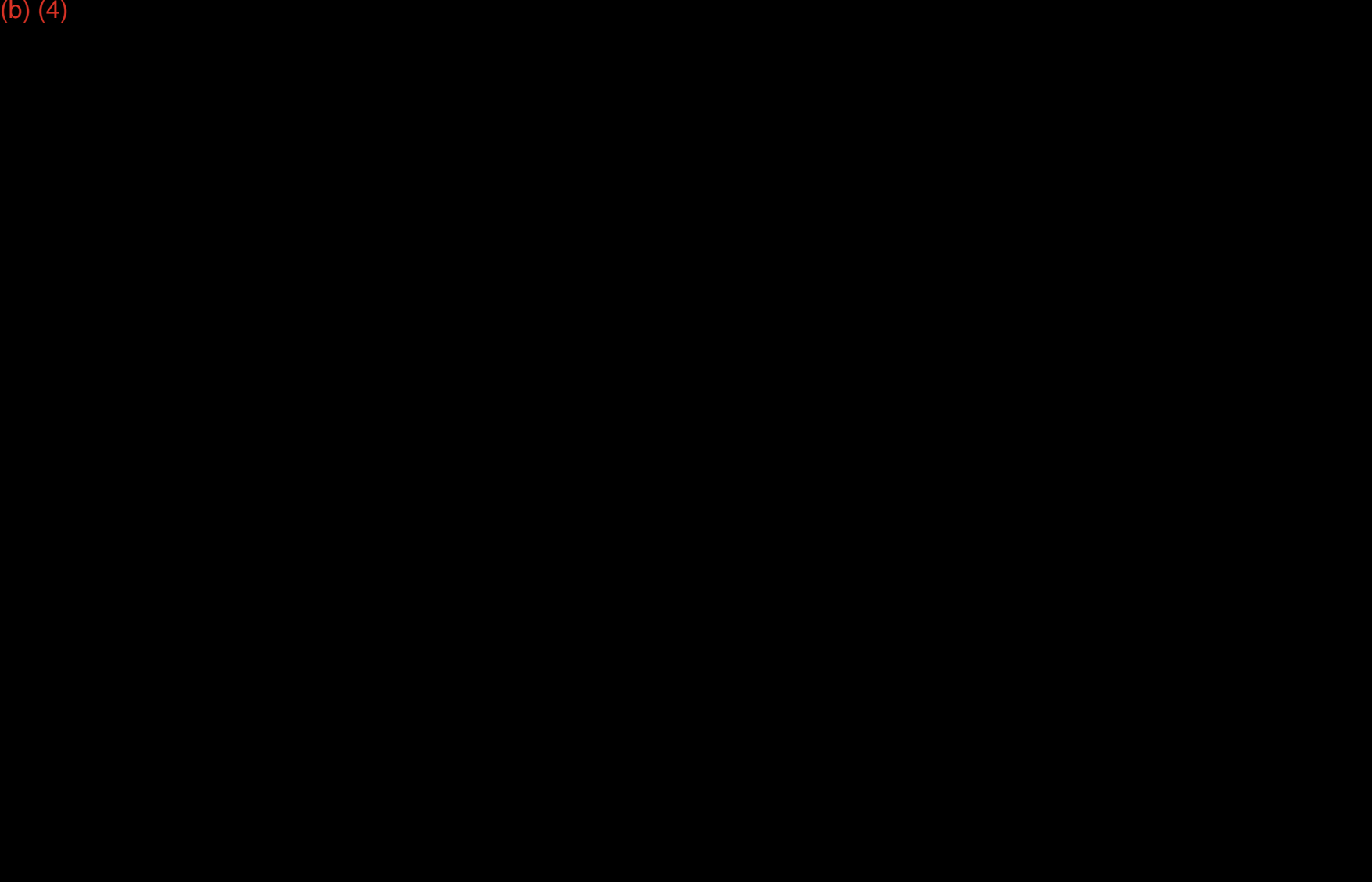
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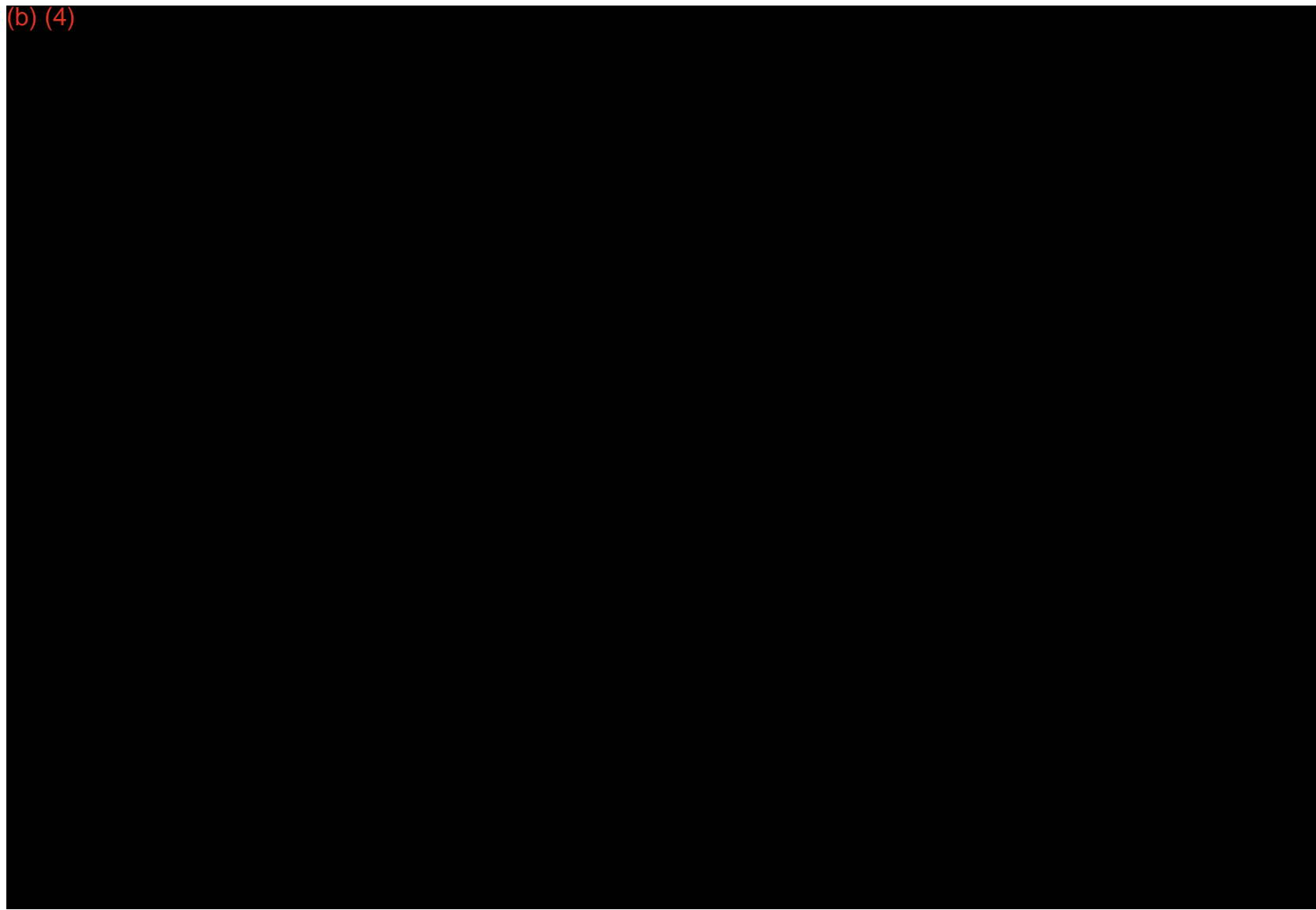


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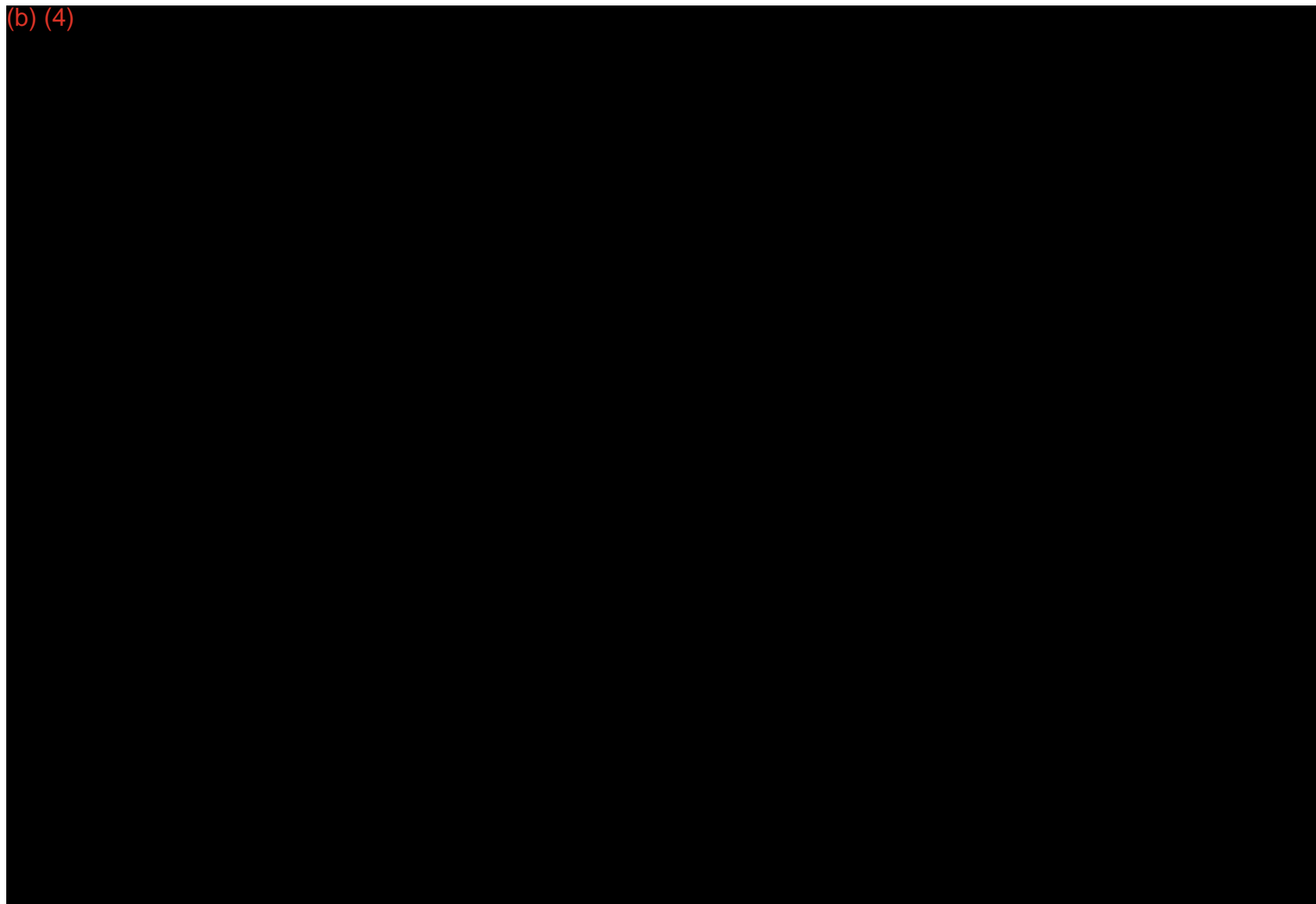
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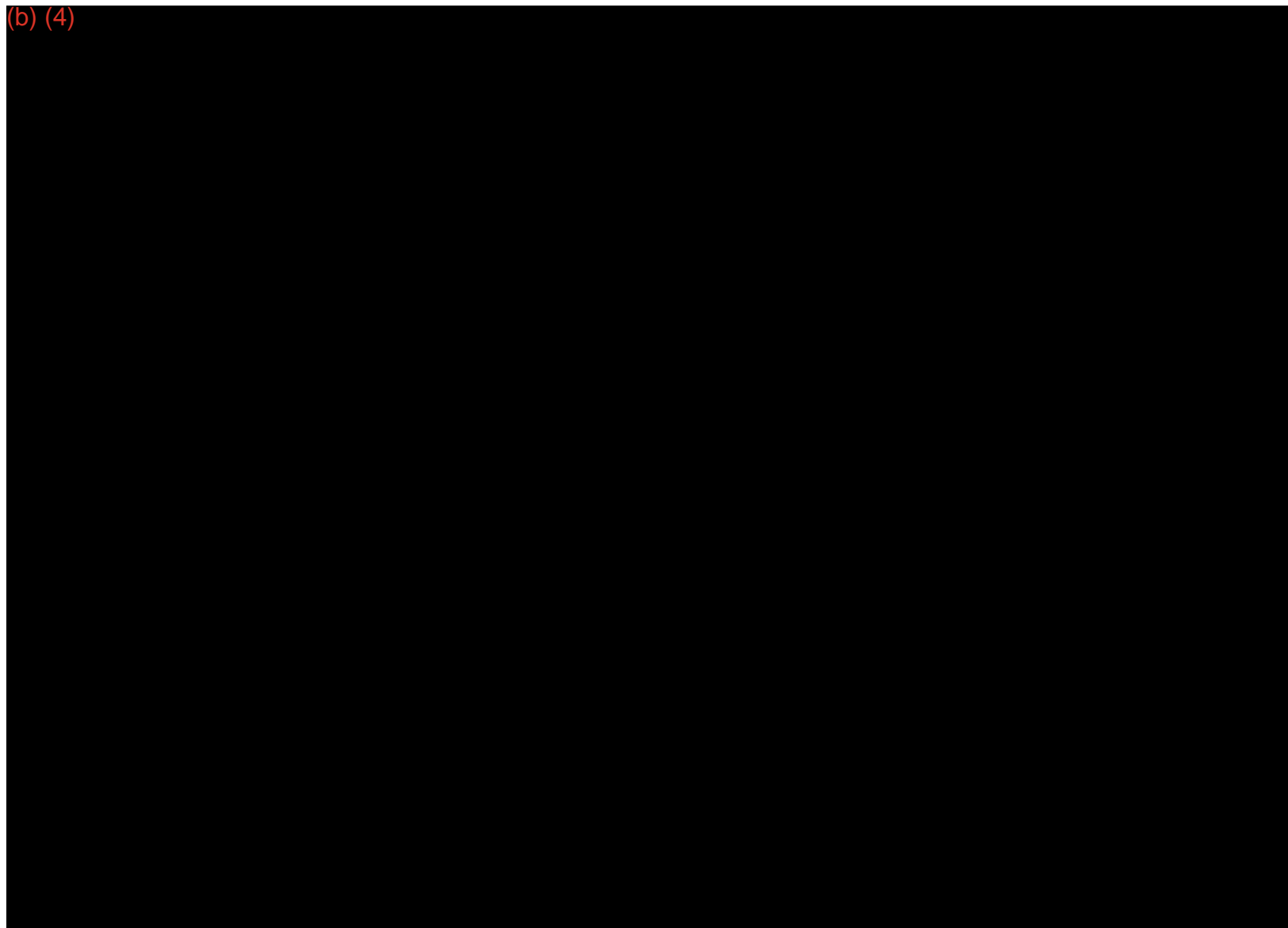
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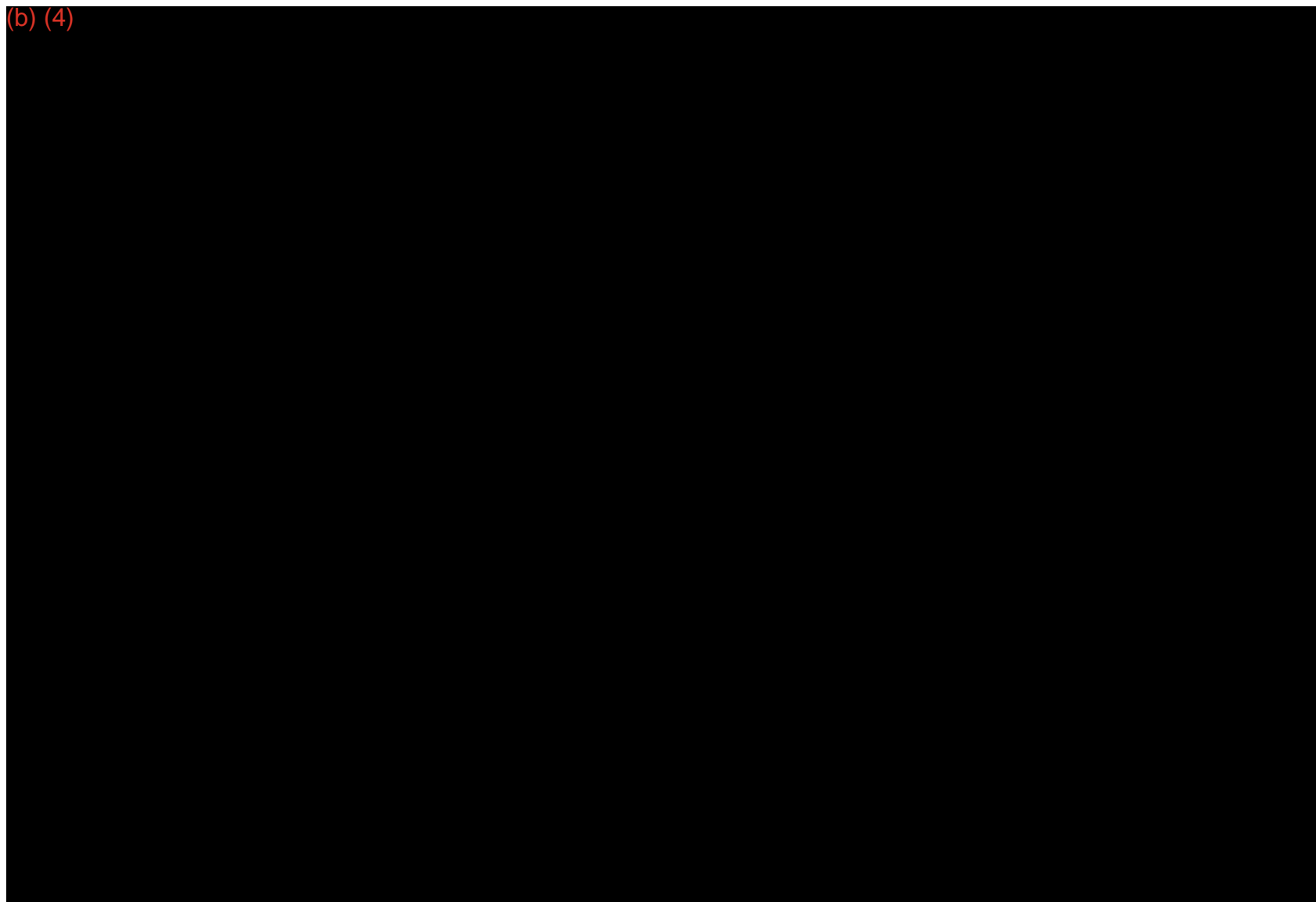
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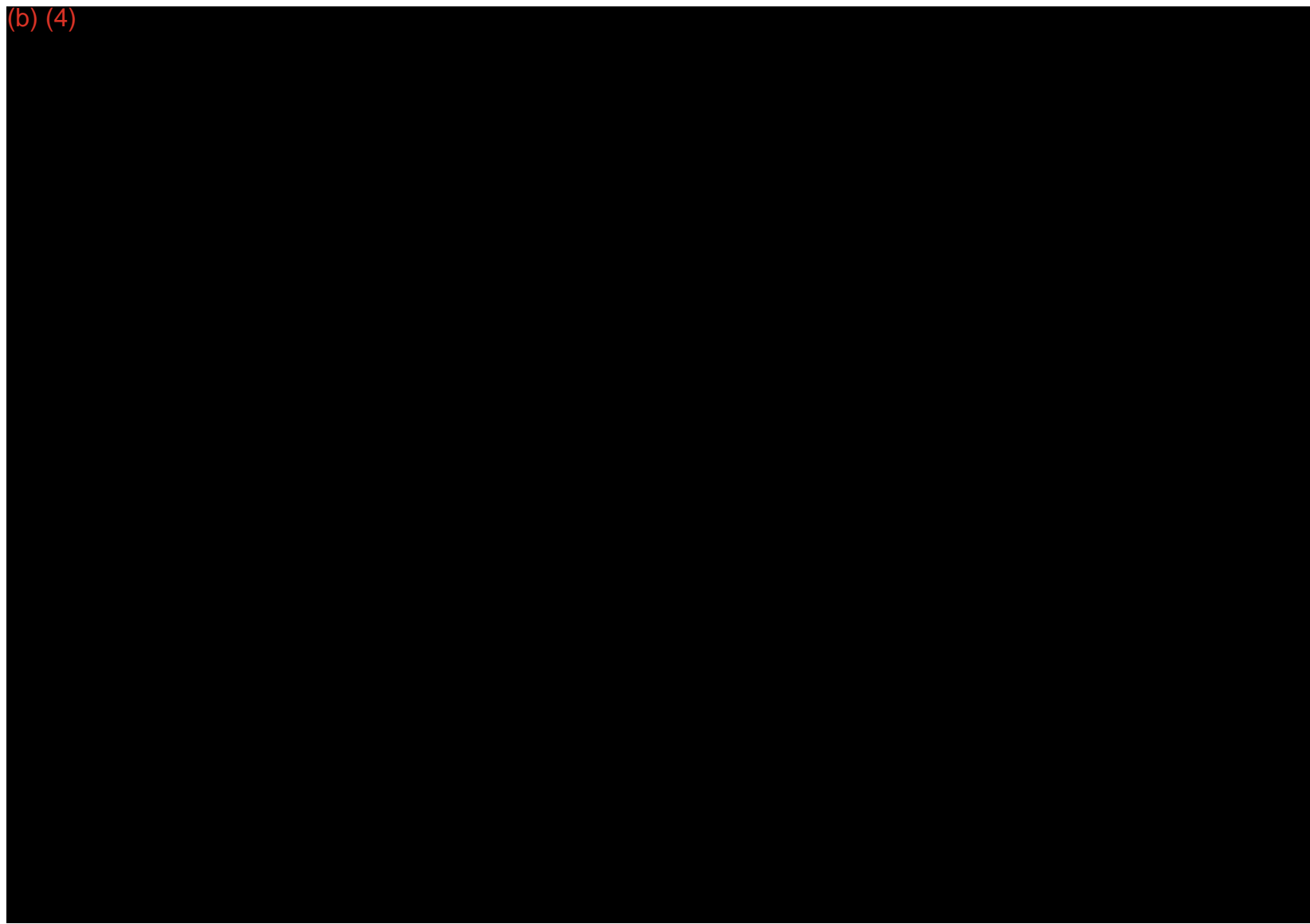
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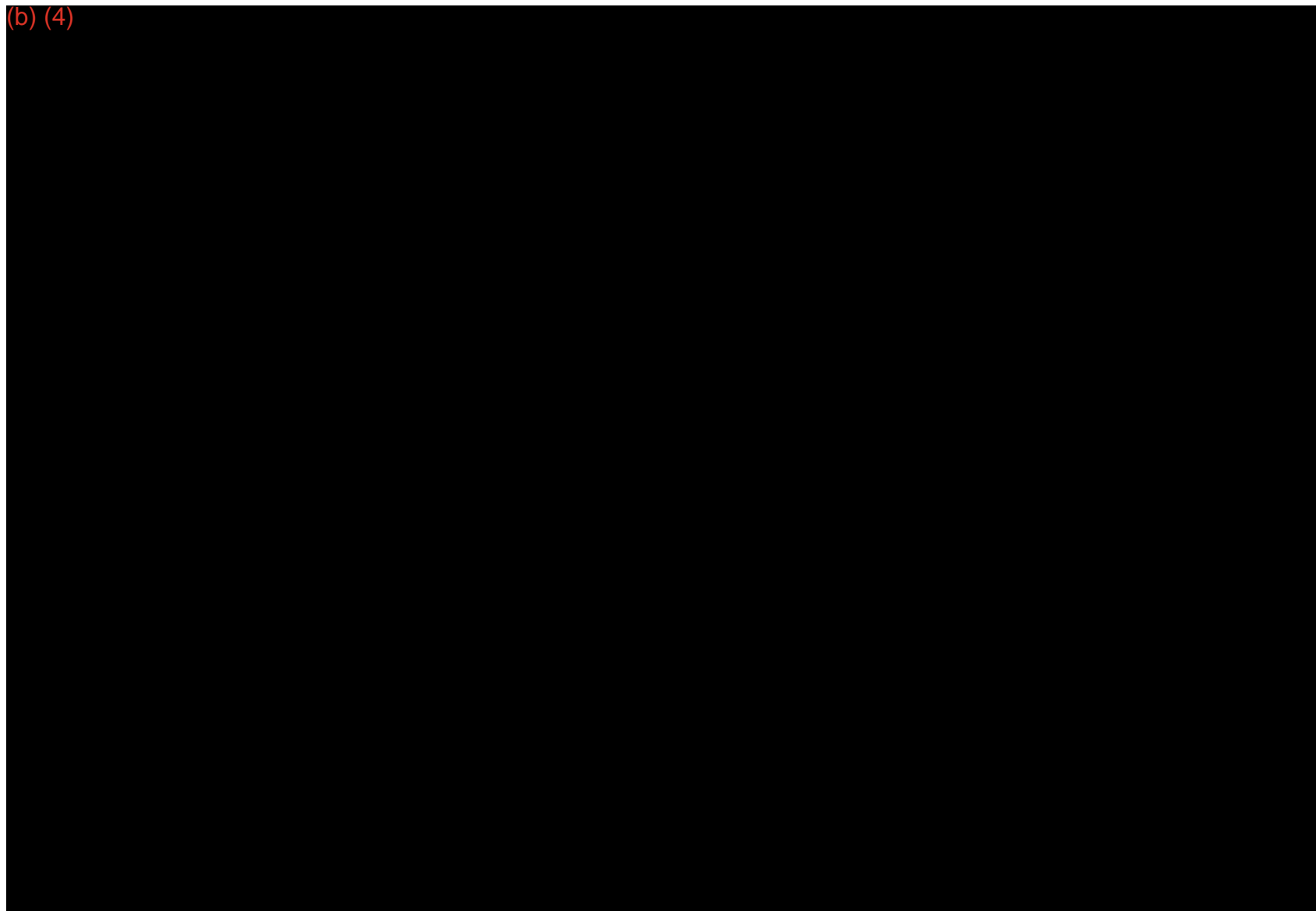
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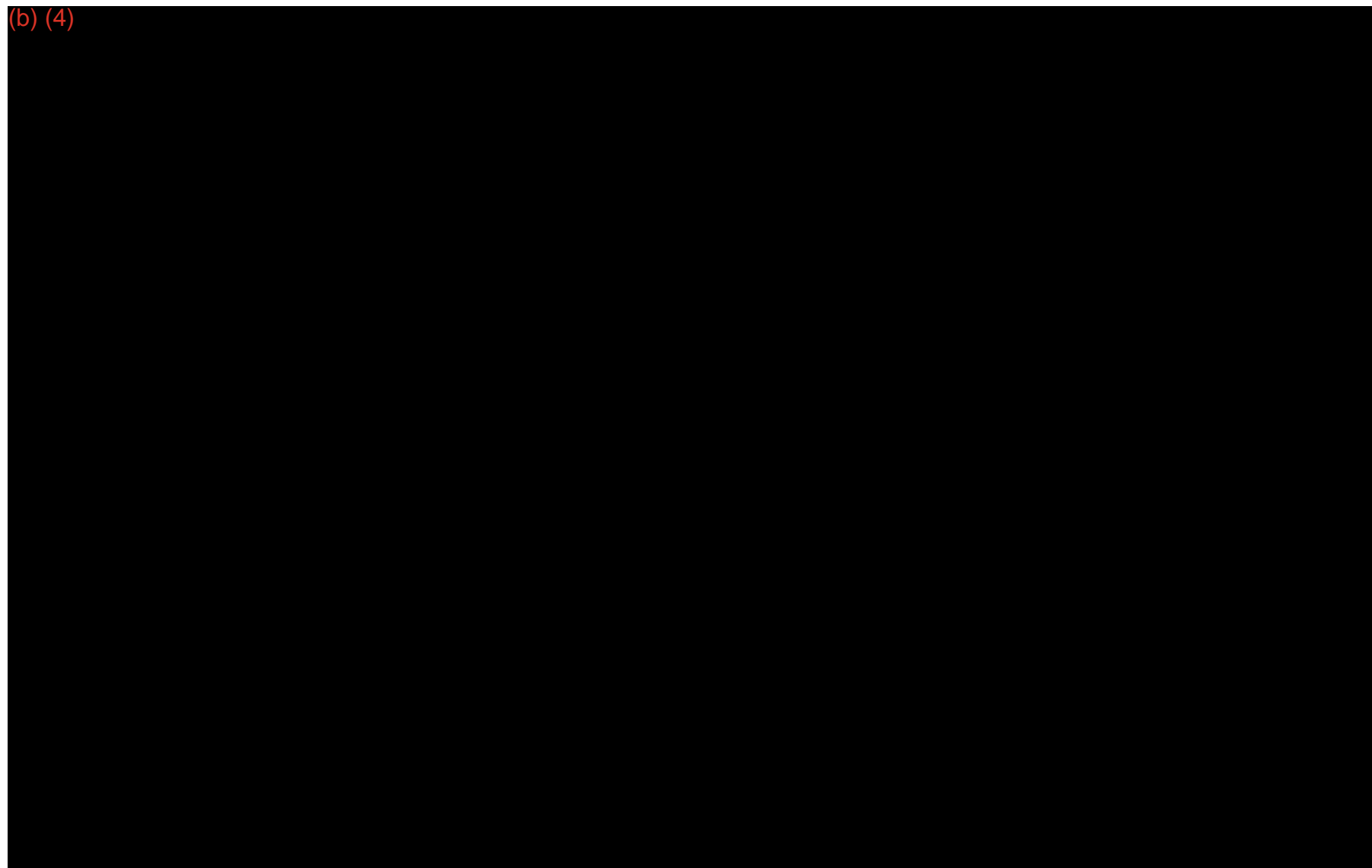
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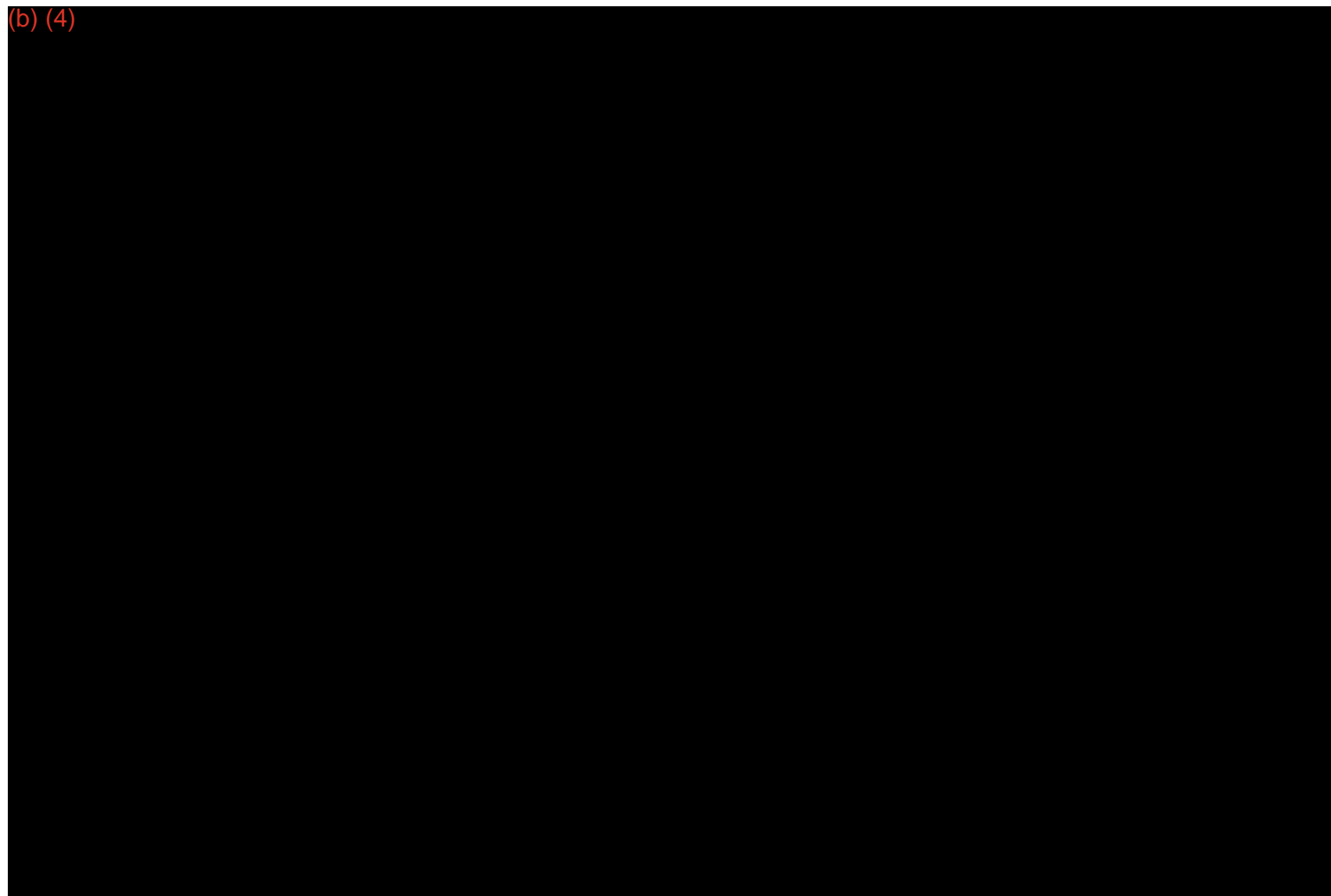
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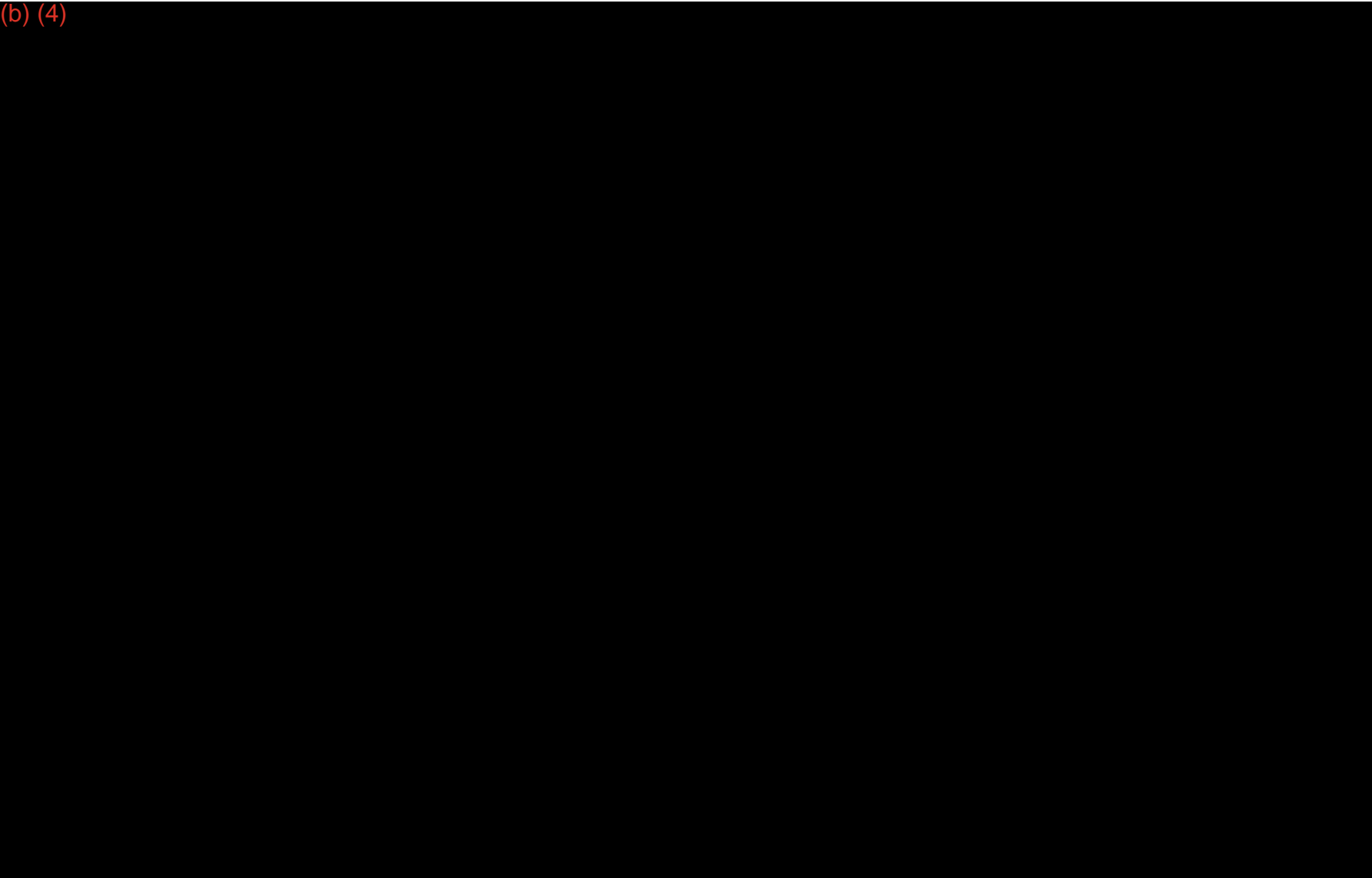
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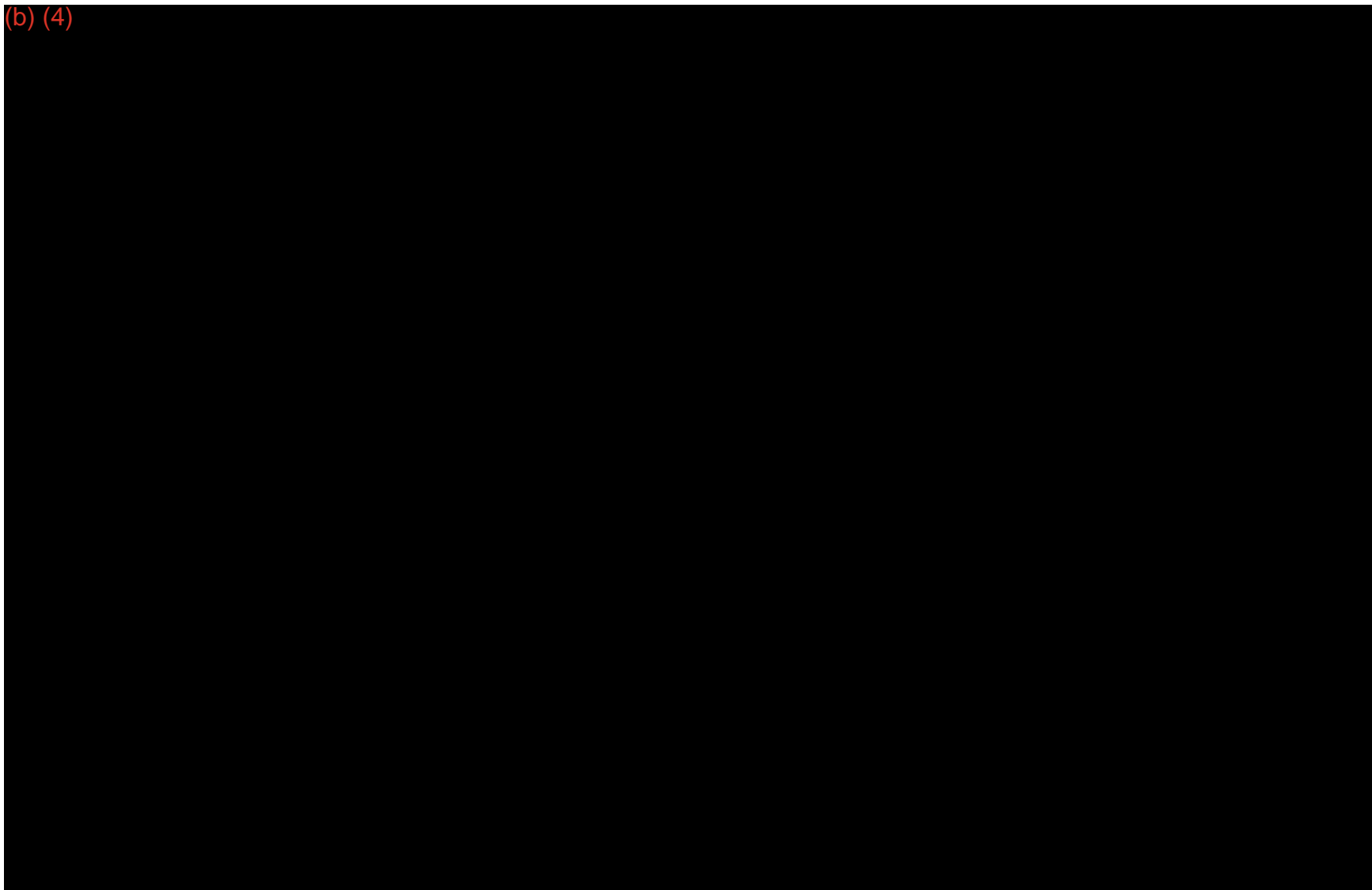
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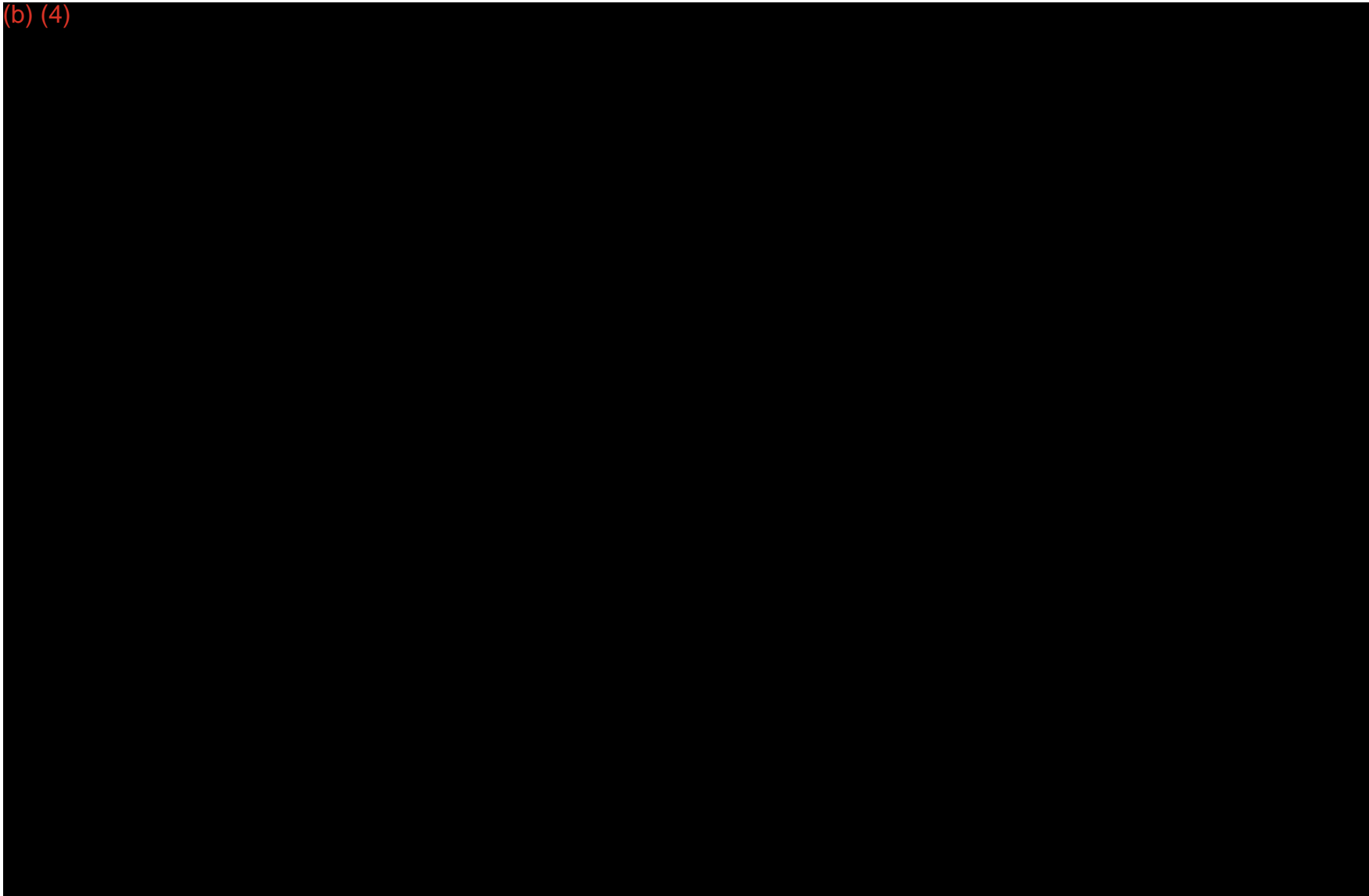
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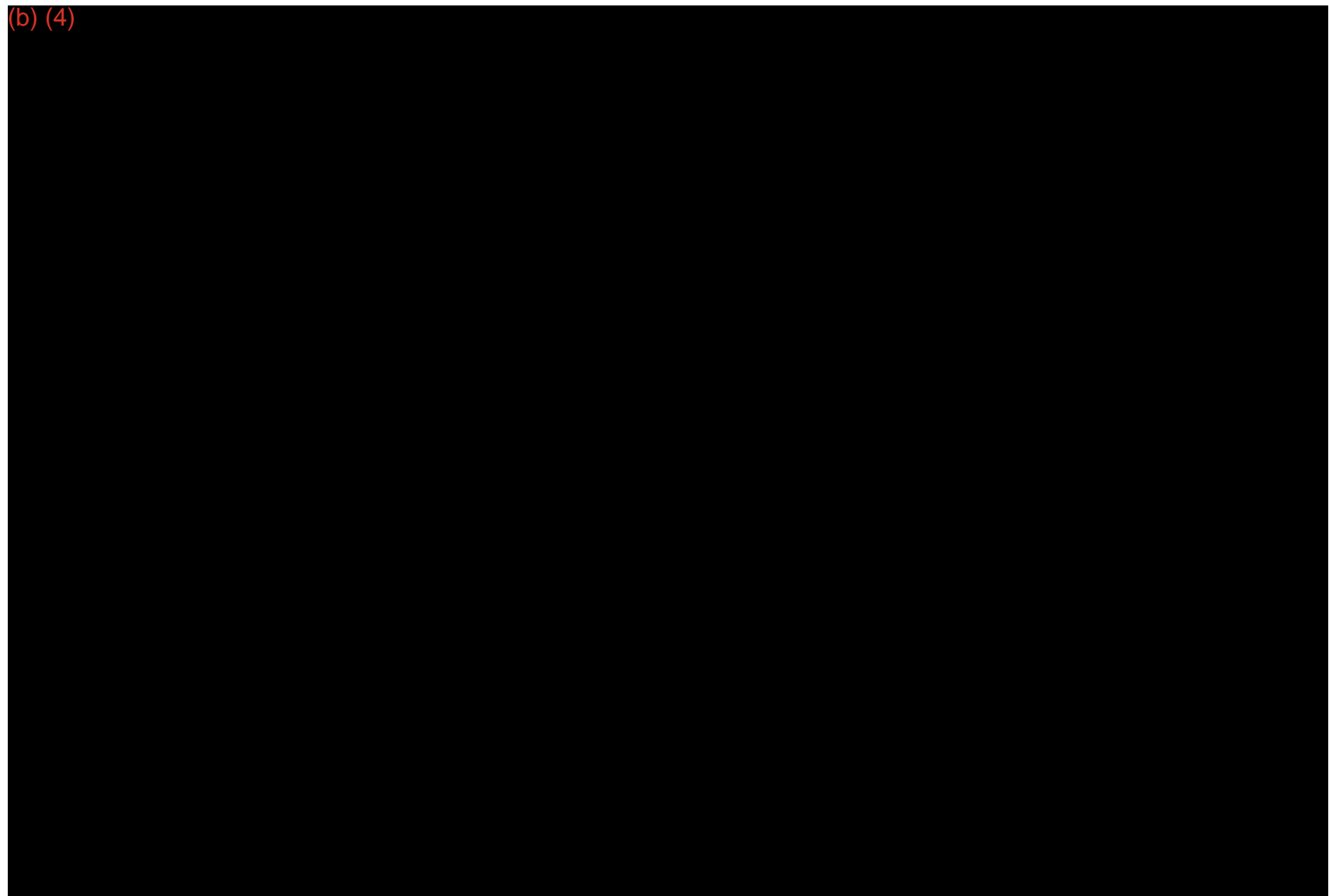




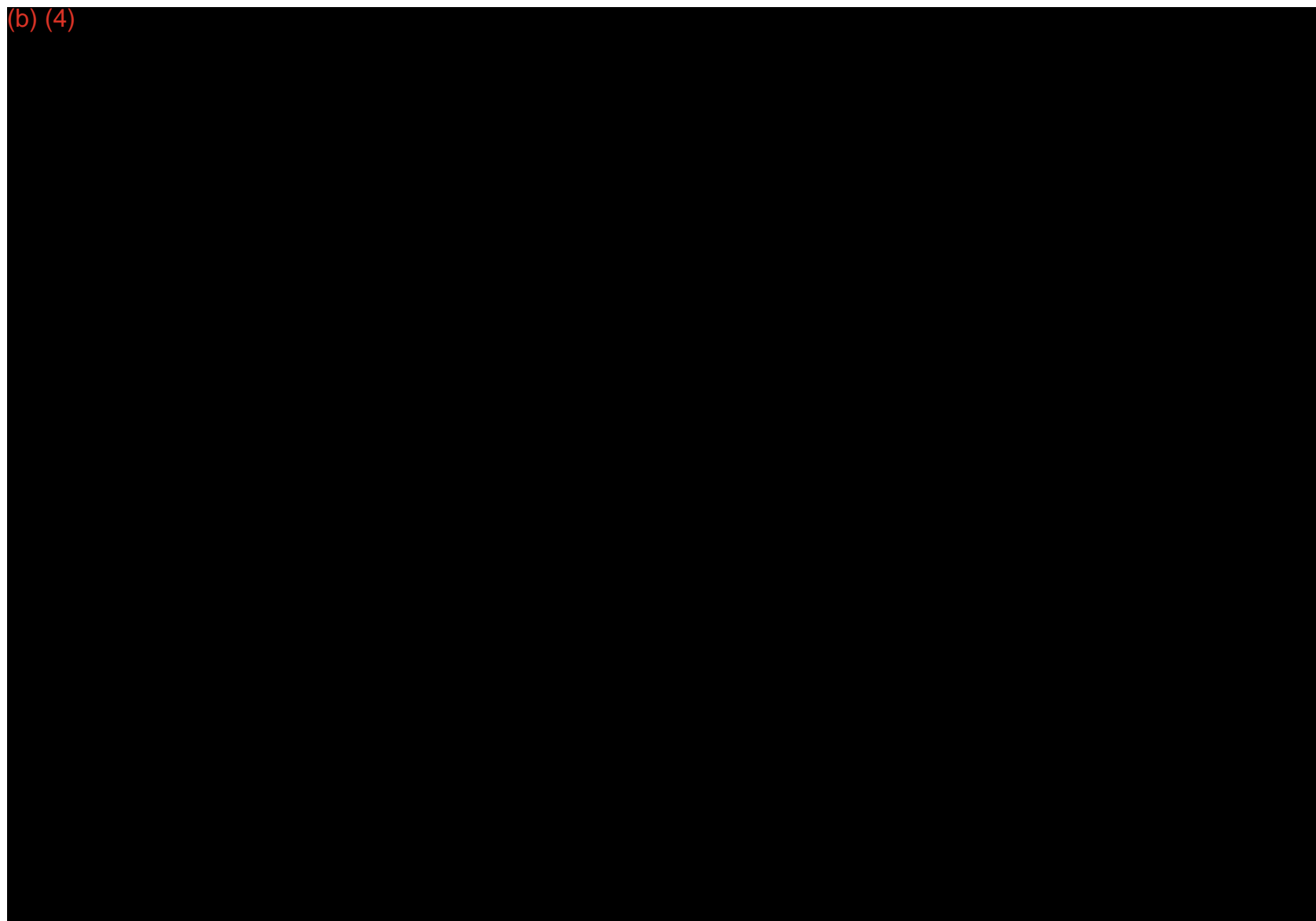
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**Listing 16.2.6-6 Dental plaque acidogenicity (pH) site 1 (FAS, Part 2)**

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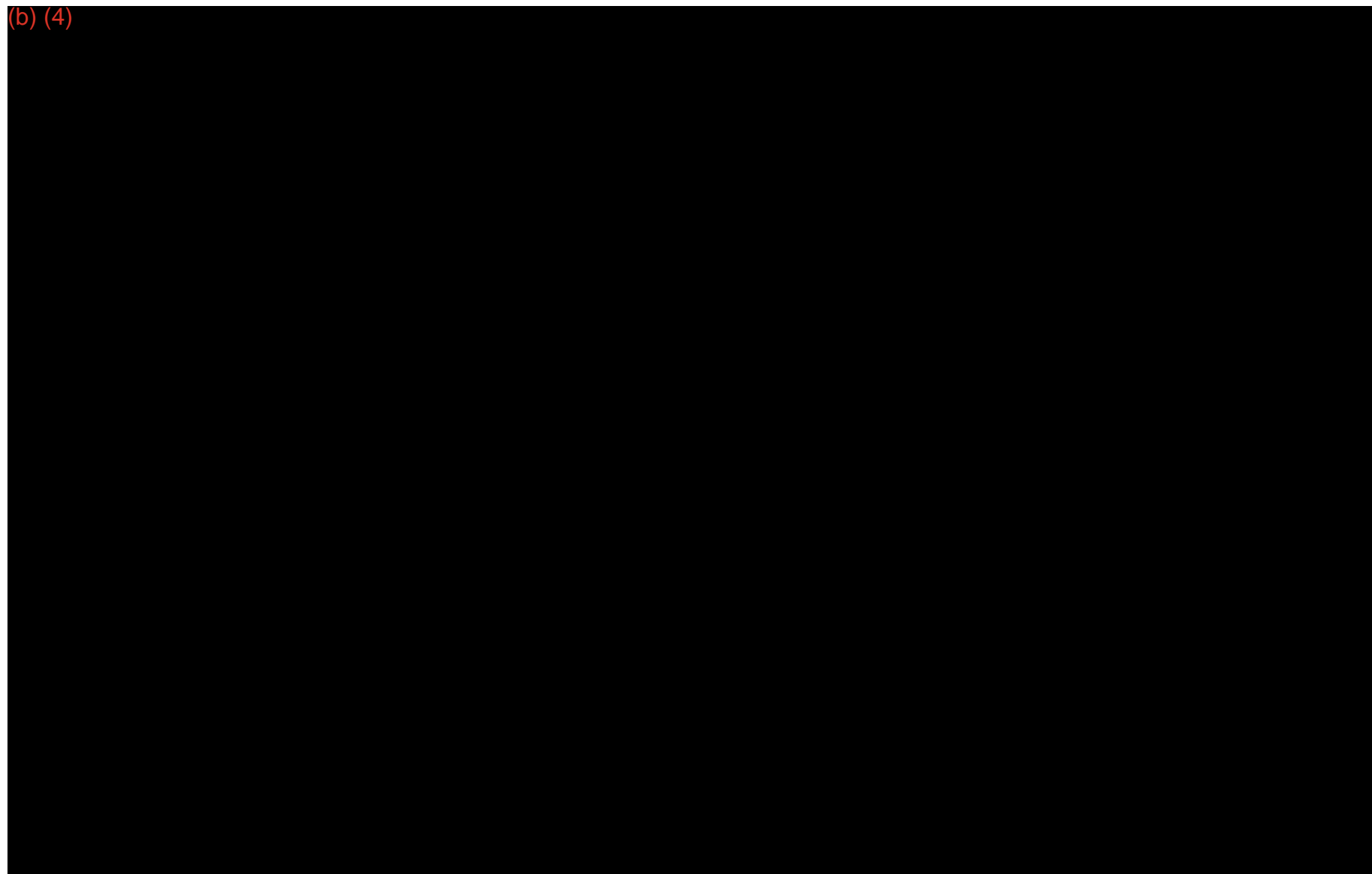


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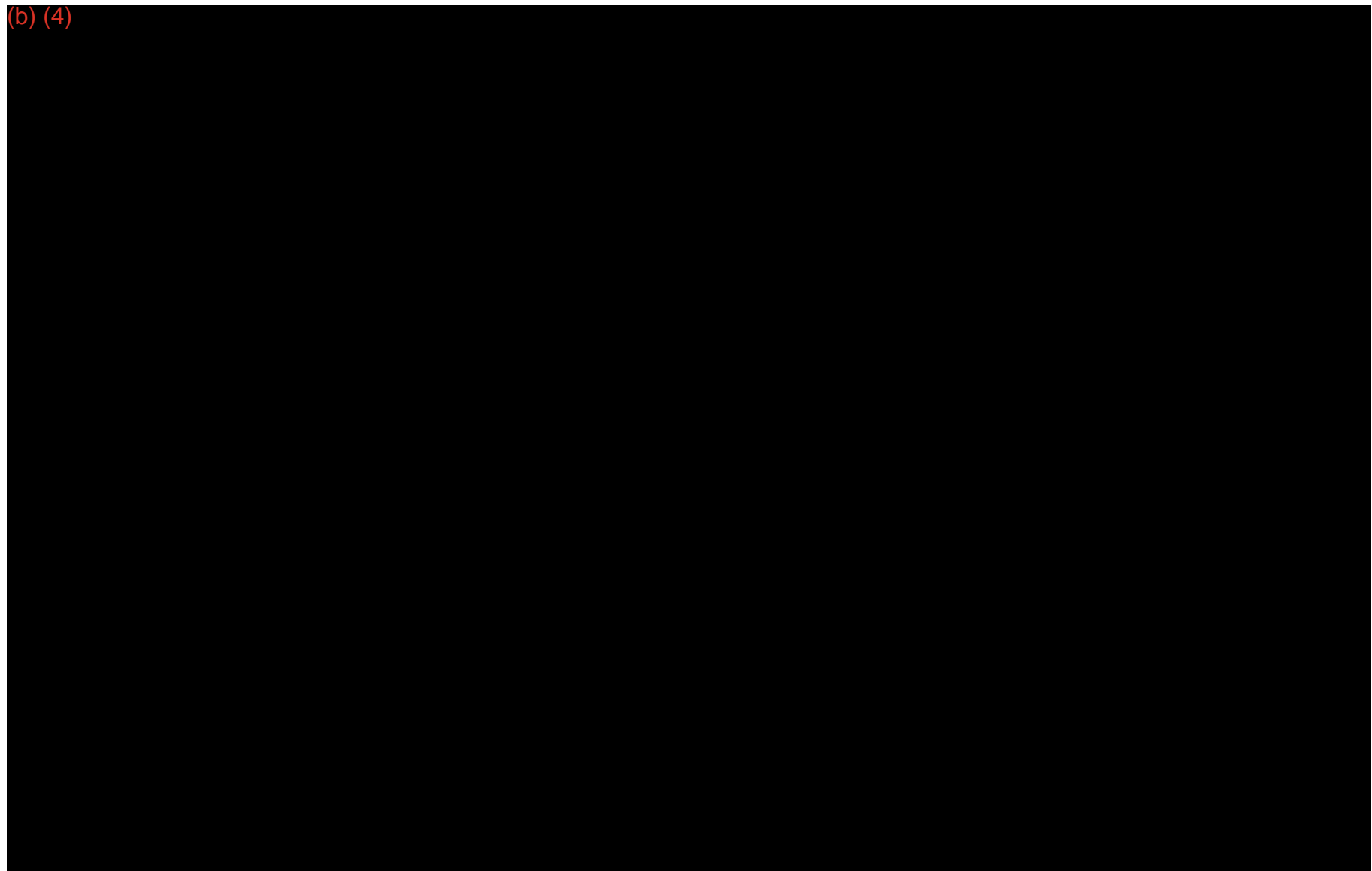
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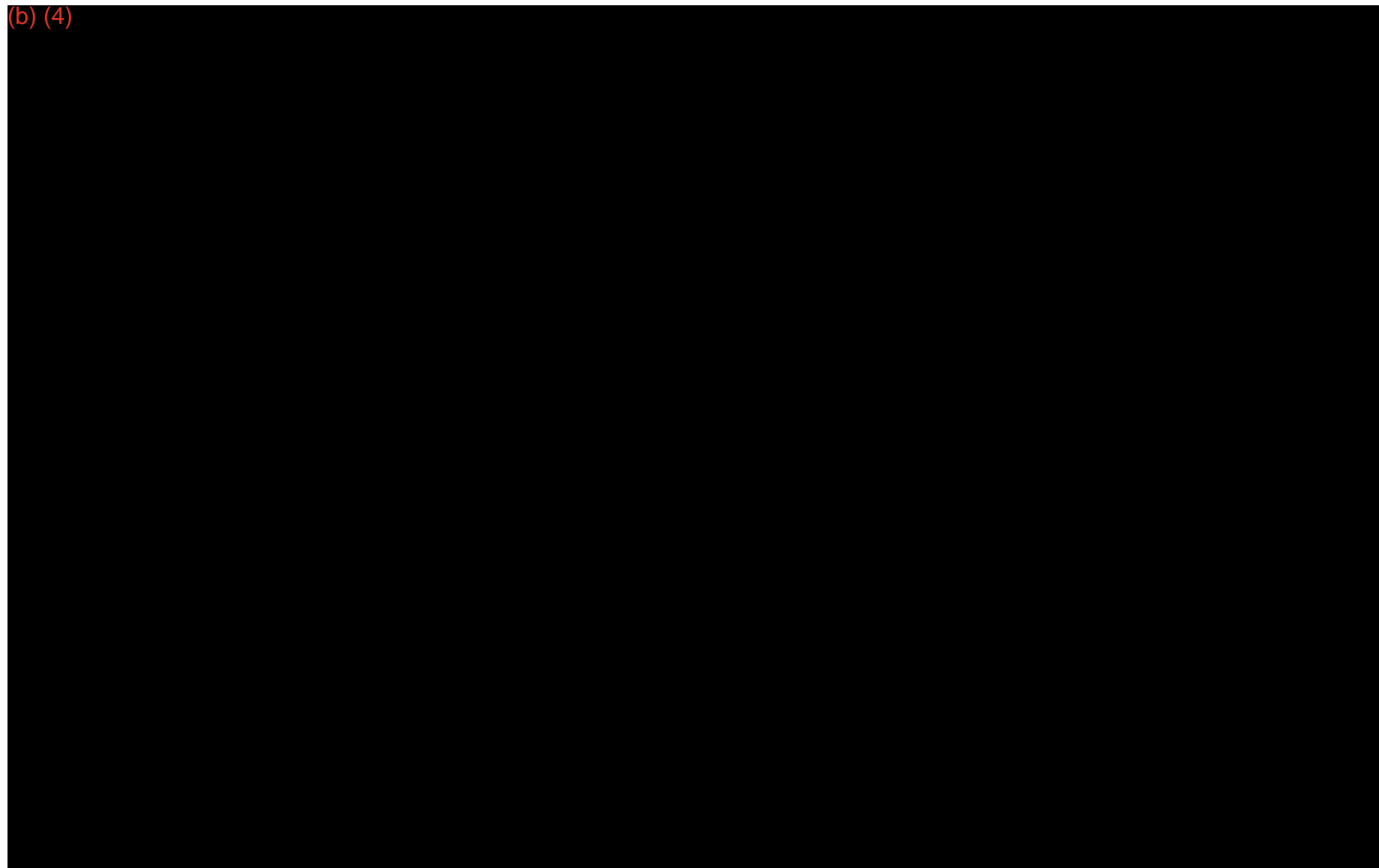
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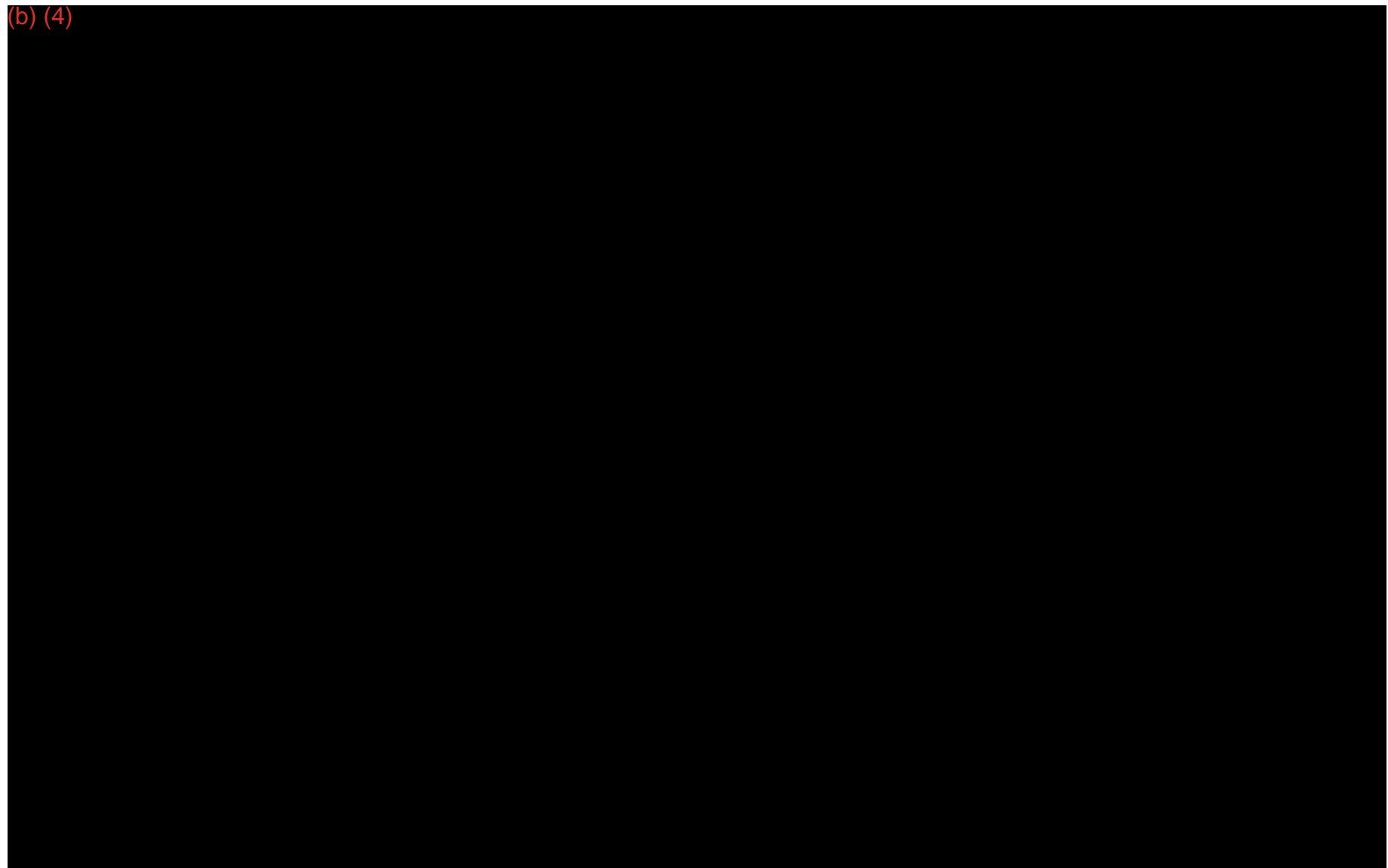
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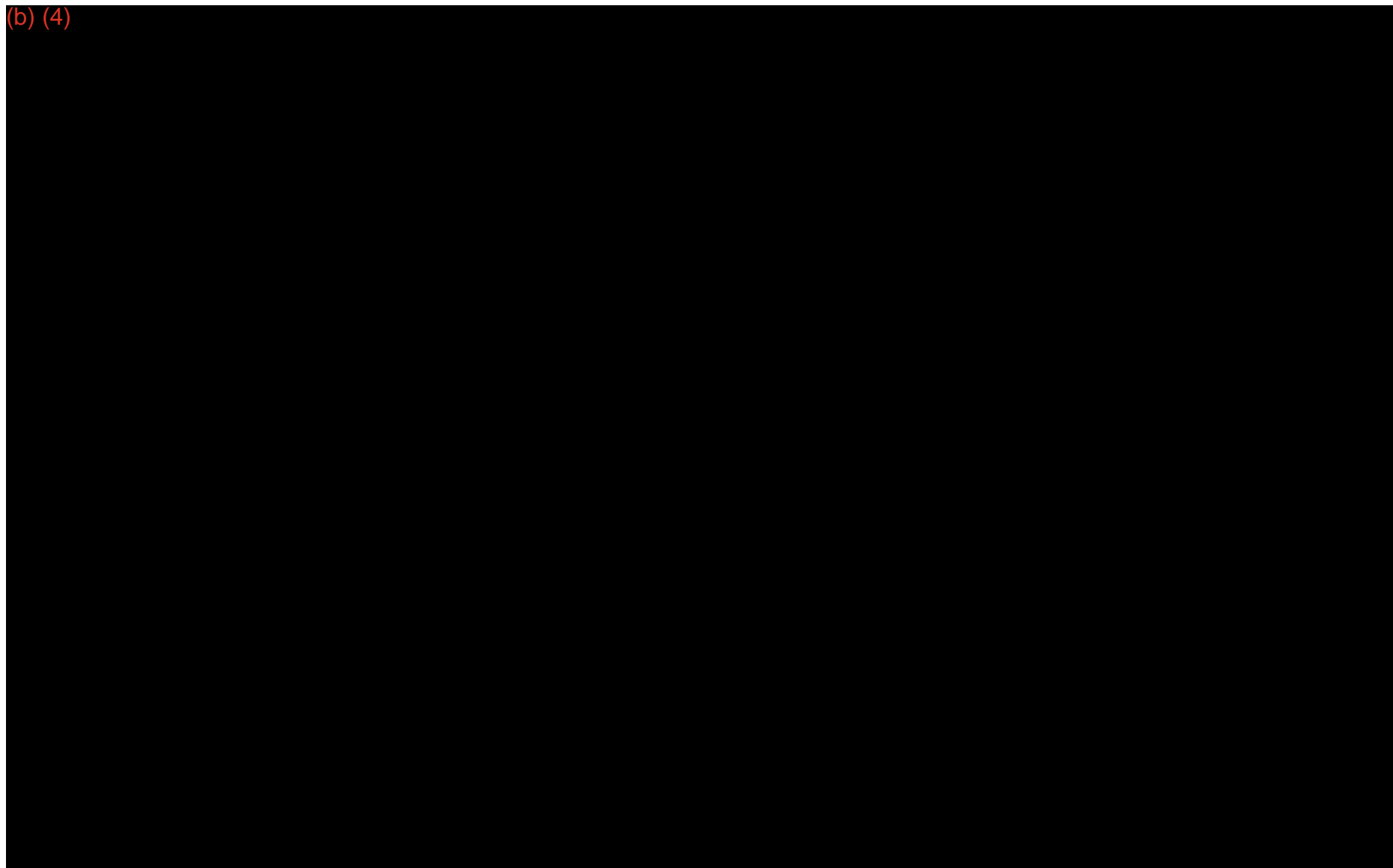


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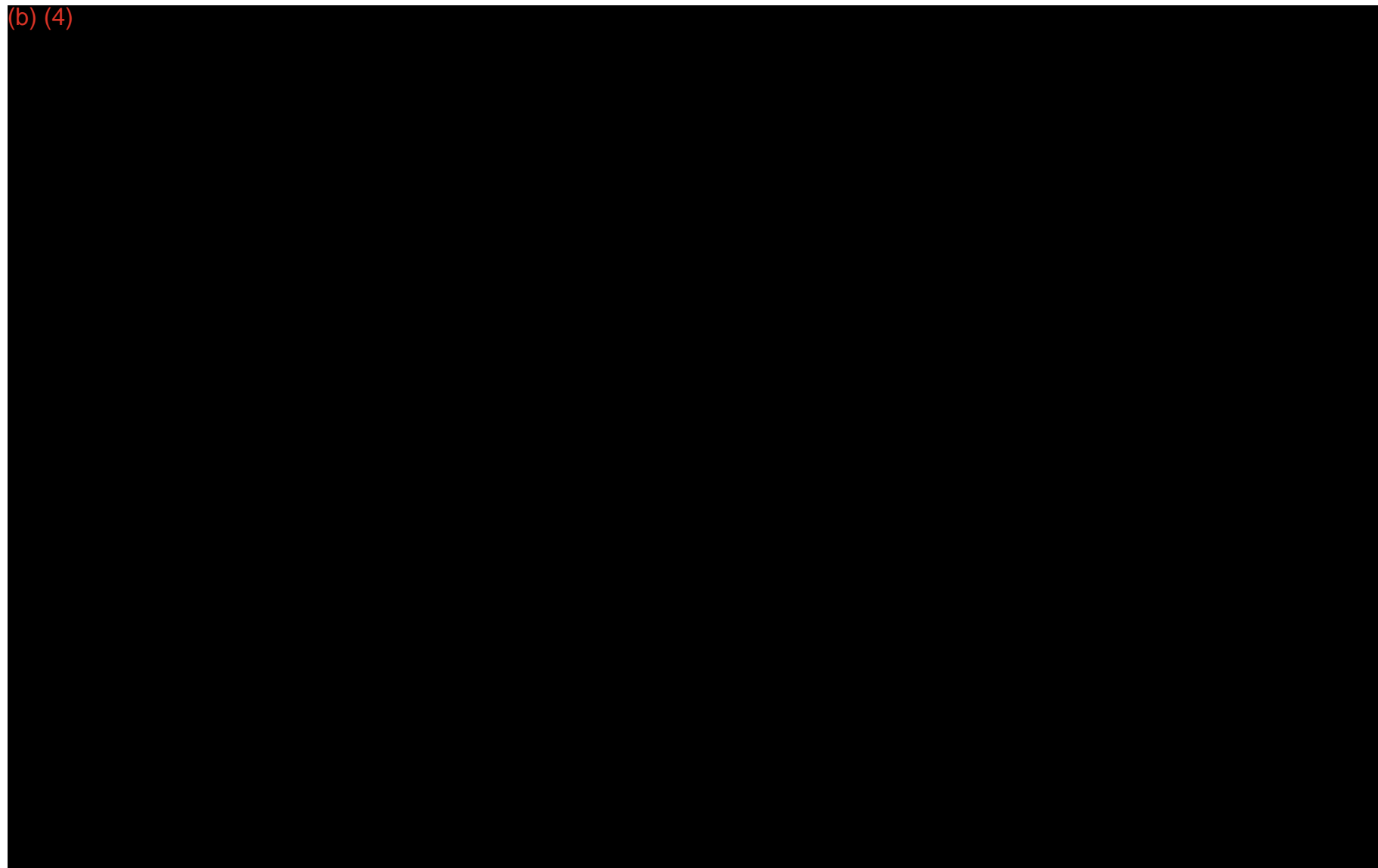


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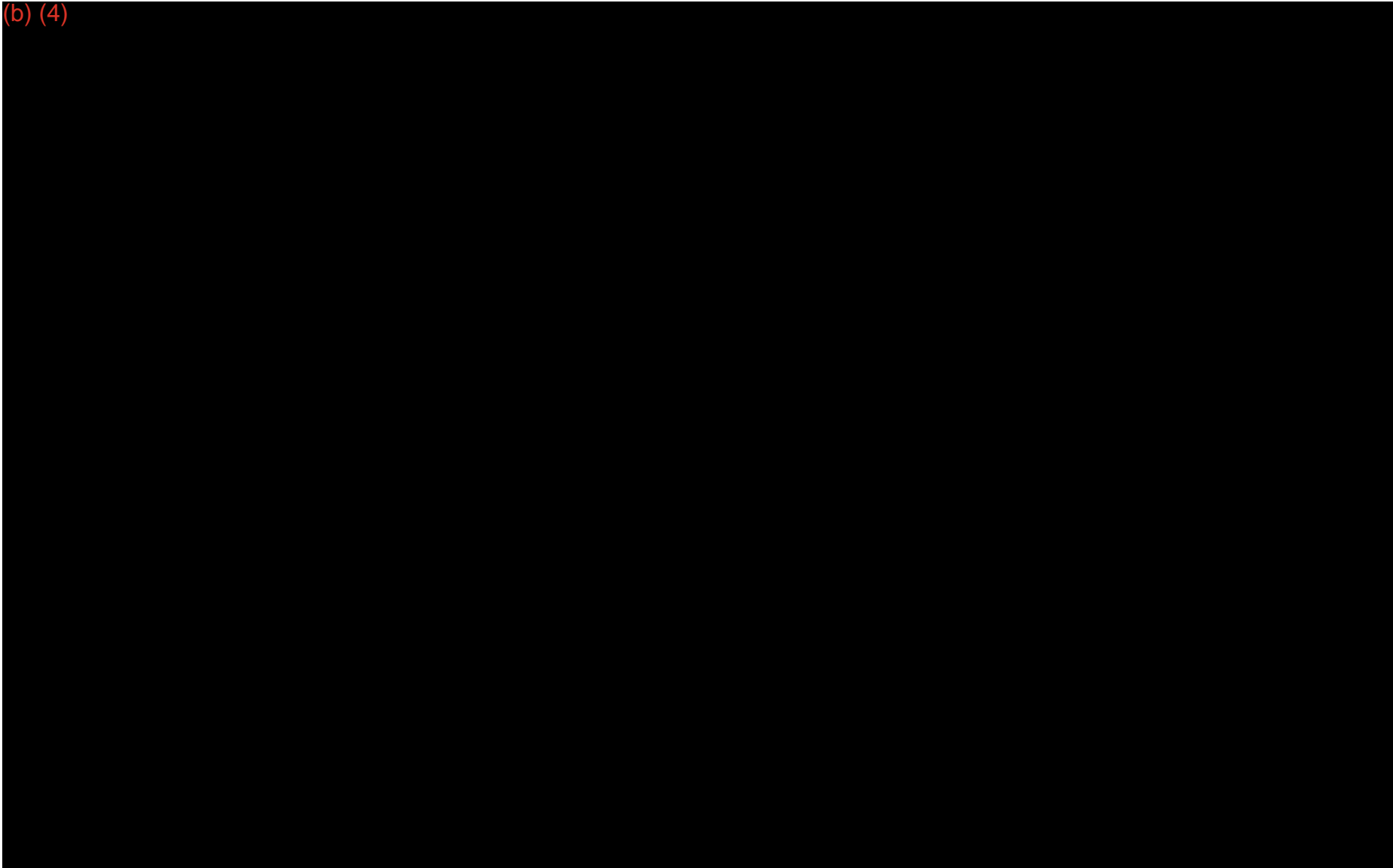


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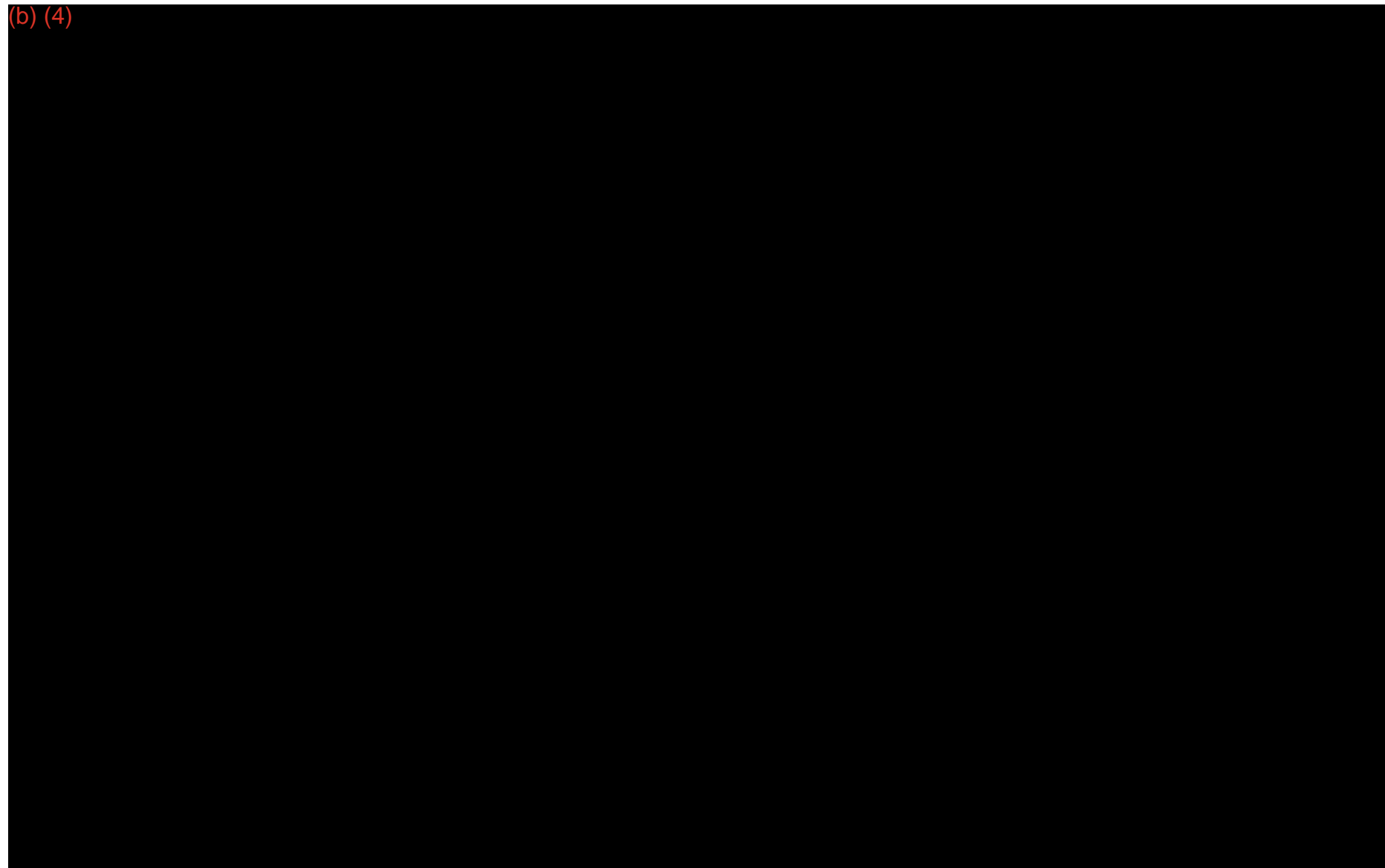




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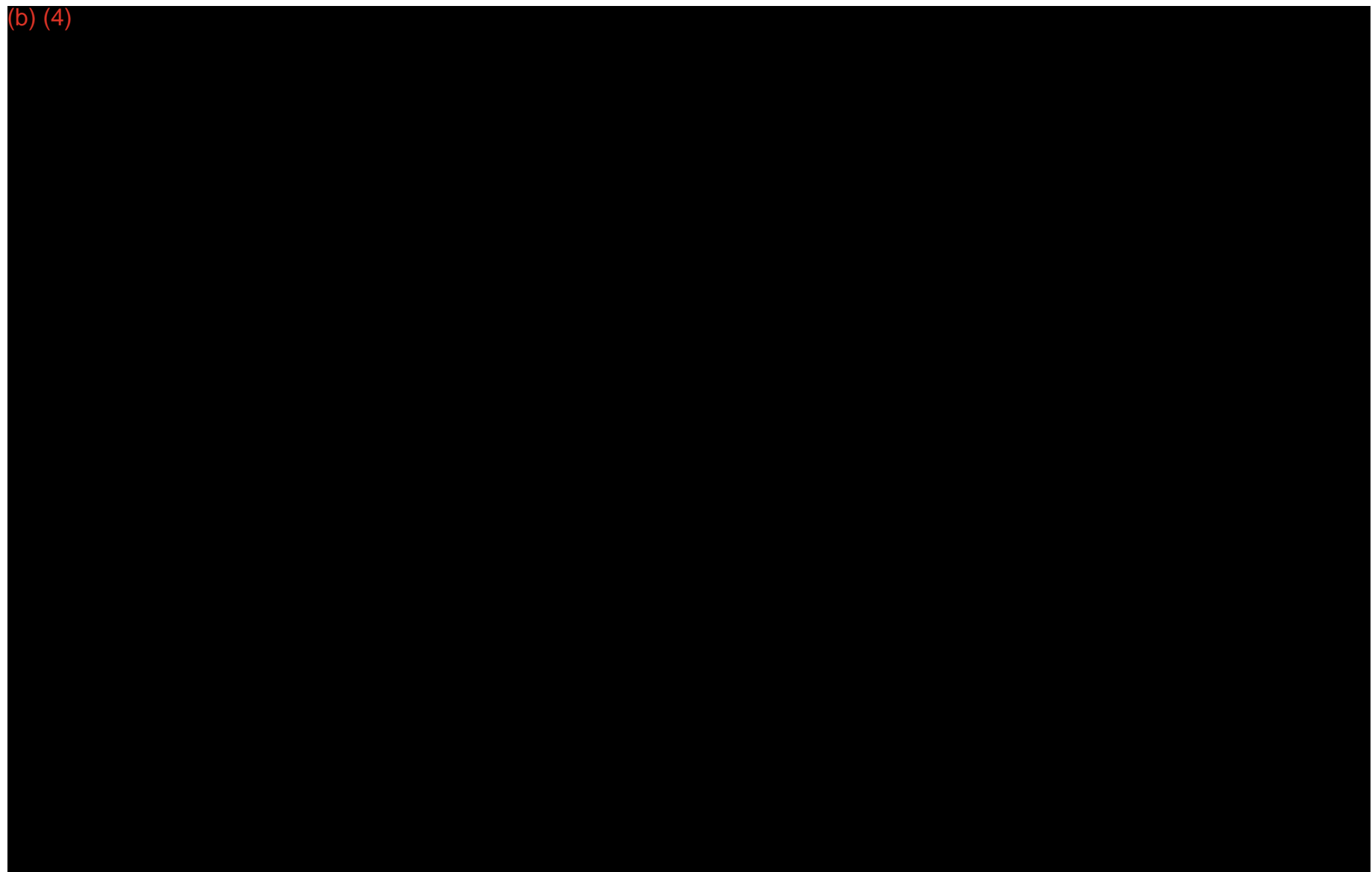
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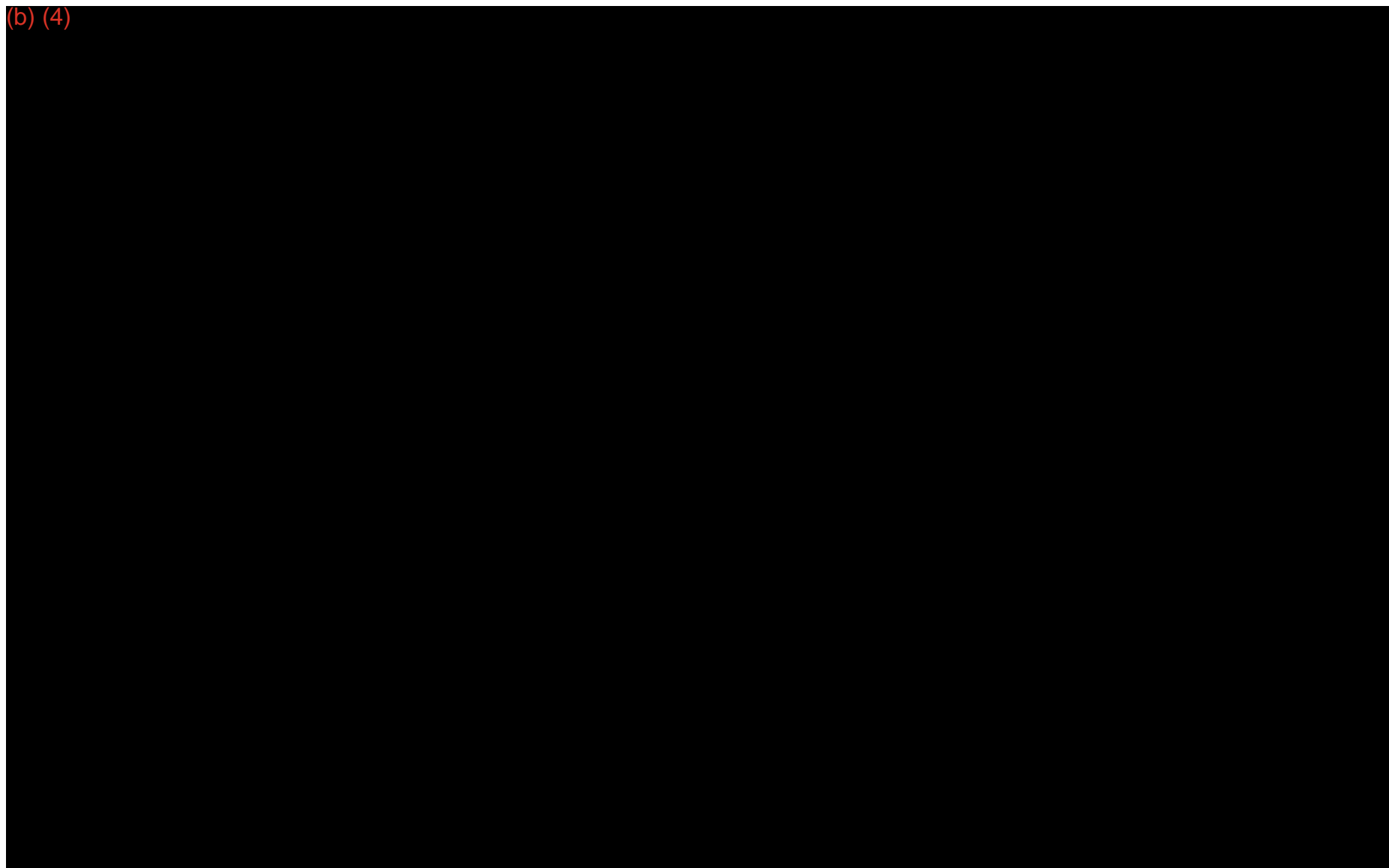


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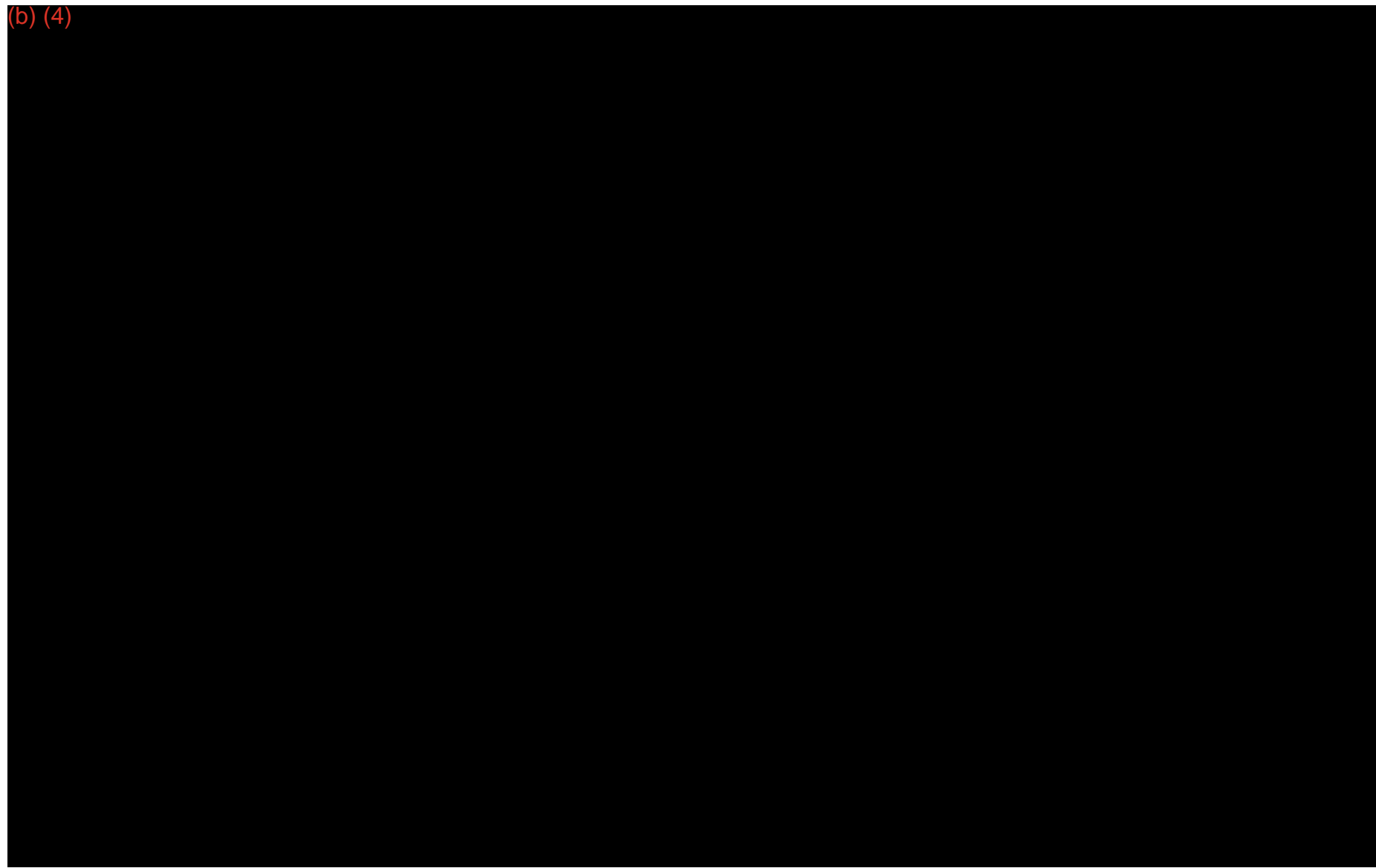
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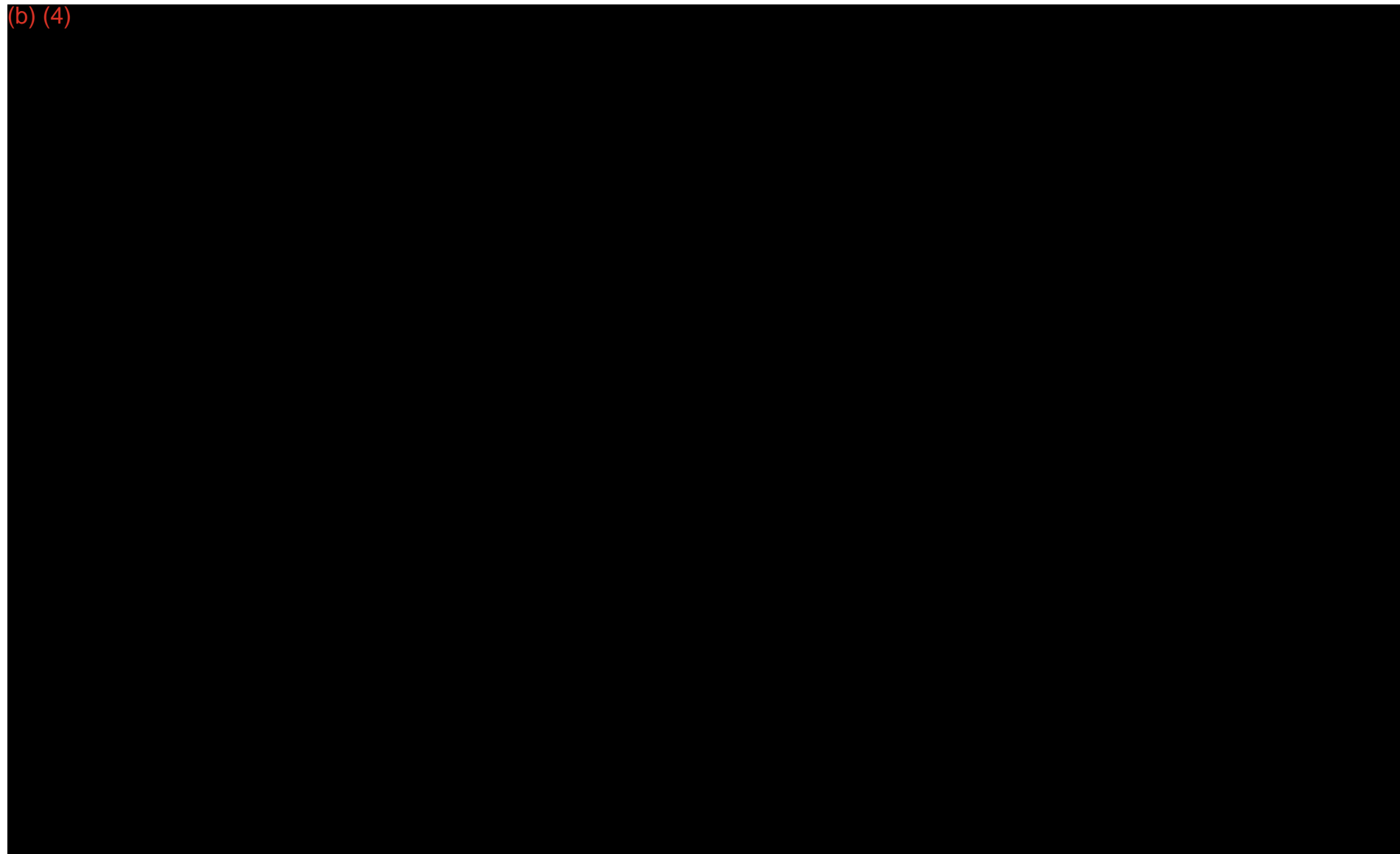




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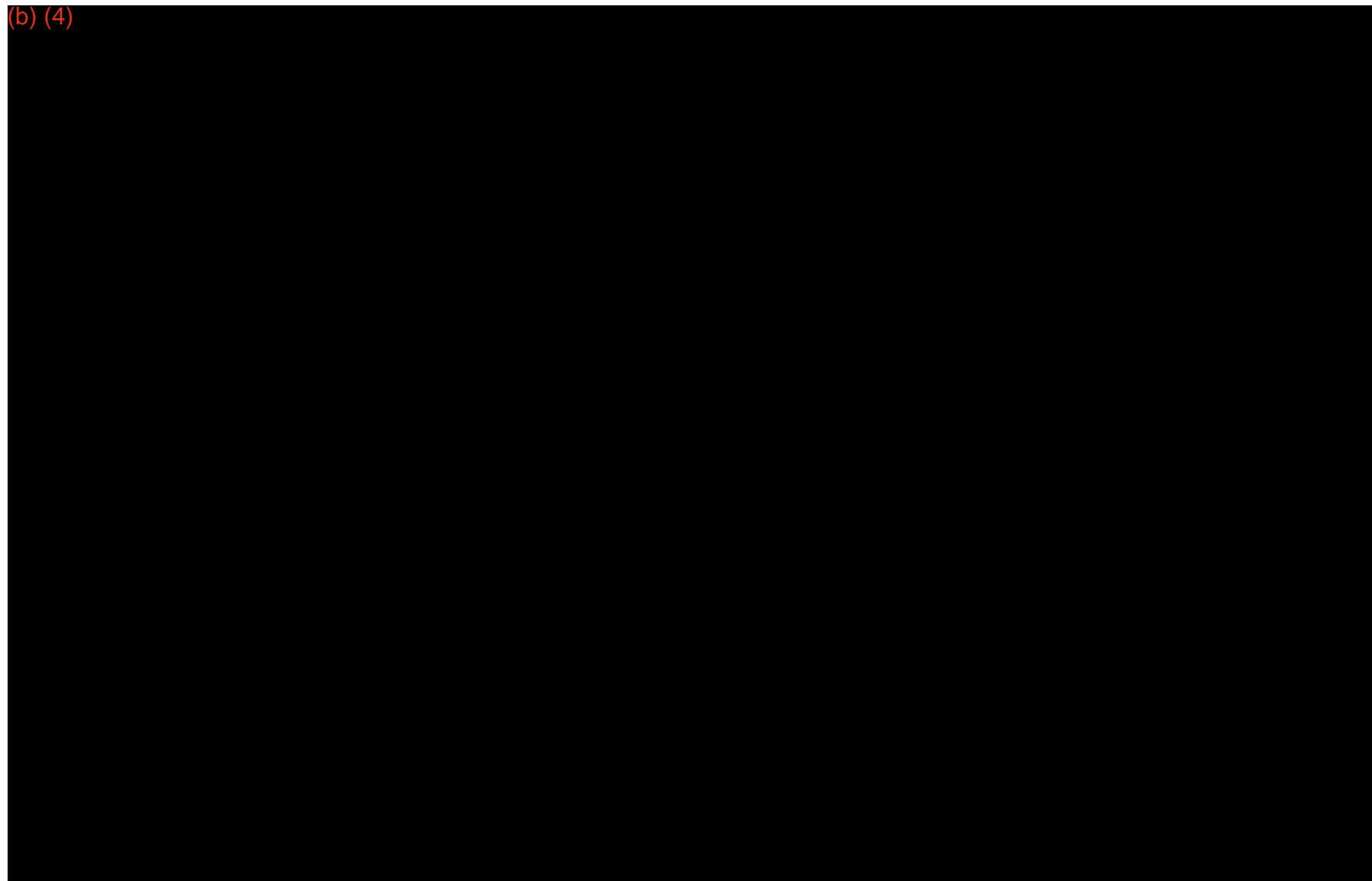
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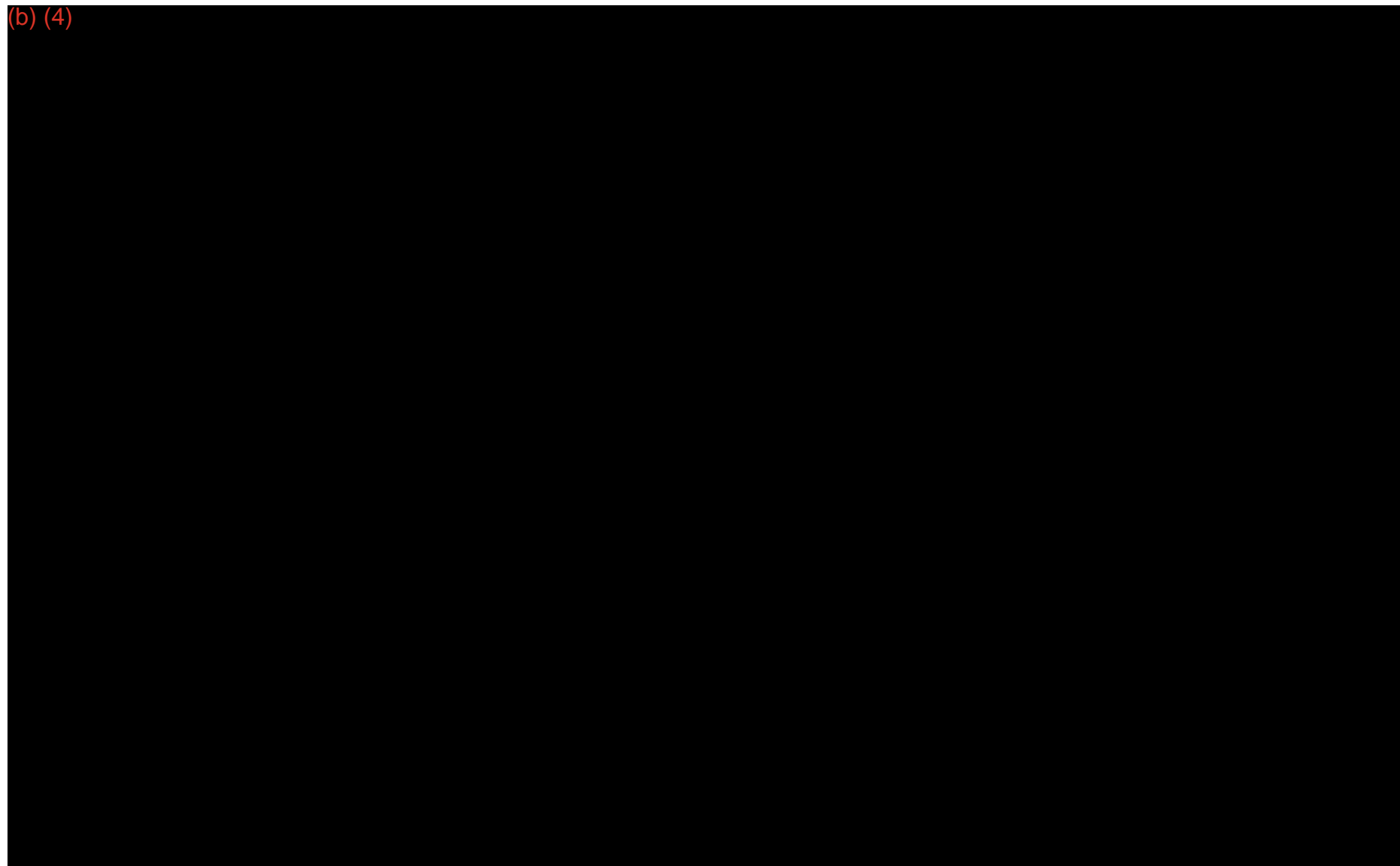
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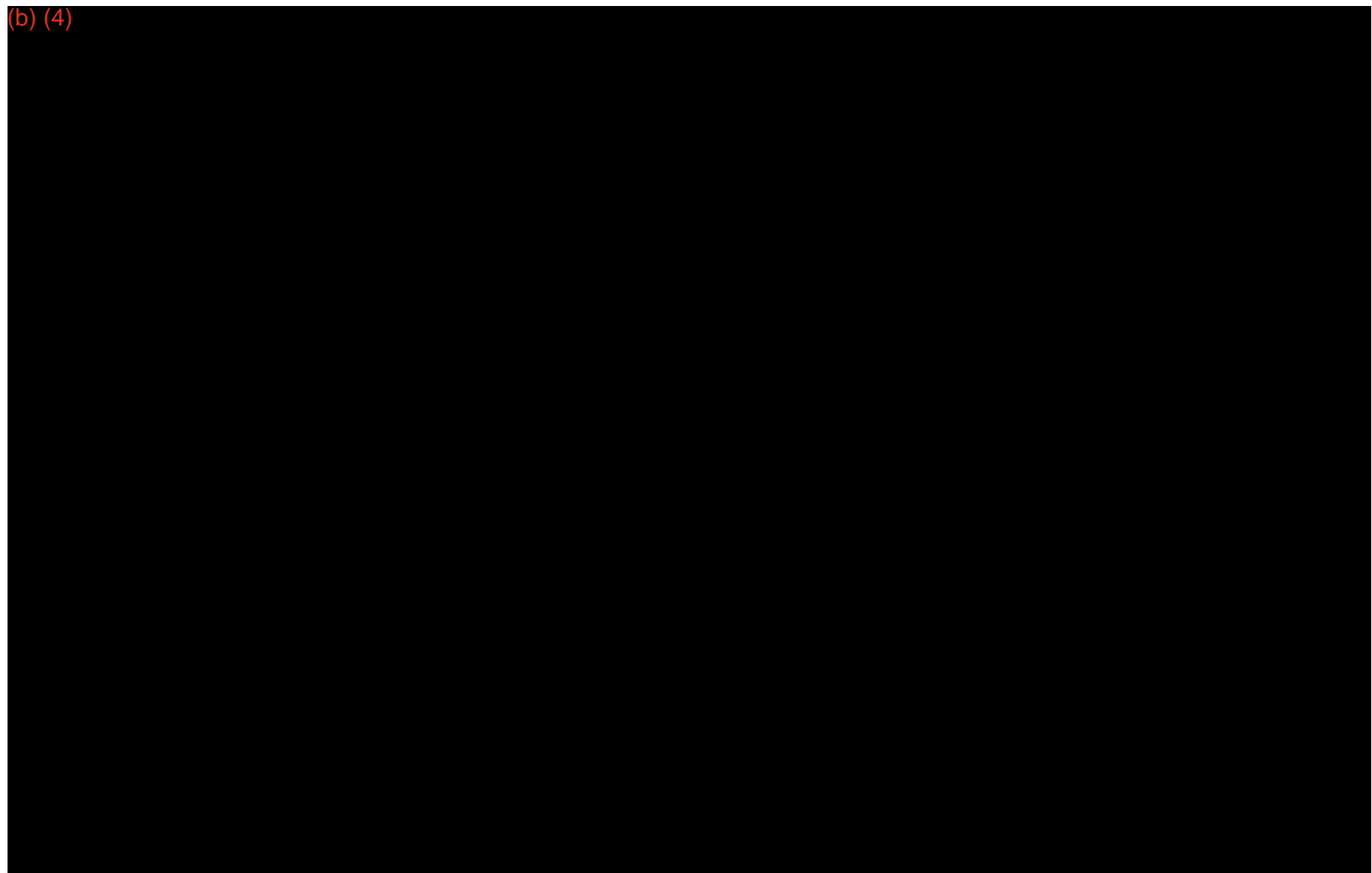
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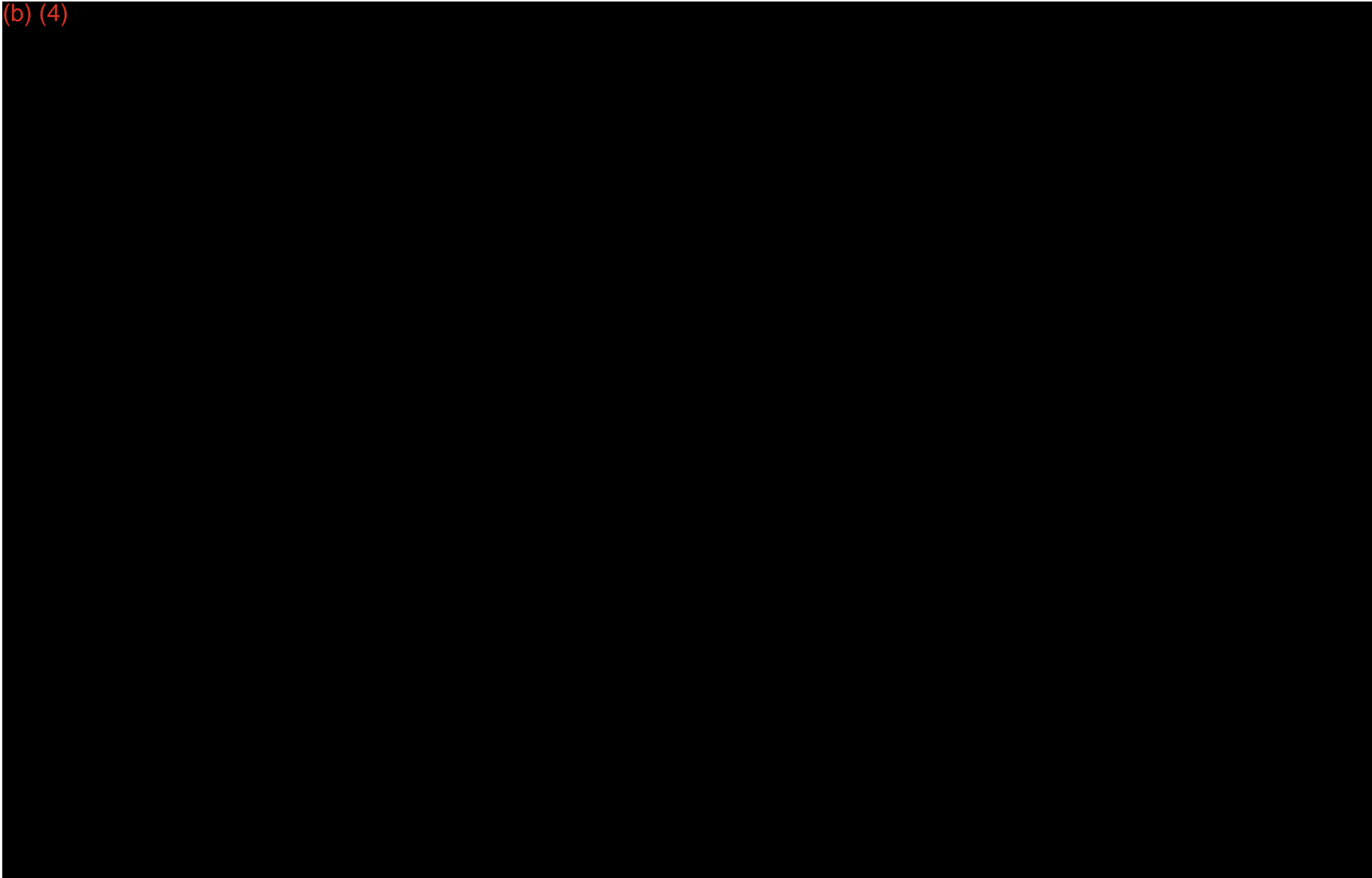
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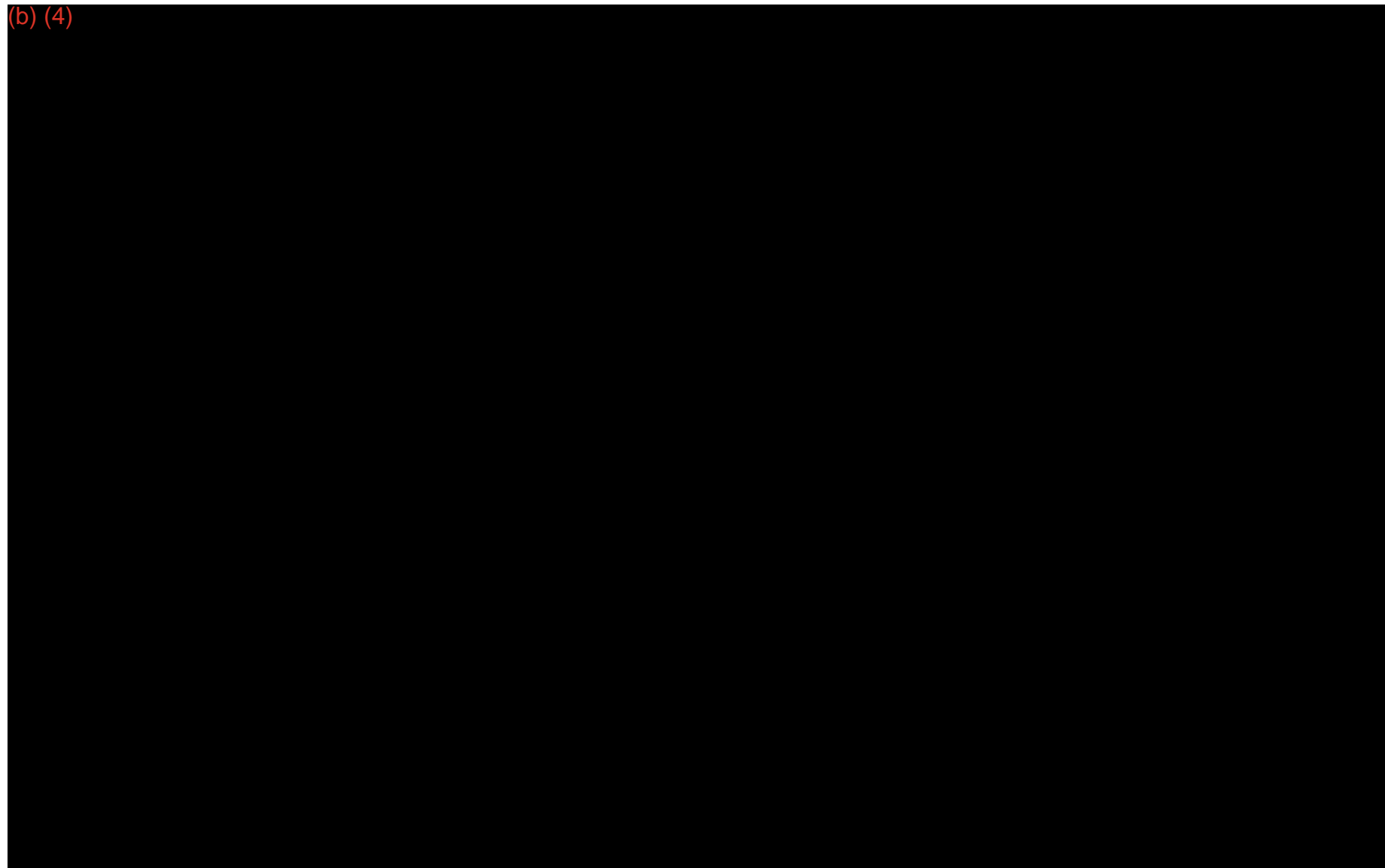
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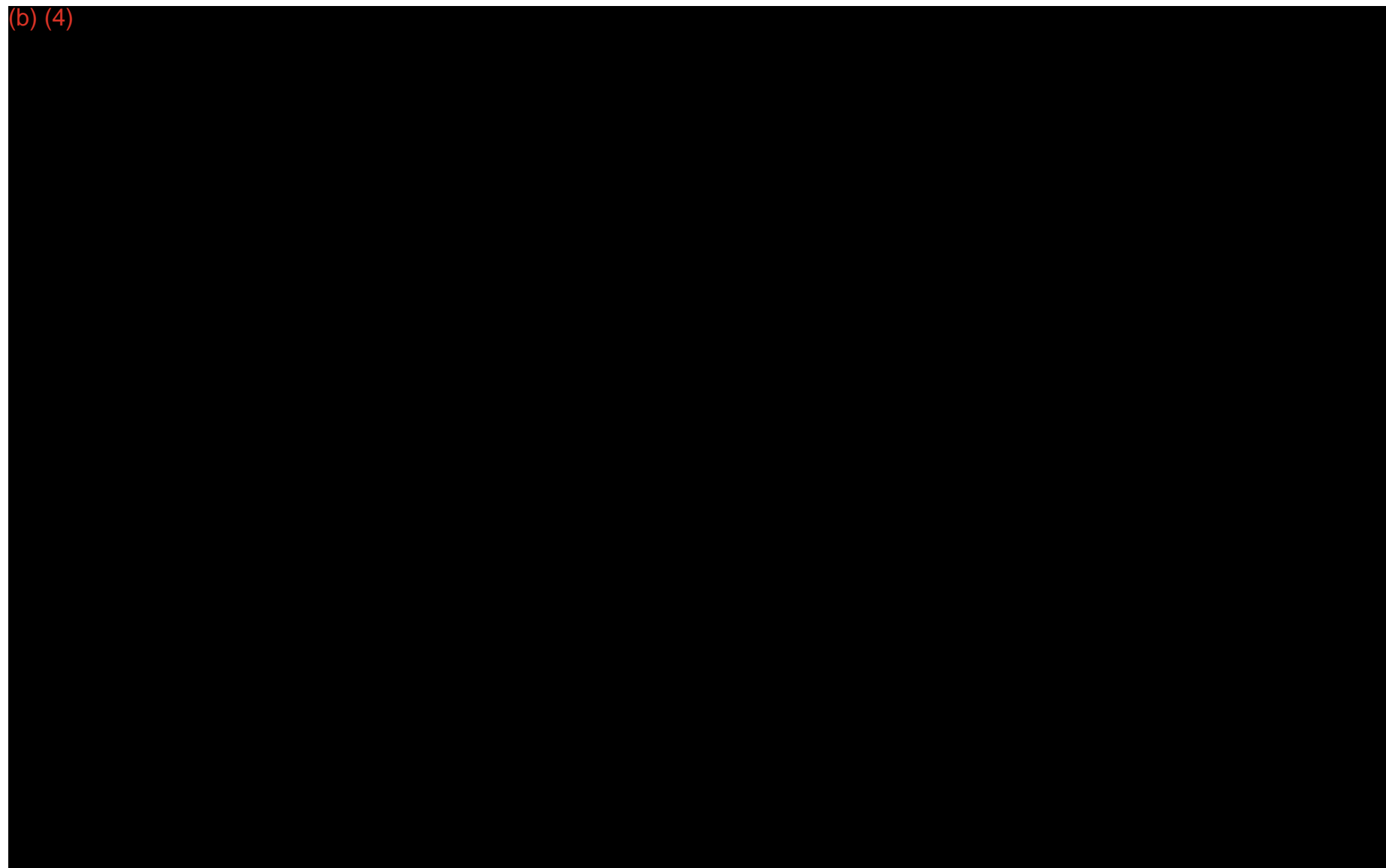




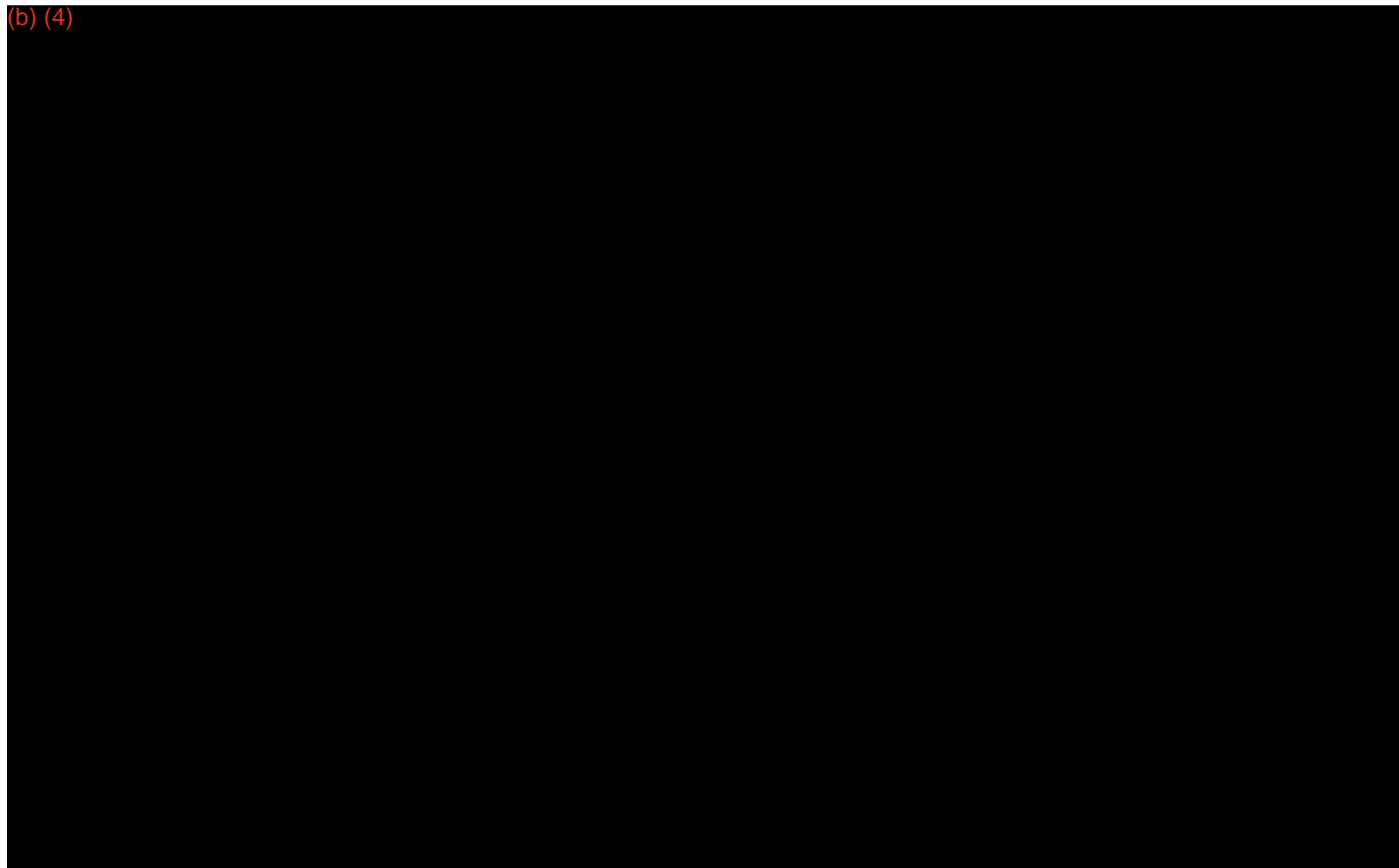
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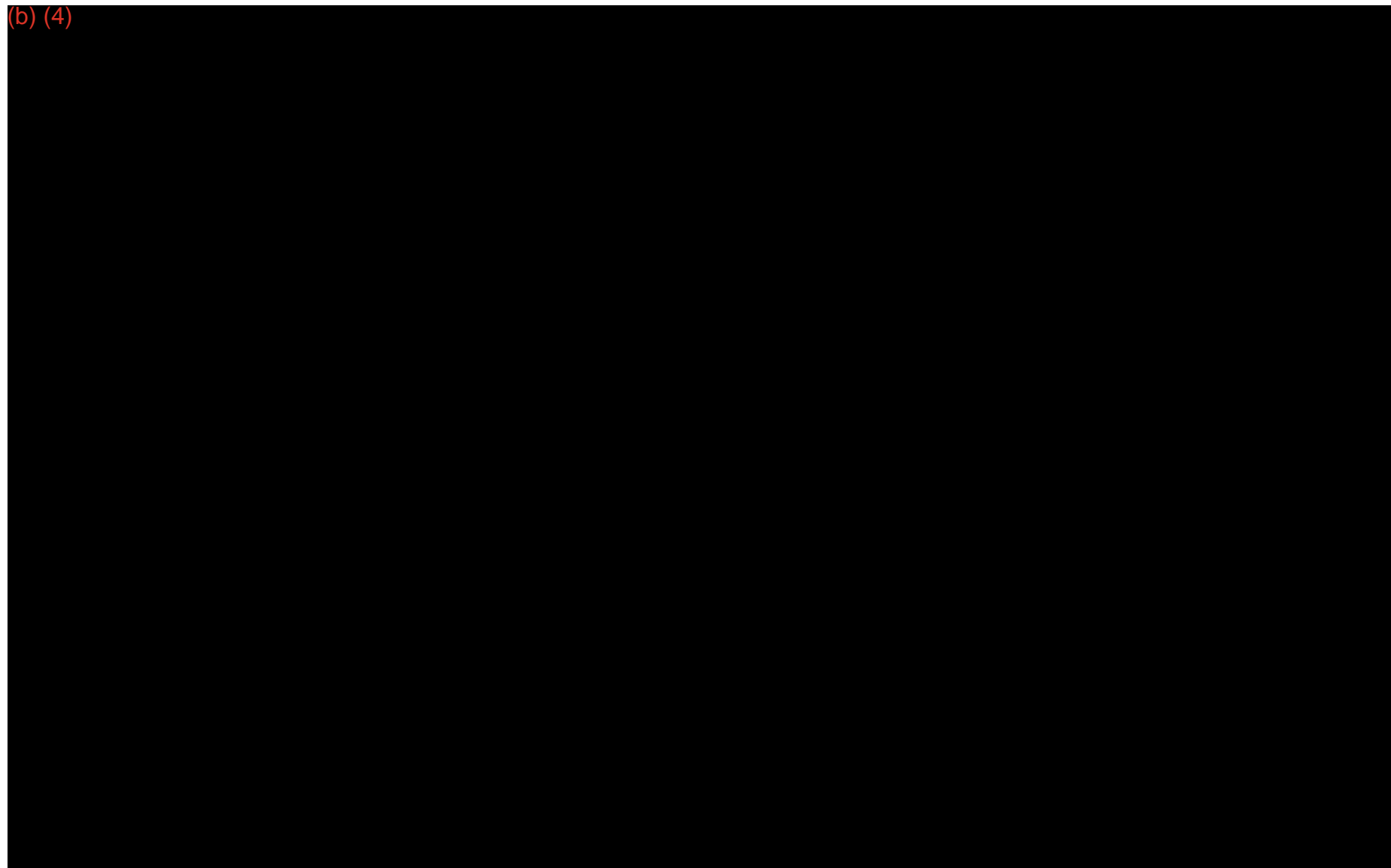
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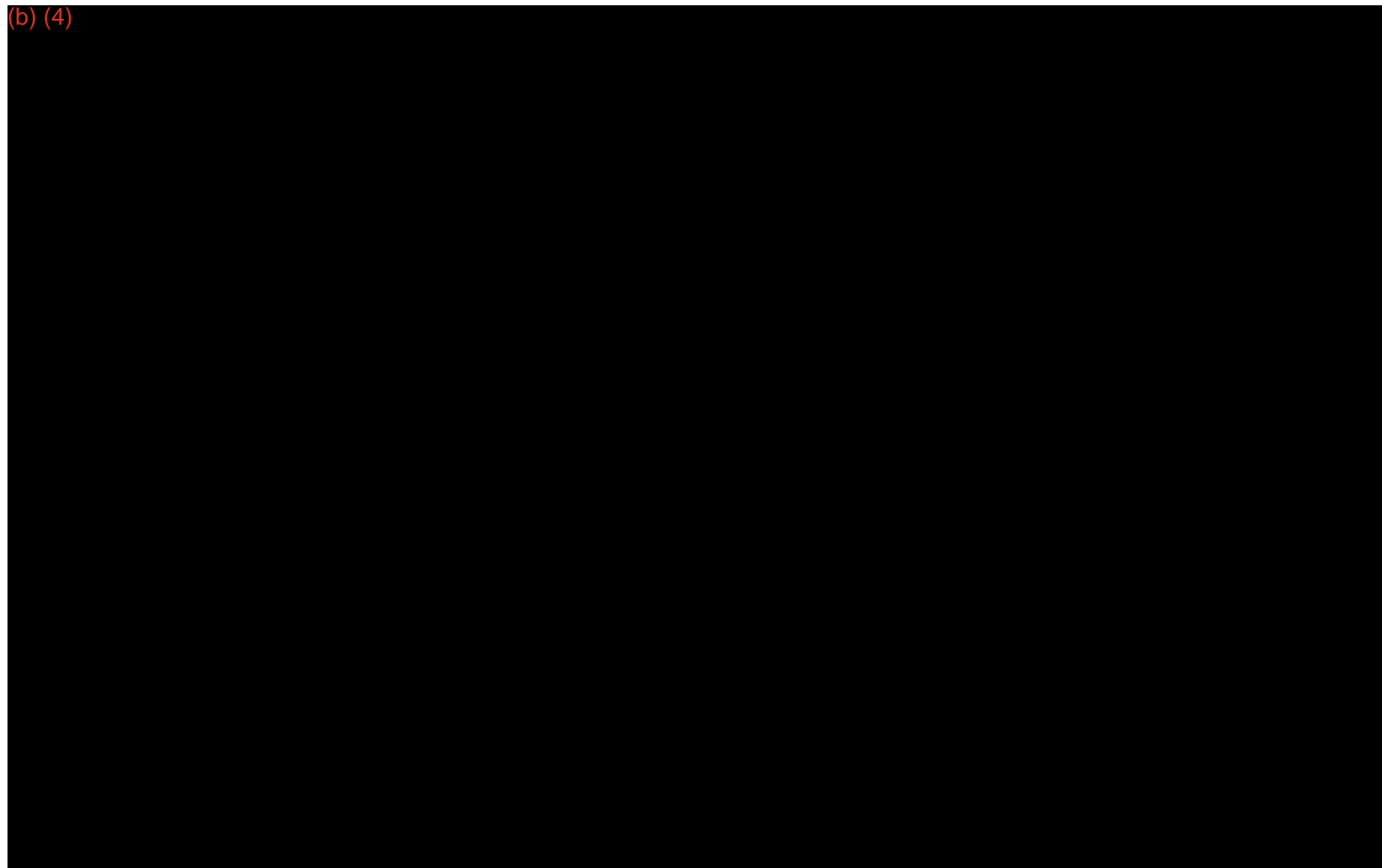
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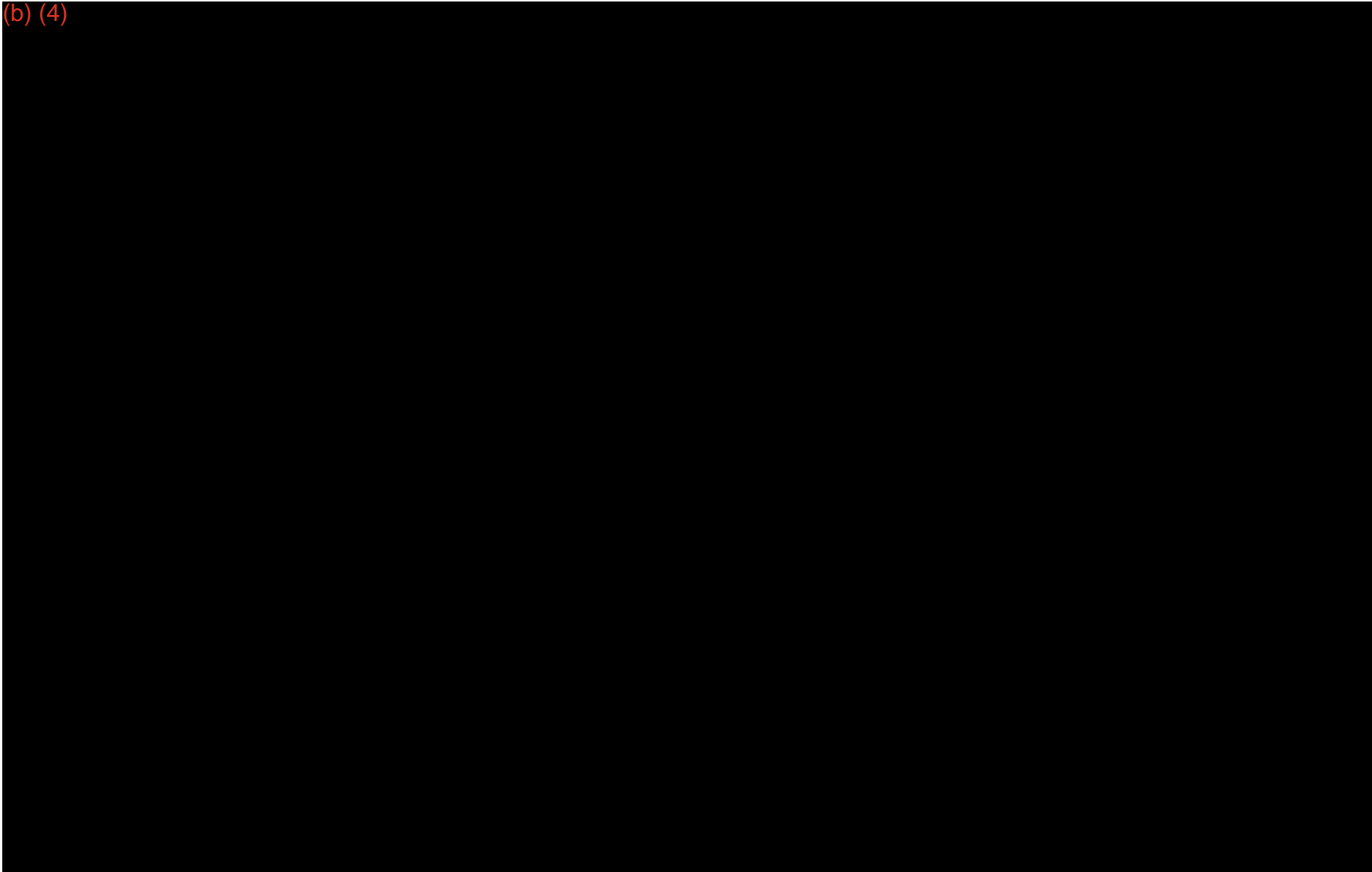
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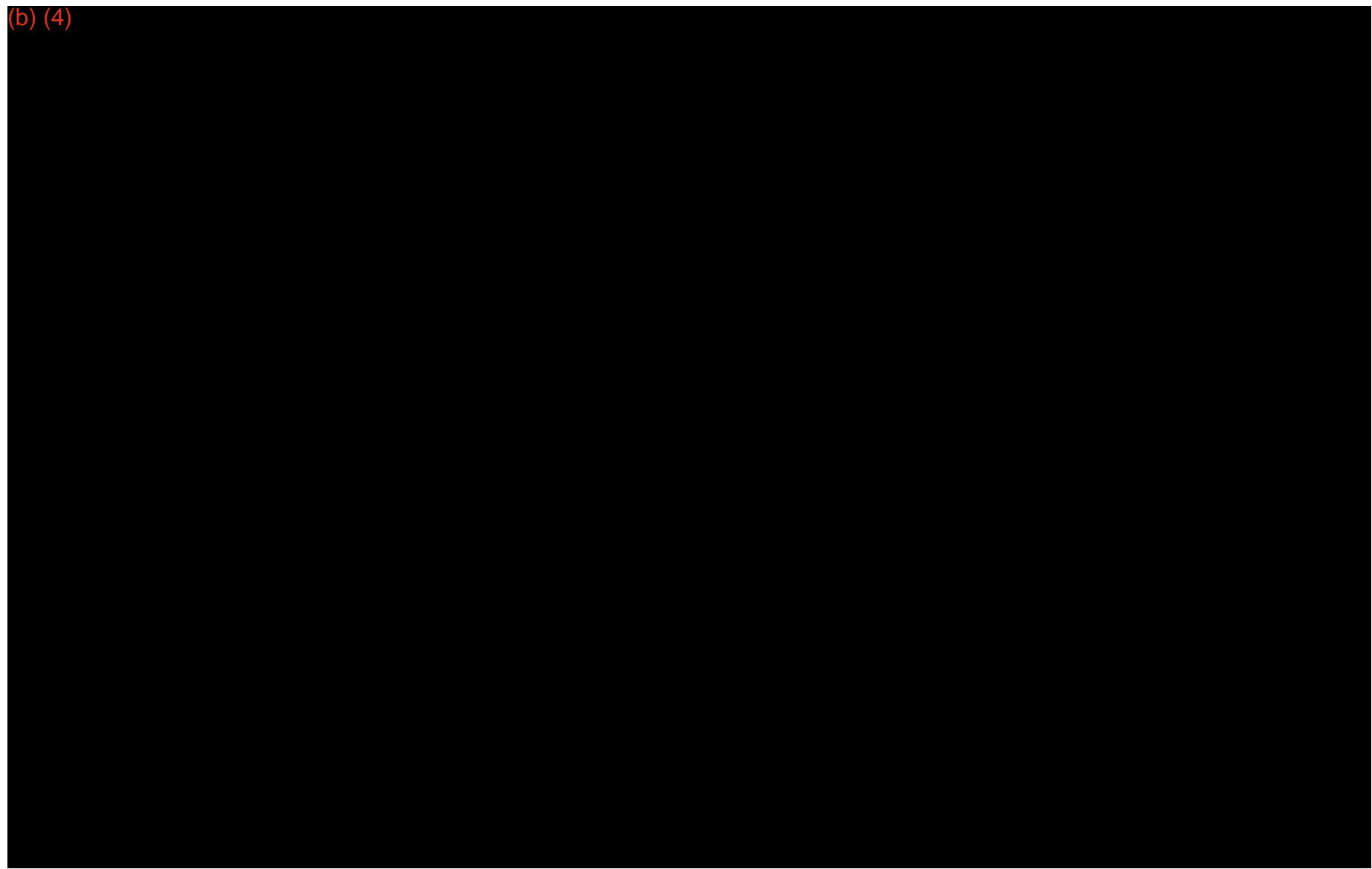
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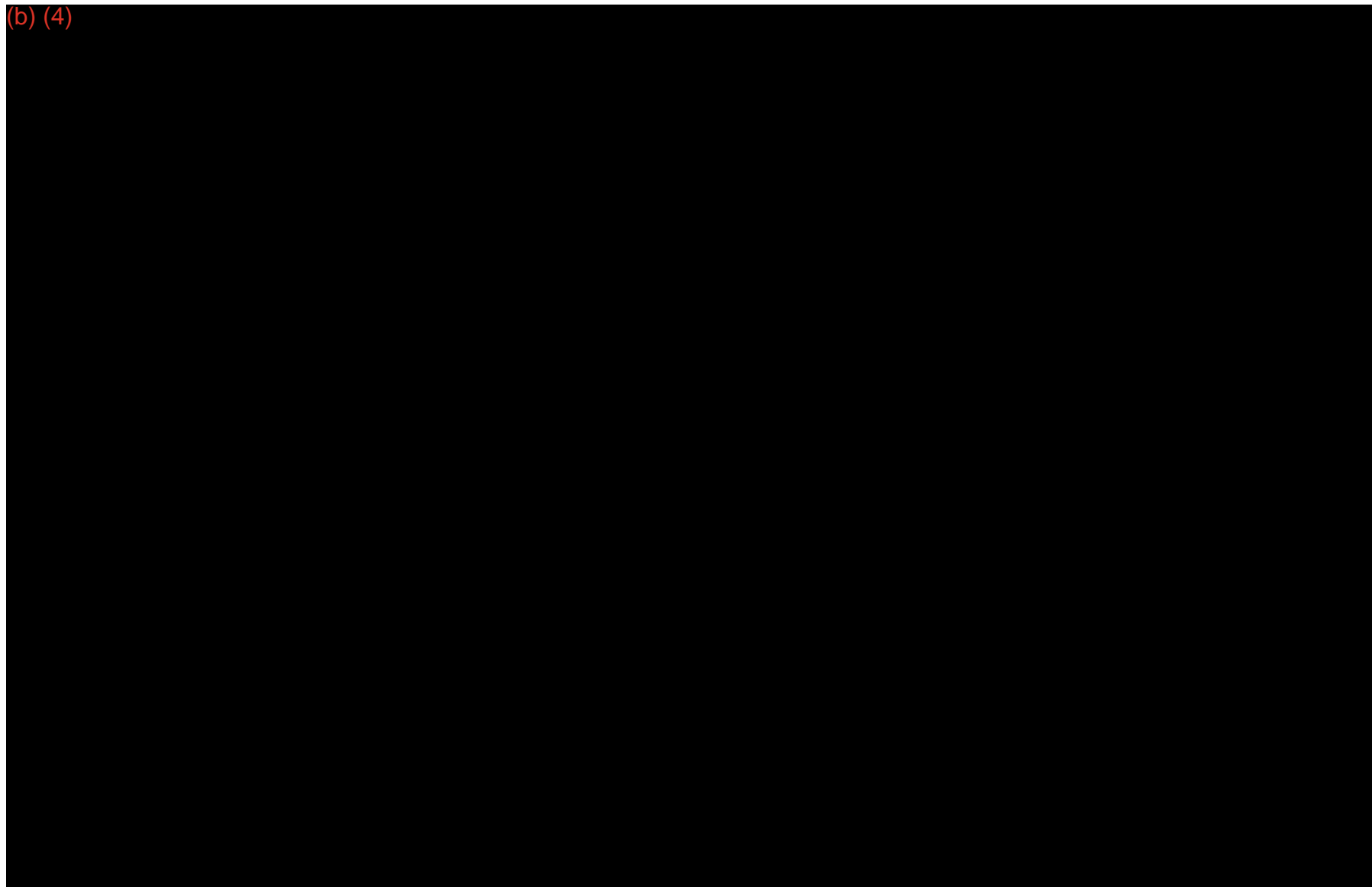
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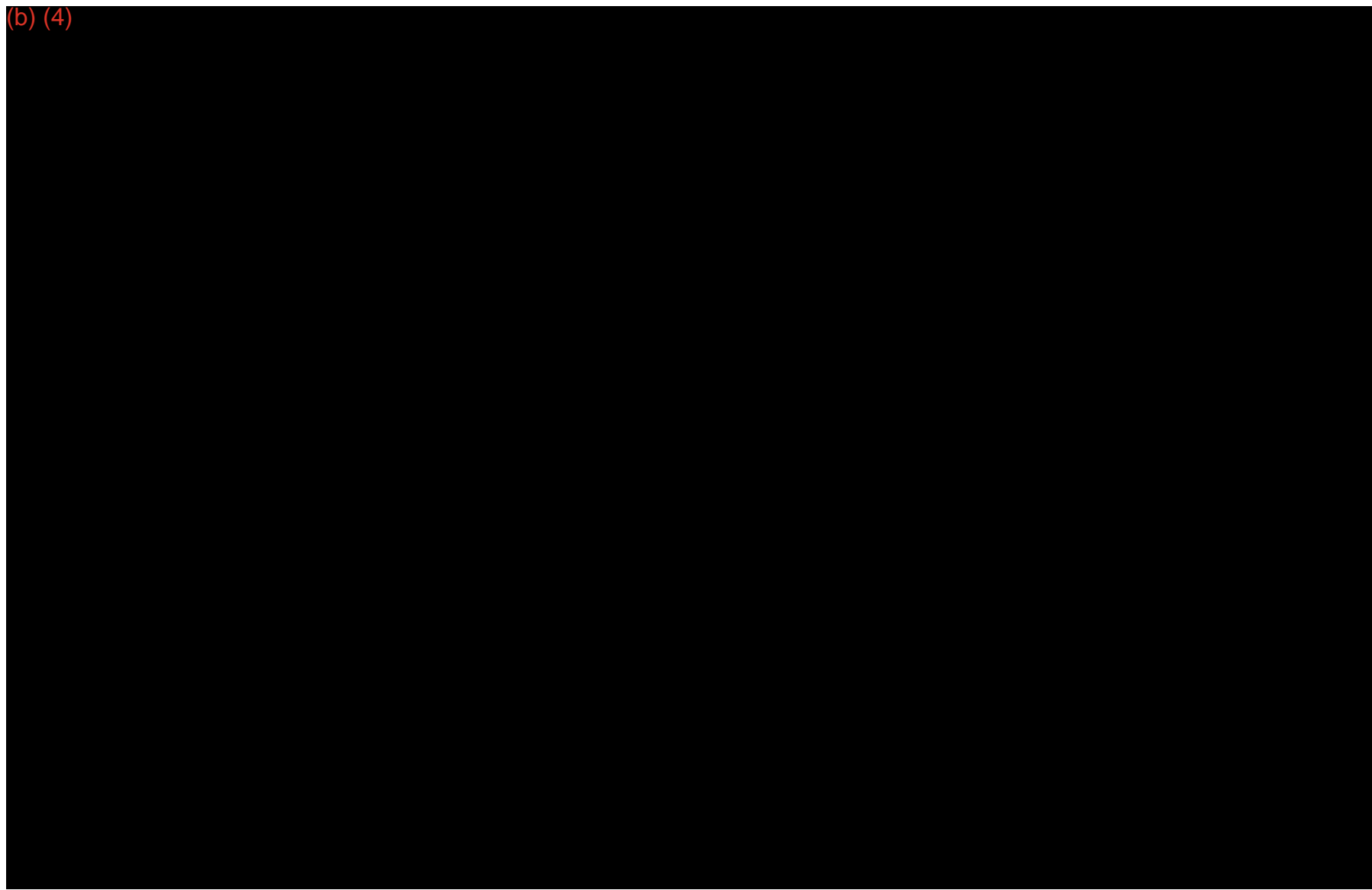
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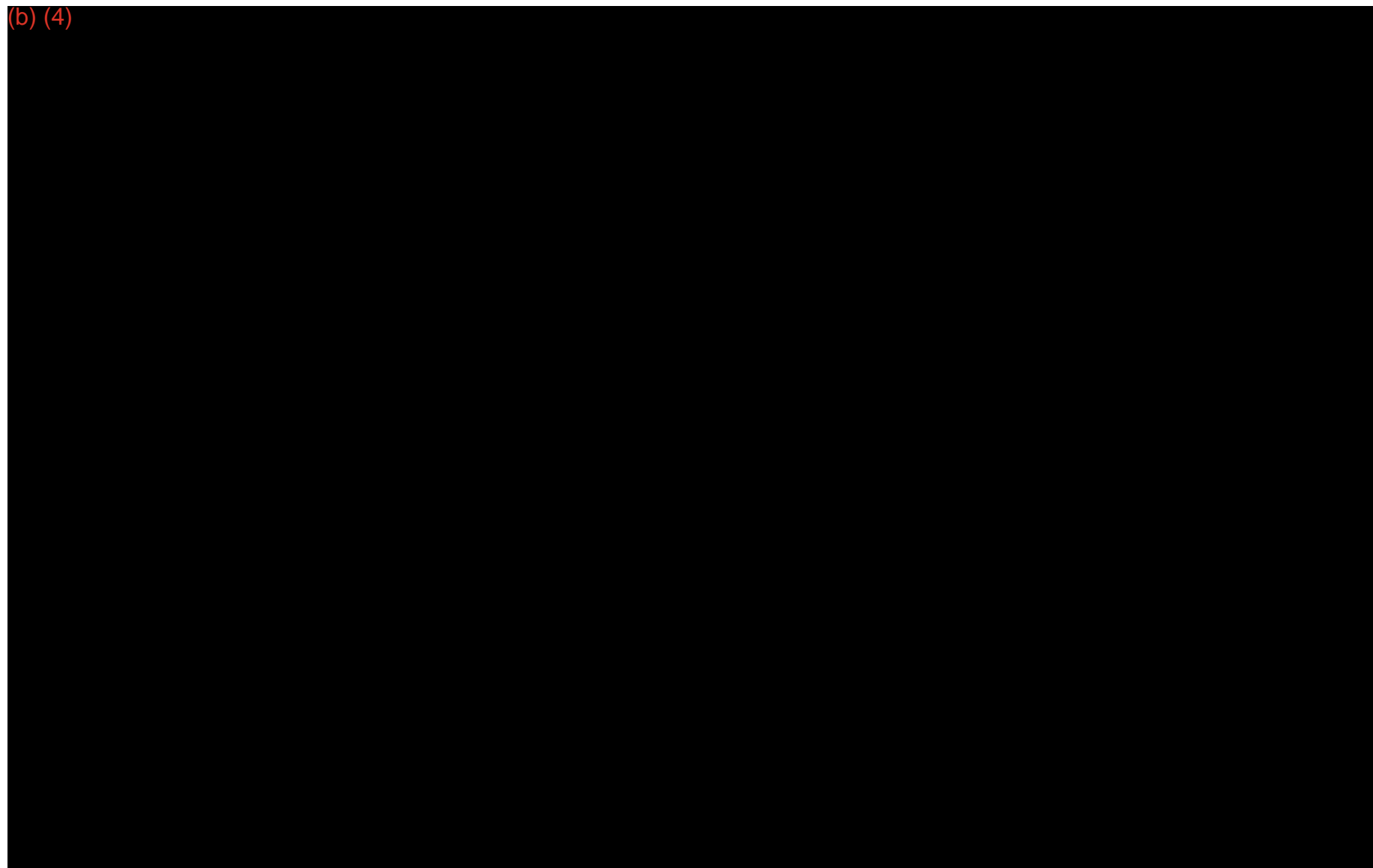


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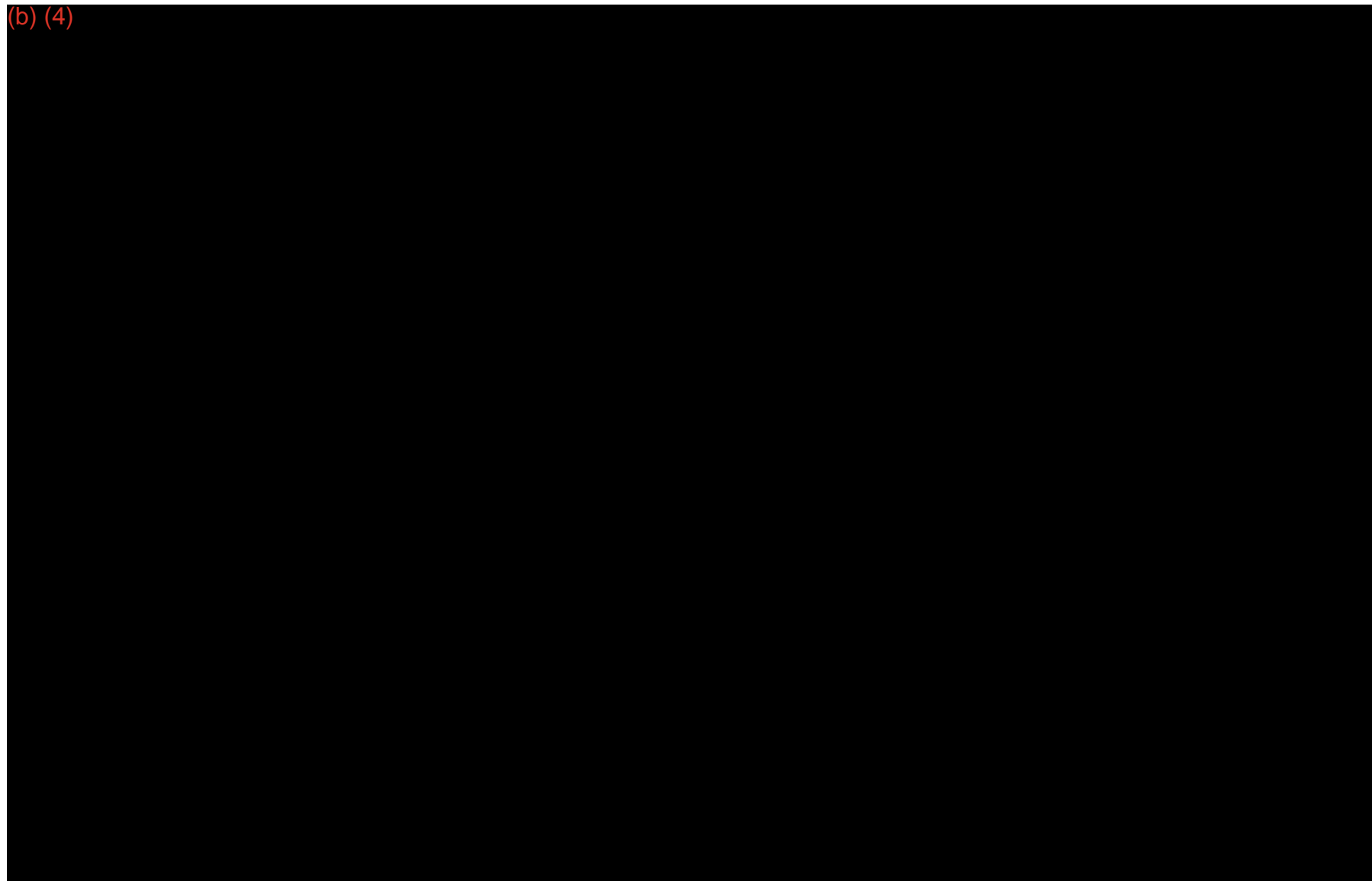
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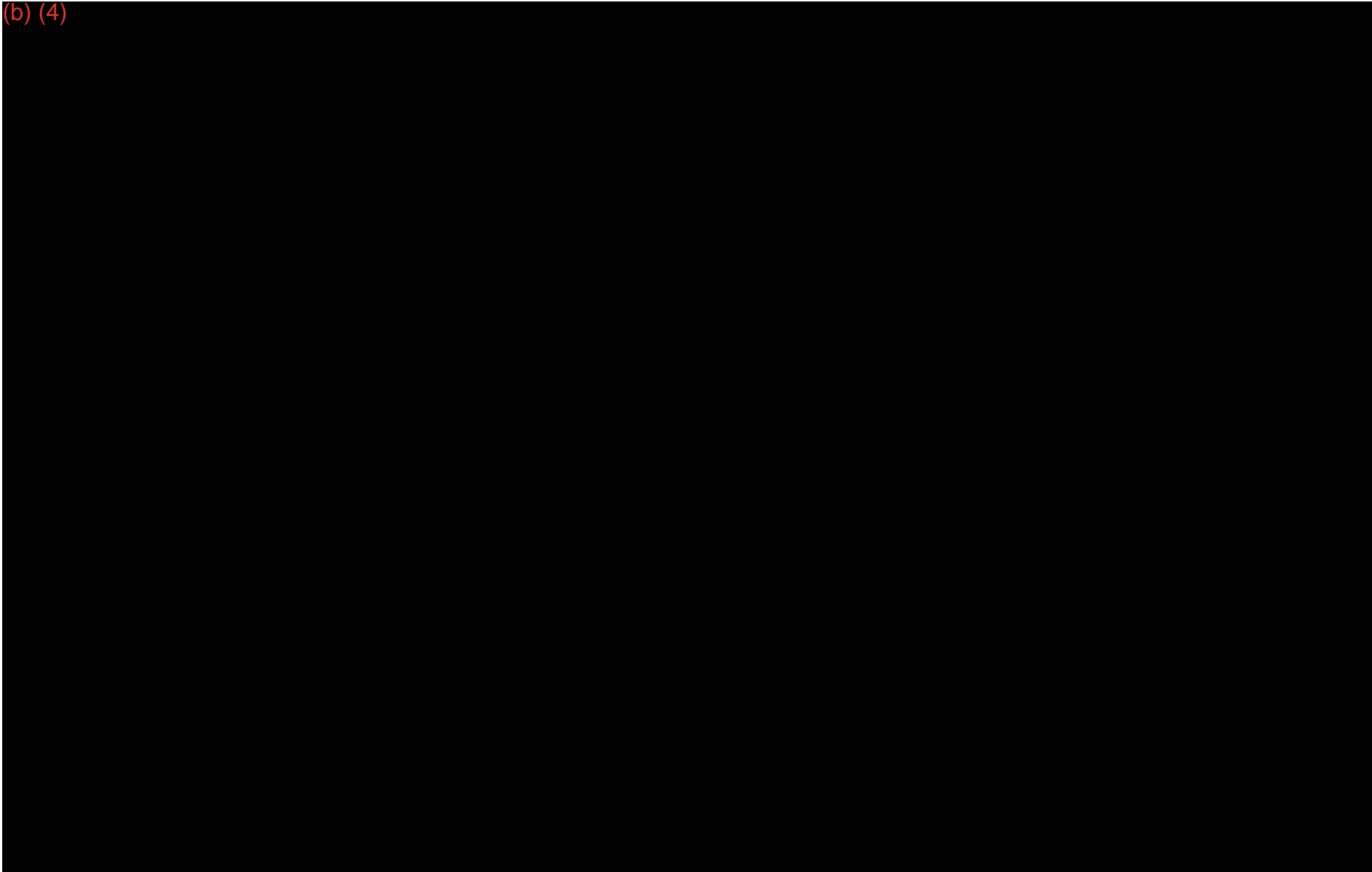
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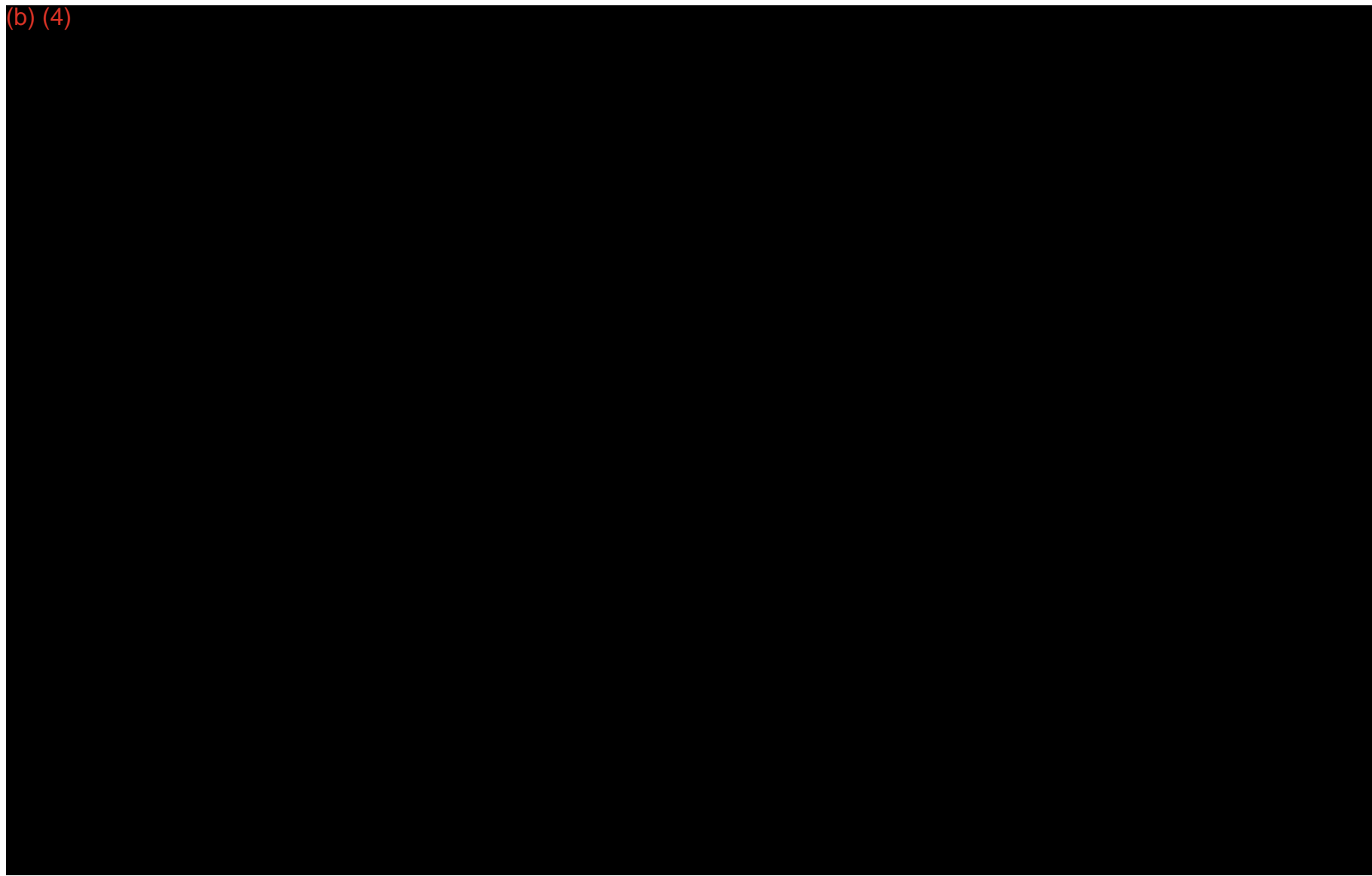
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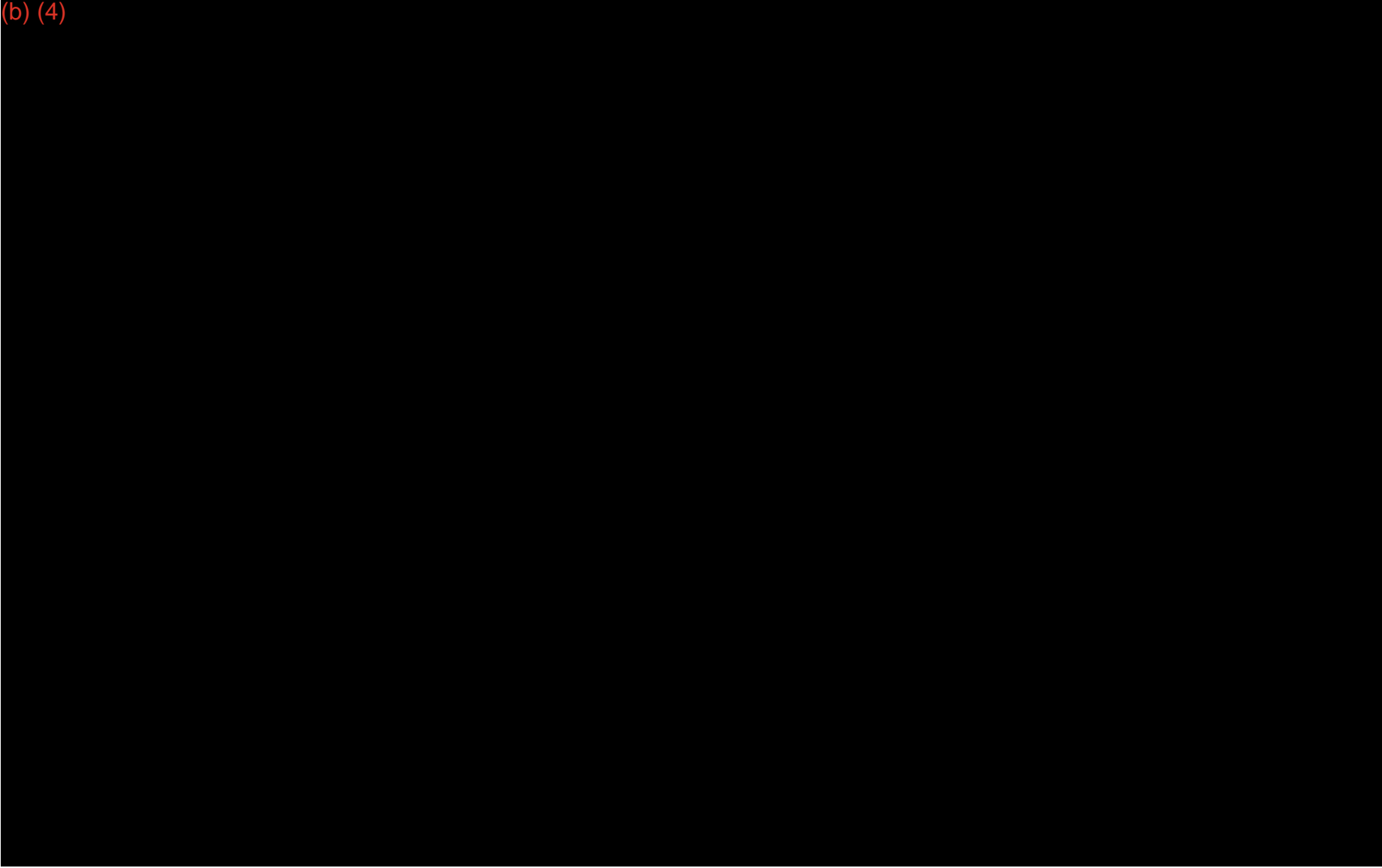


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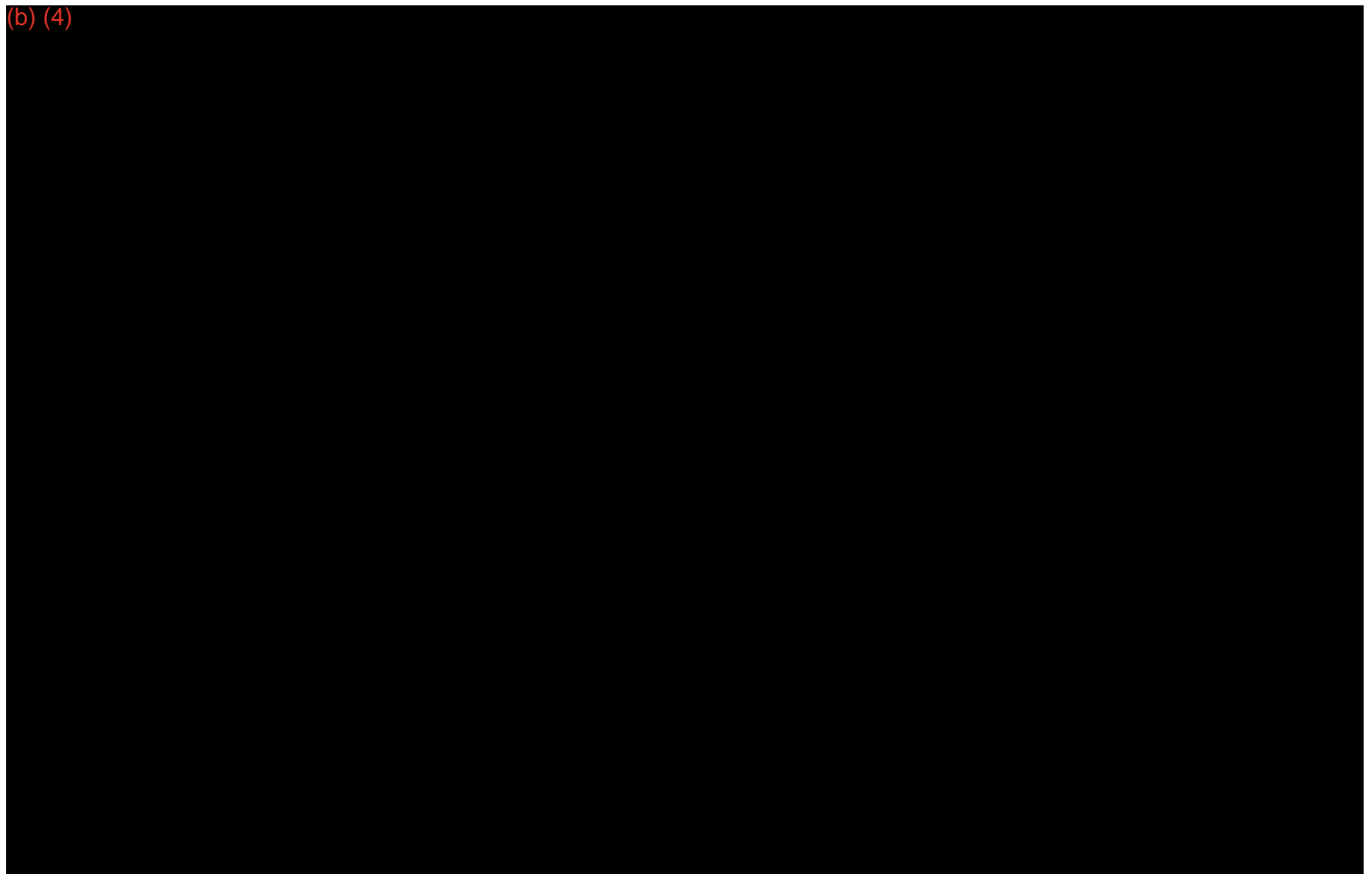


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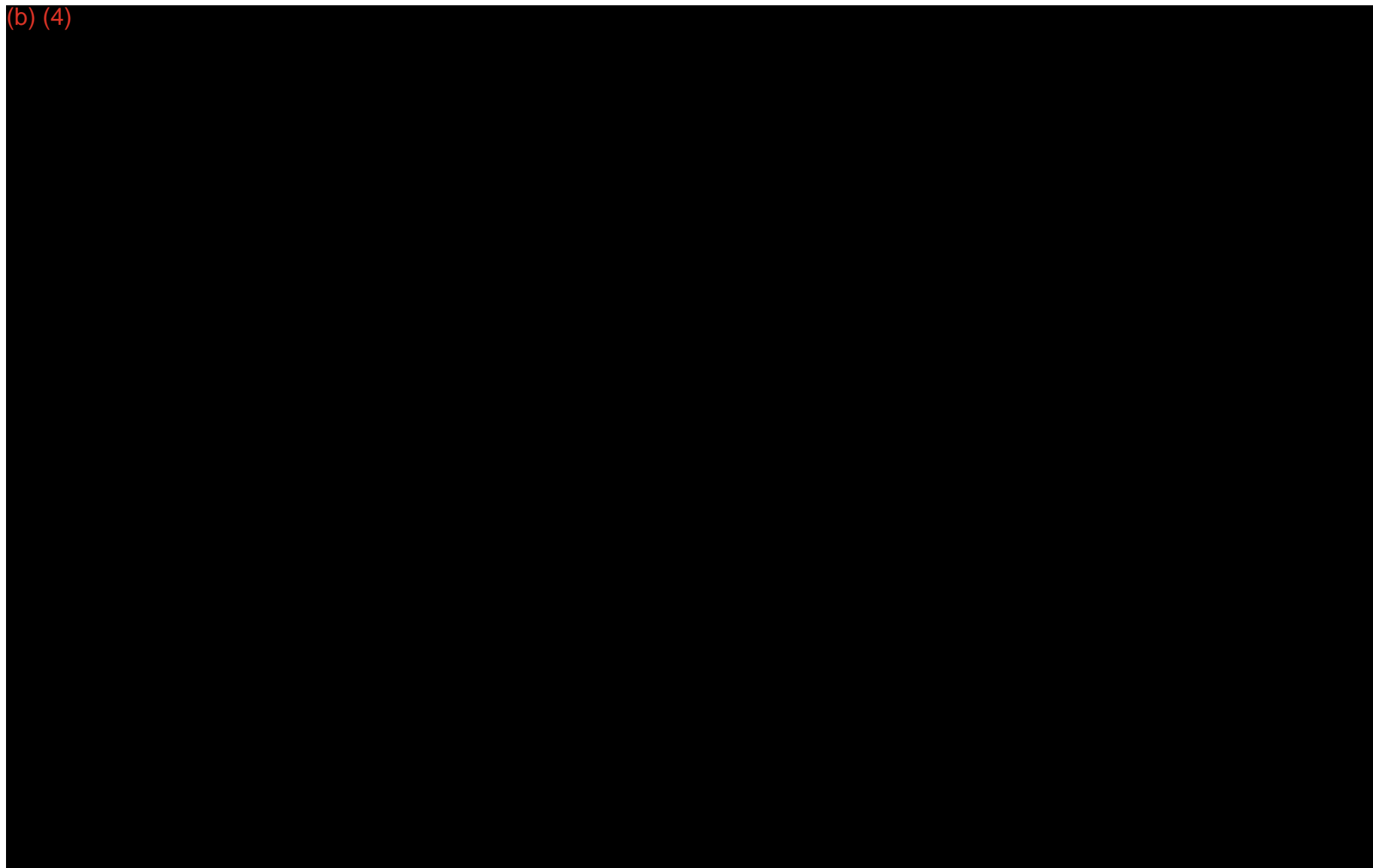
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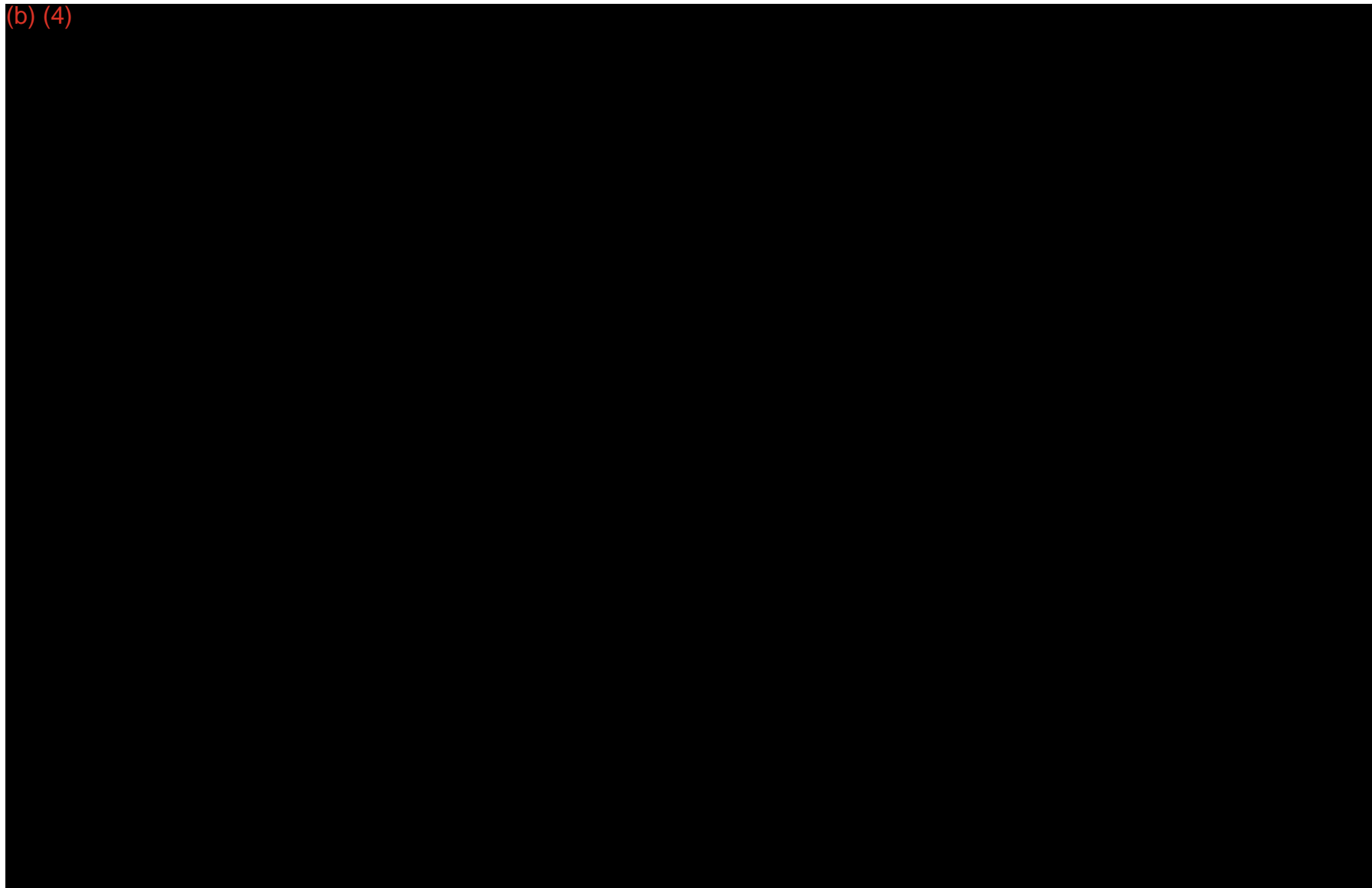
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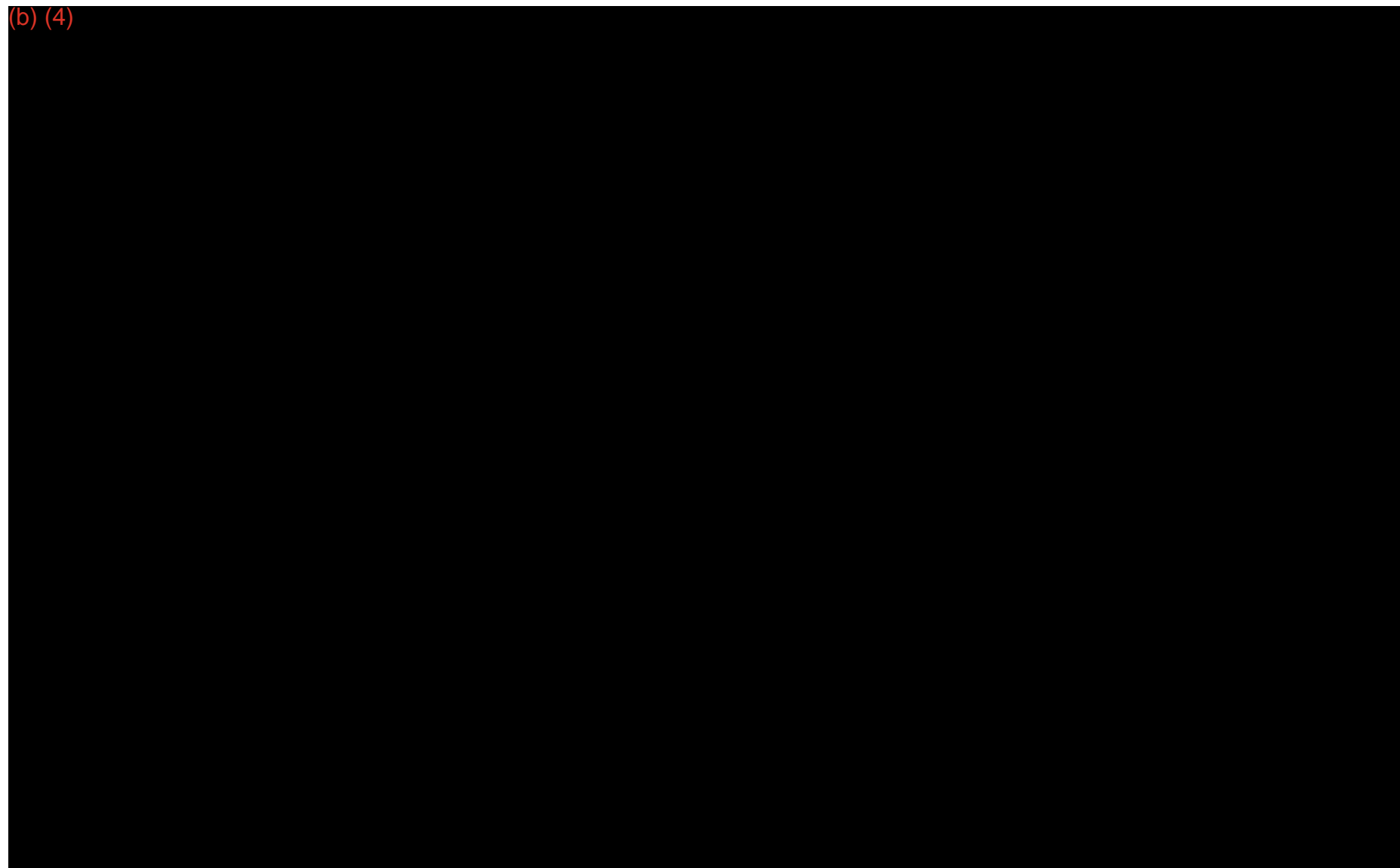




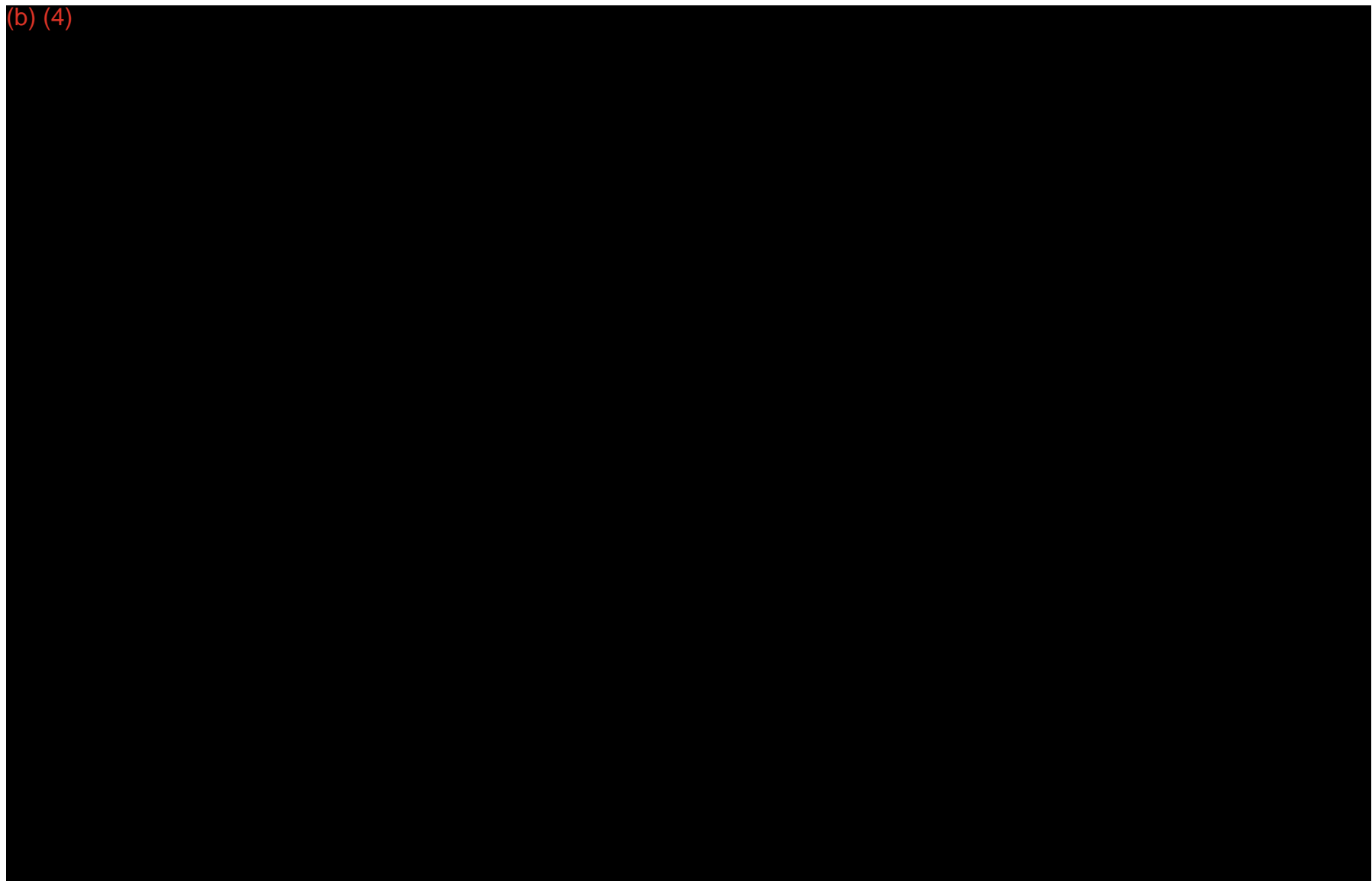
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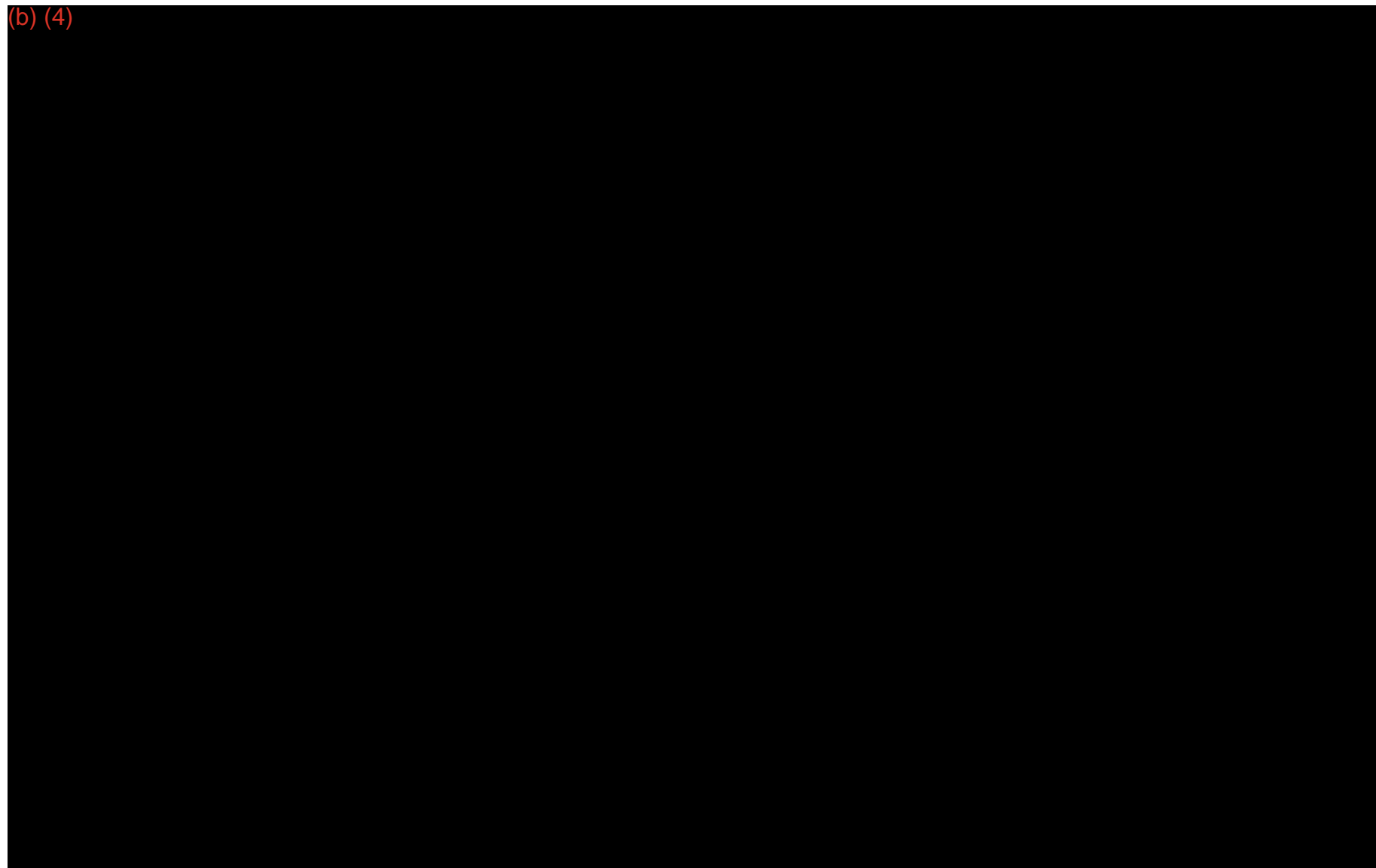




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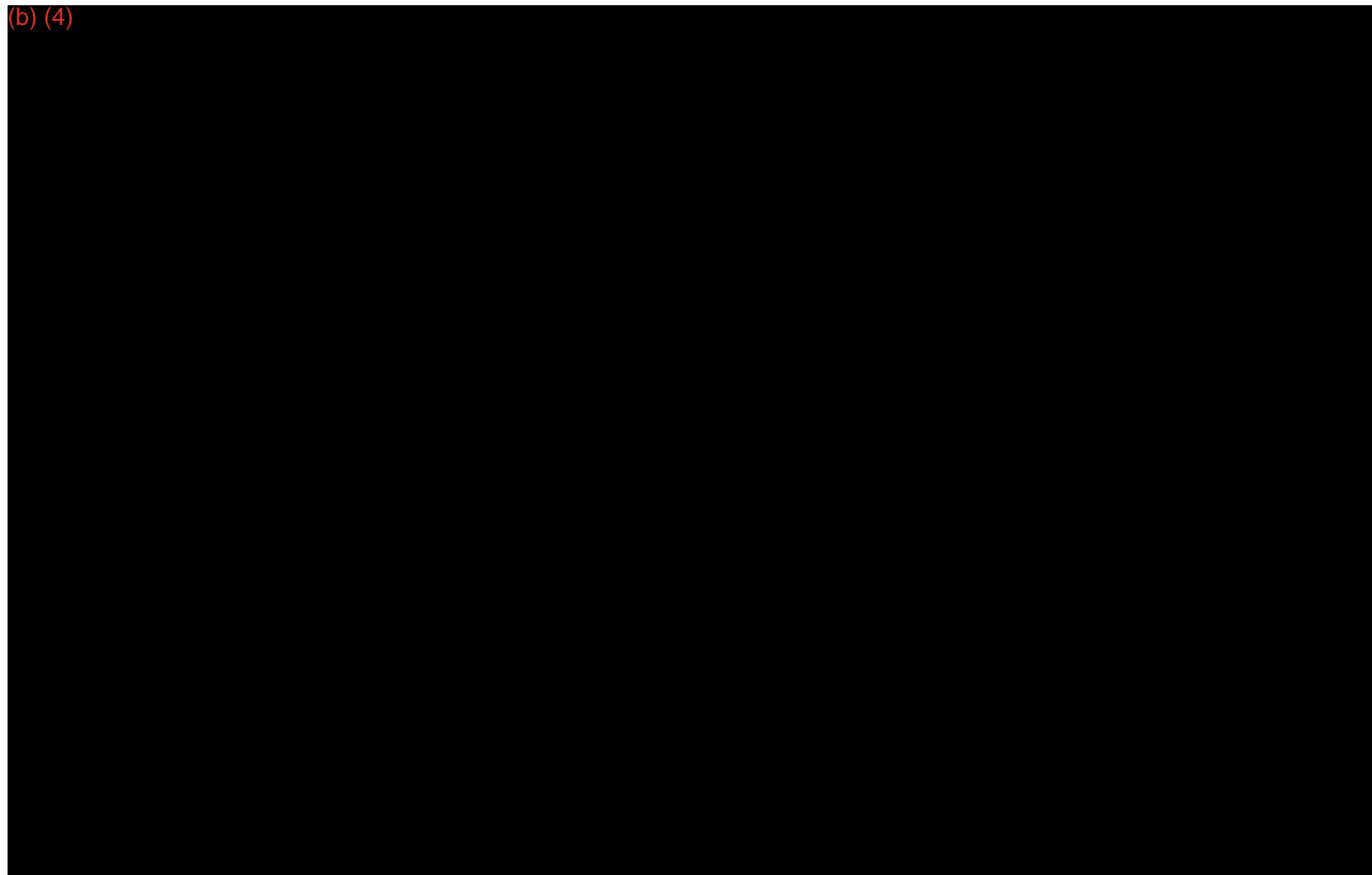
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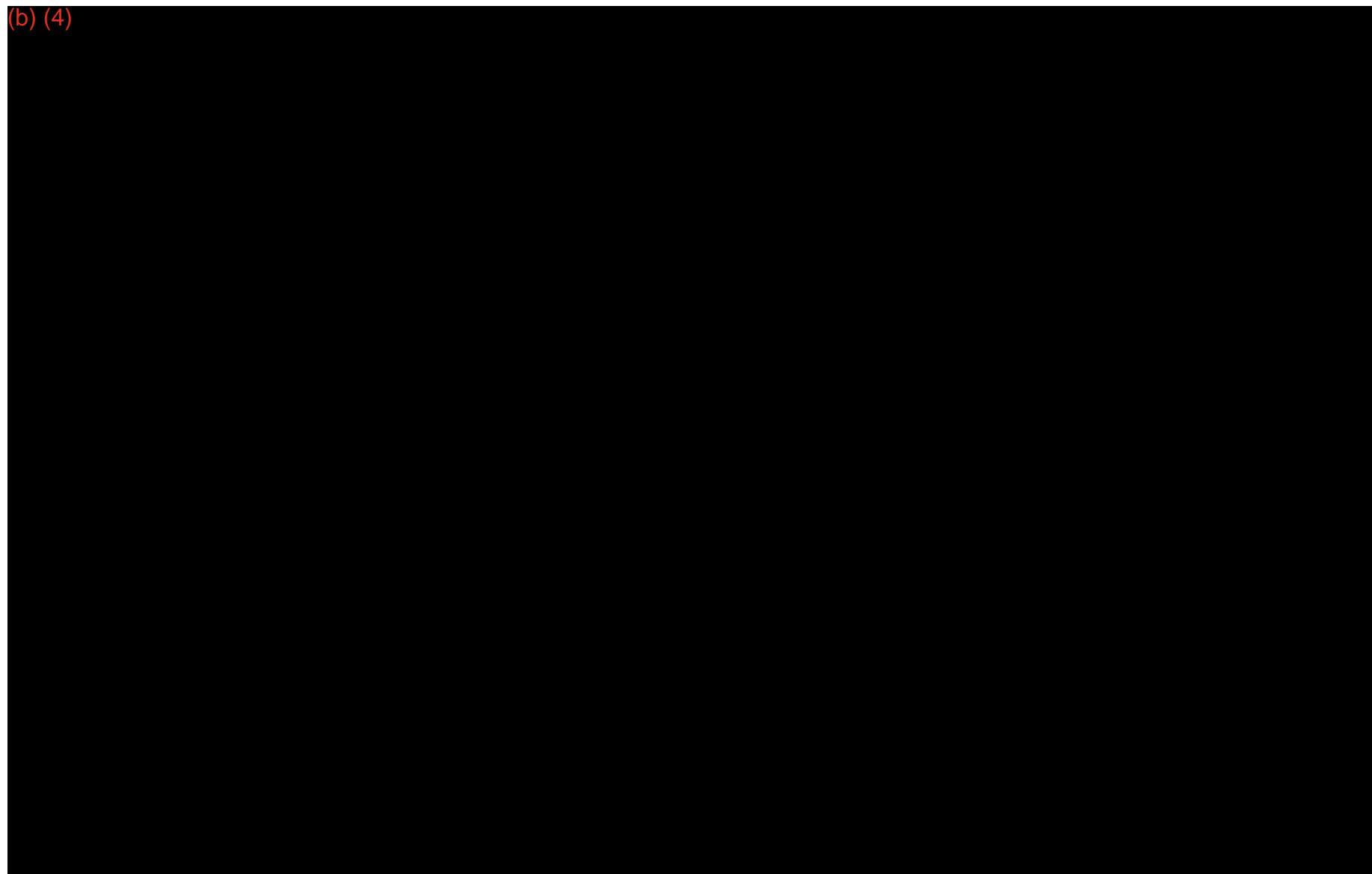
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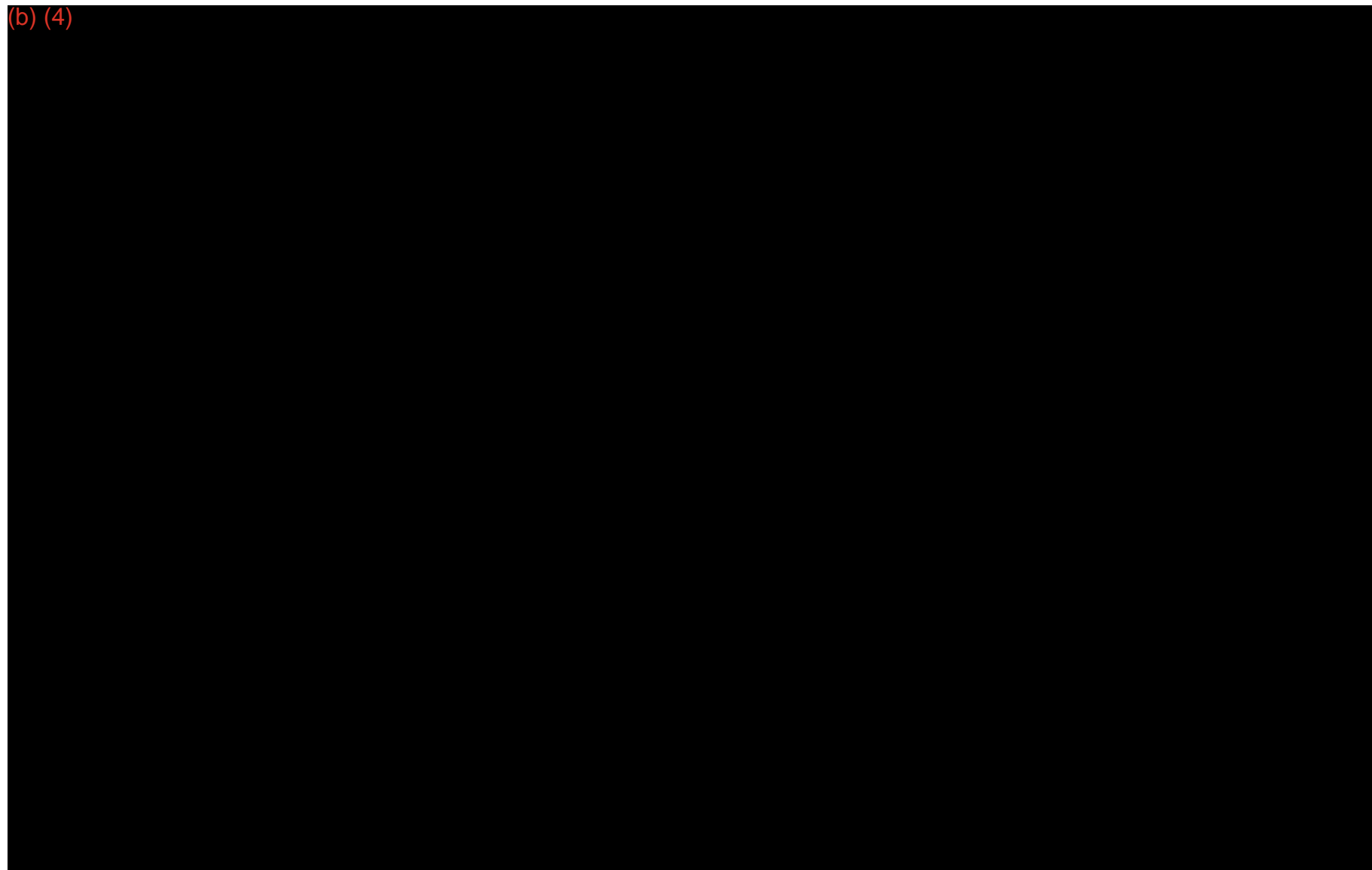
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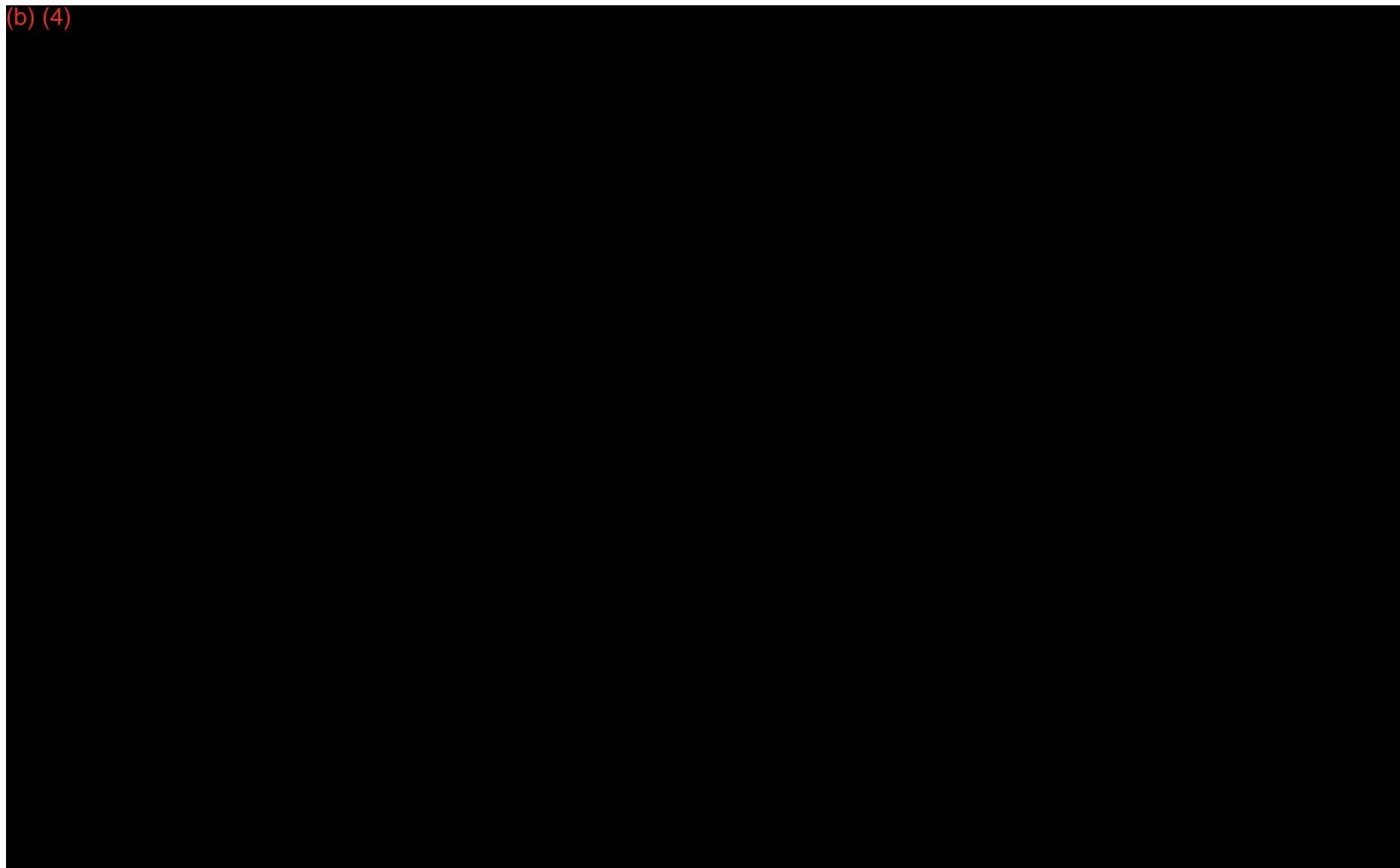


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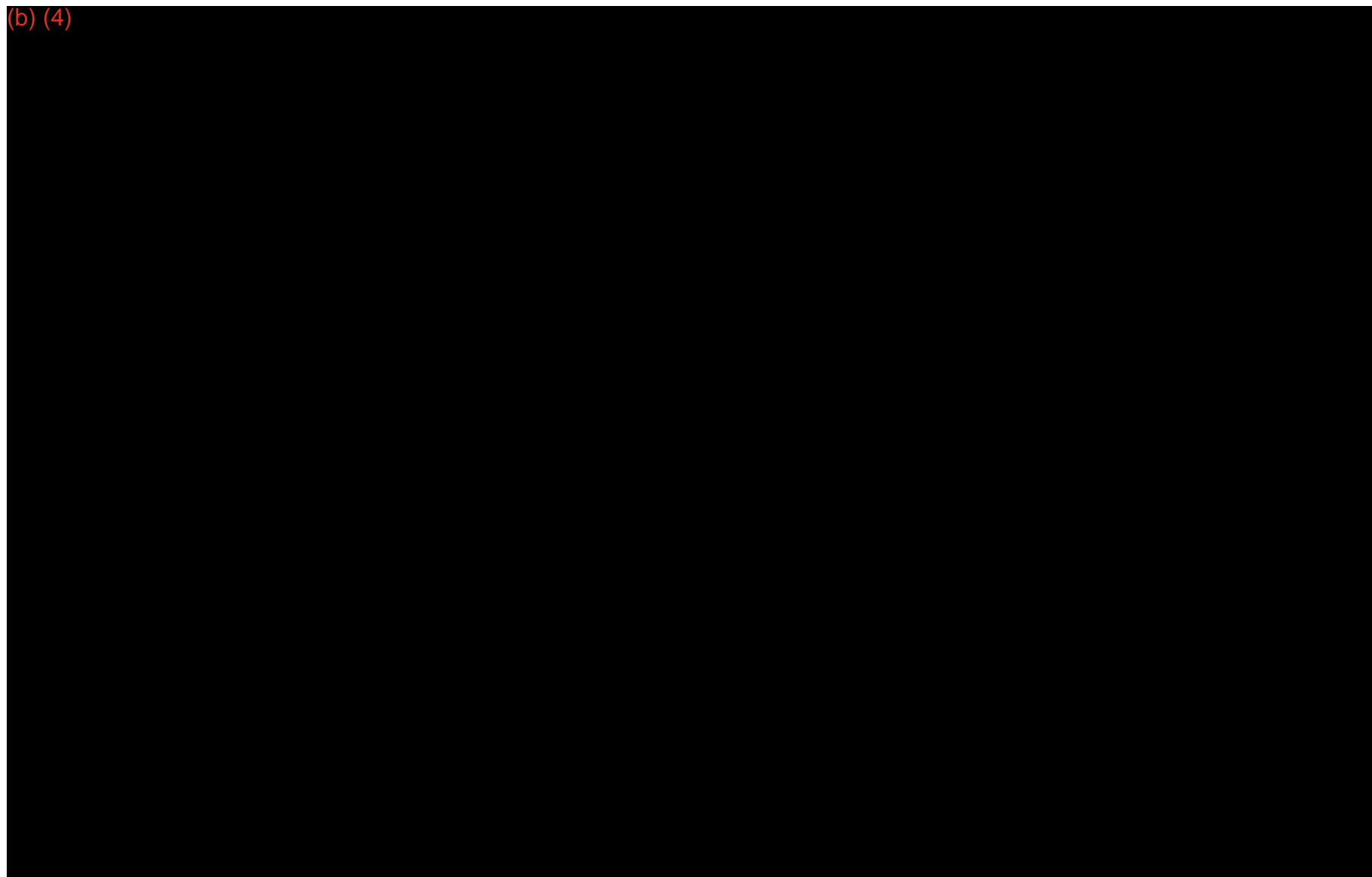
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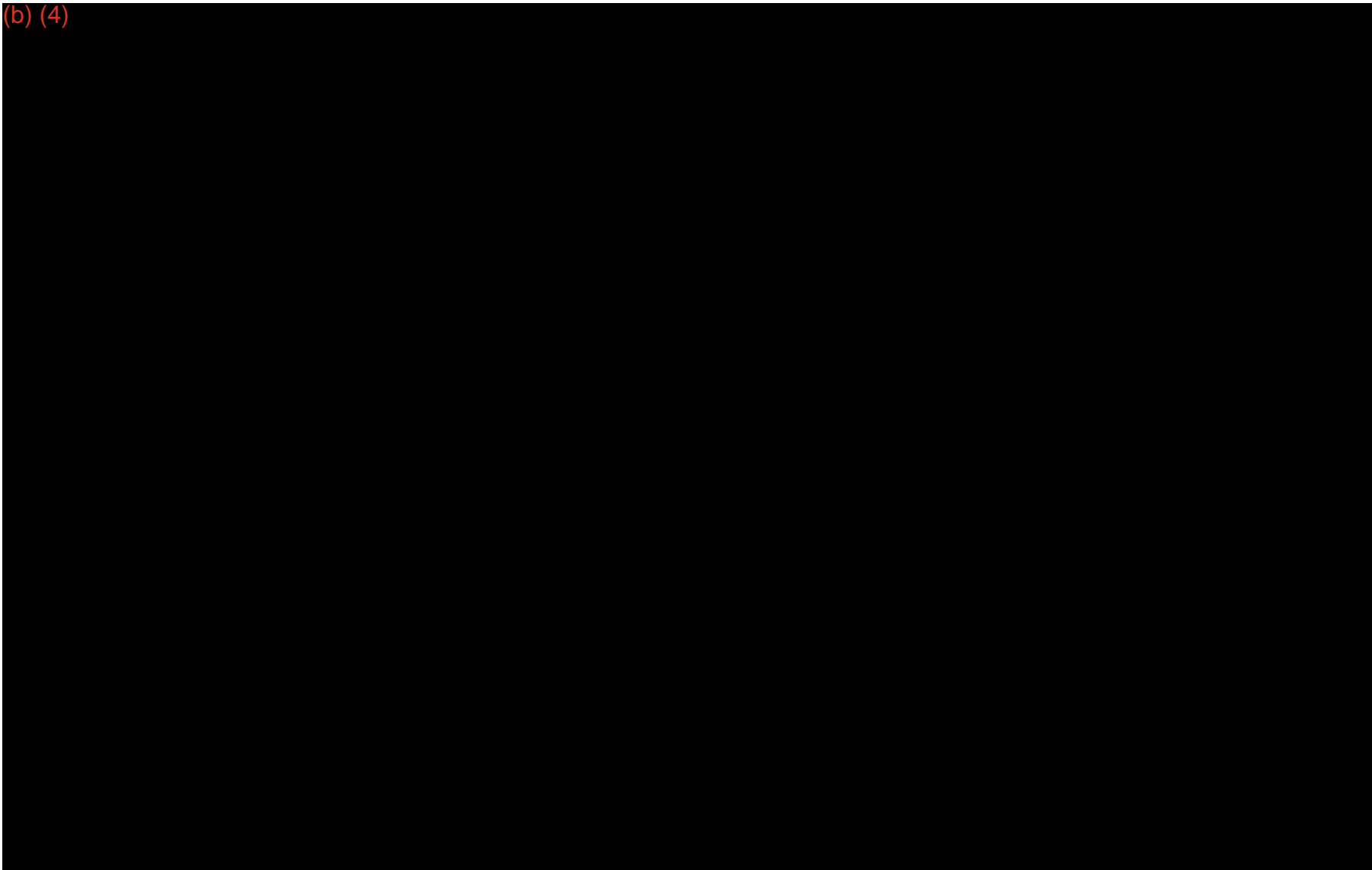
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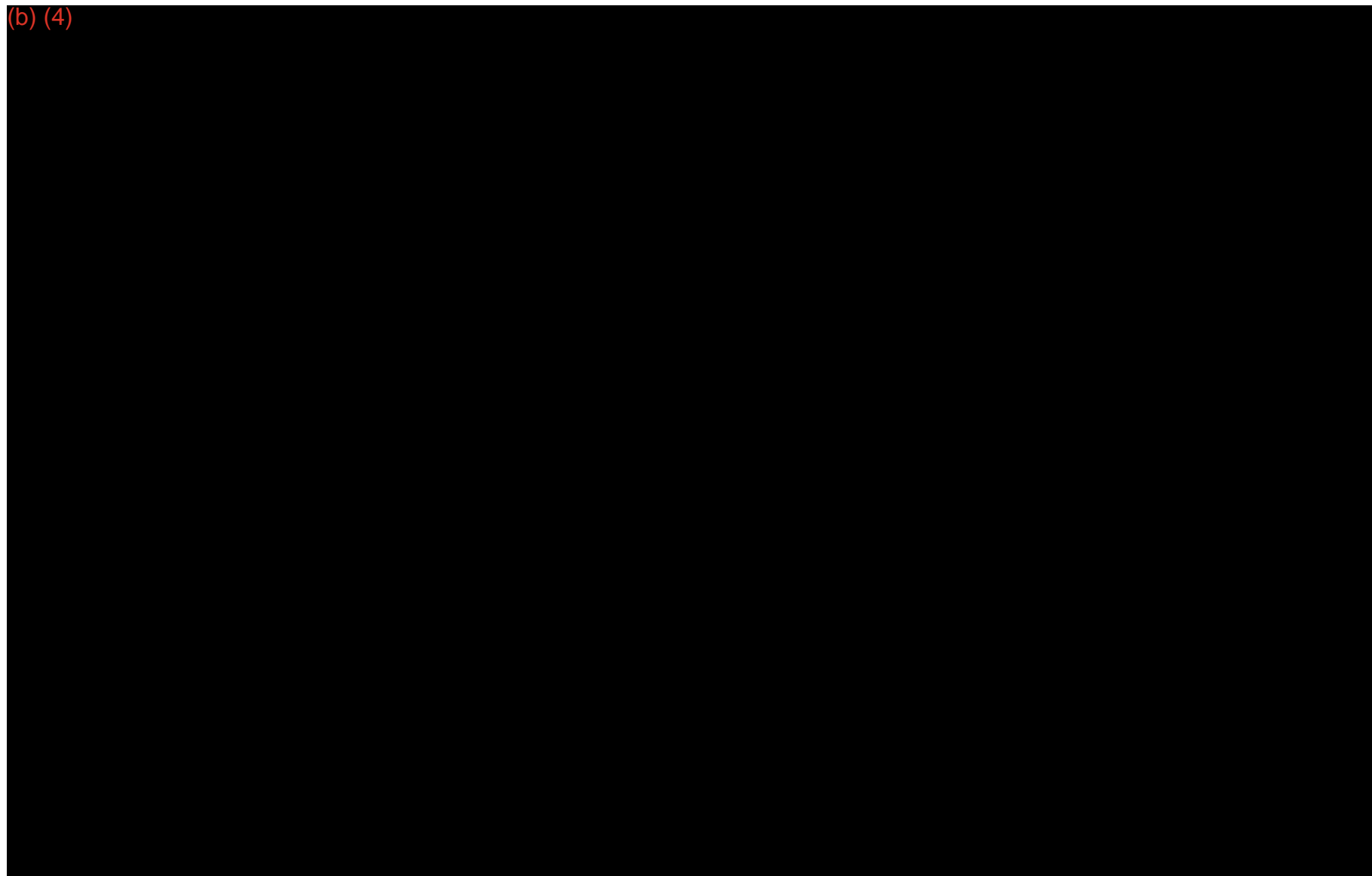


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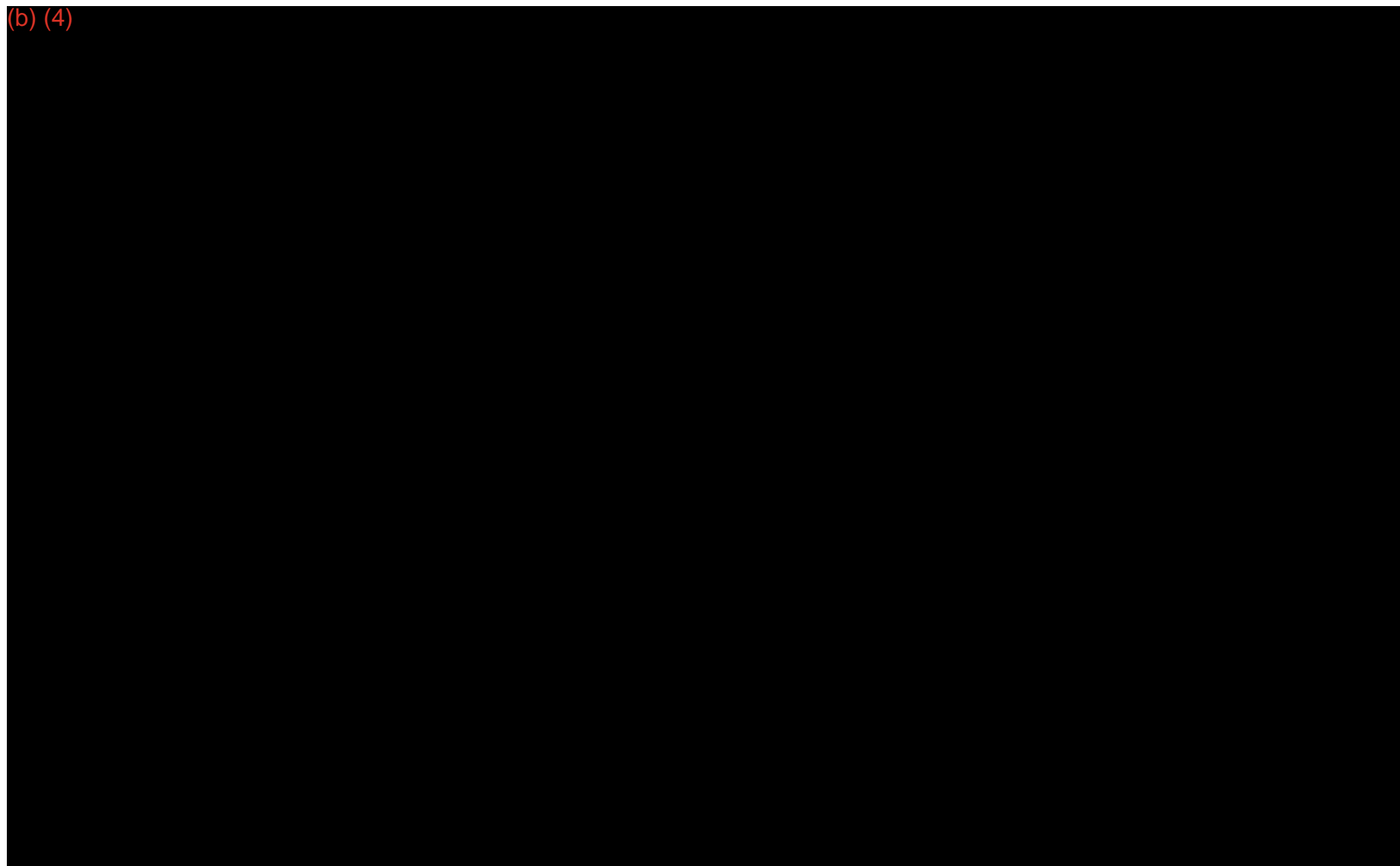




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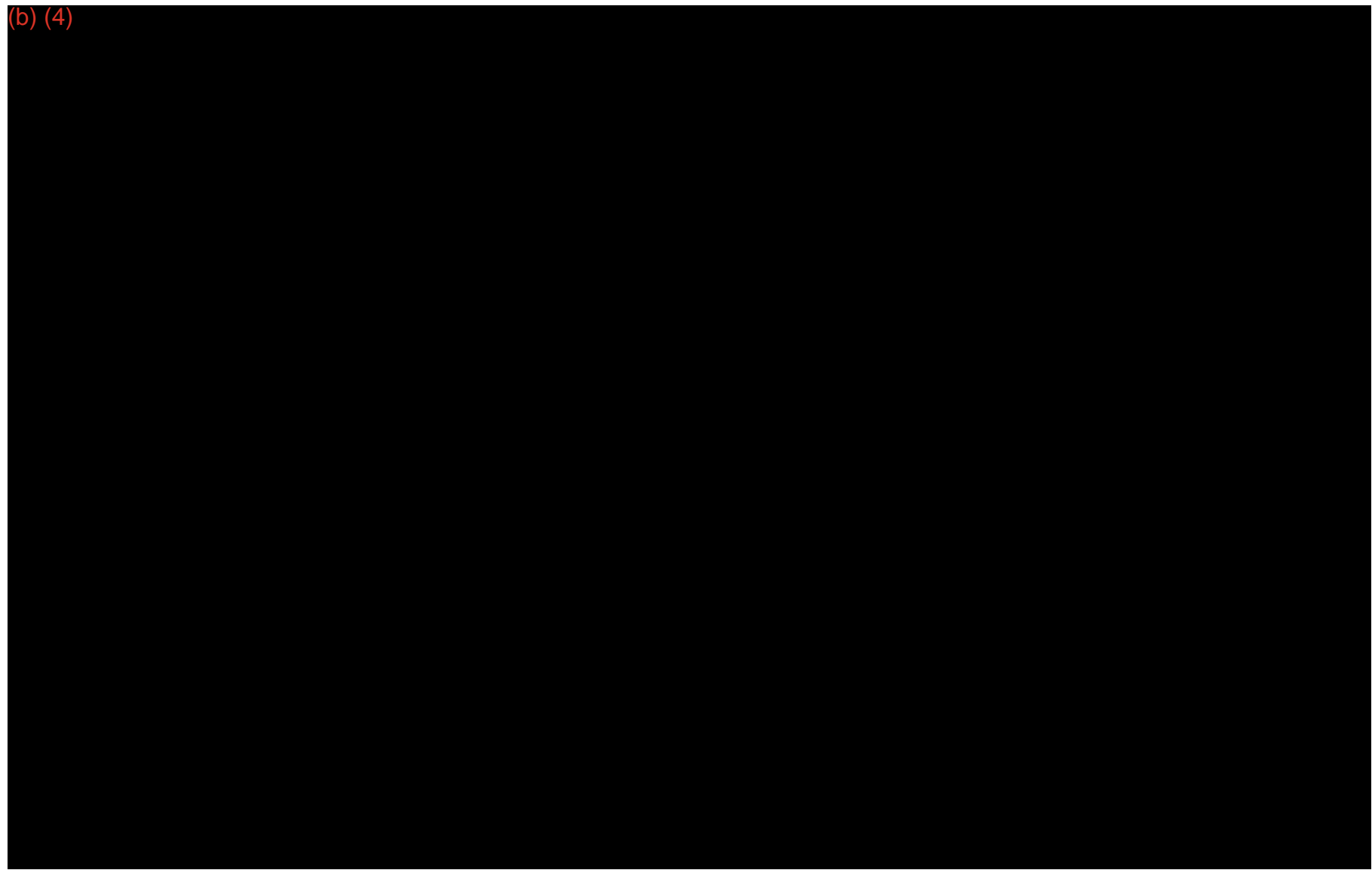
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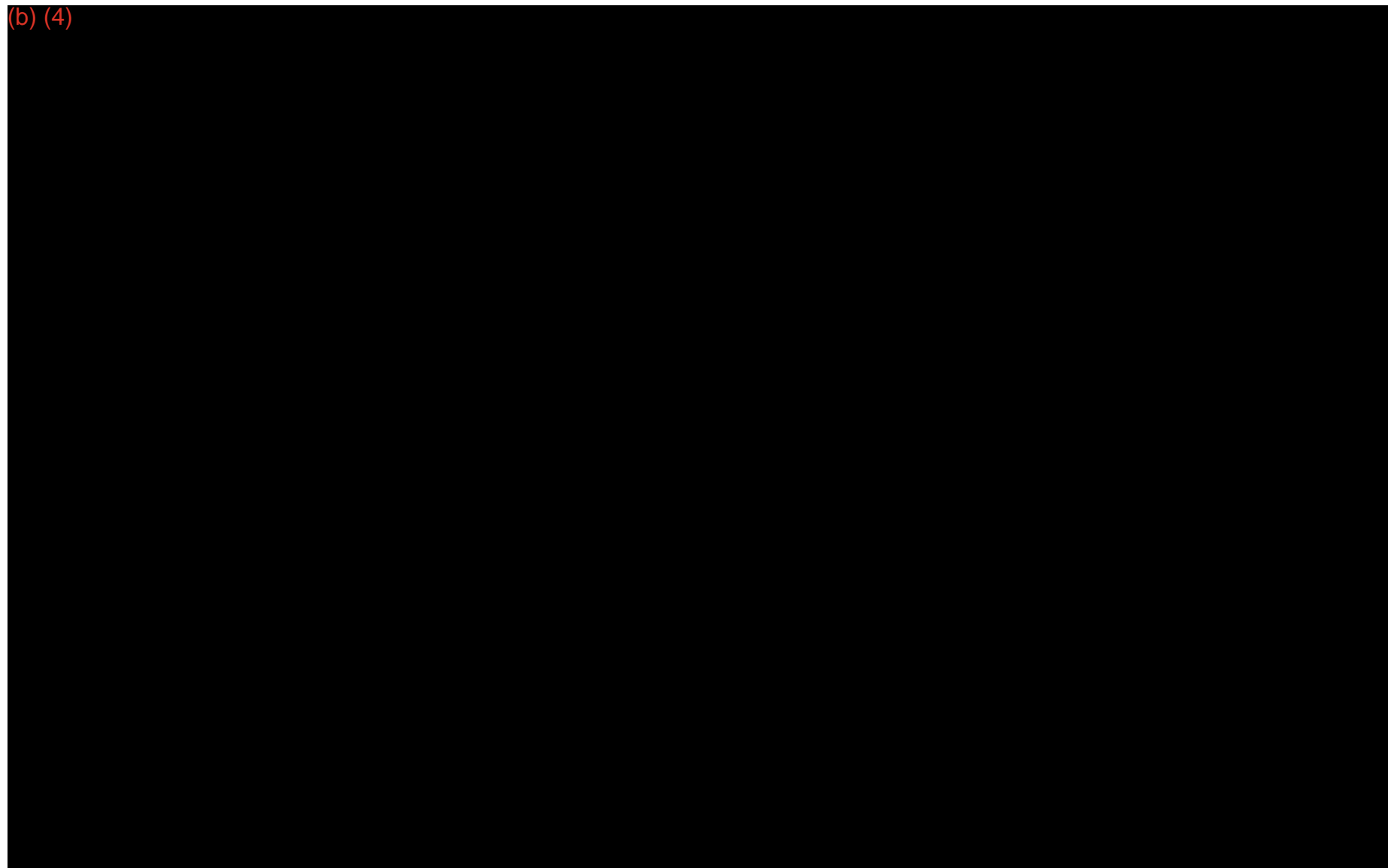
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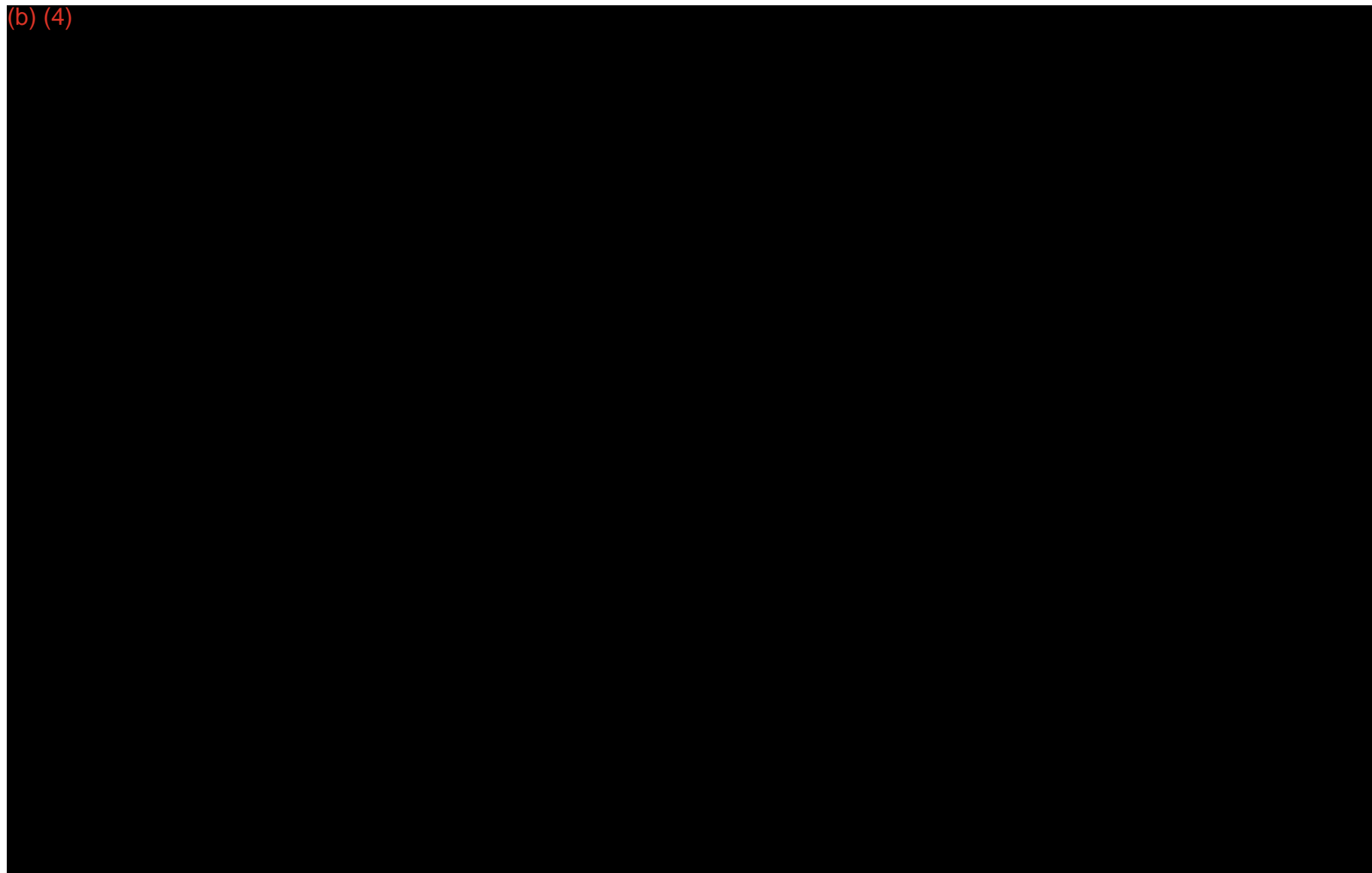


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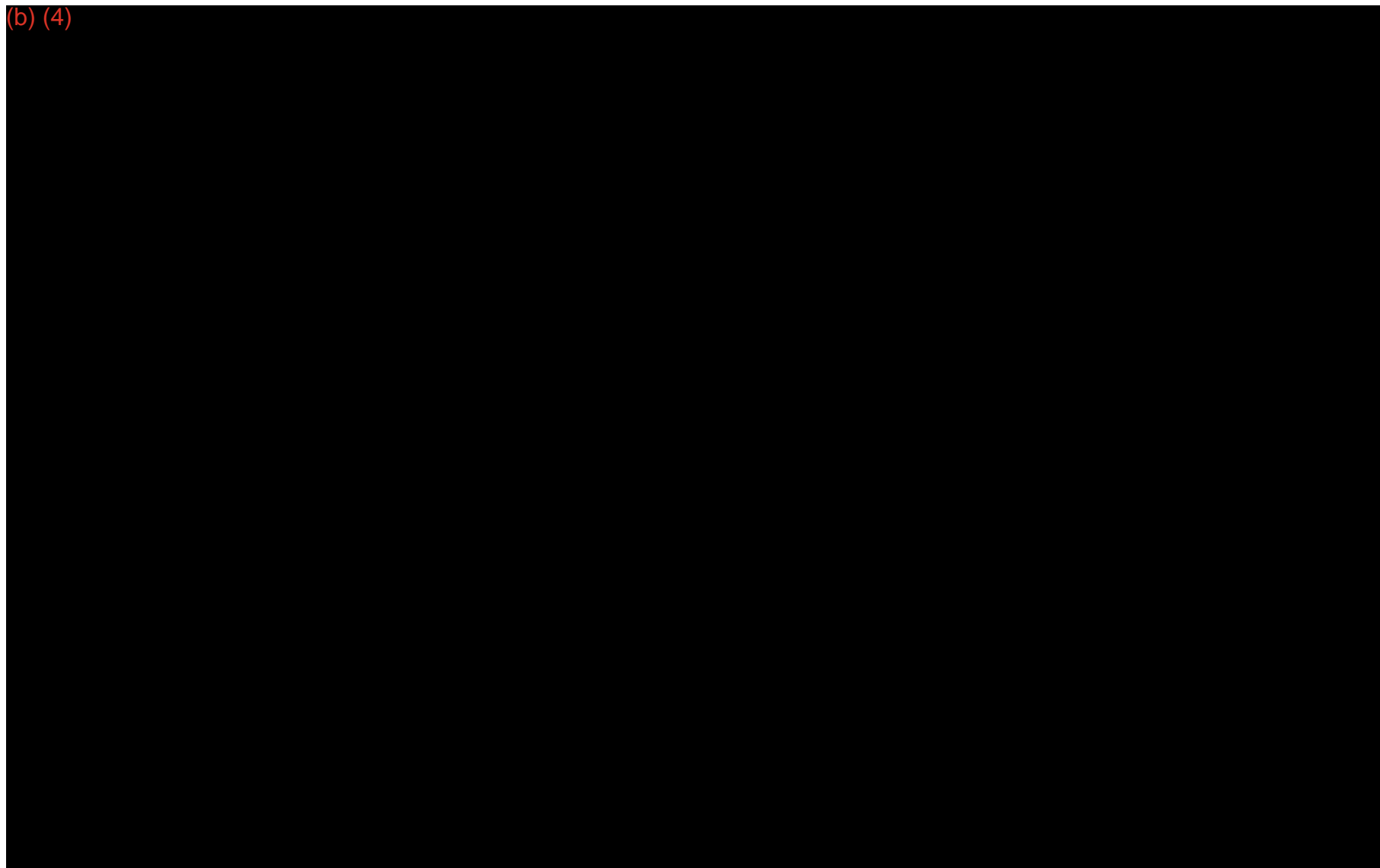




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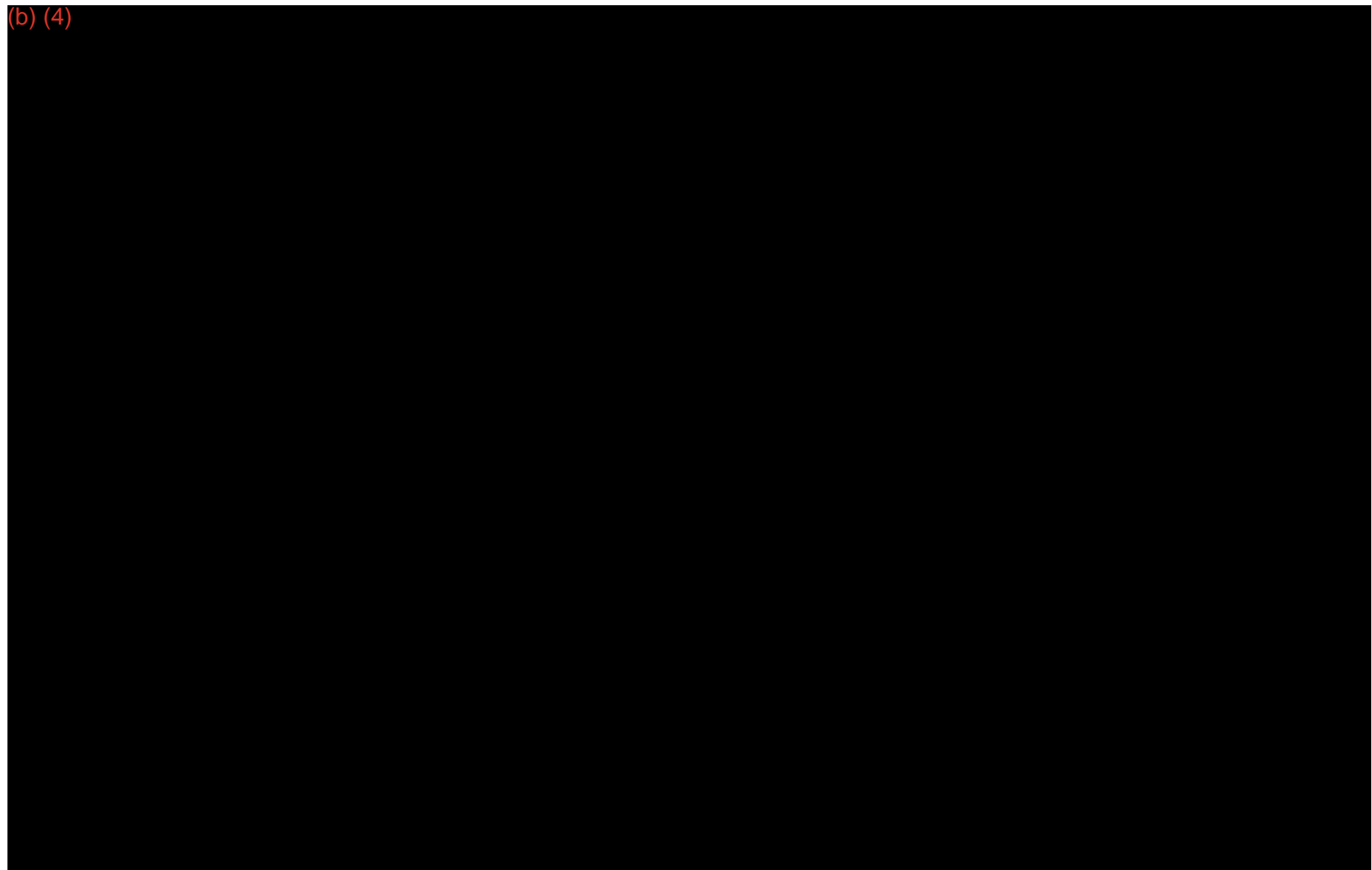
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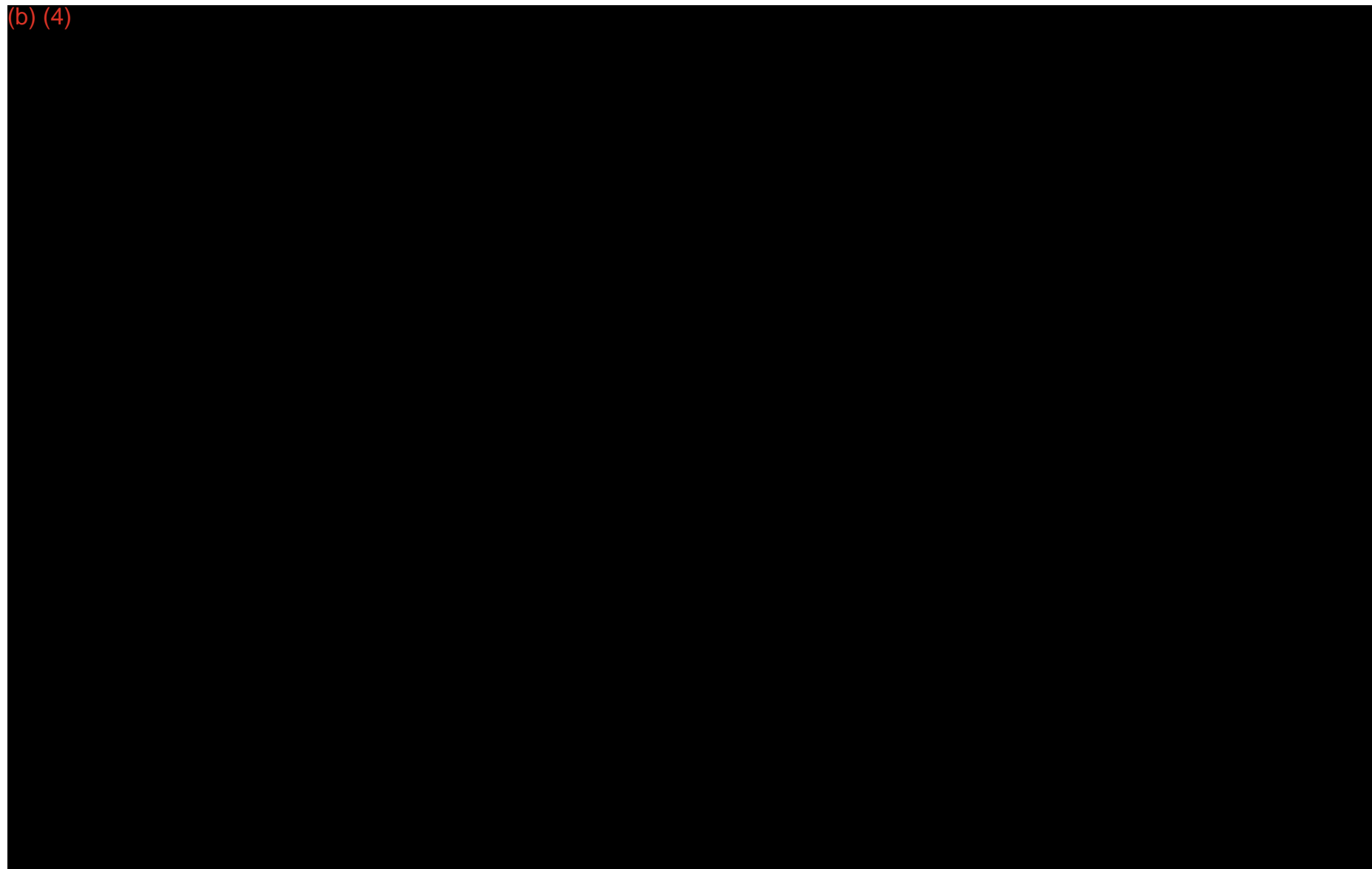
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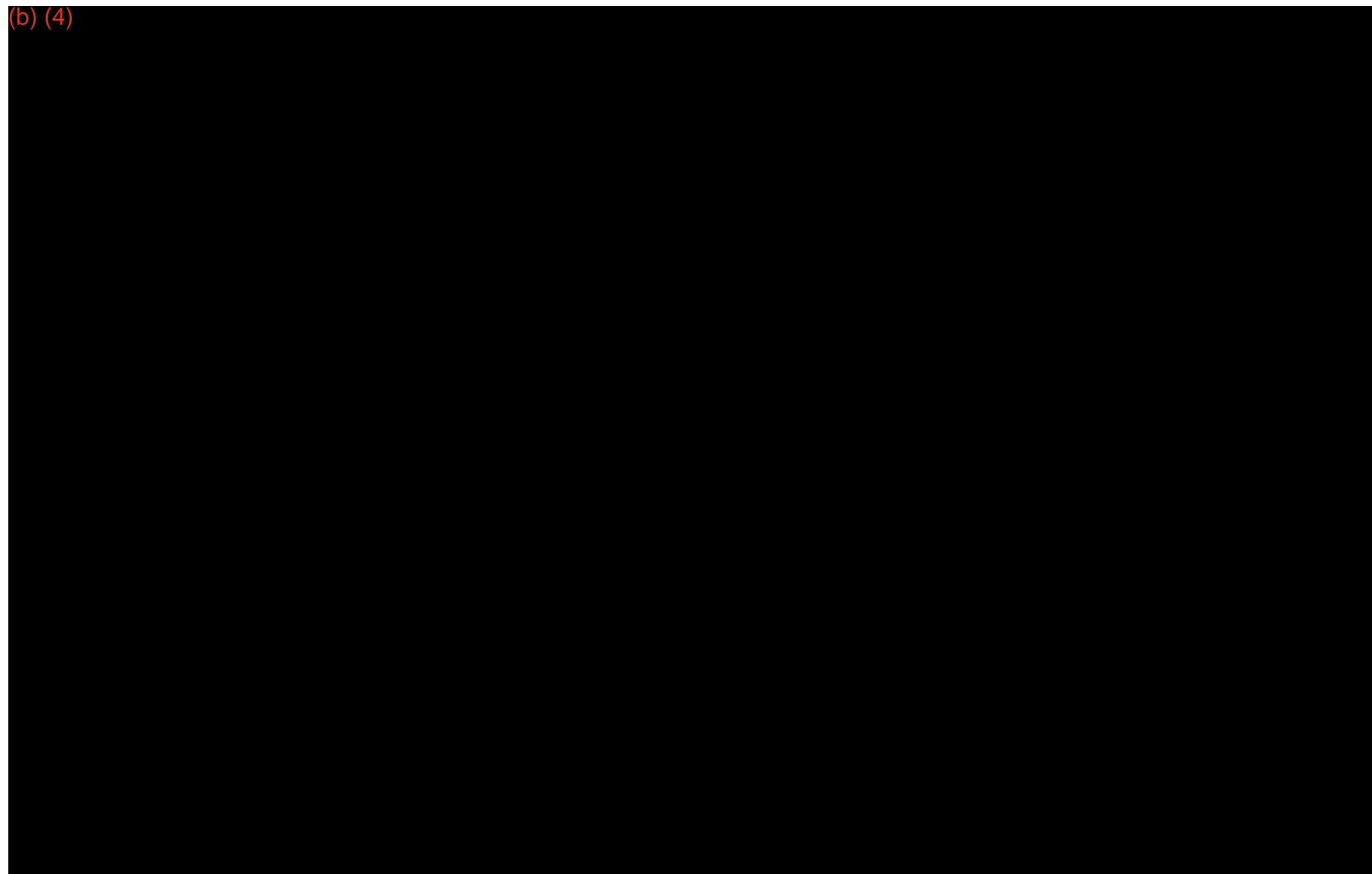
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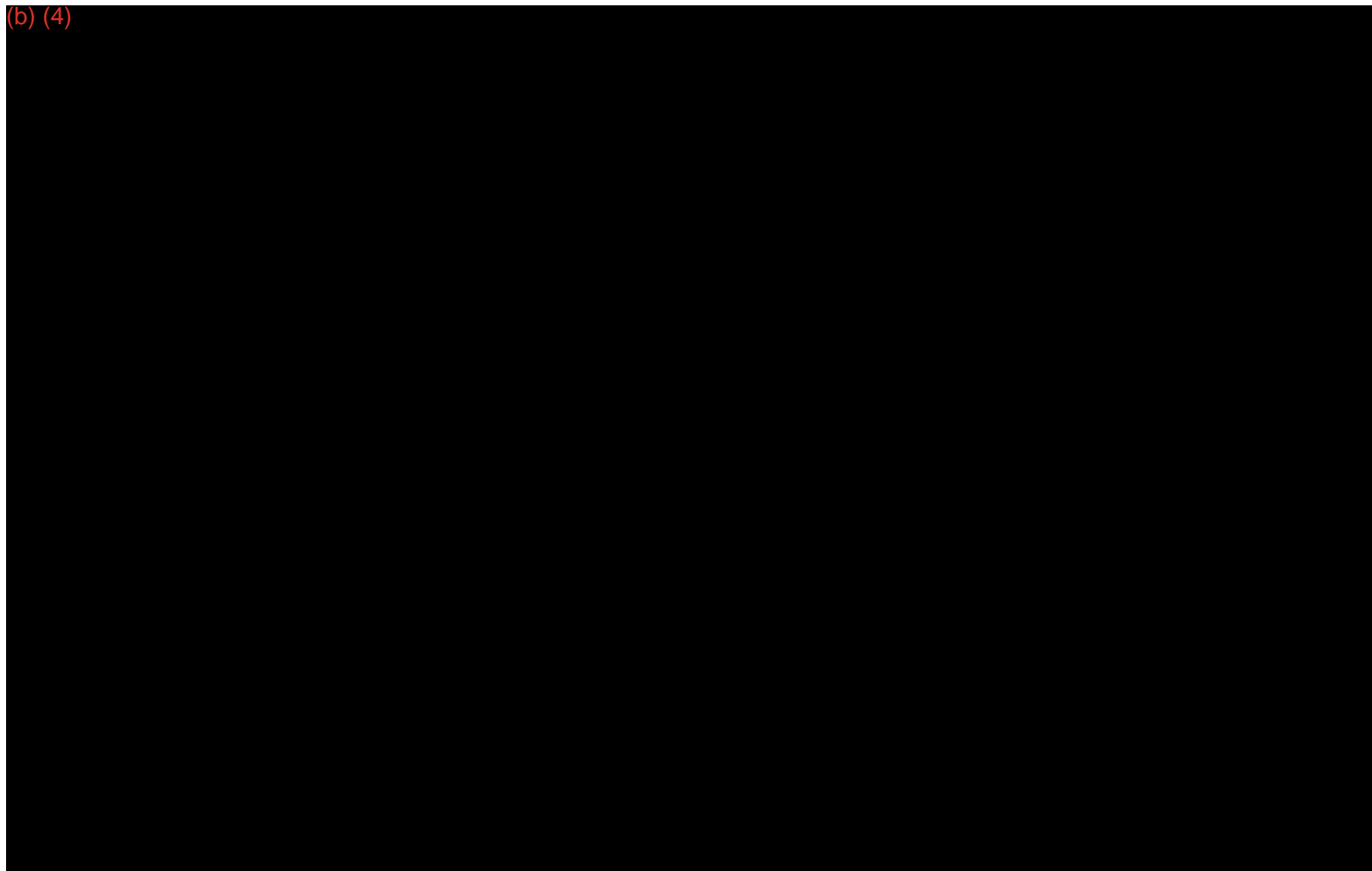
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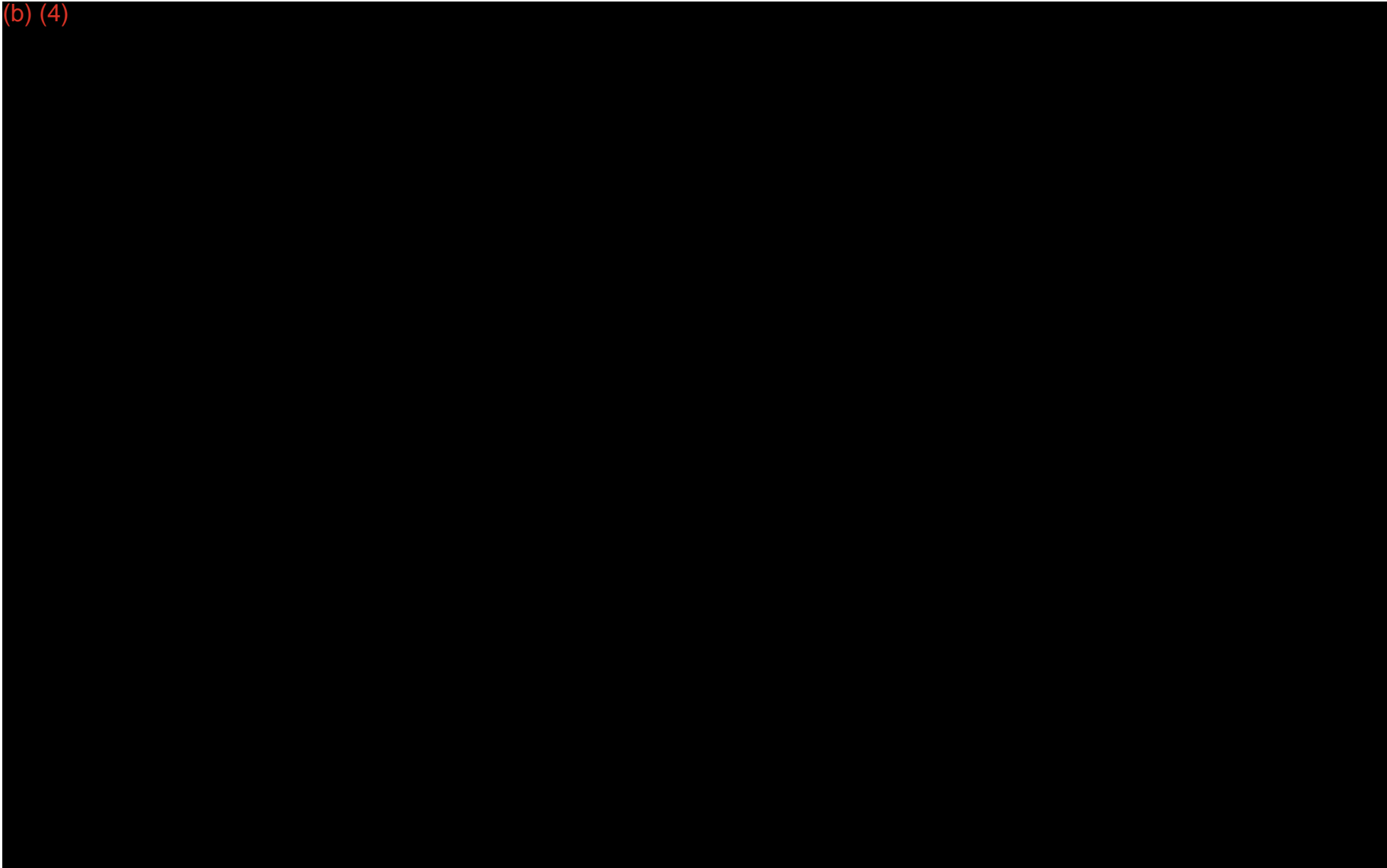
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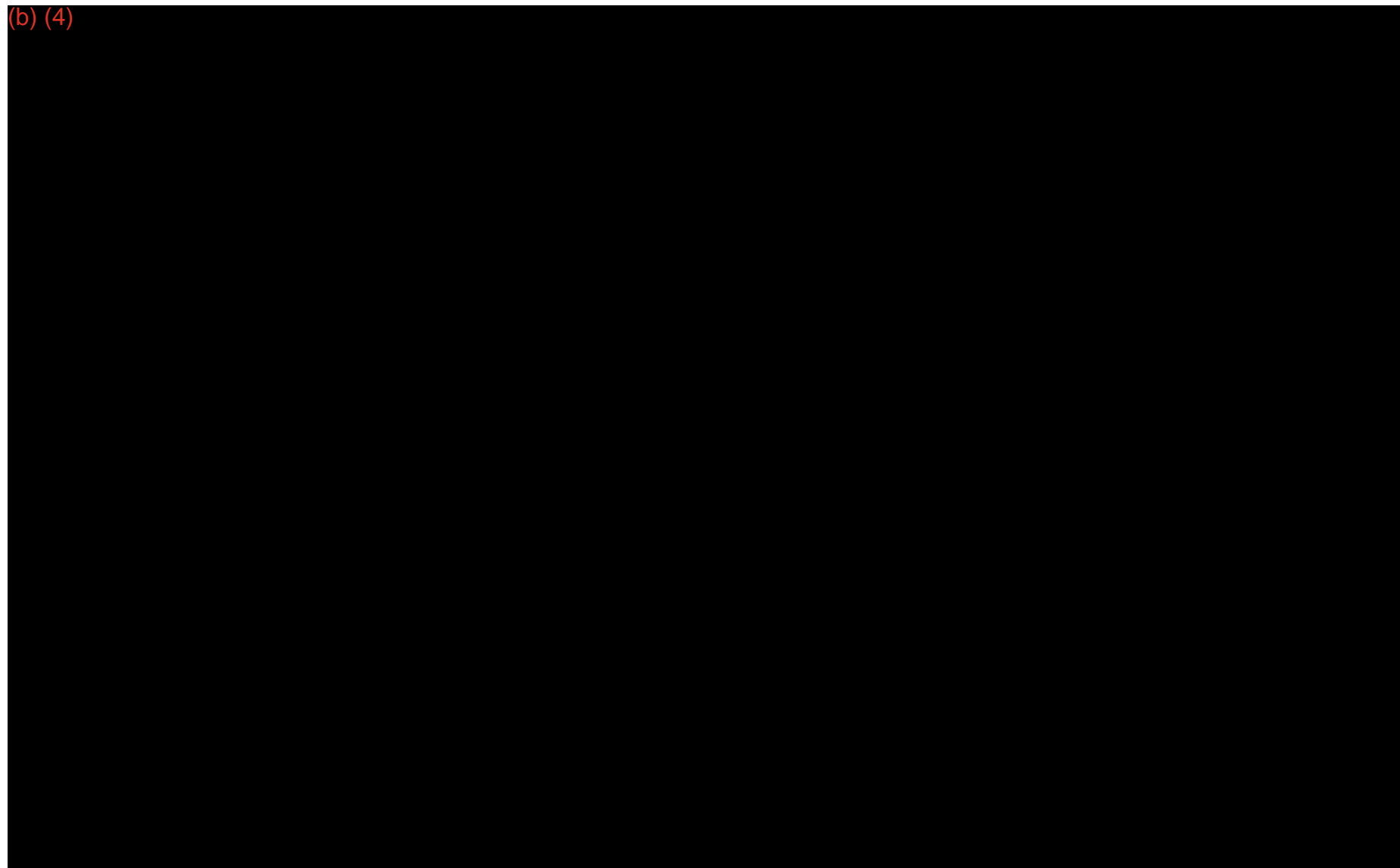
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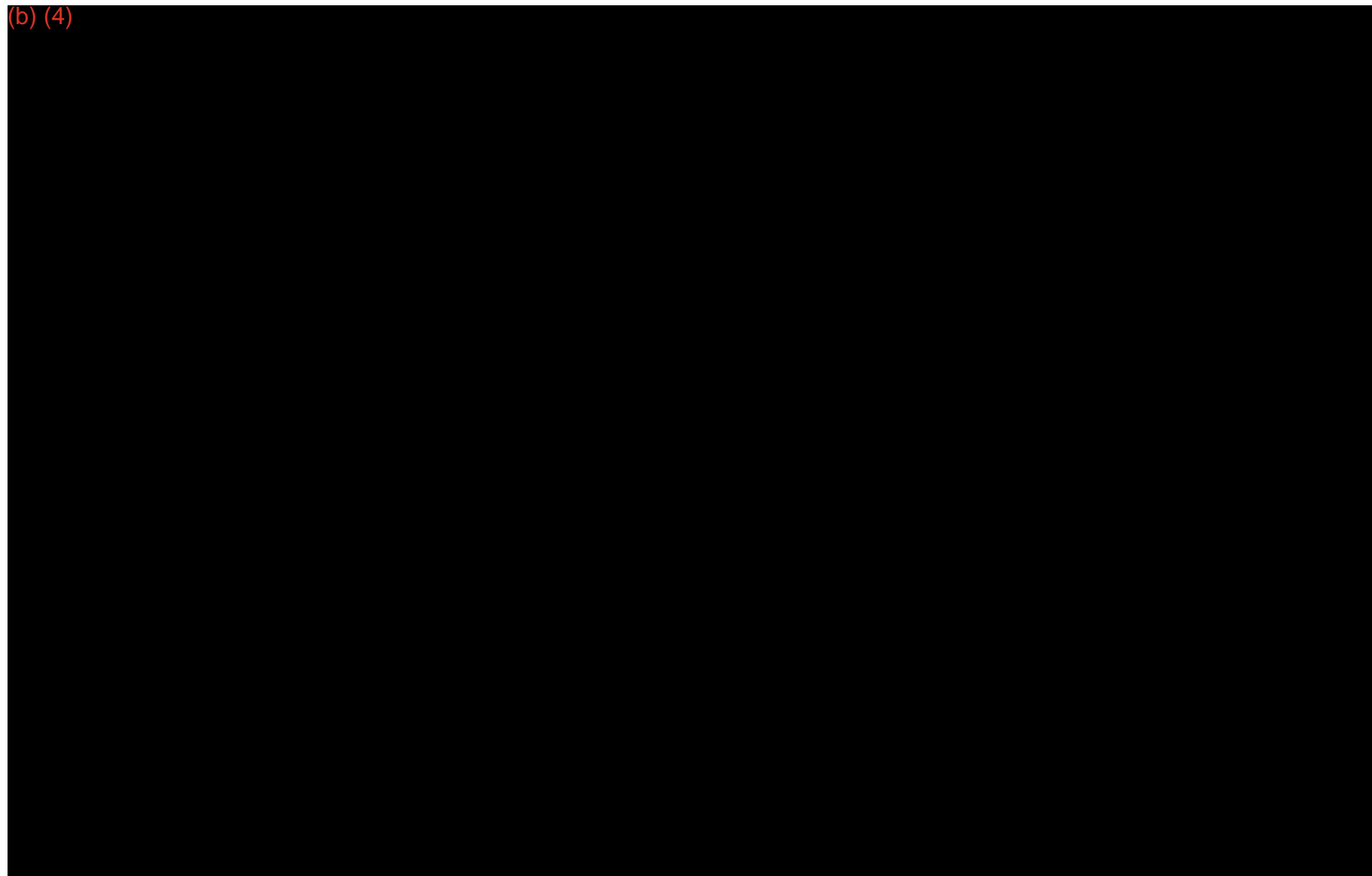


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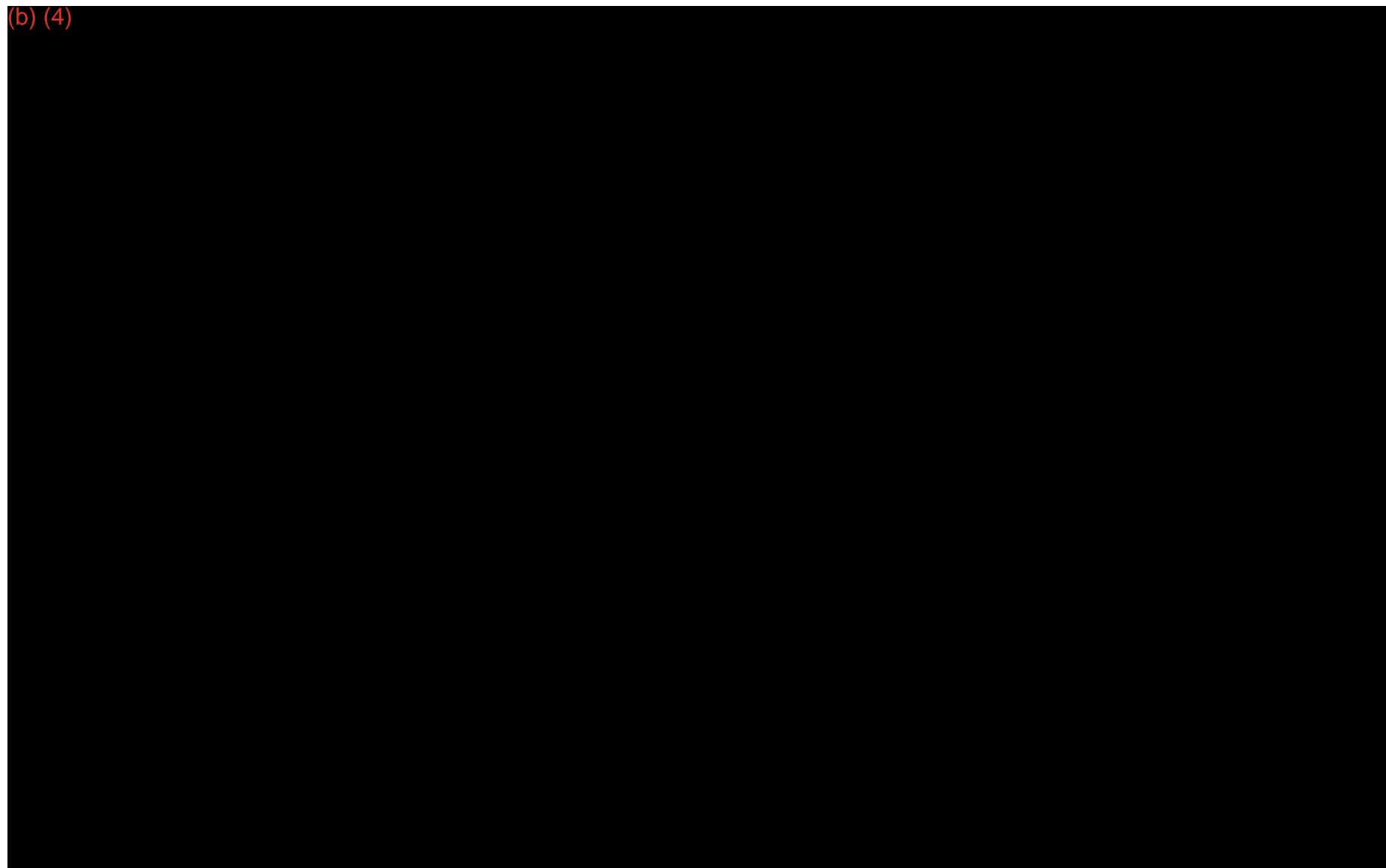
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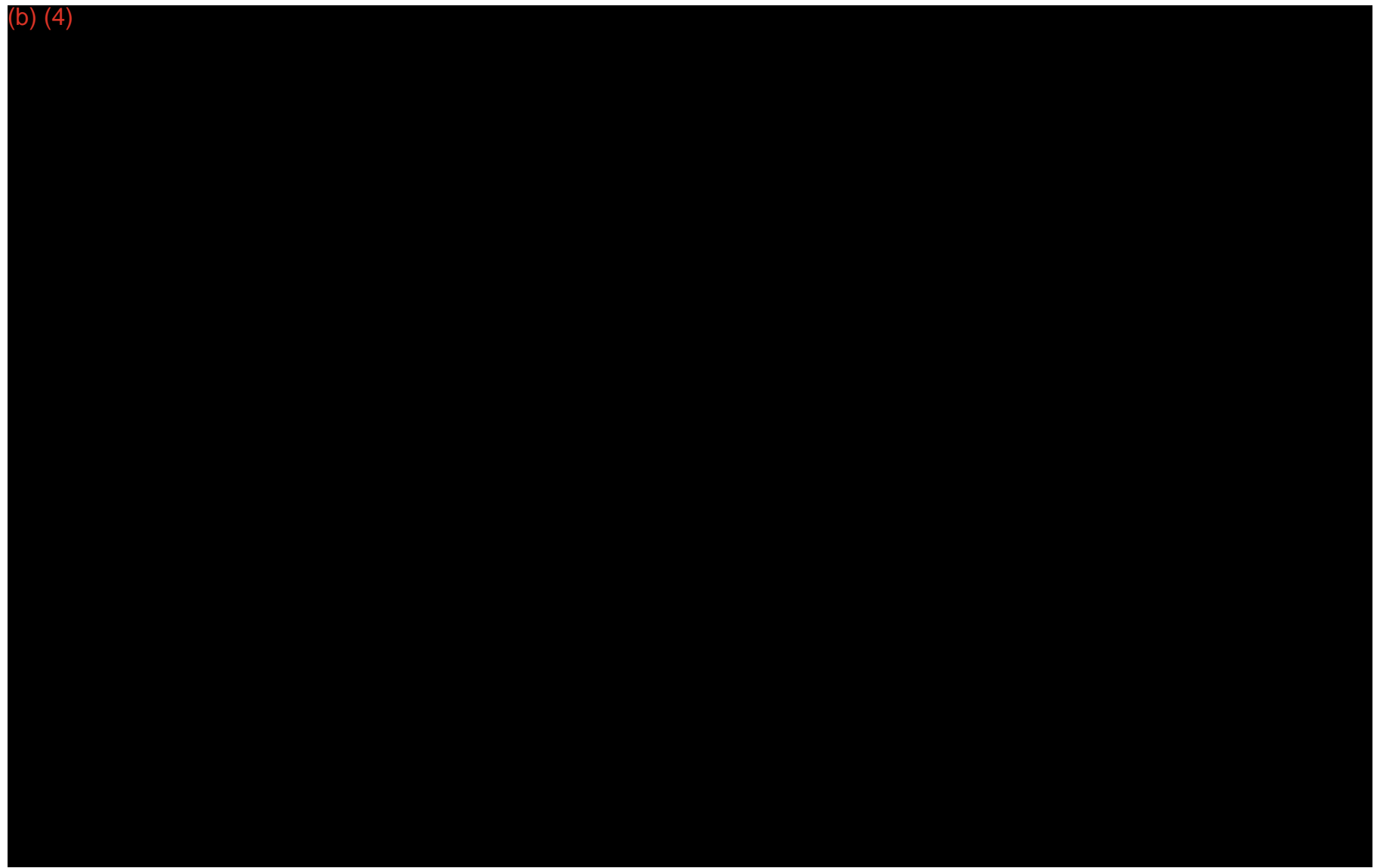


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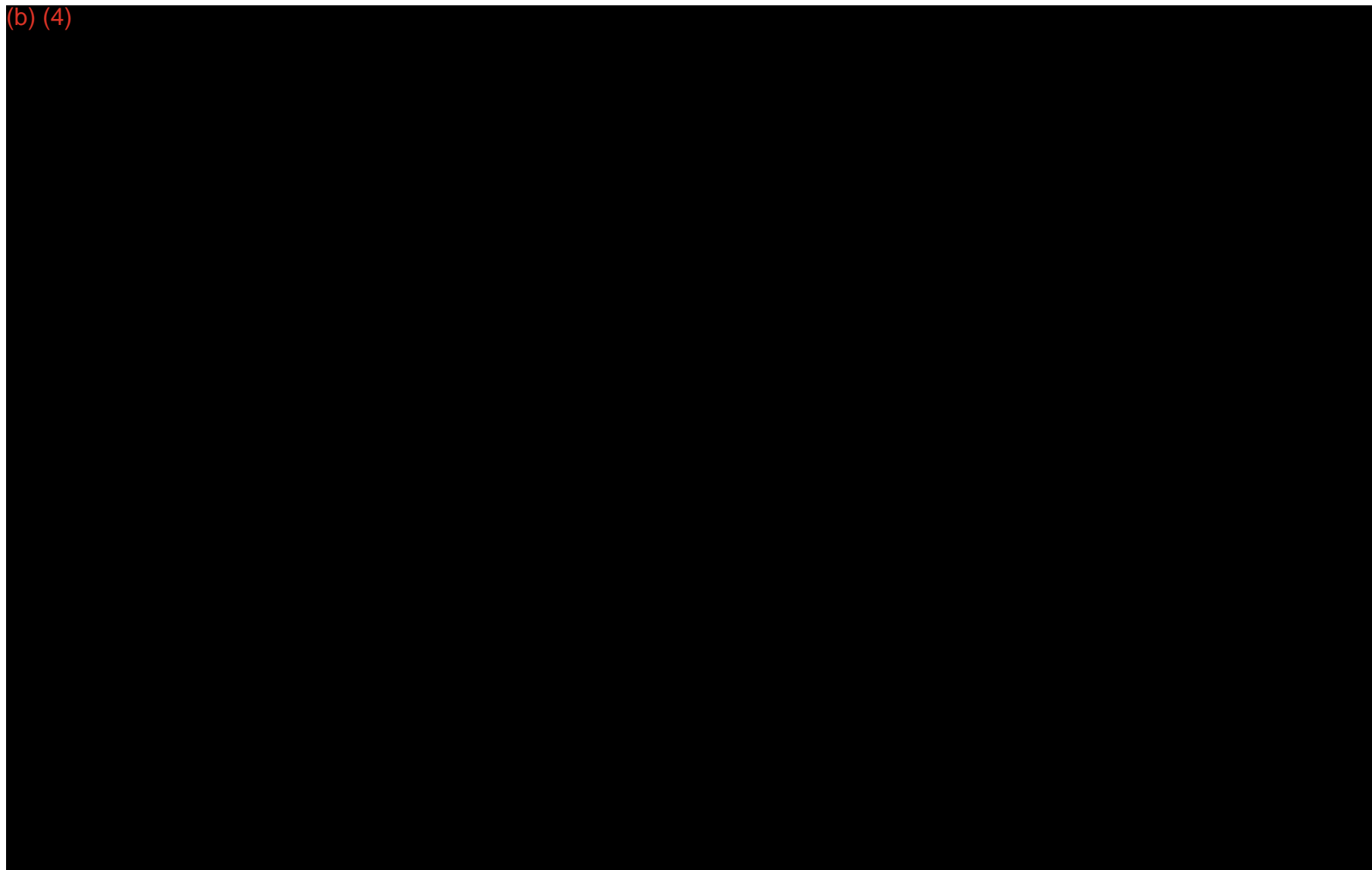
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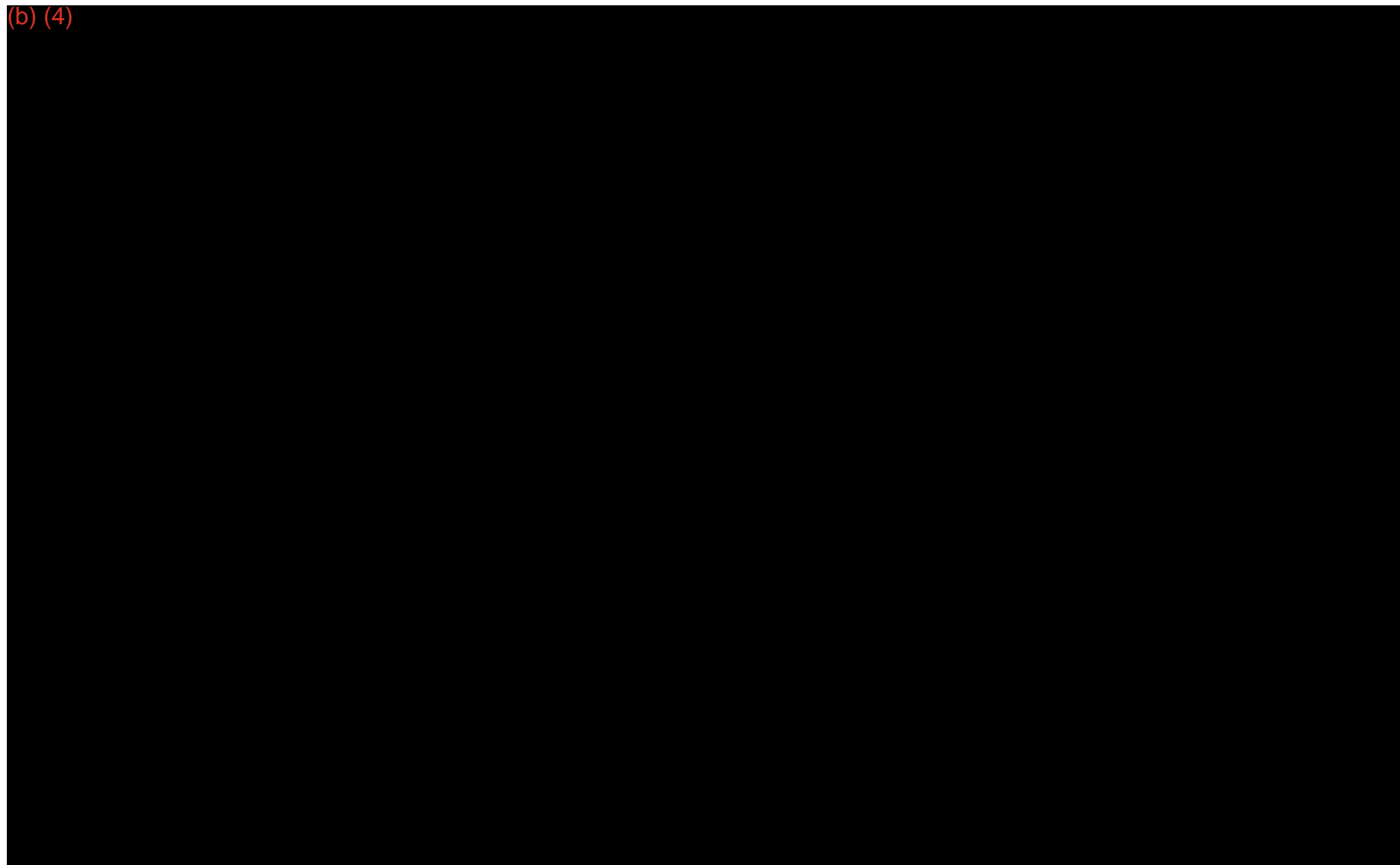




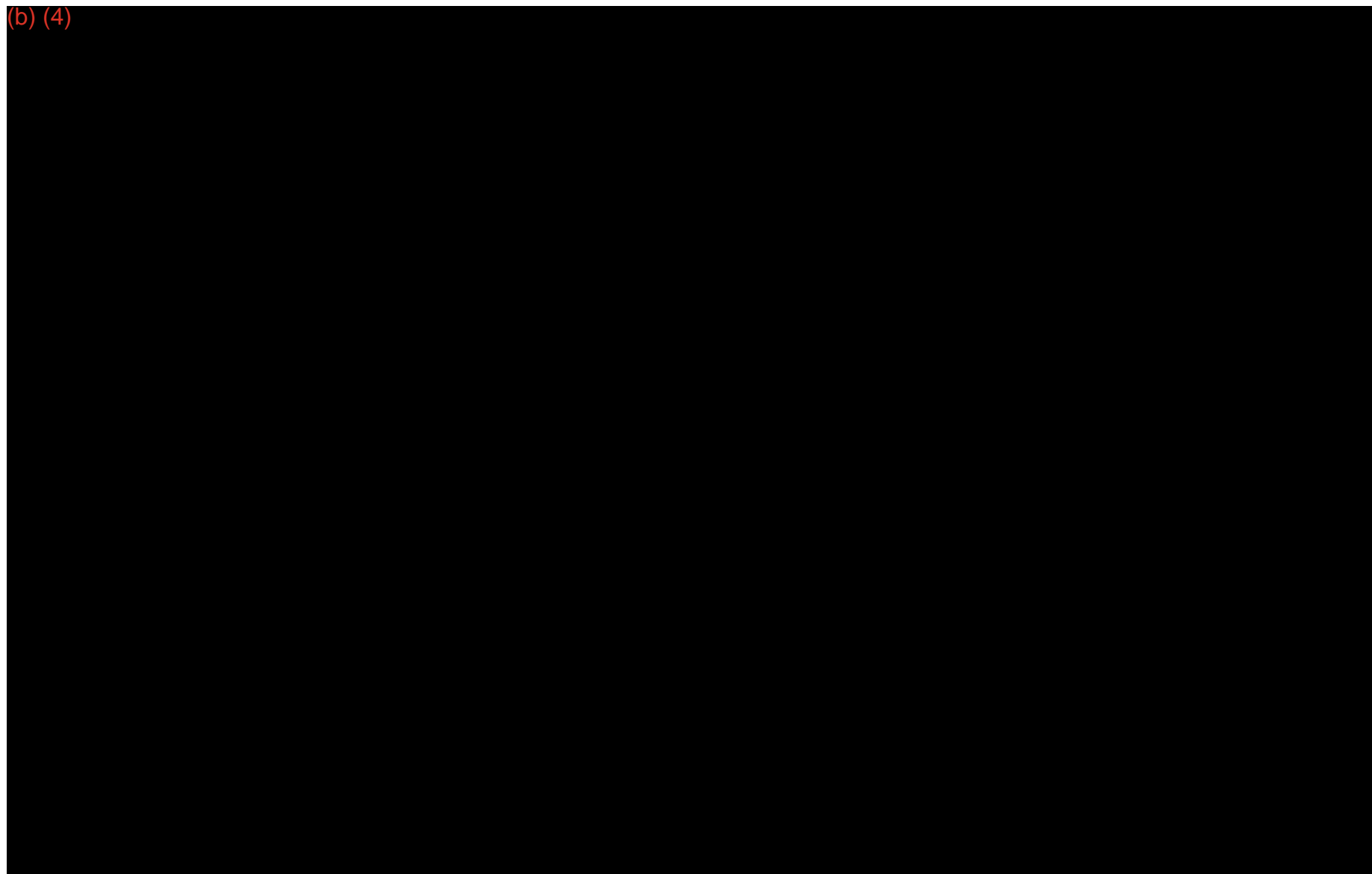
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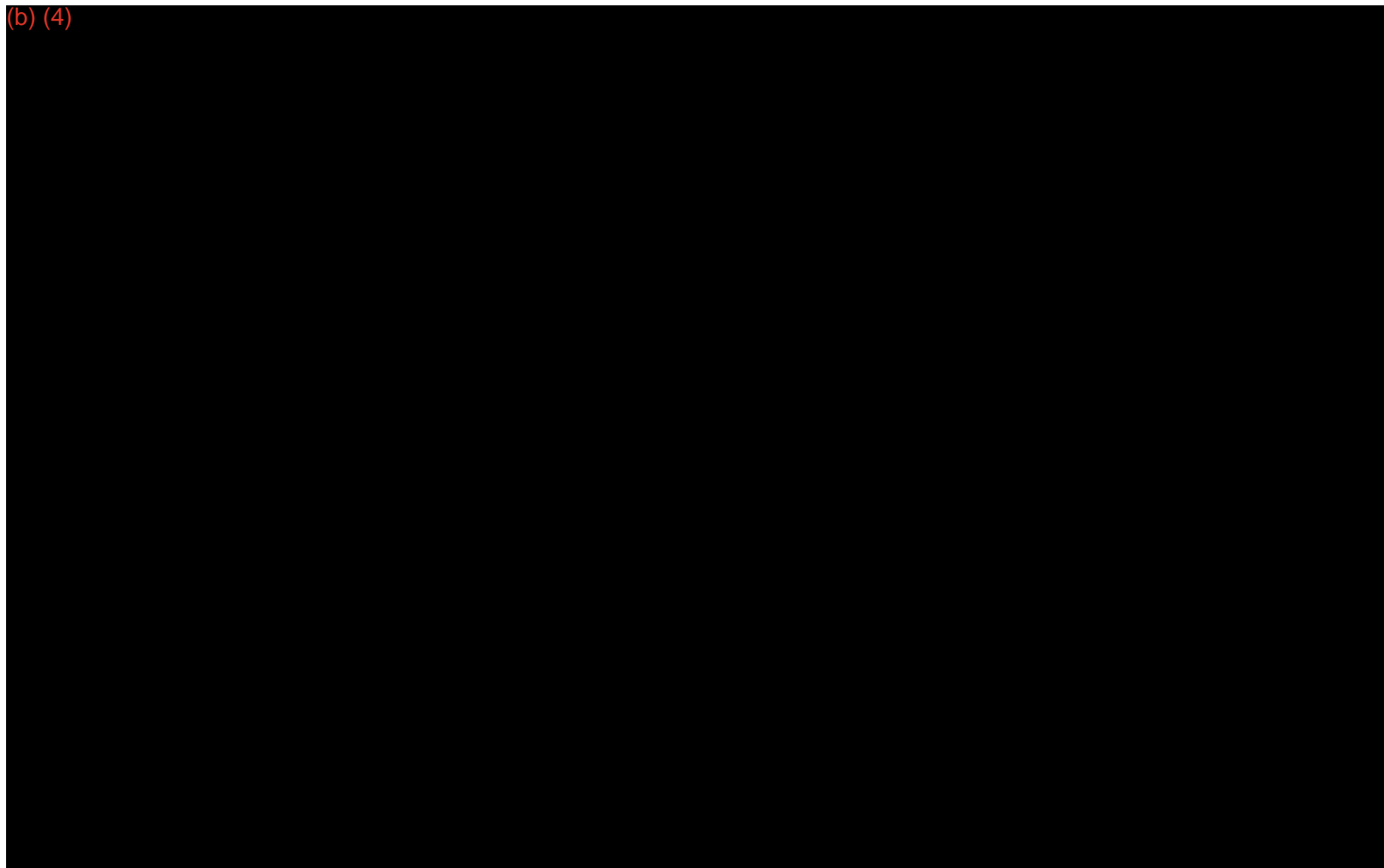
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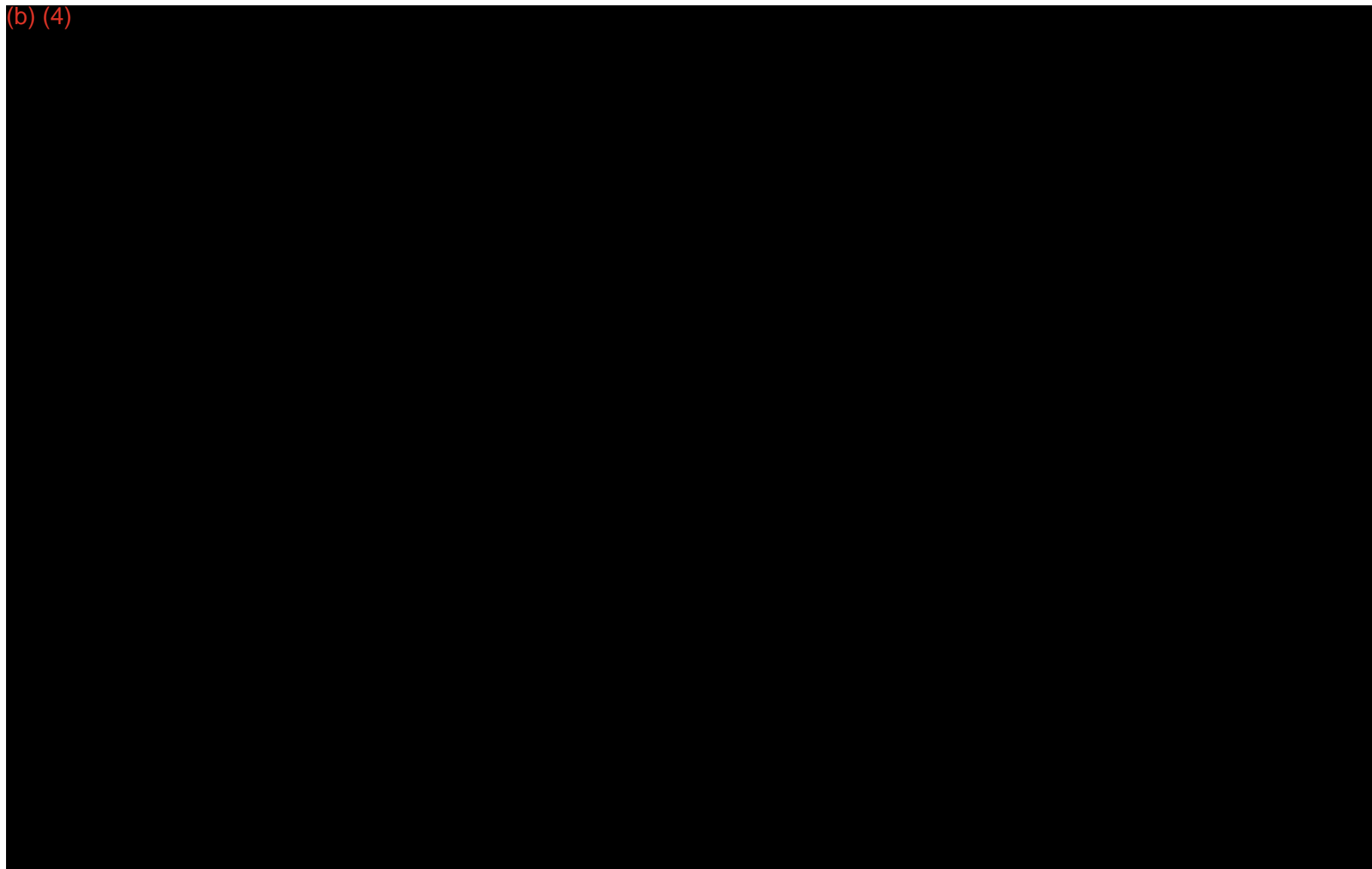


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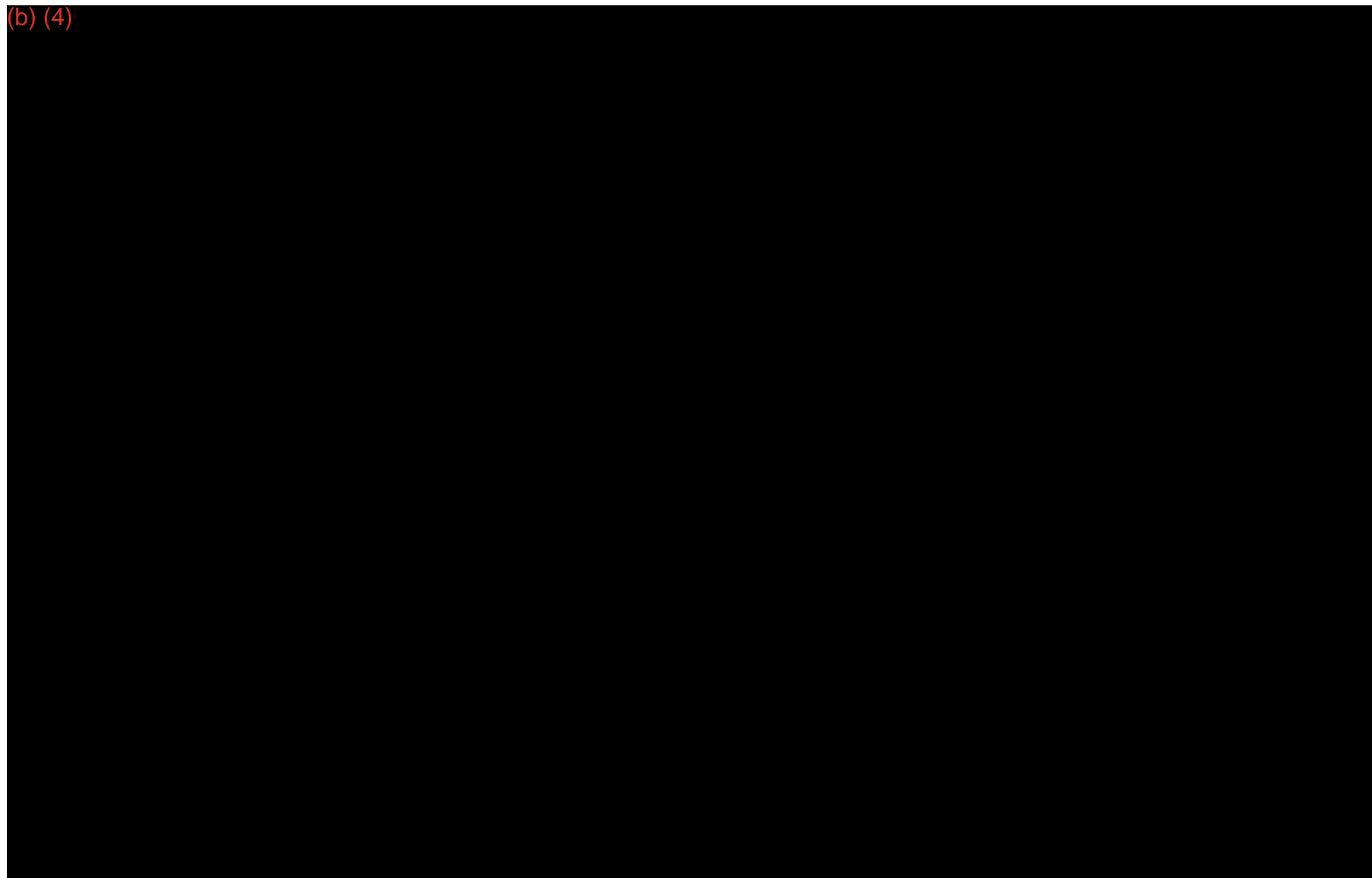


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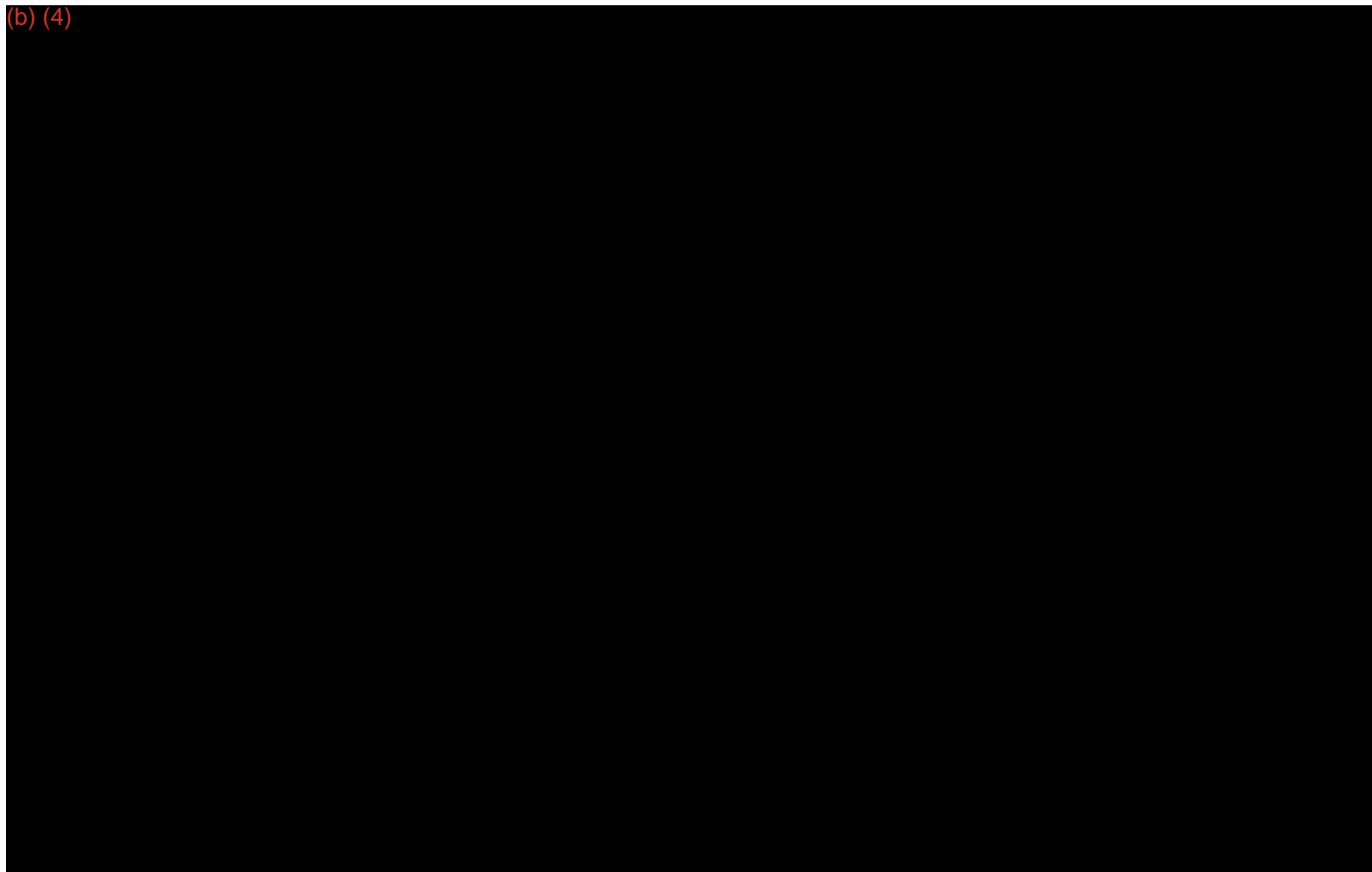


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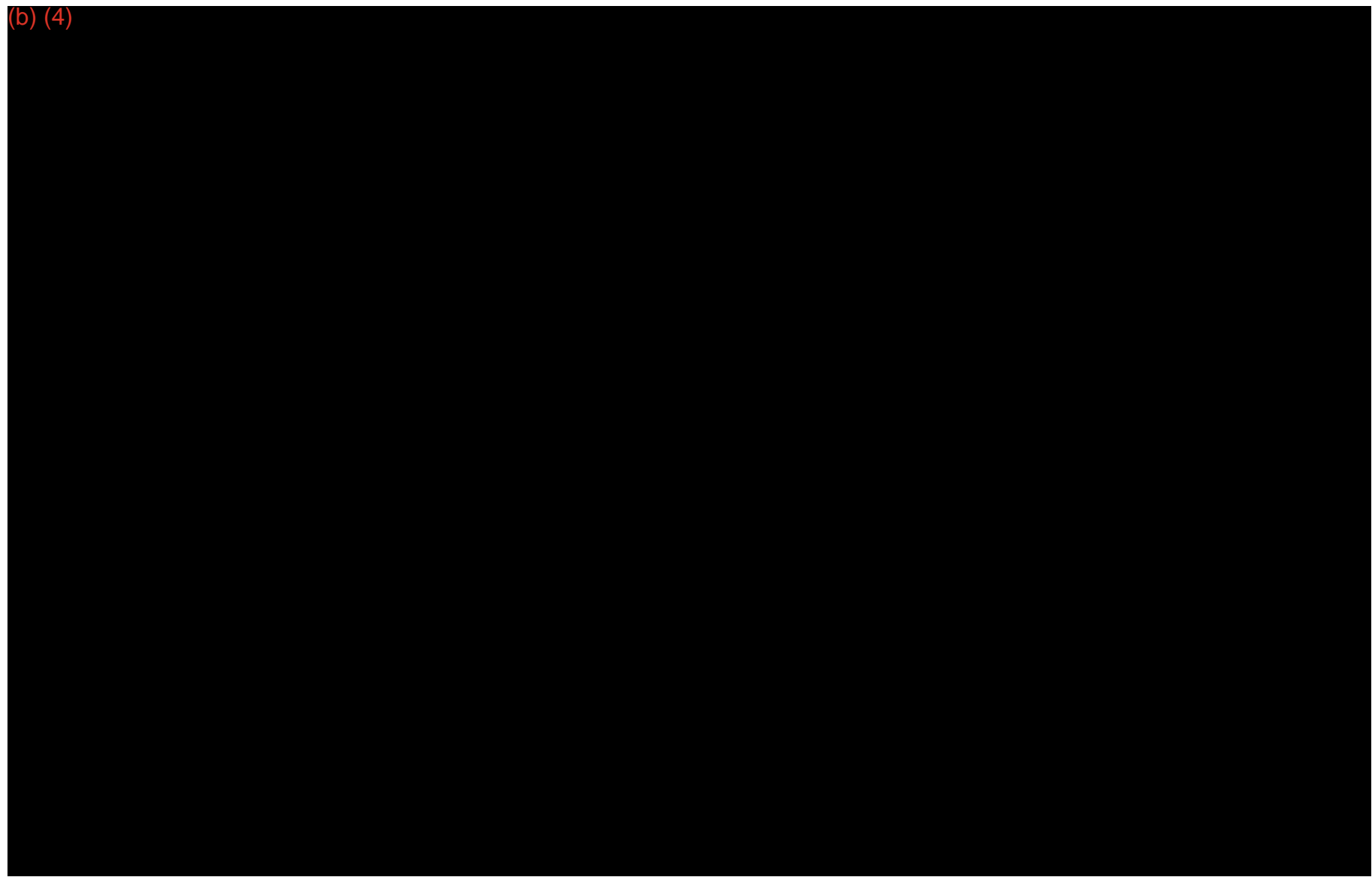
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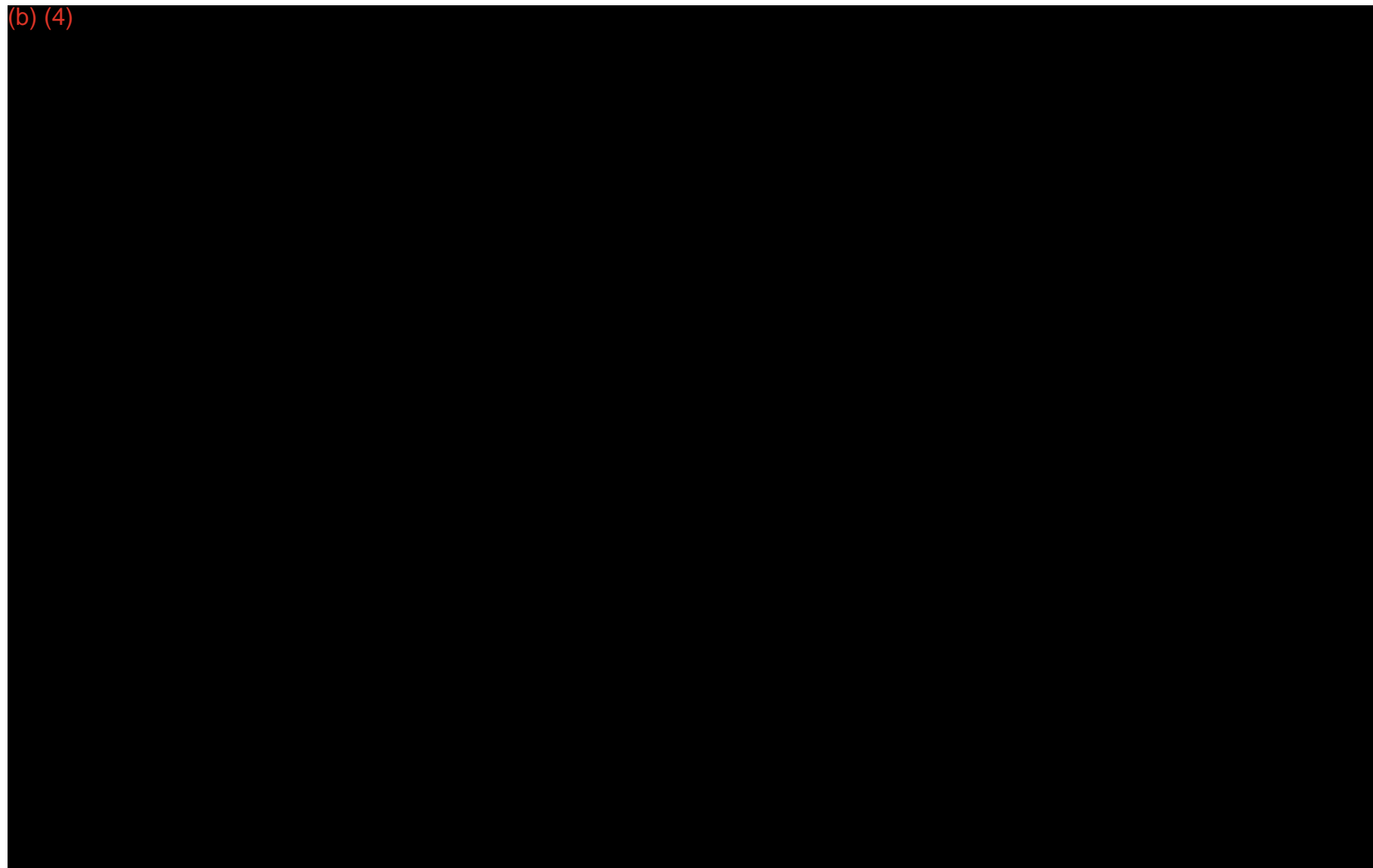
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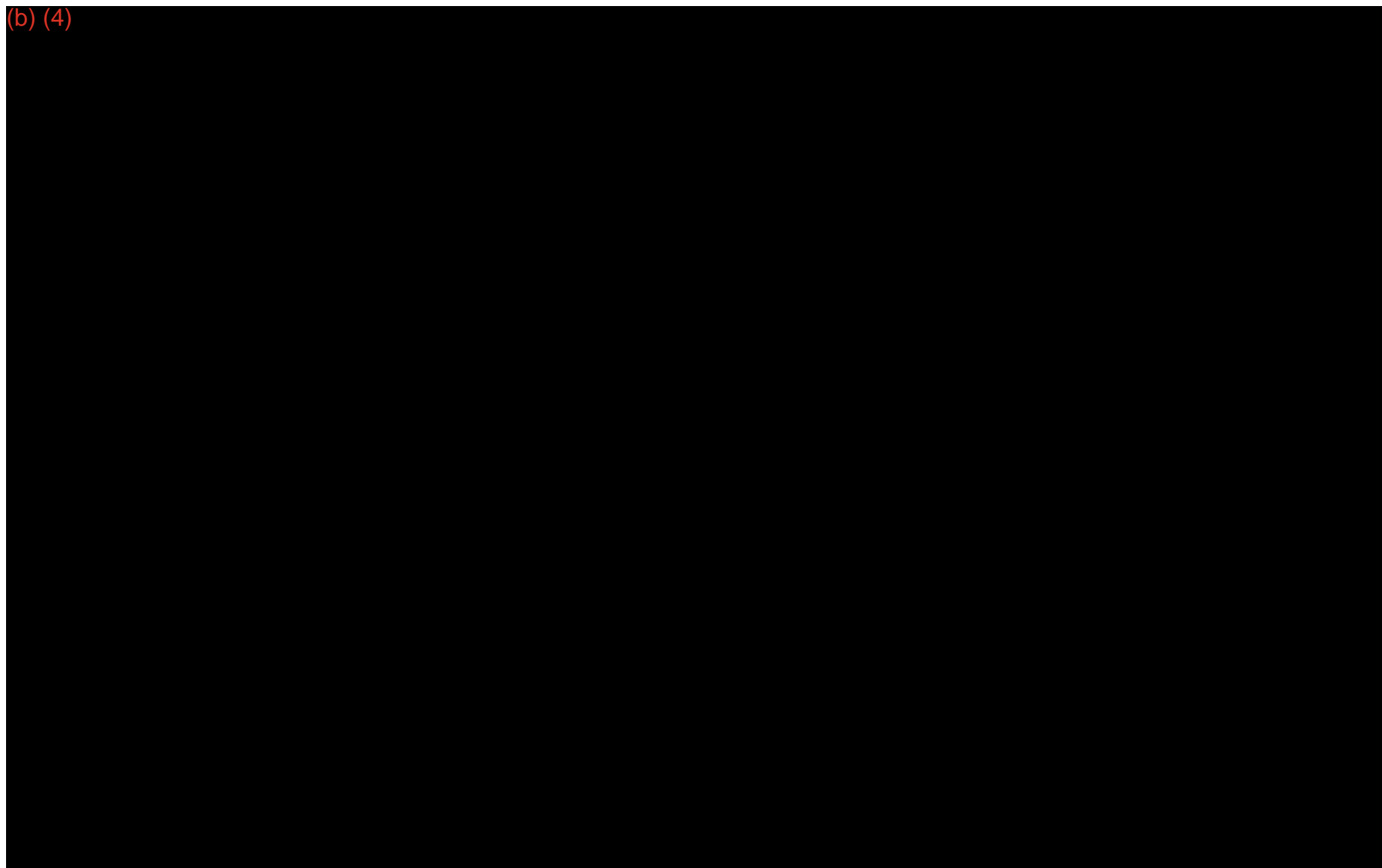


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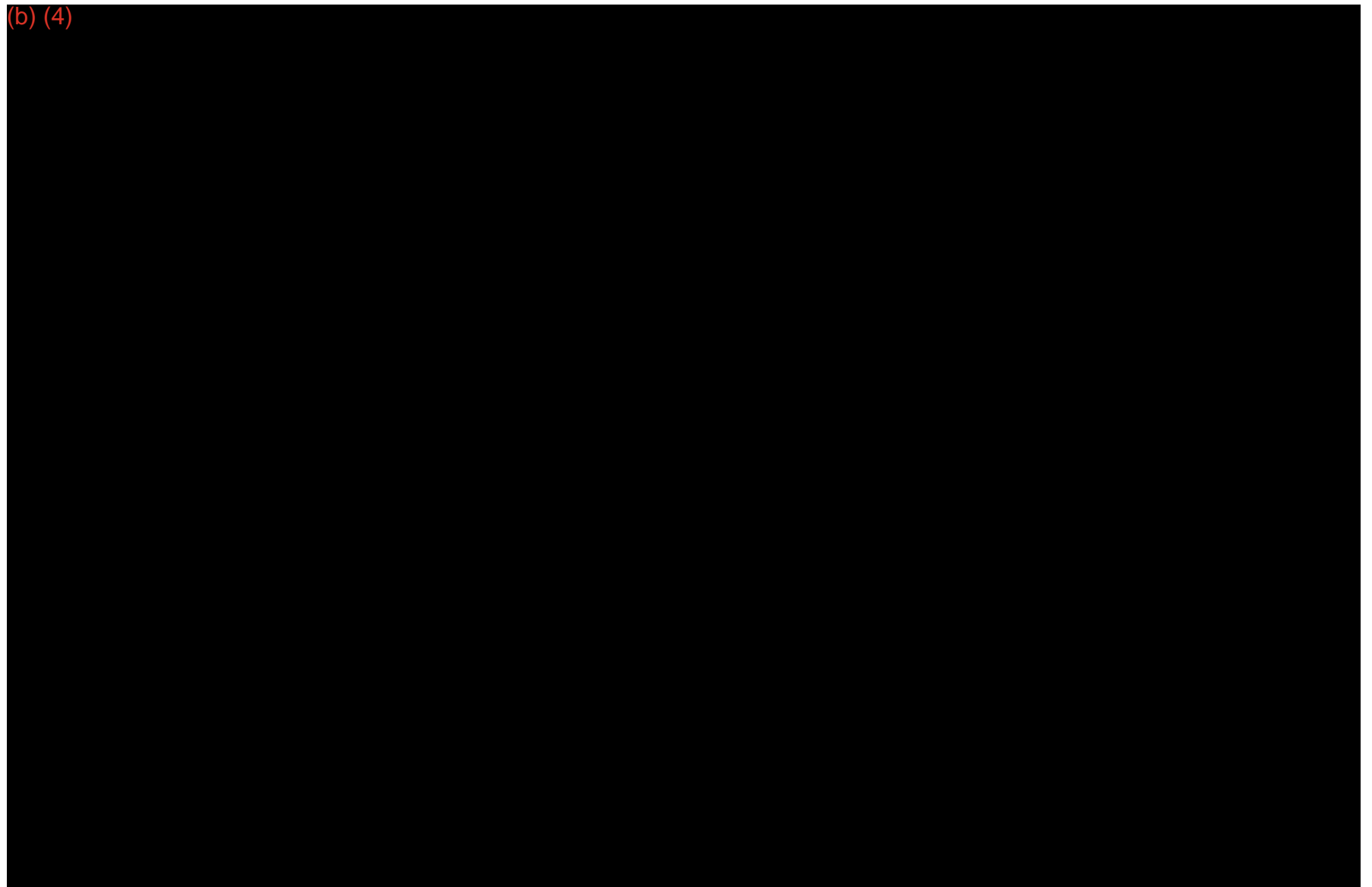


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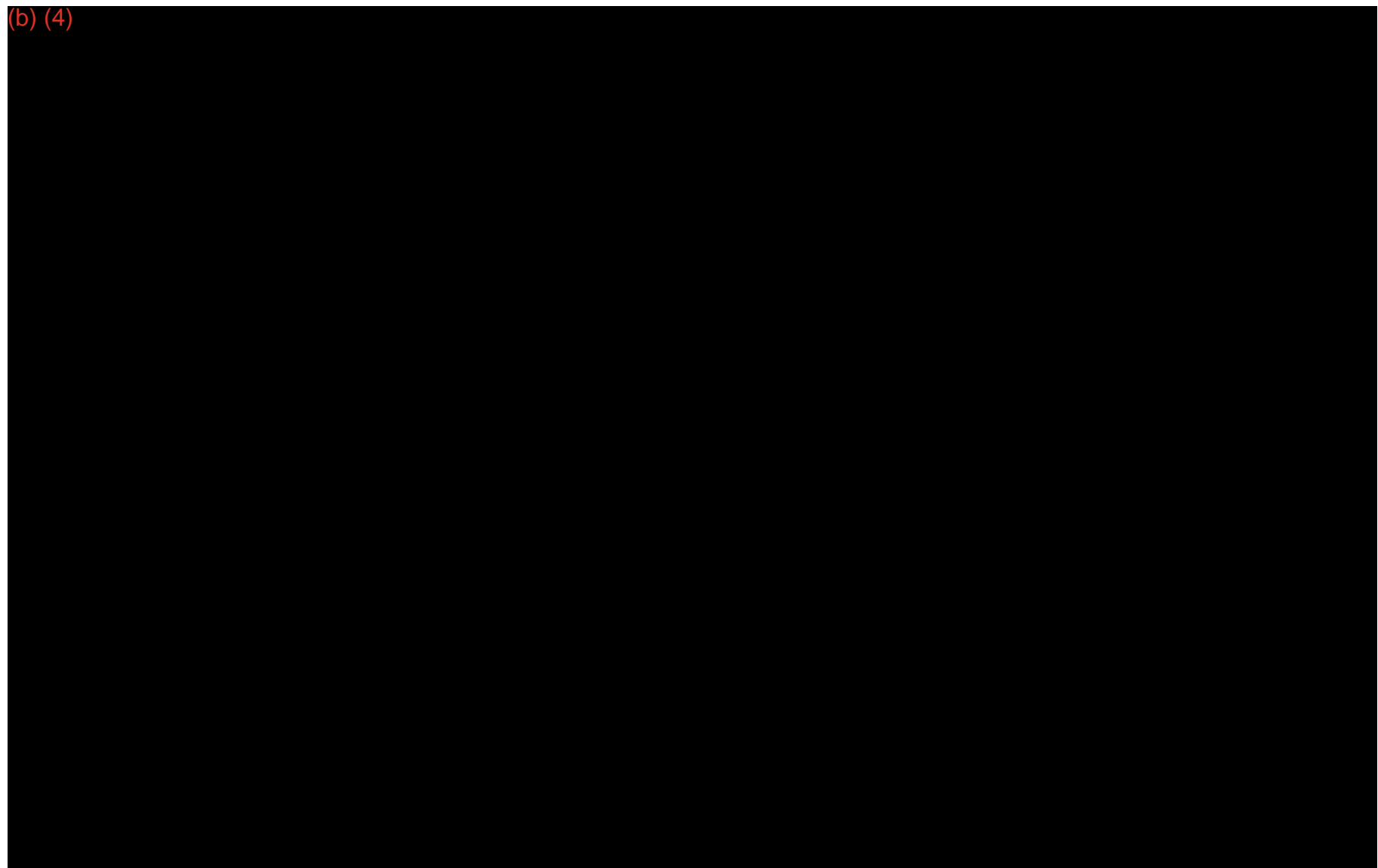


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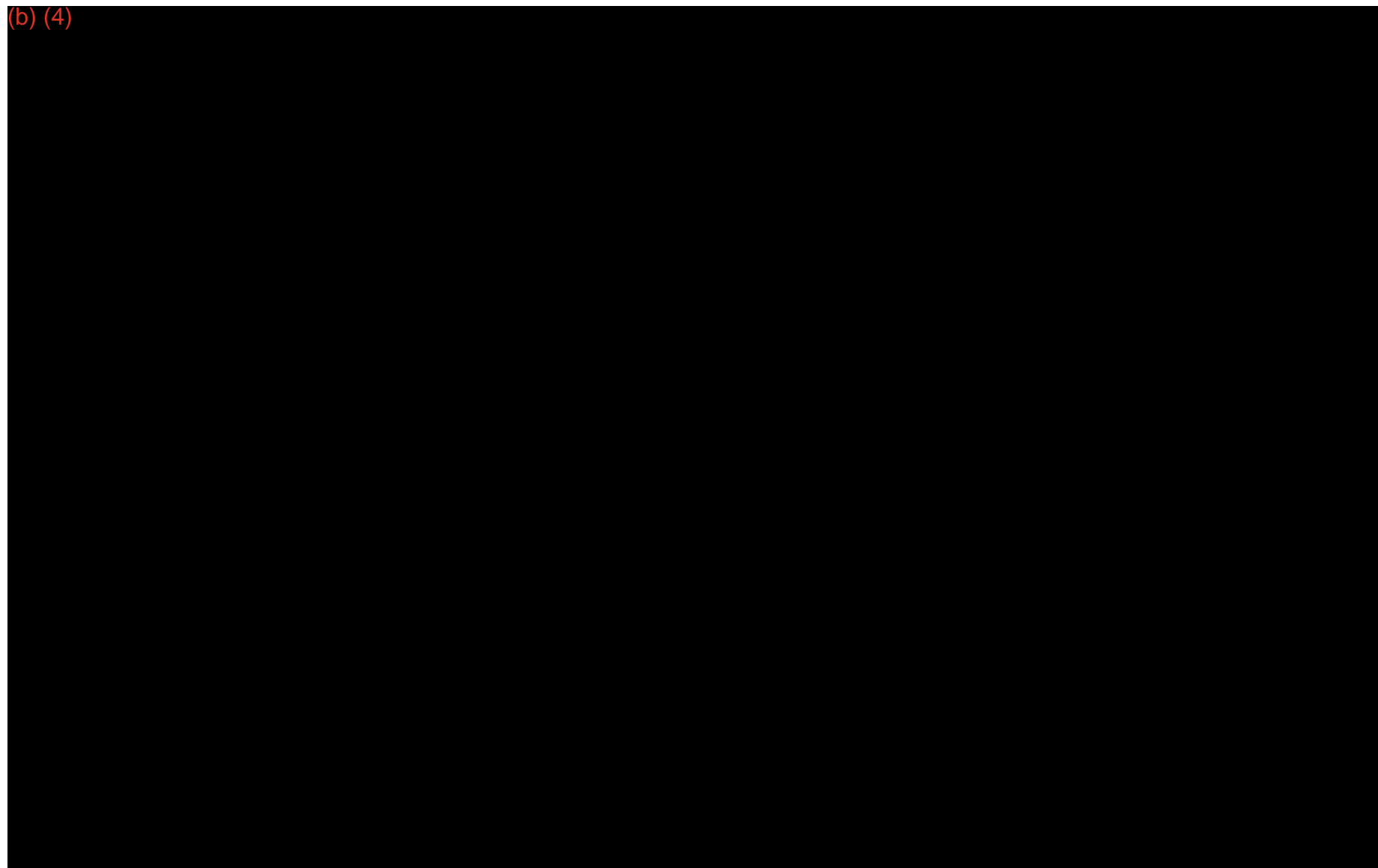
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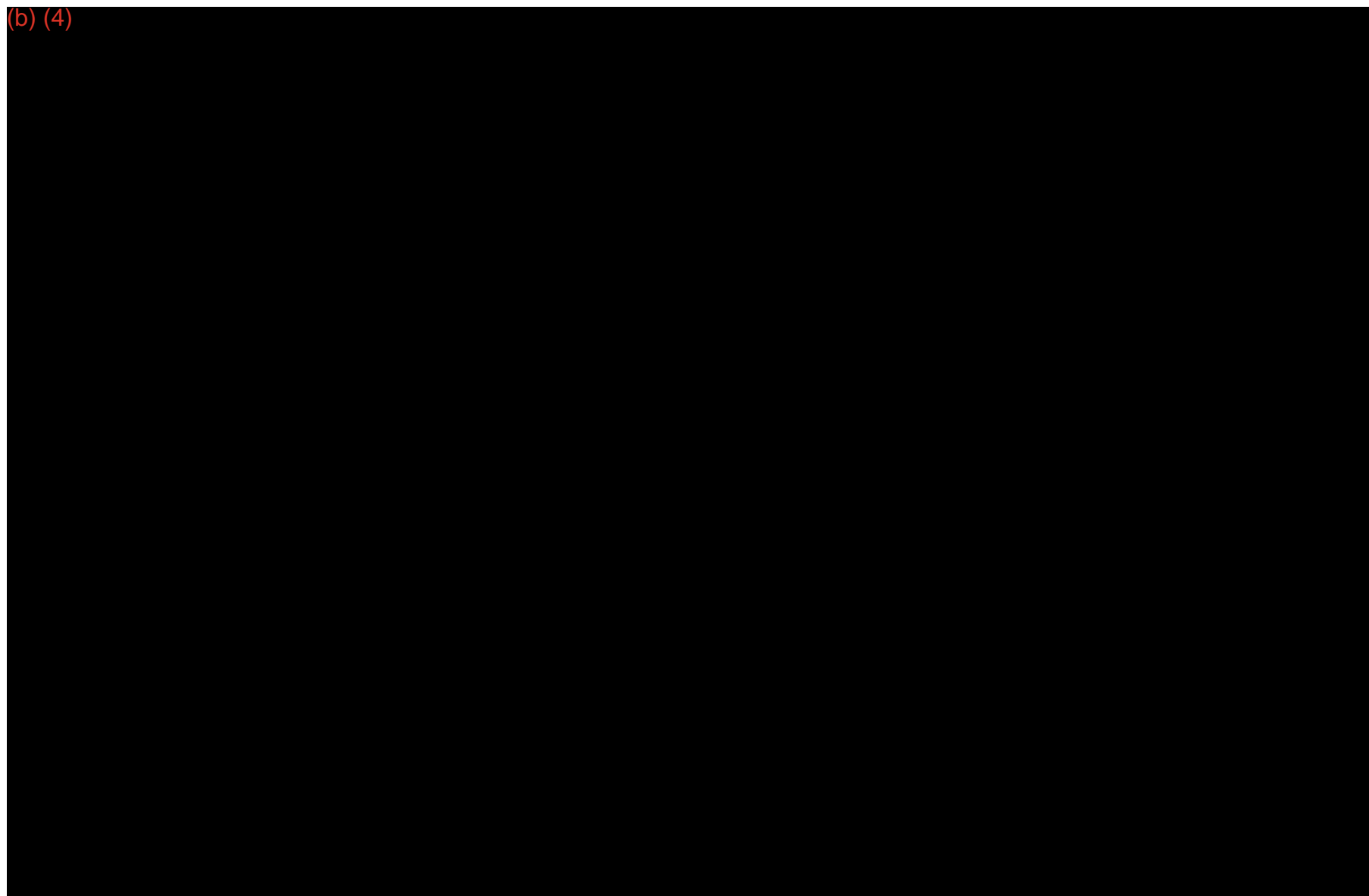


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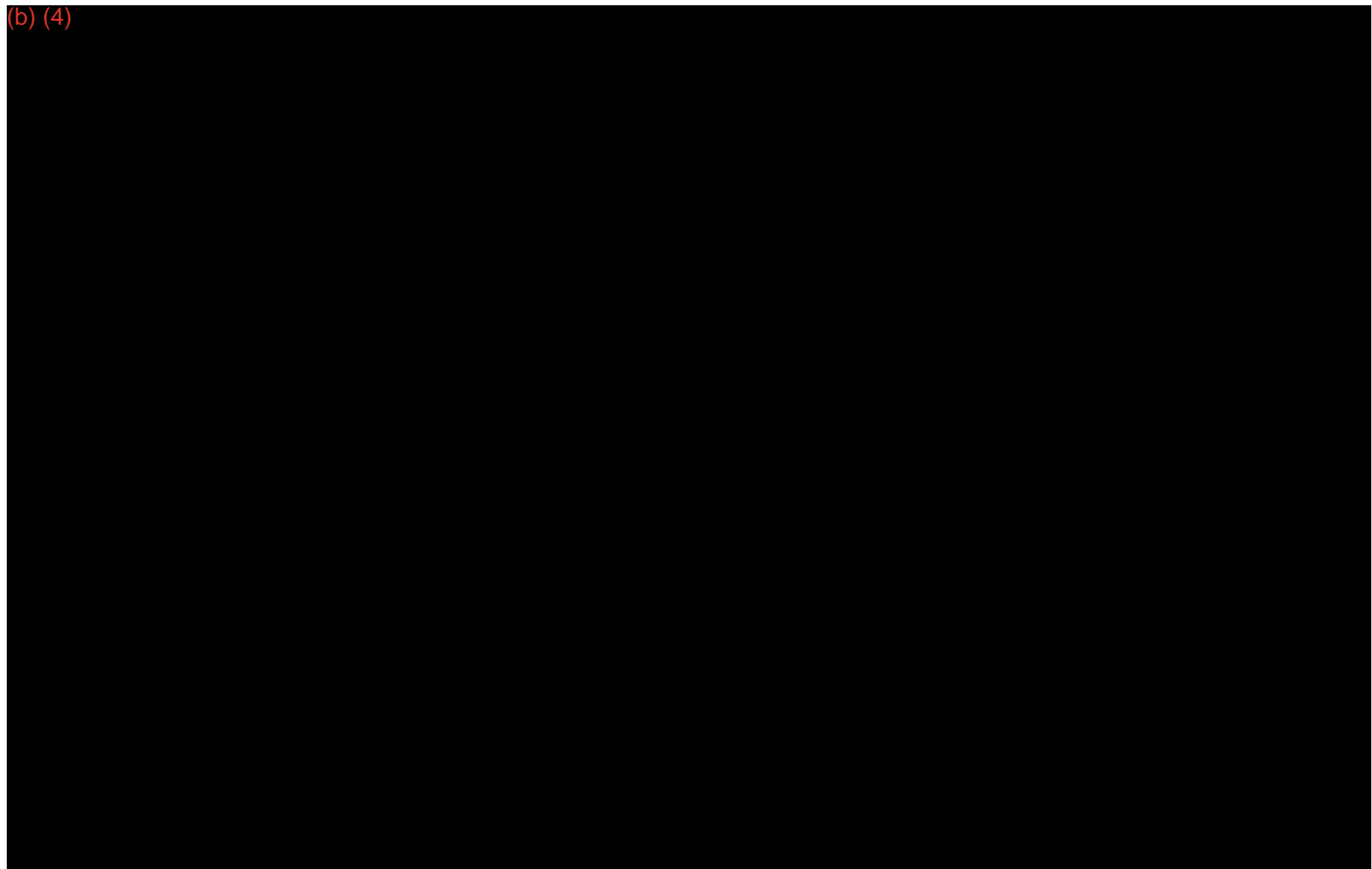
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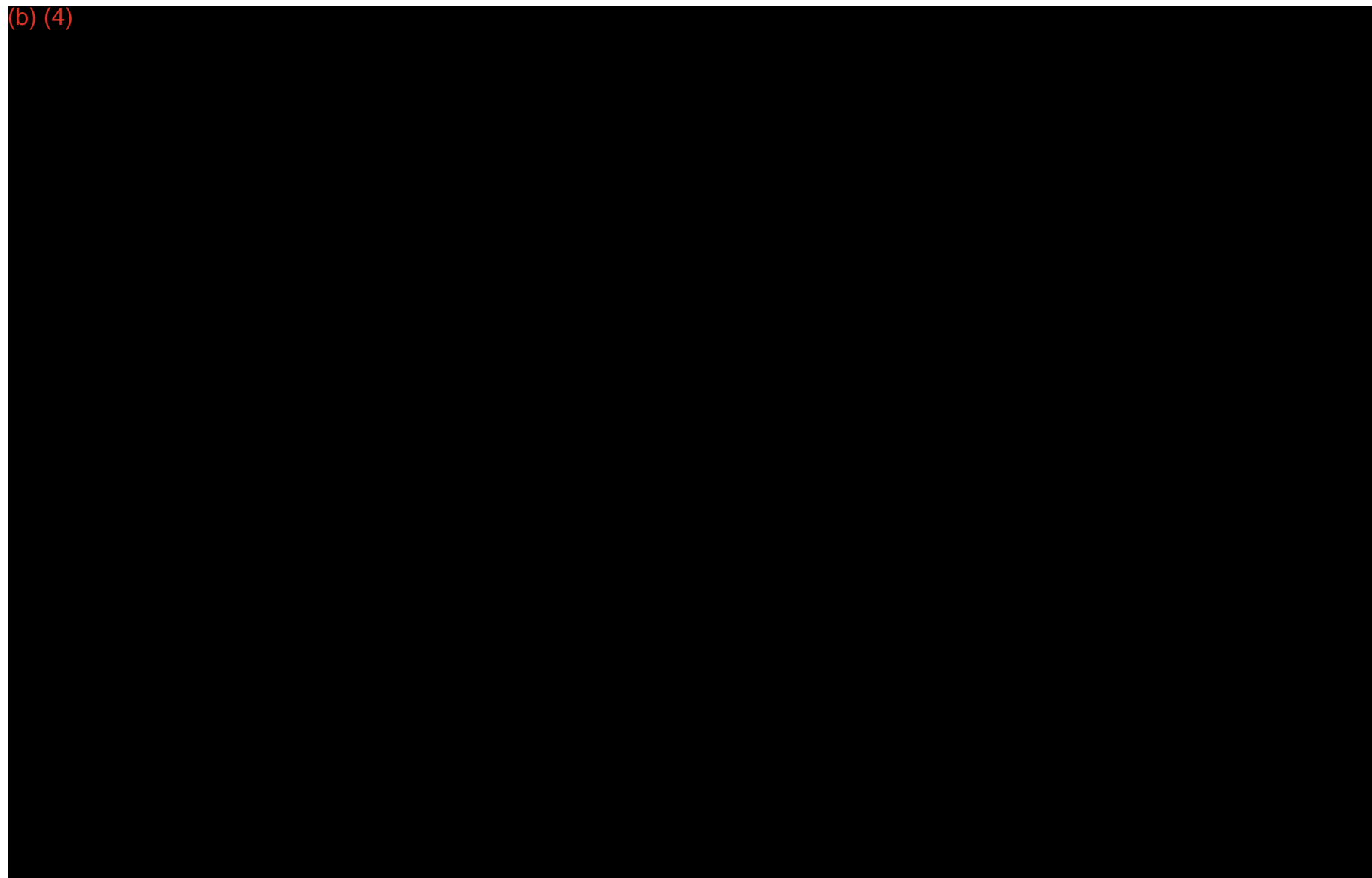


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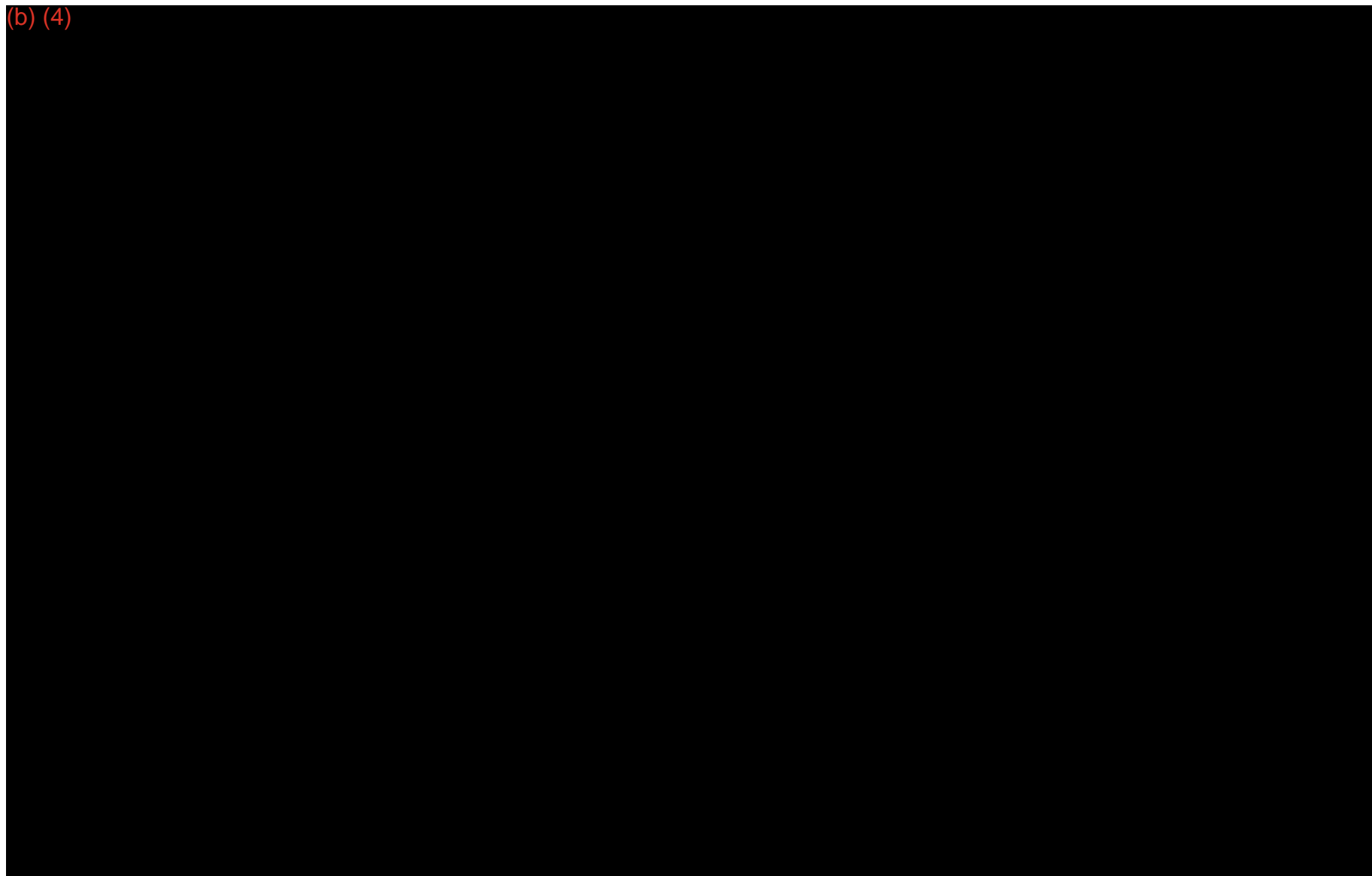


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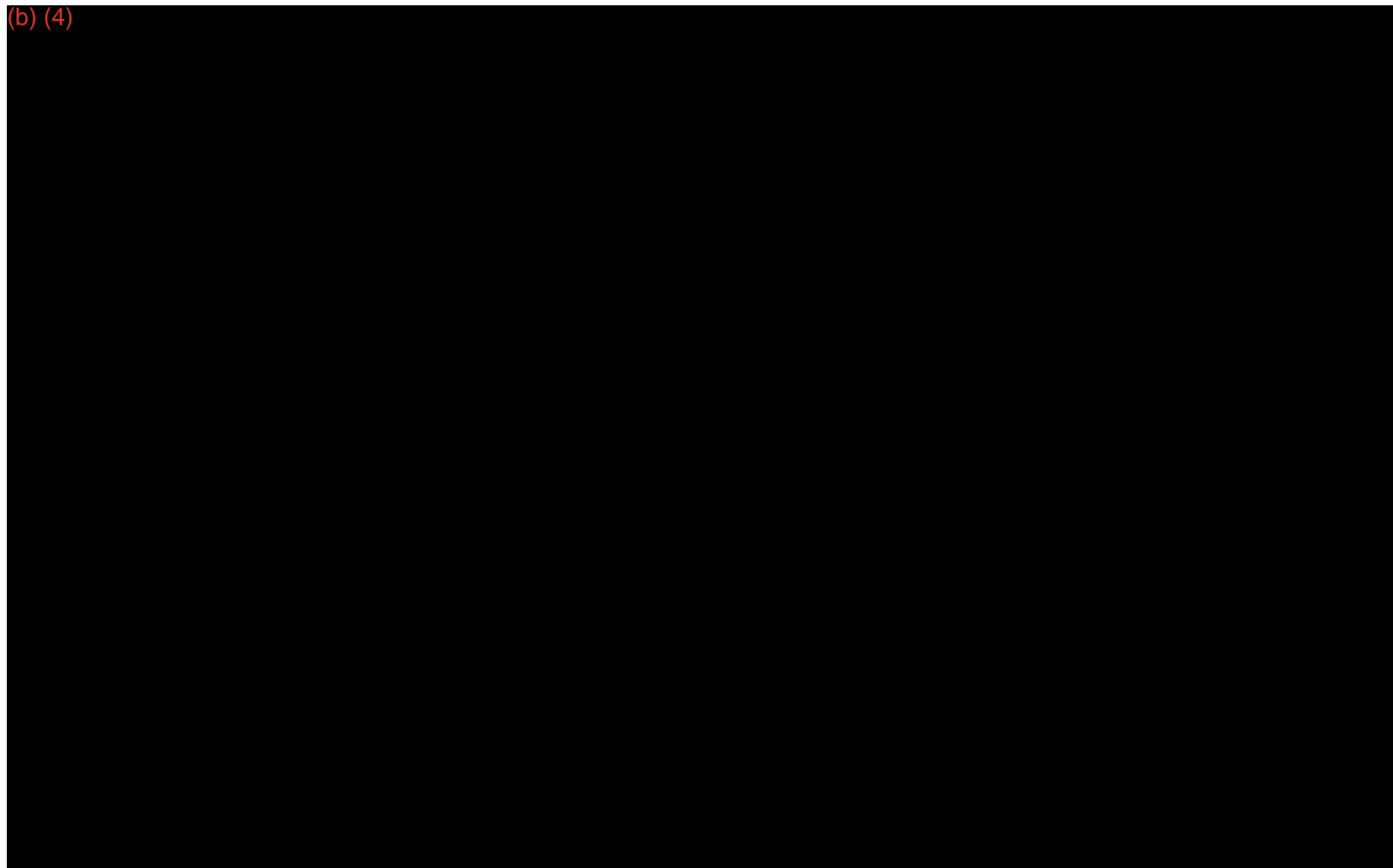
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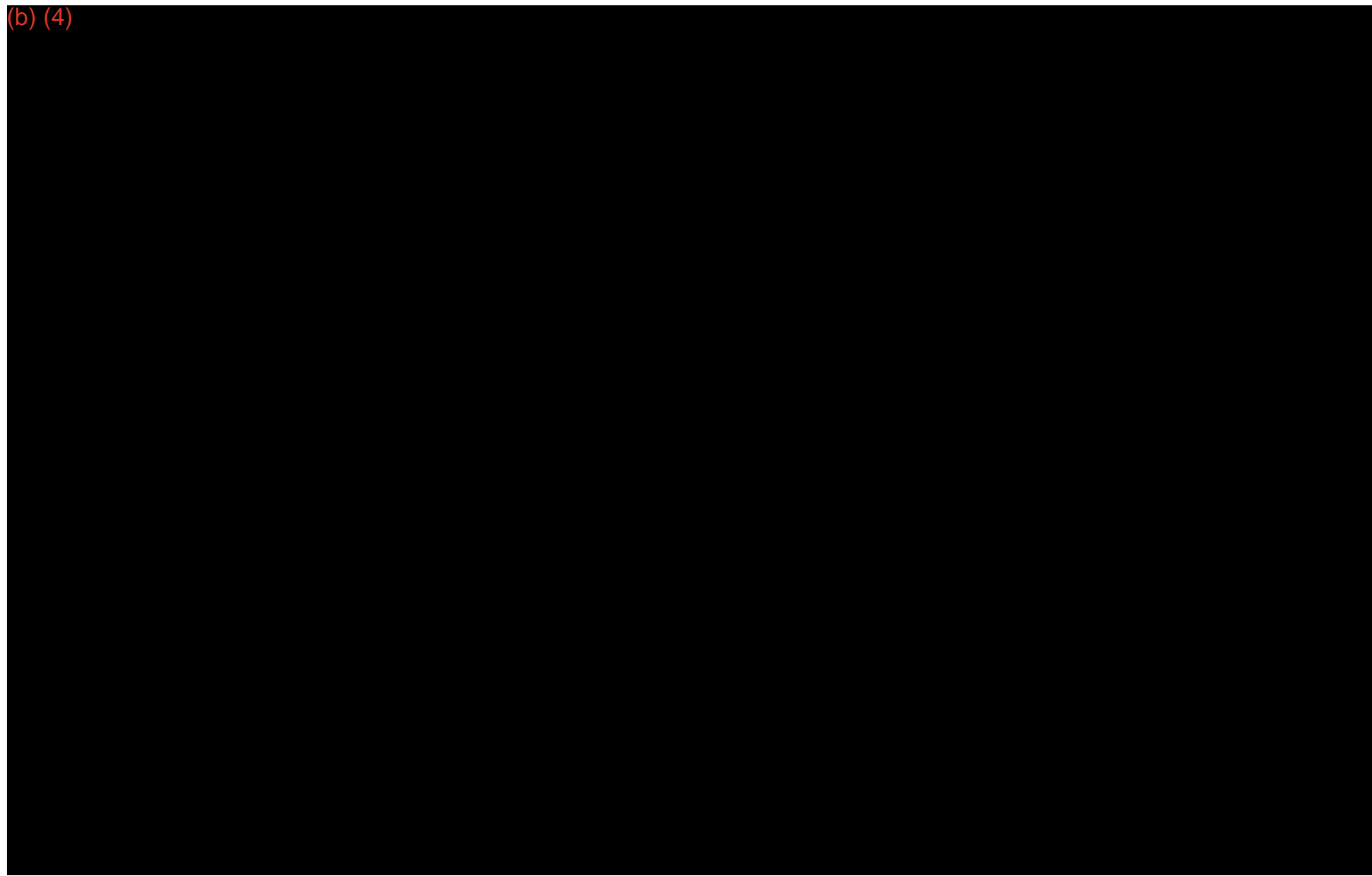
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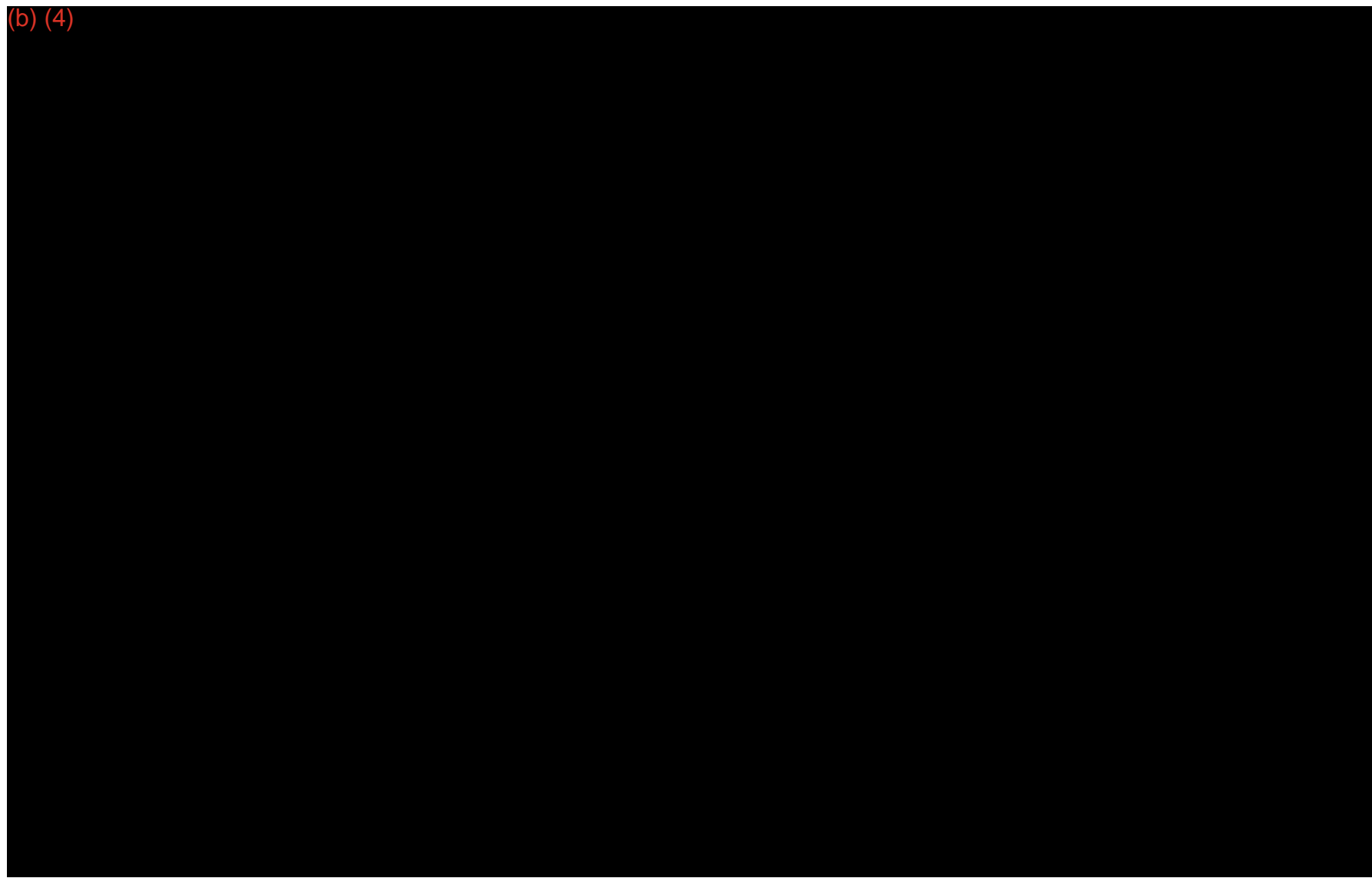
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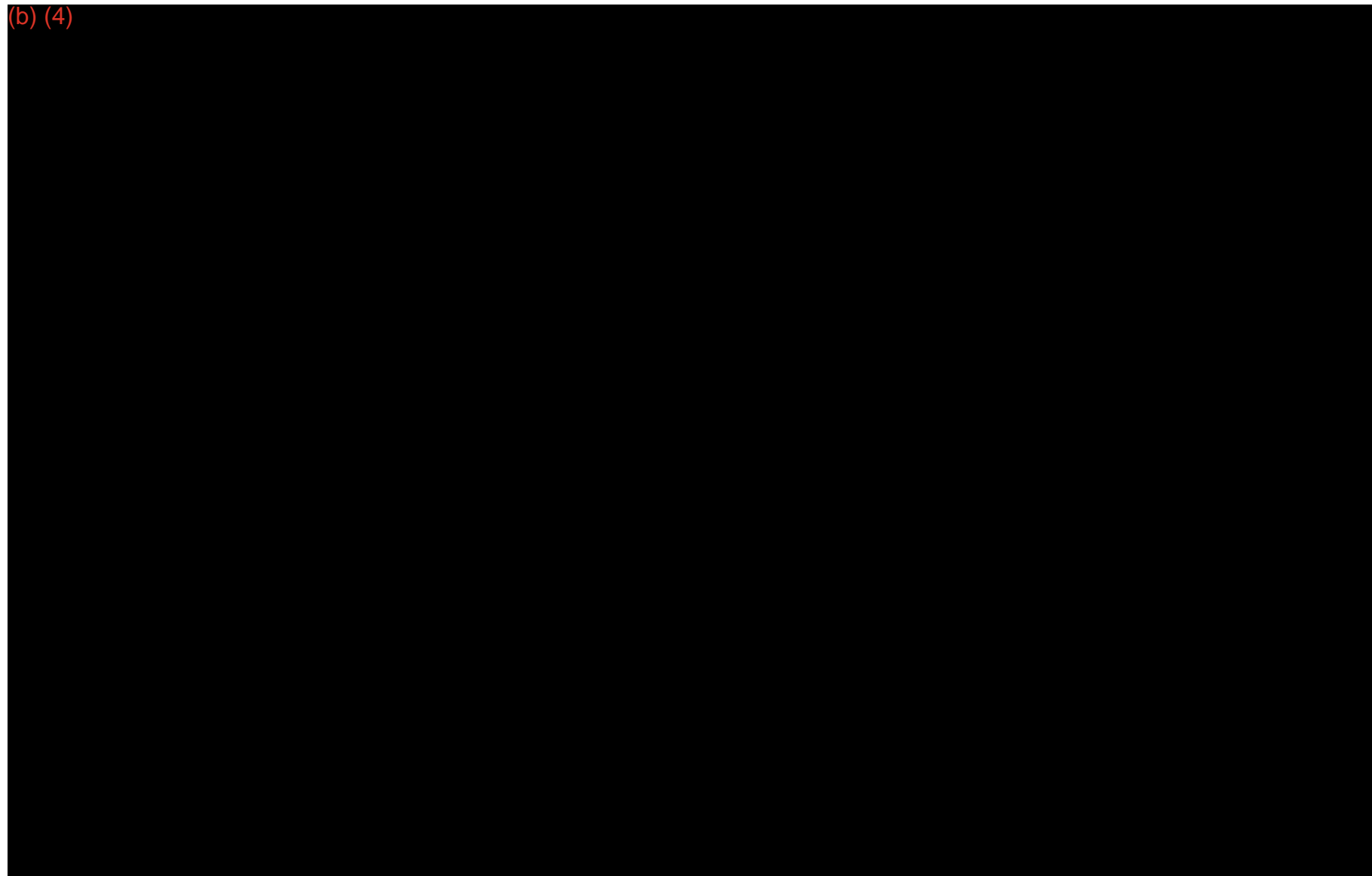
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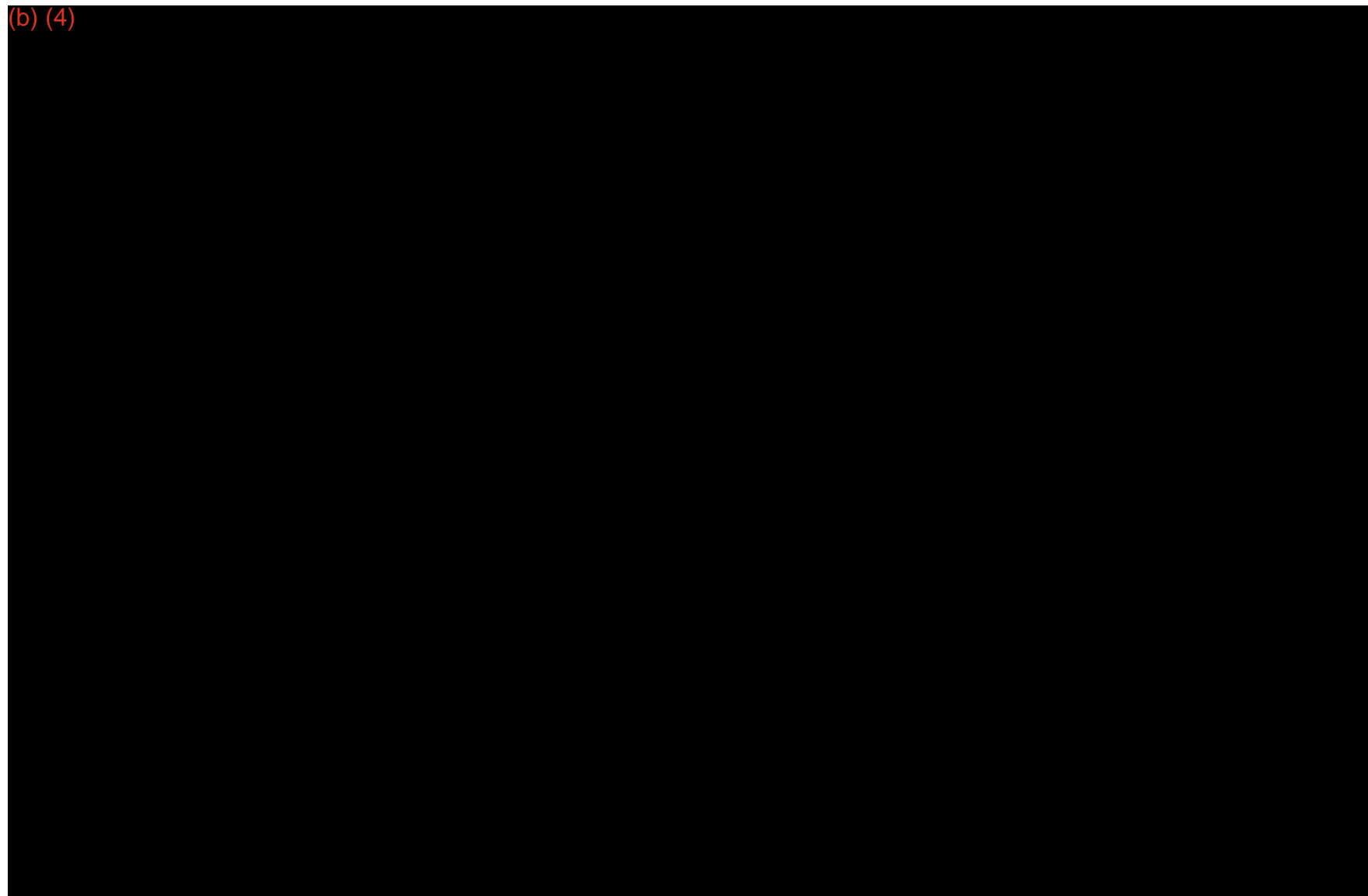


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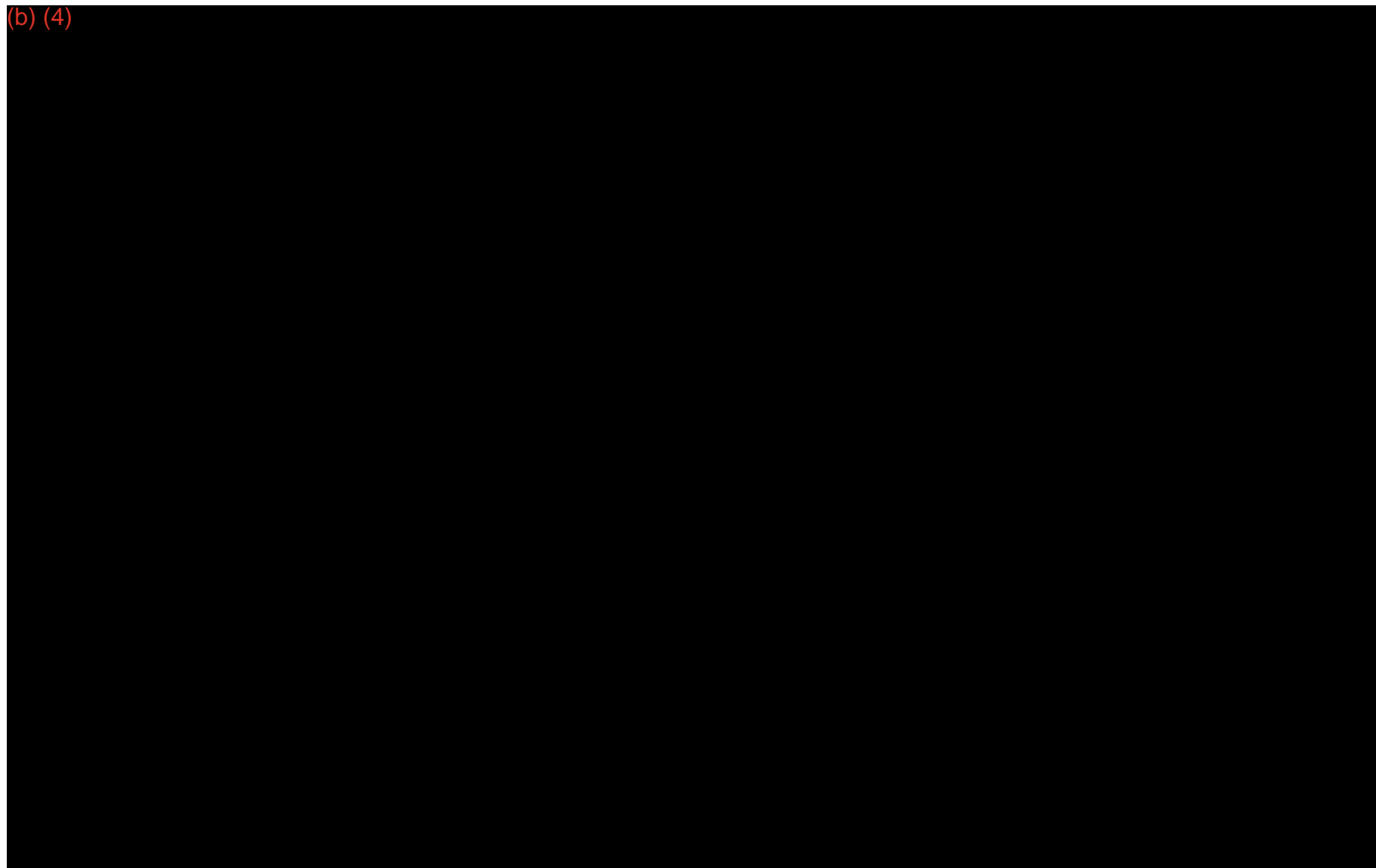


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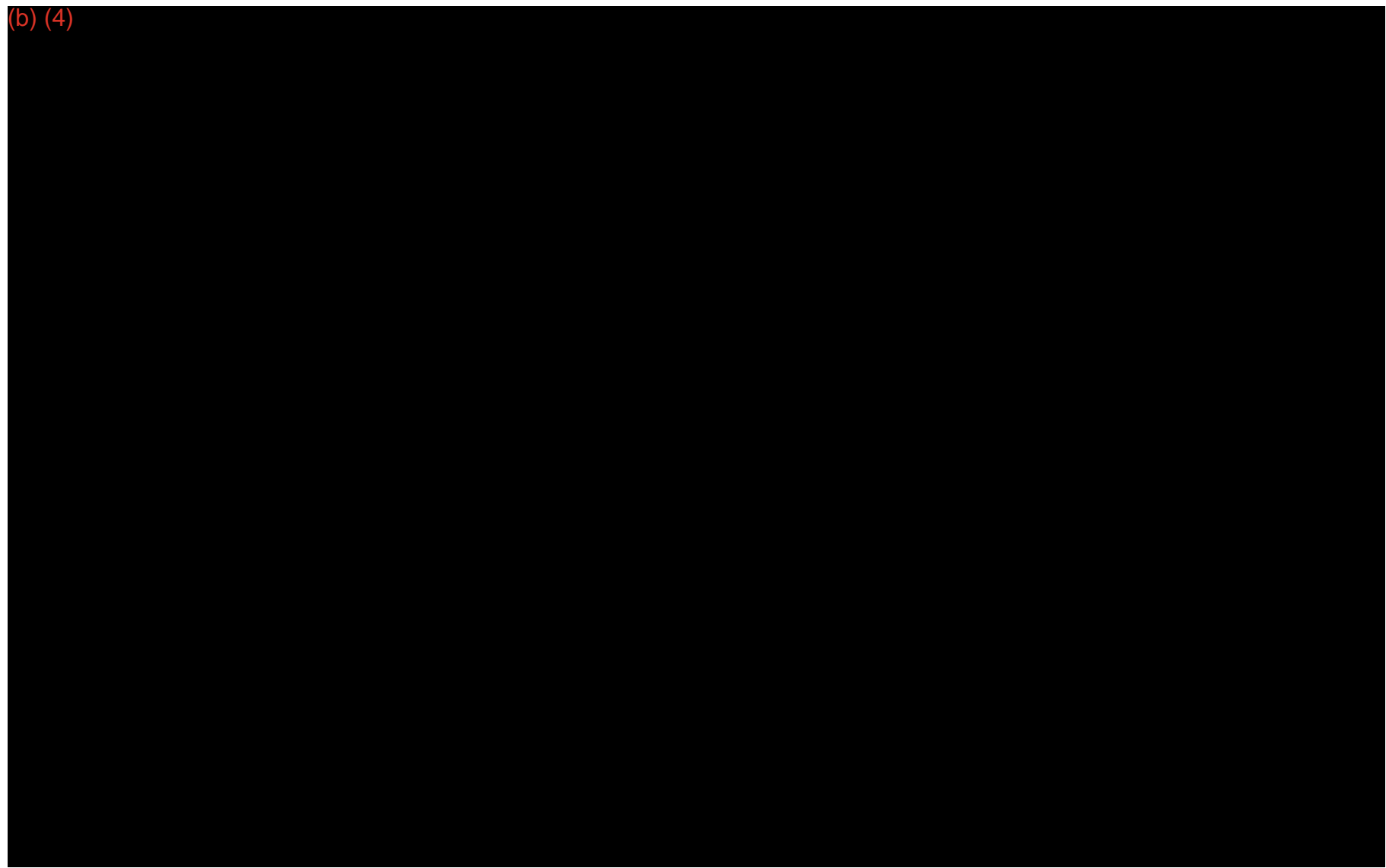


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**Listing 16.2.6-8 Dental plaque acidogenicity (pH) mean of site 1 and site 2 (FAS, Part 2)**

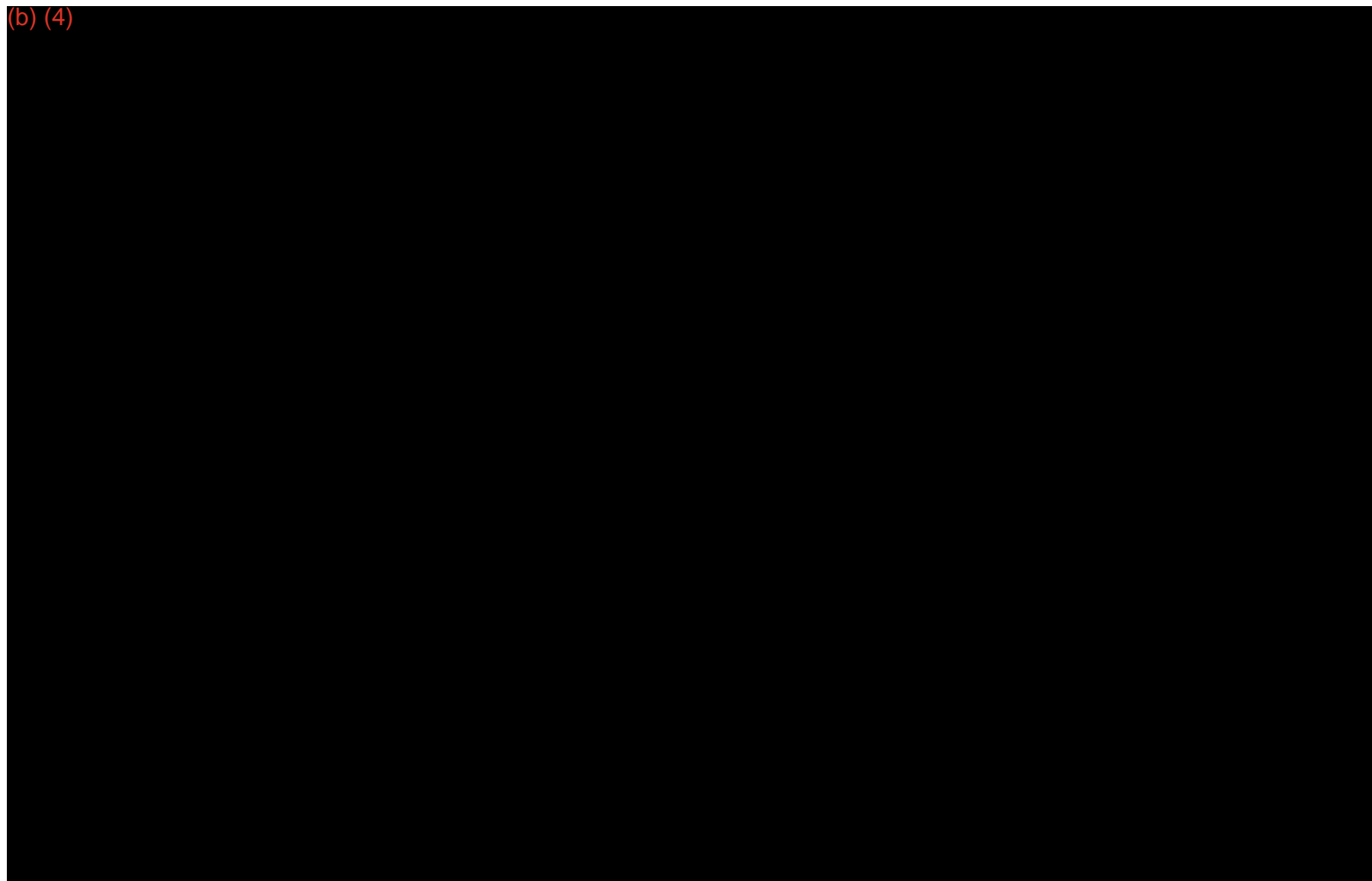
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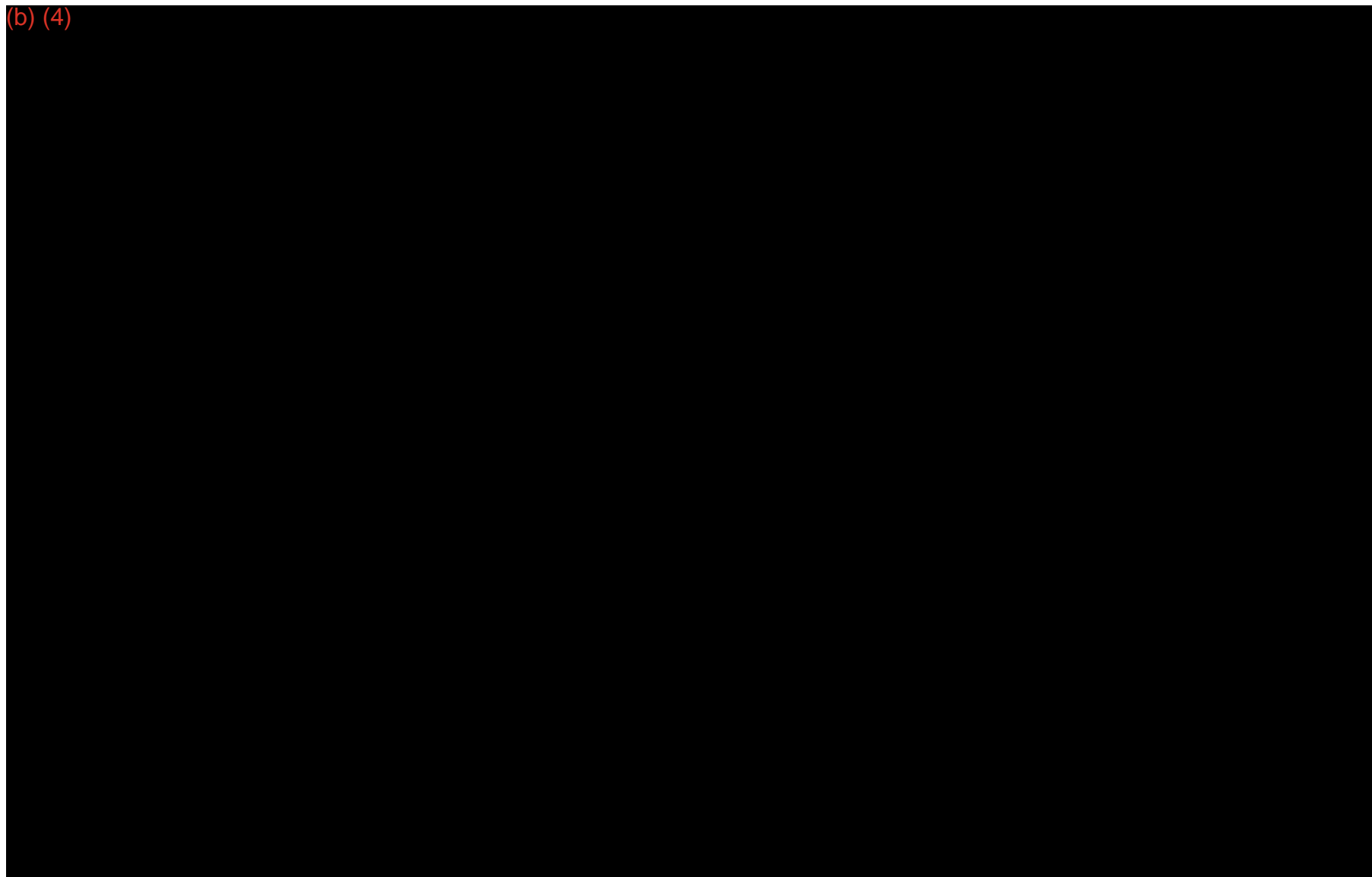




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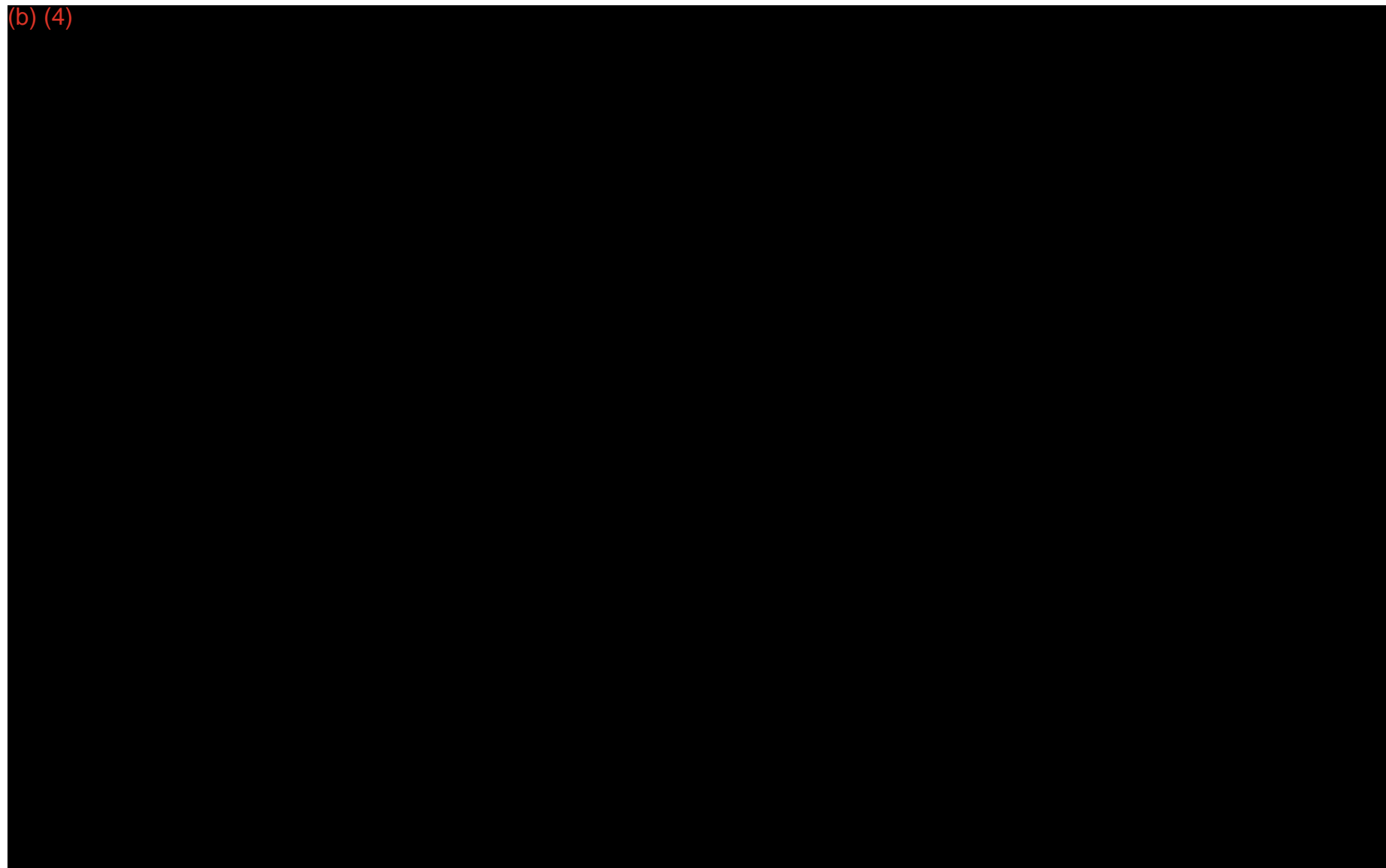


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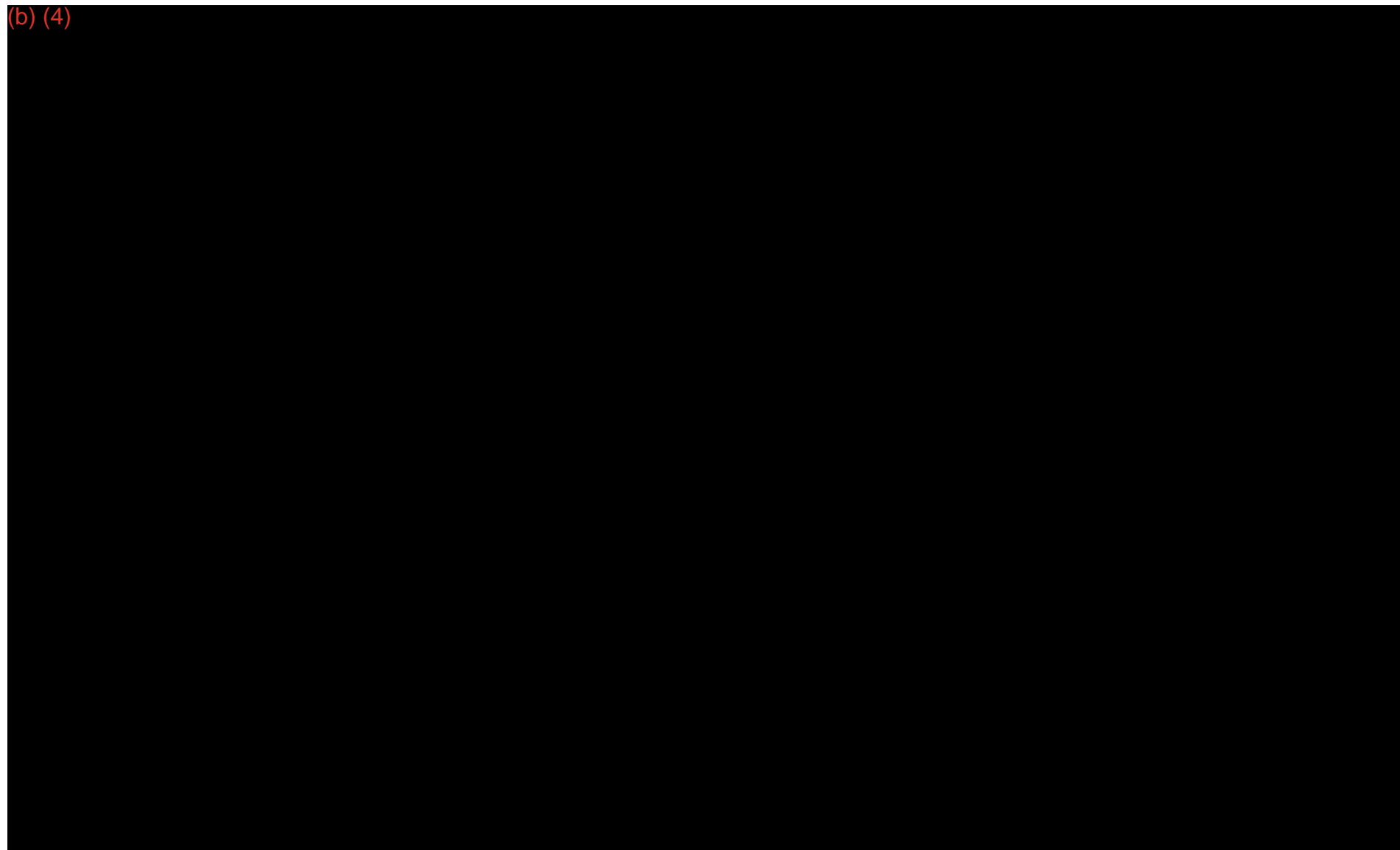
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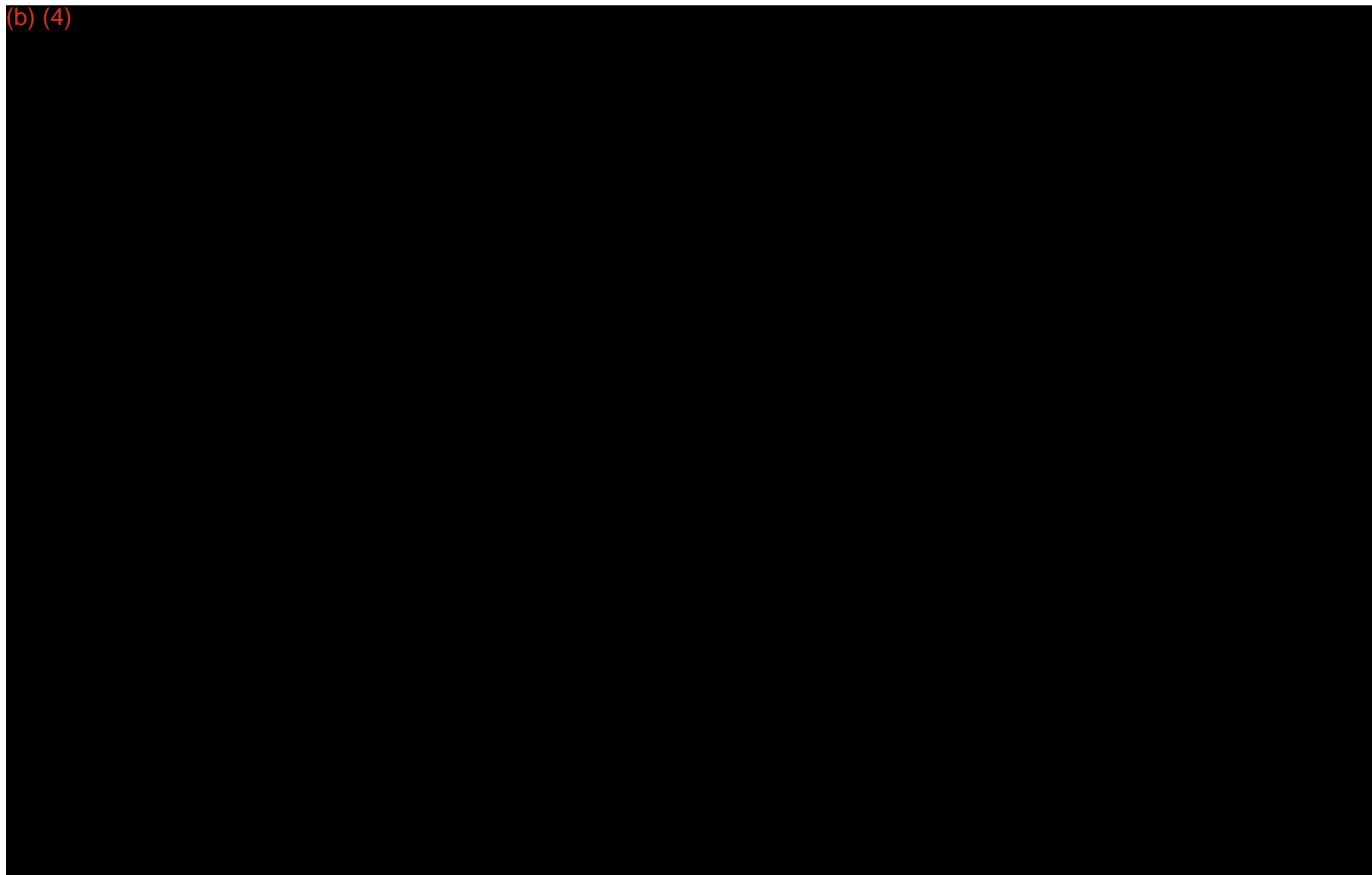
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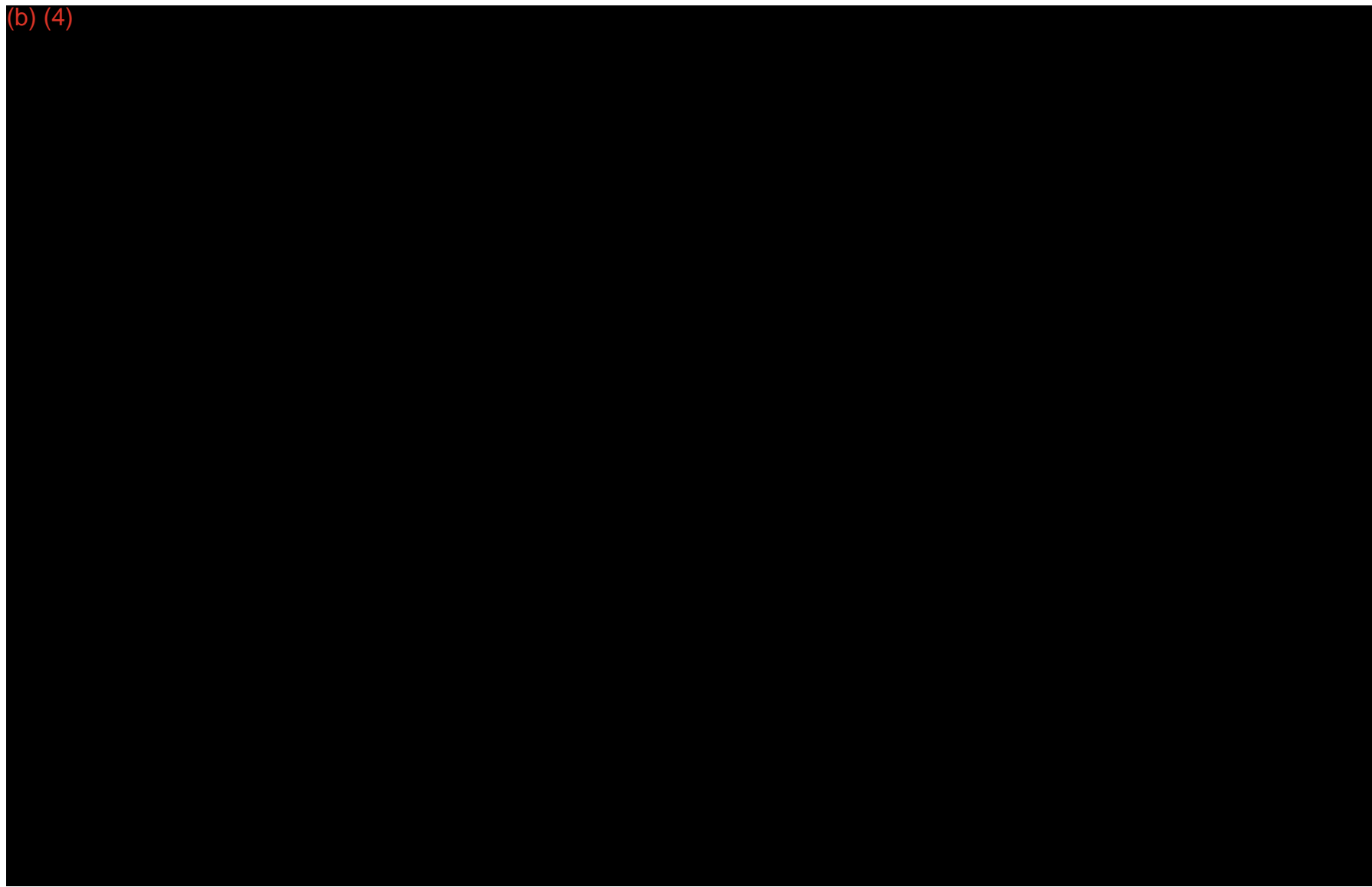


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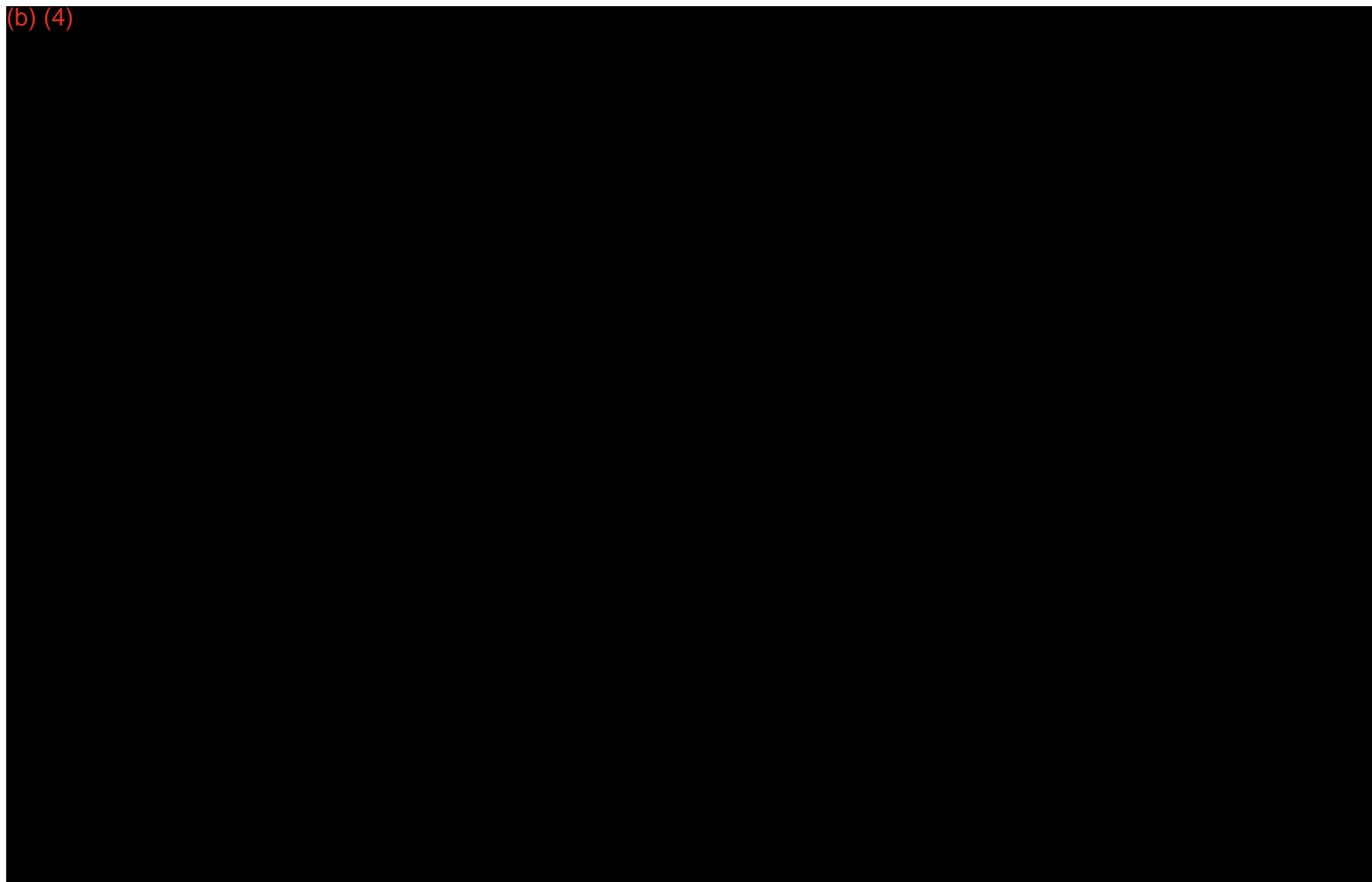
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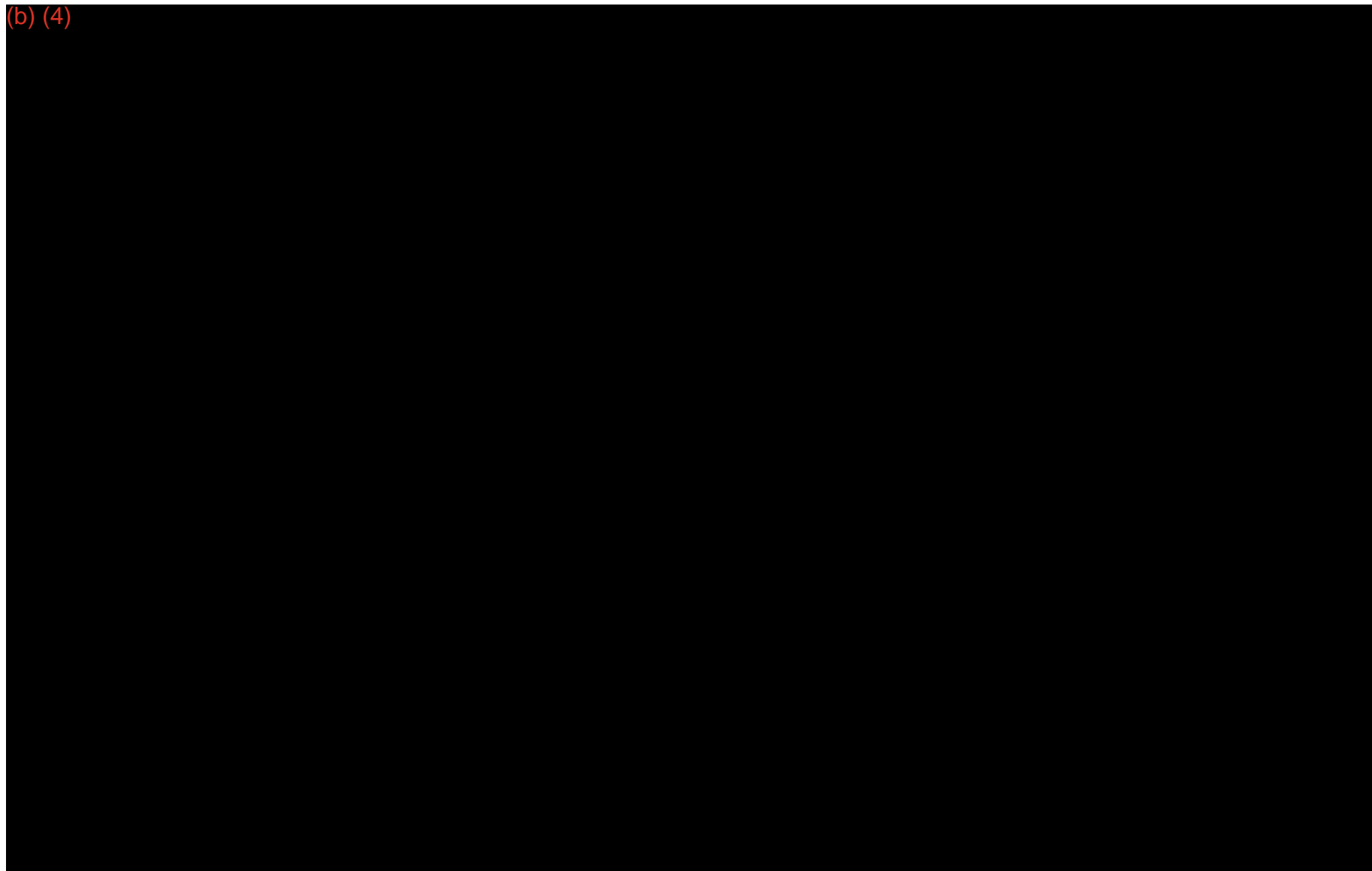
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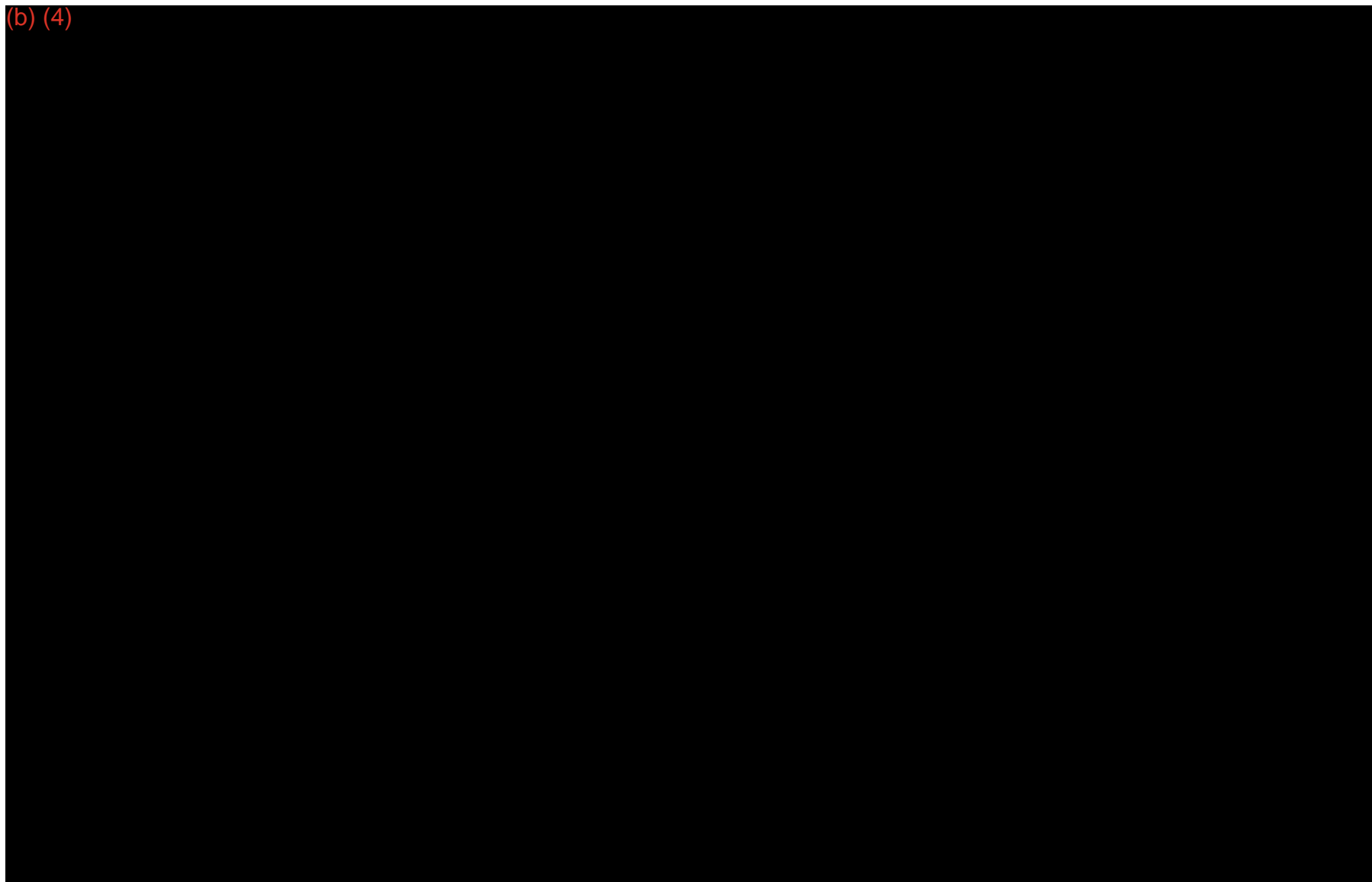


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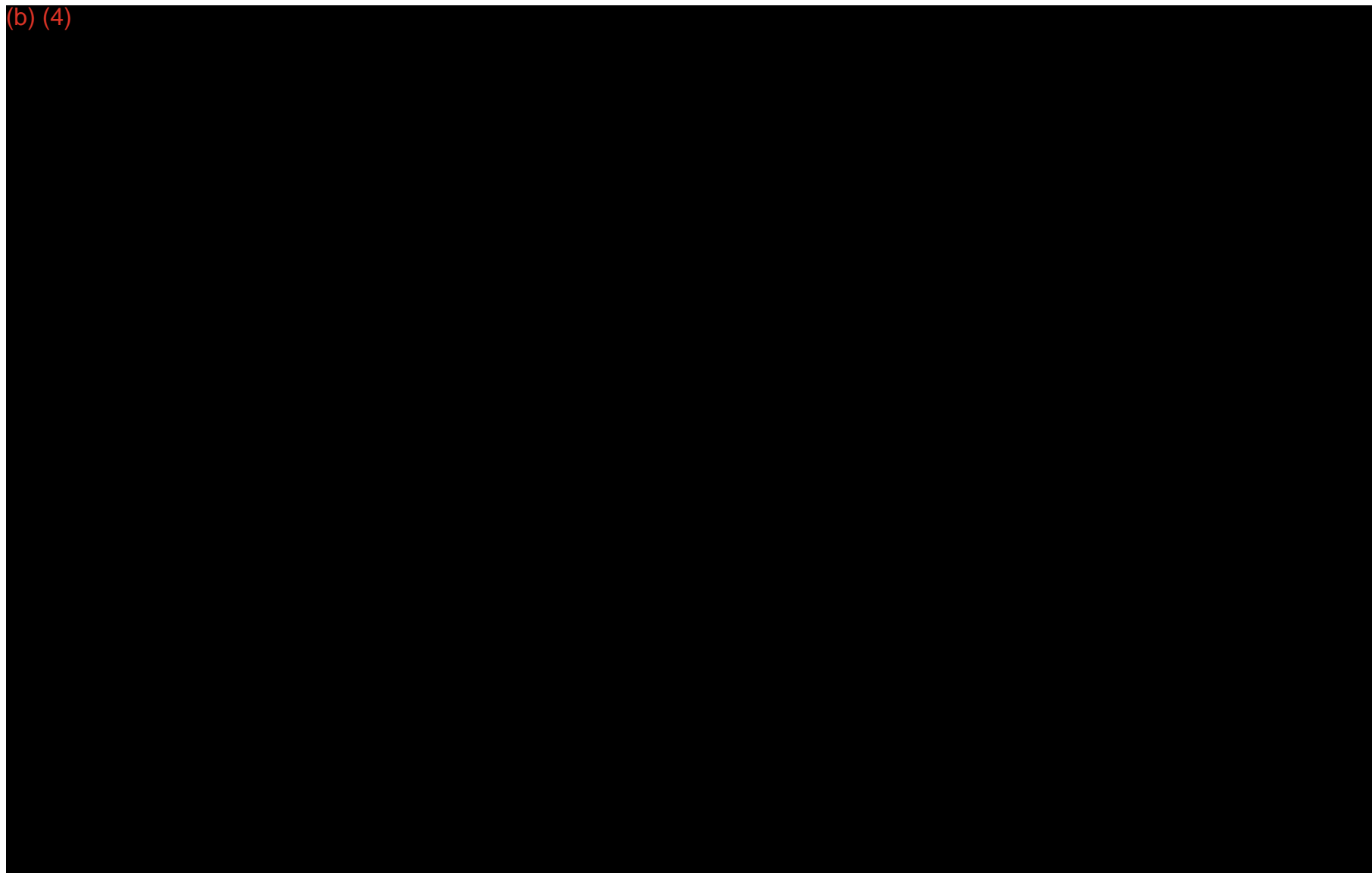


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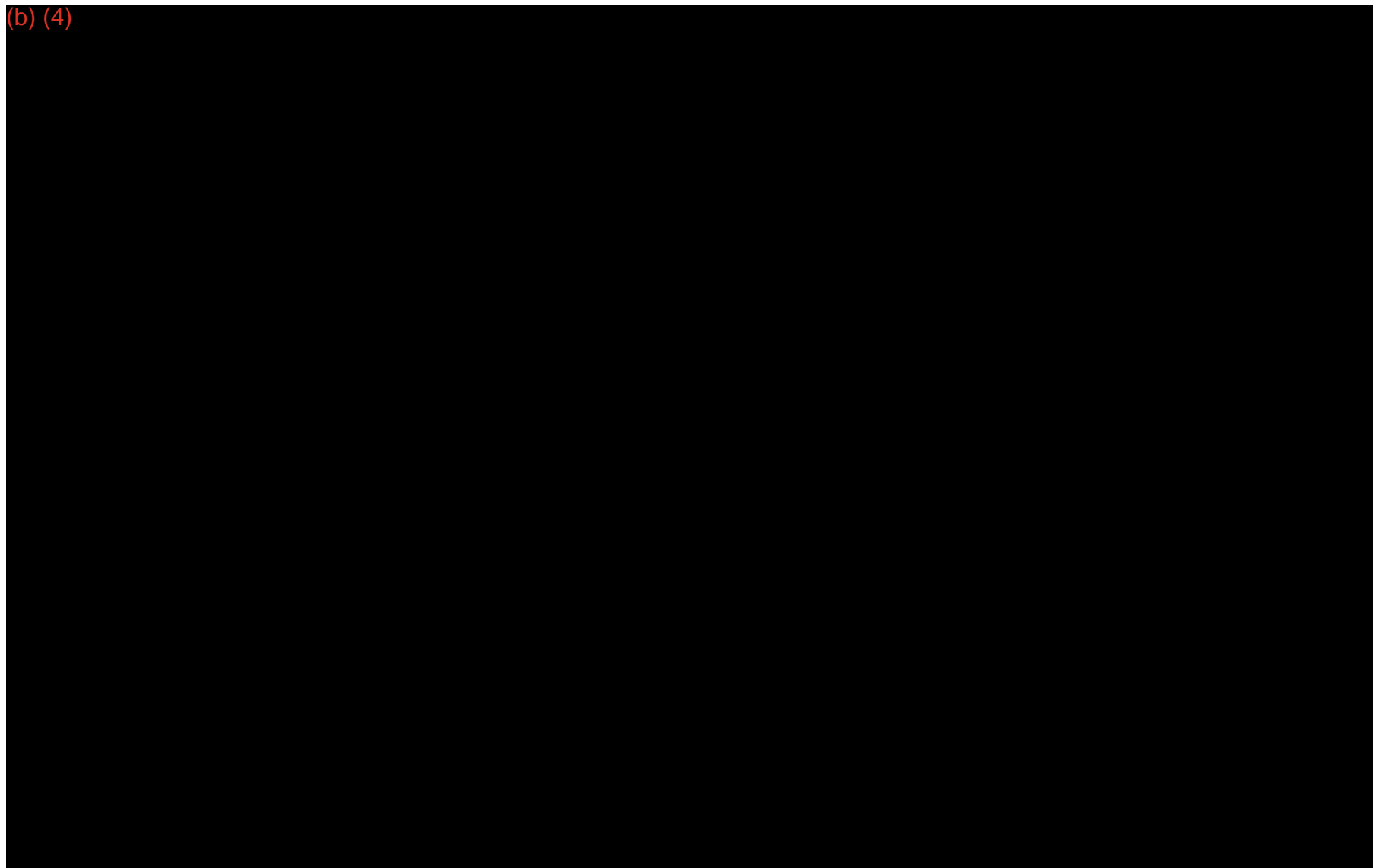


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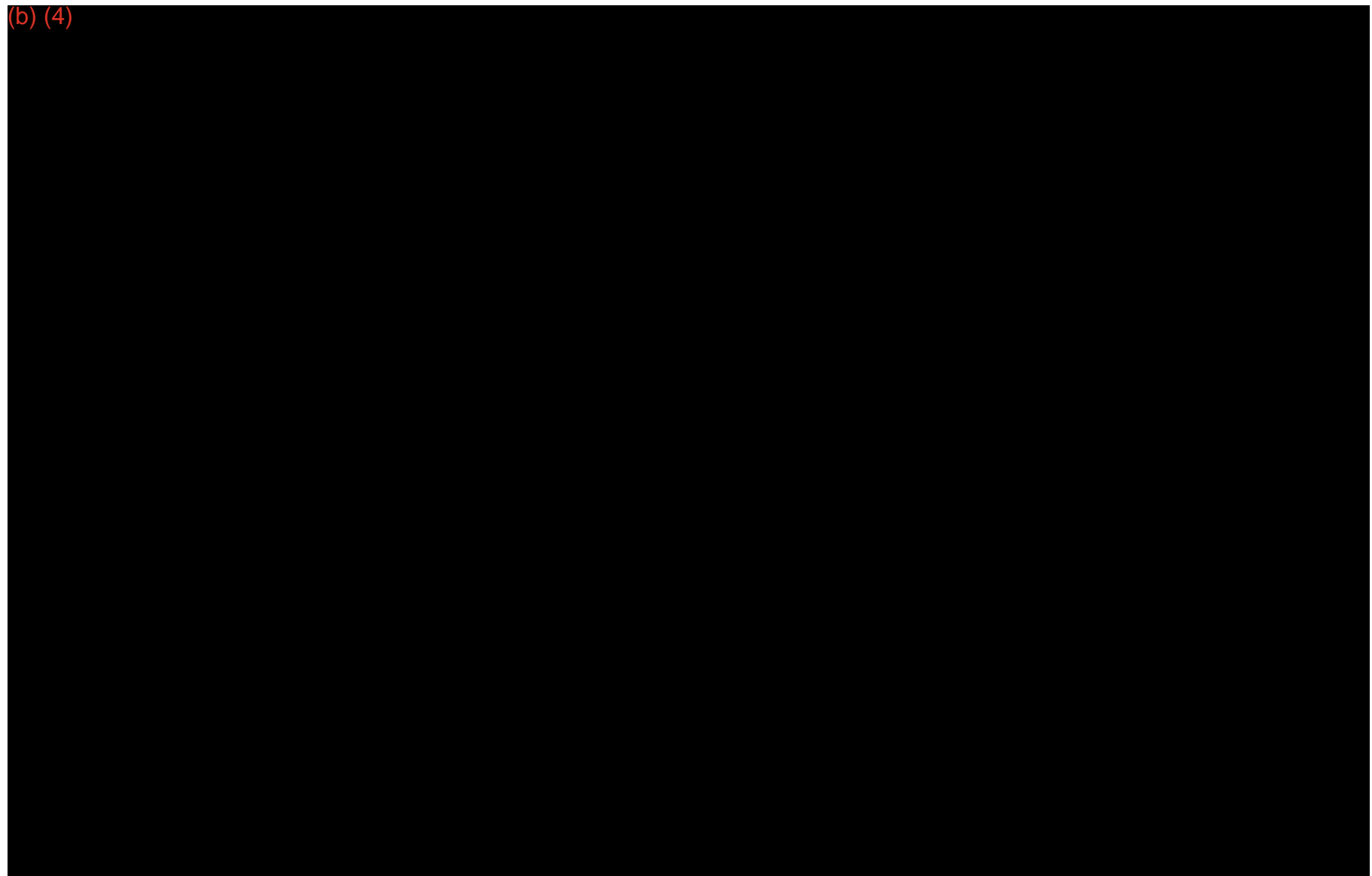


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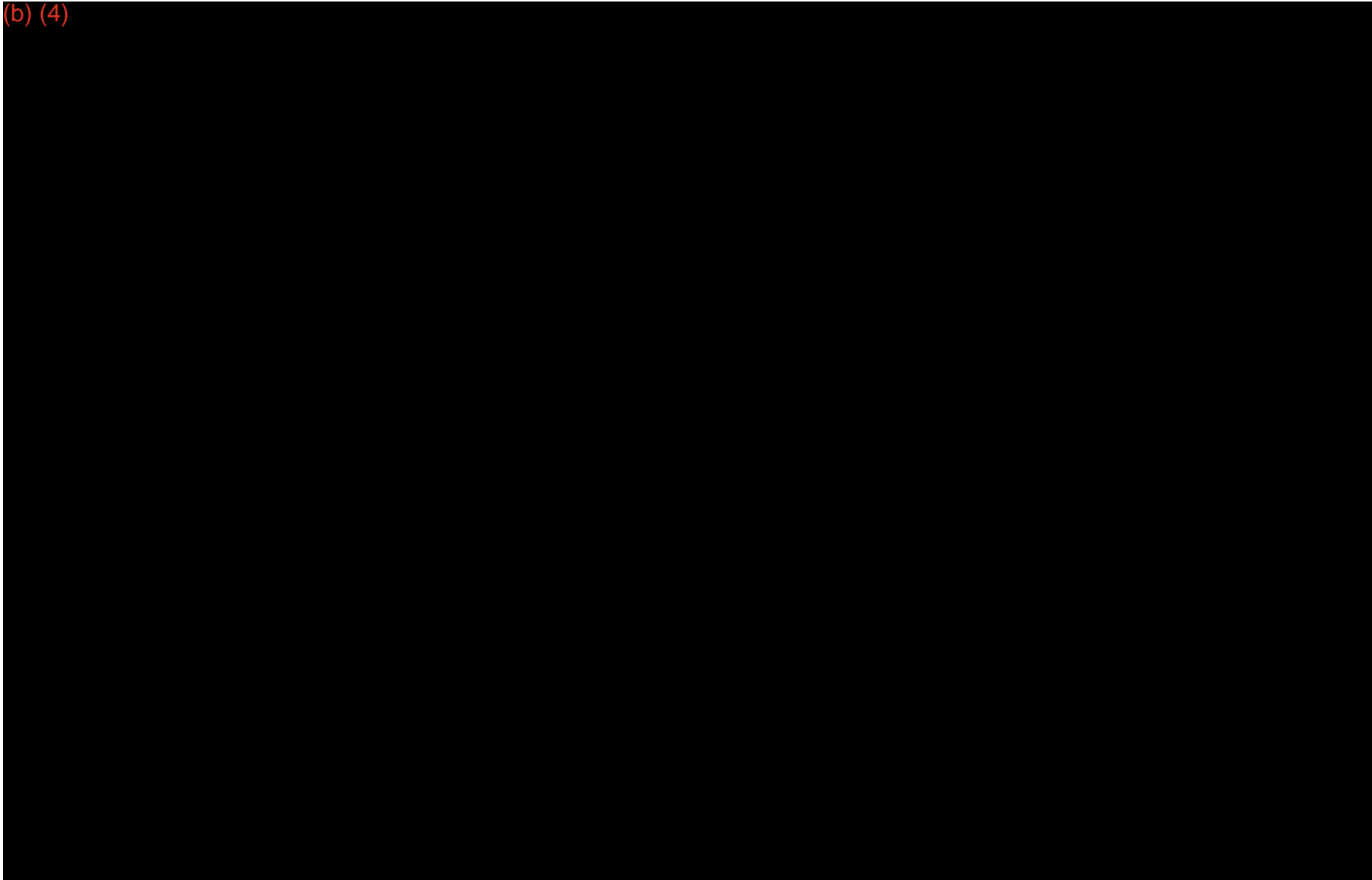


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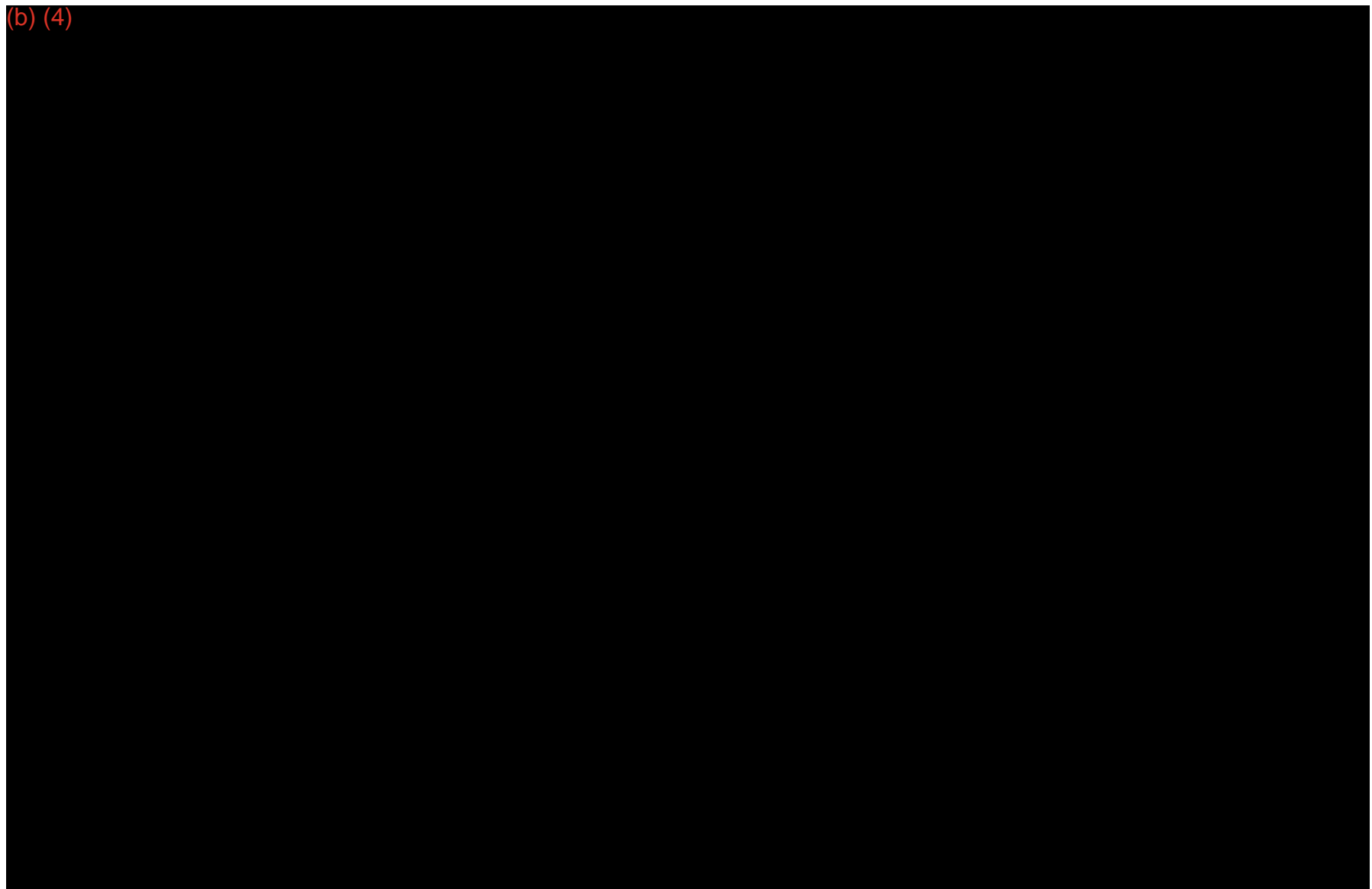


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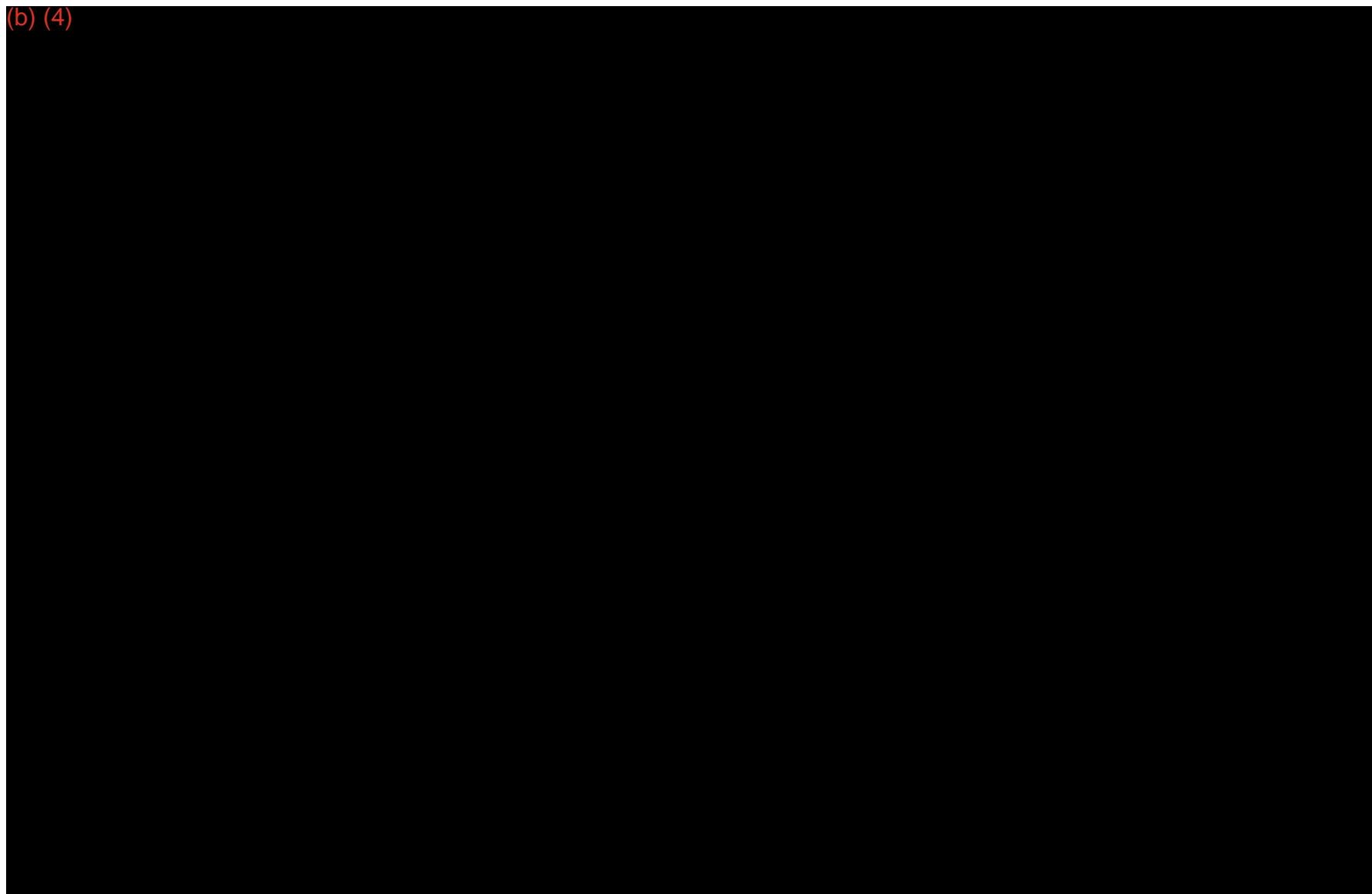


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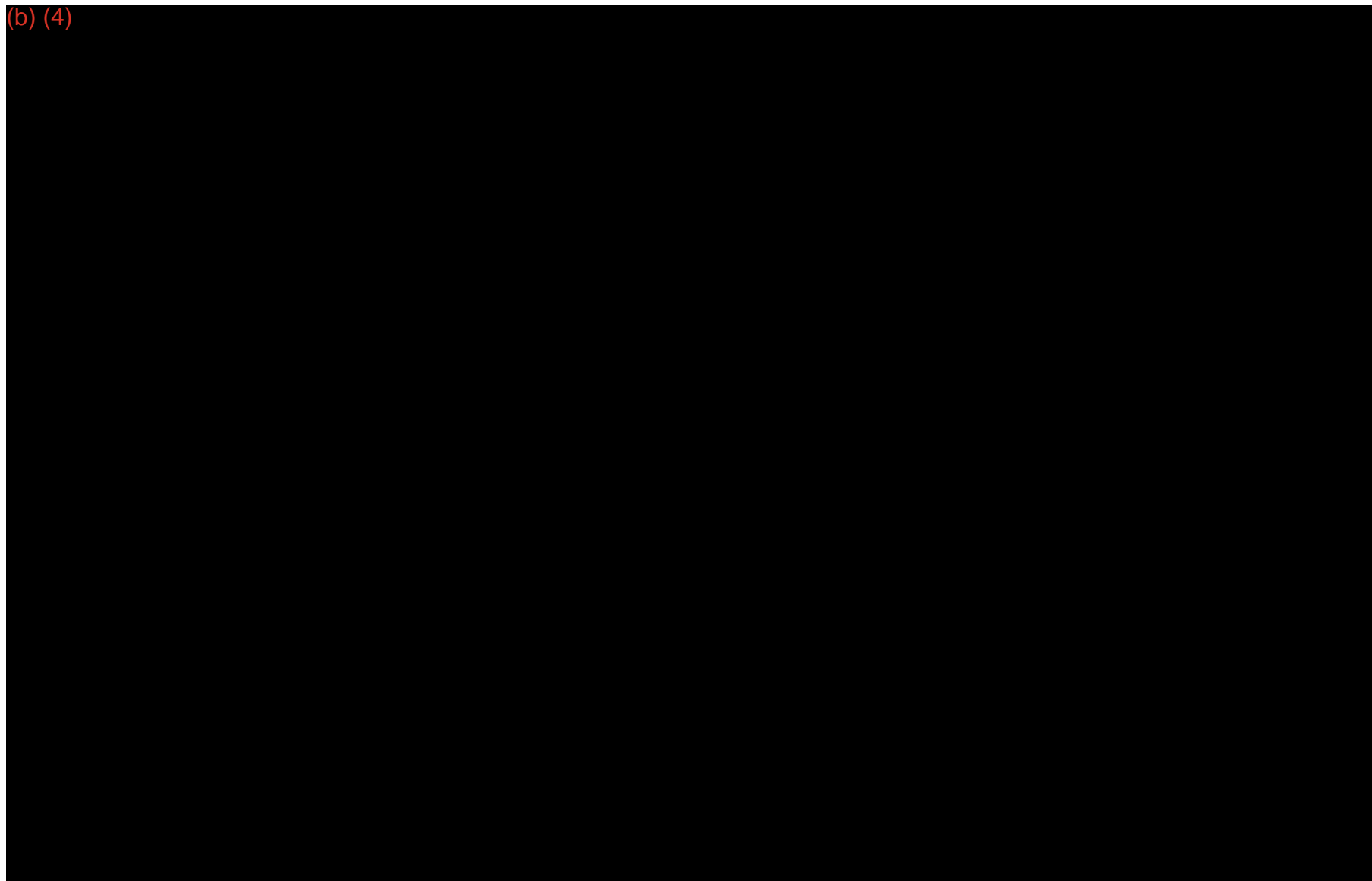
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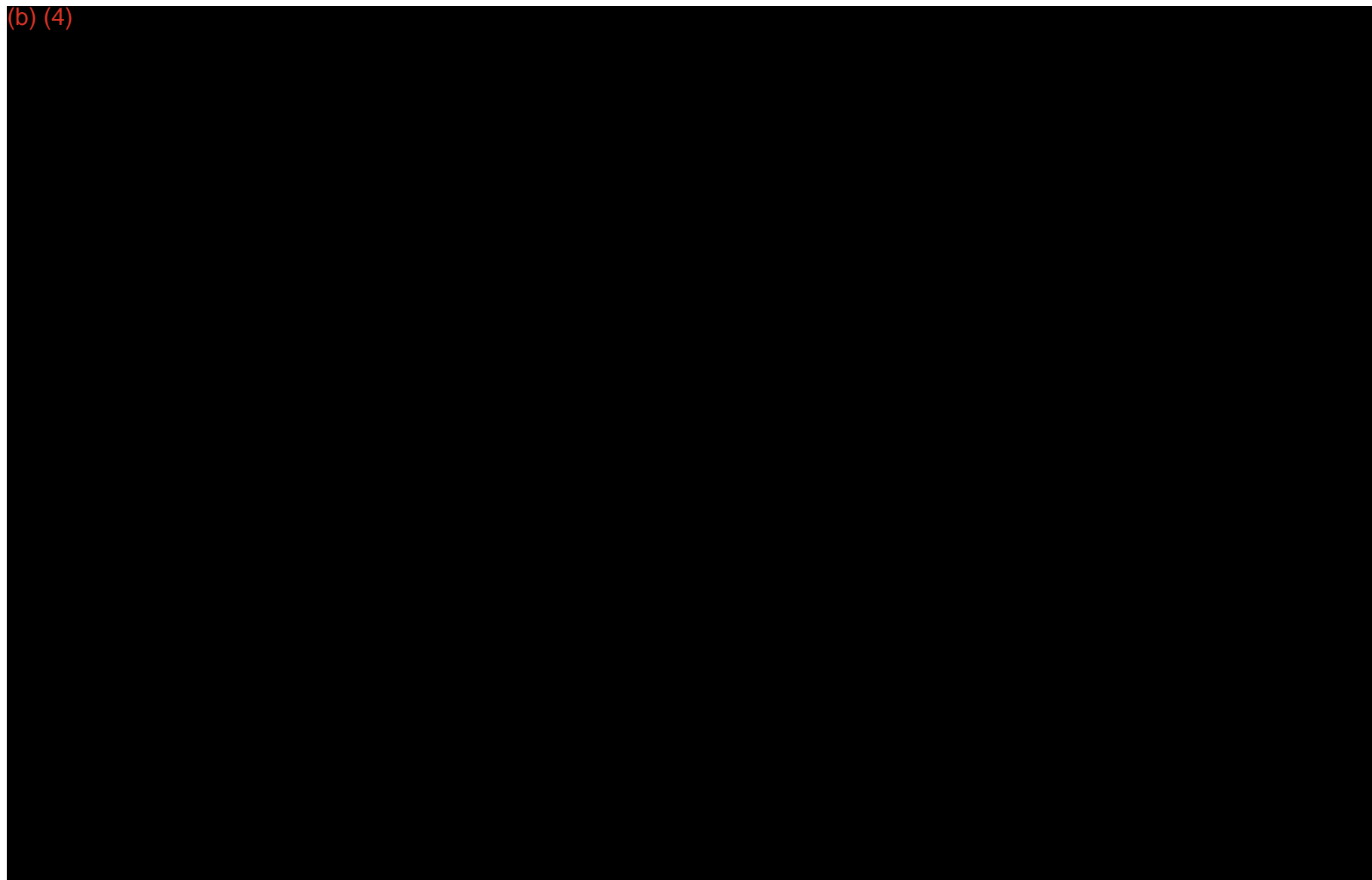


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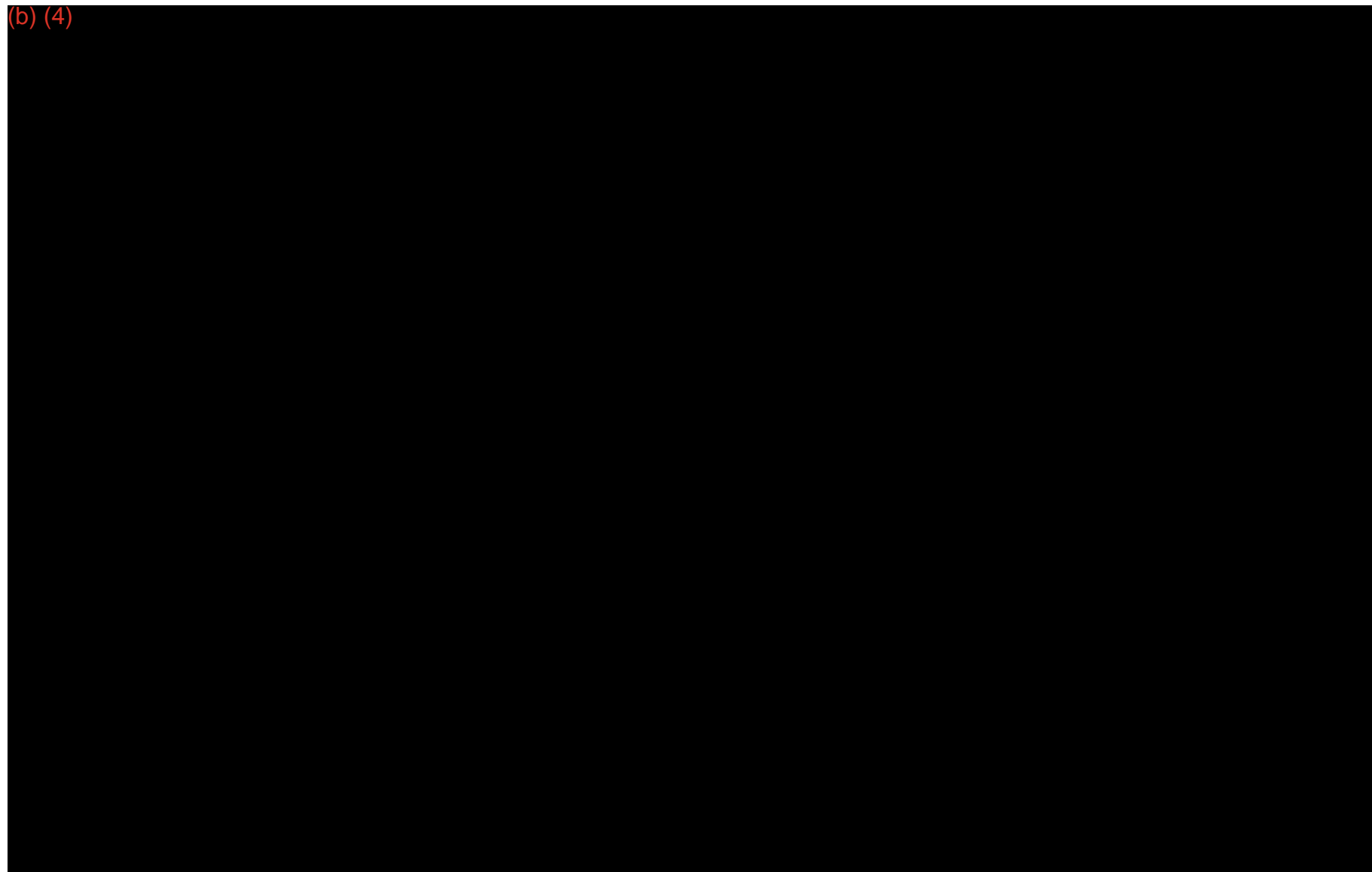
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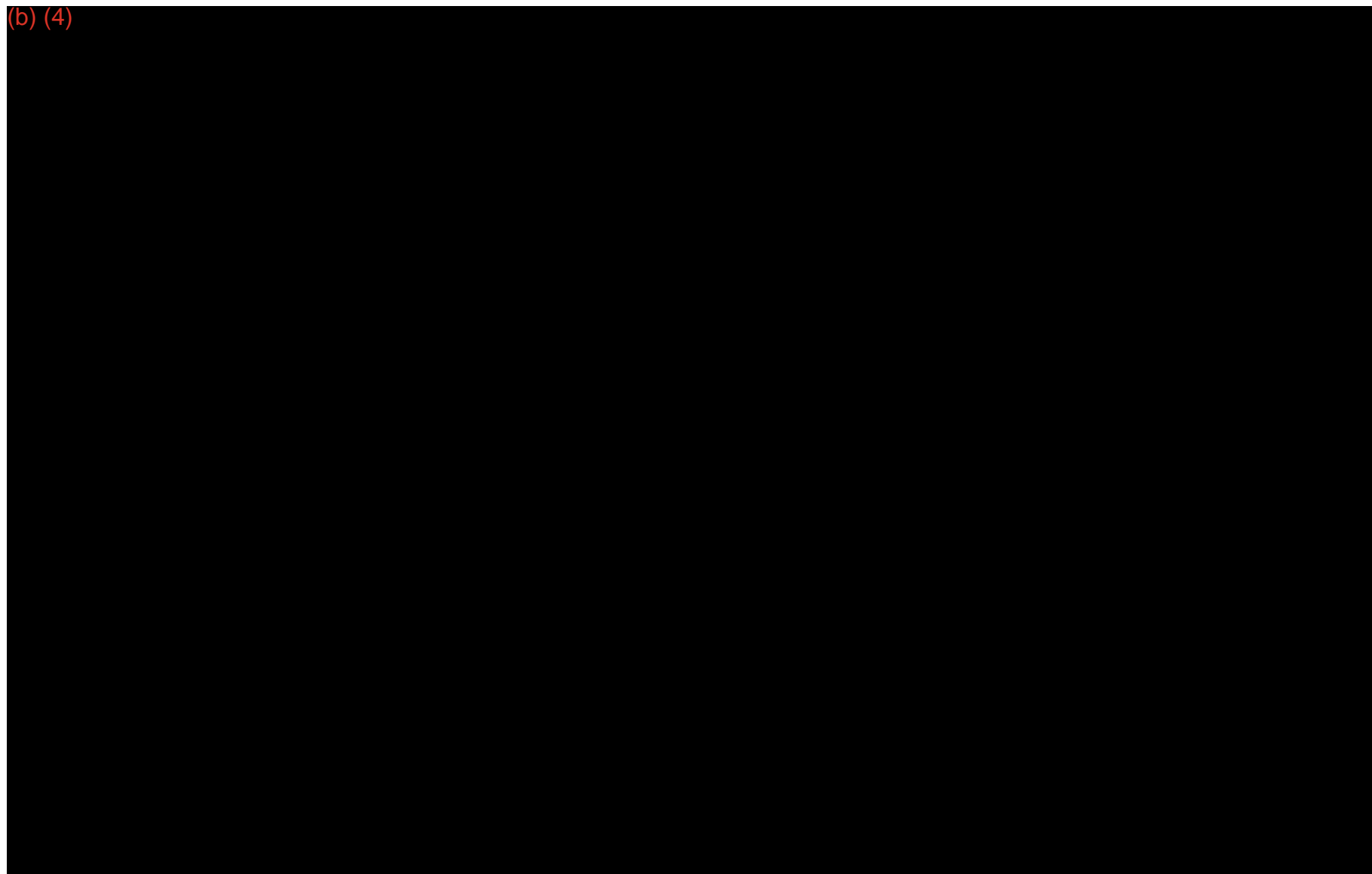


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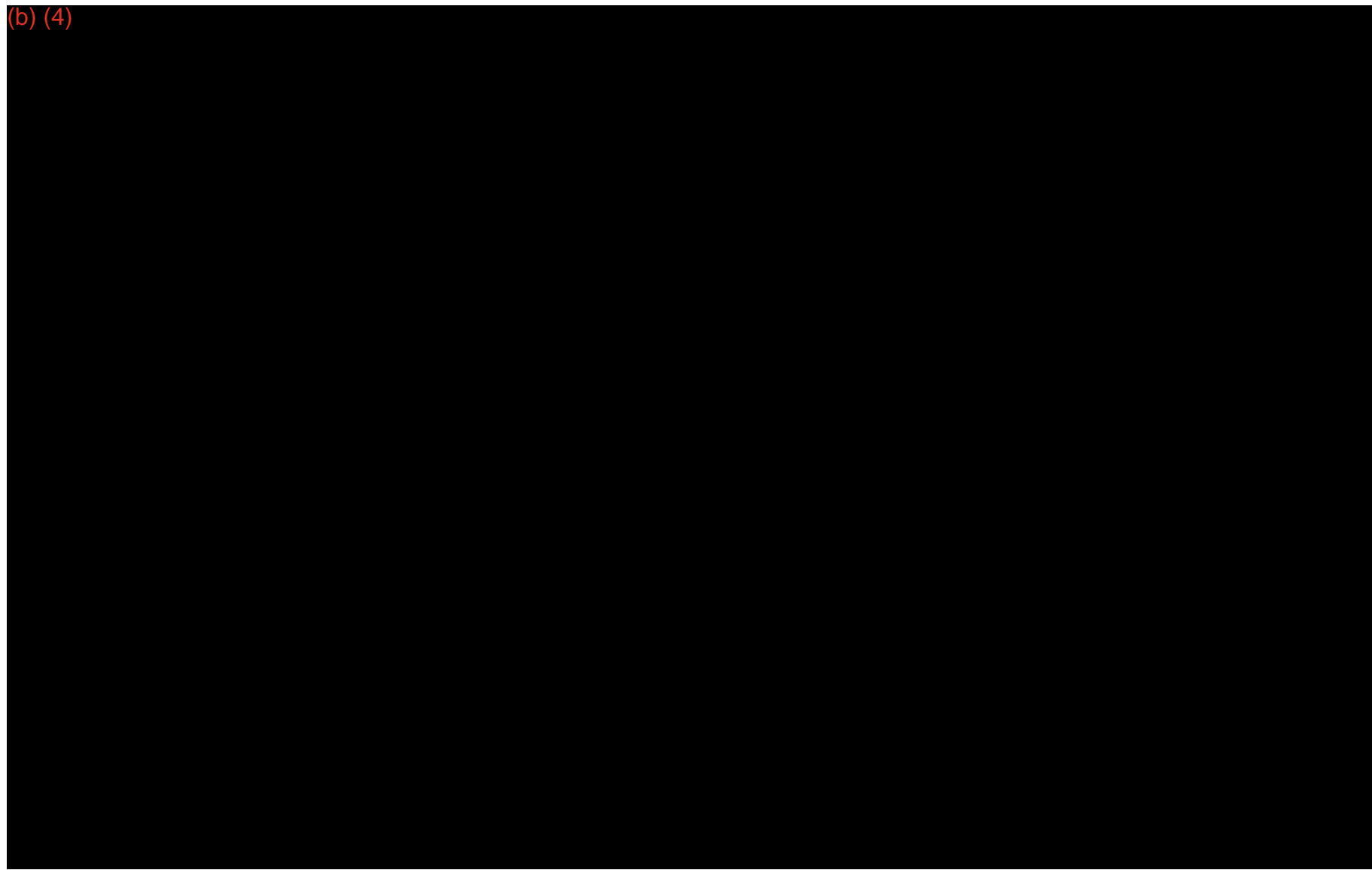
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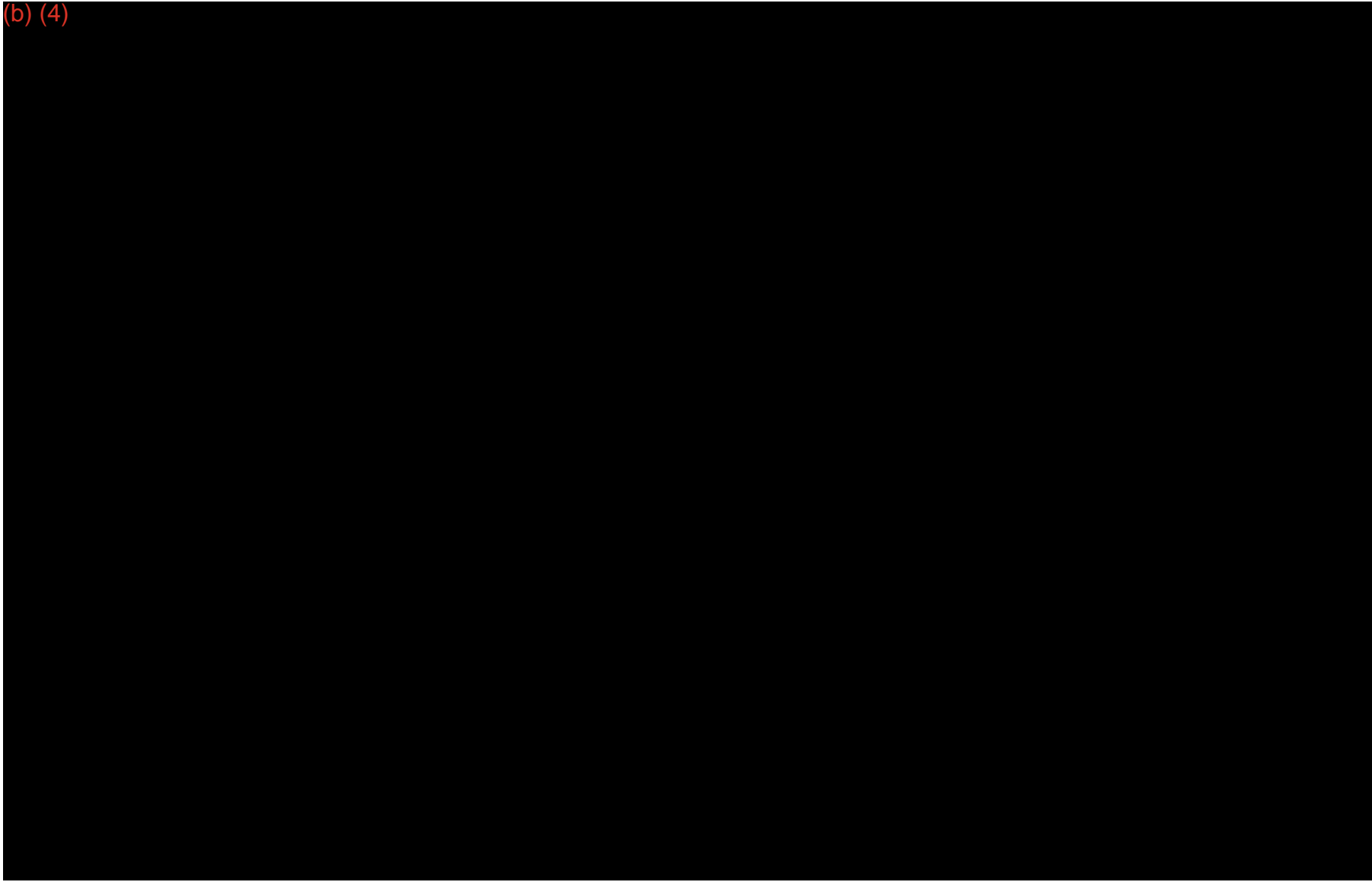
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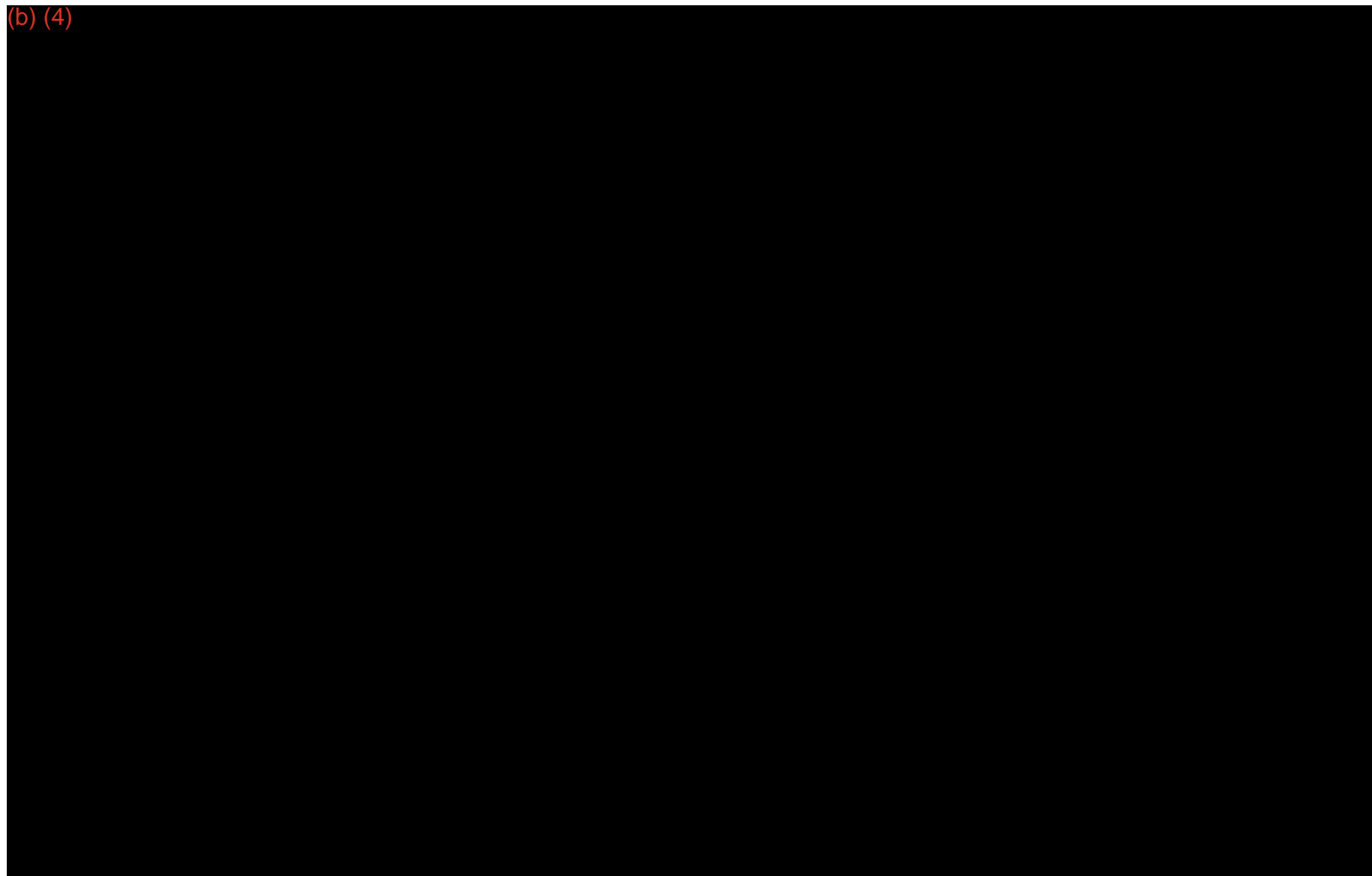


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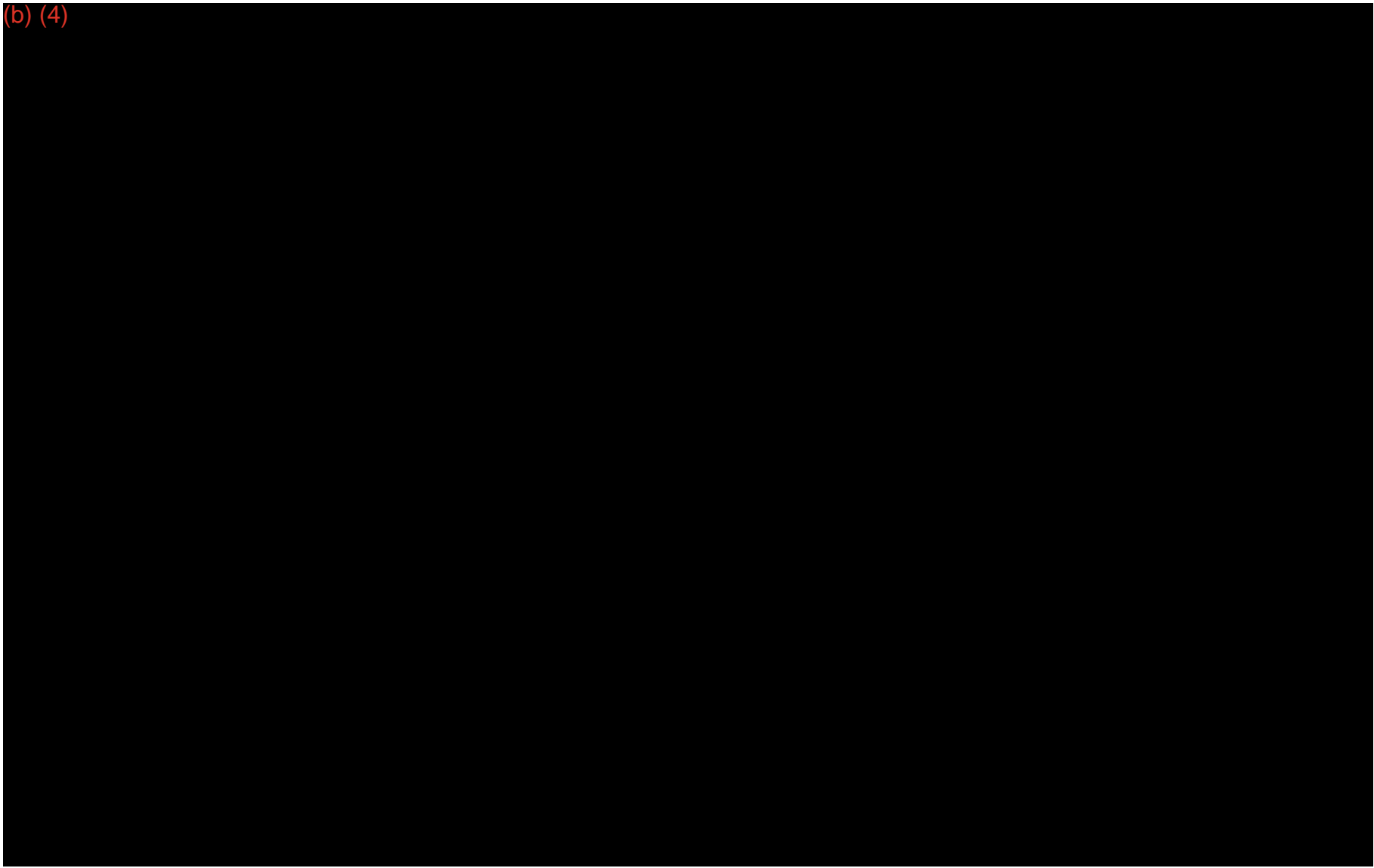
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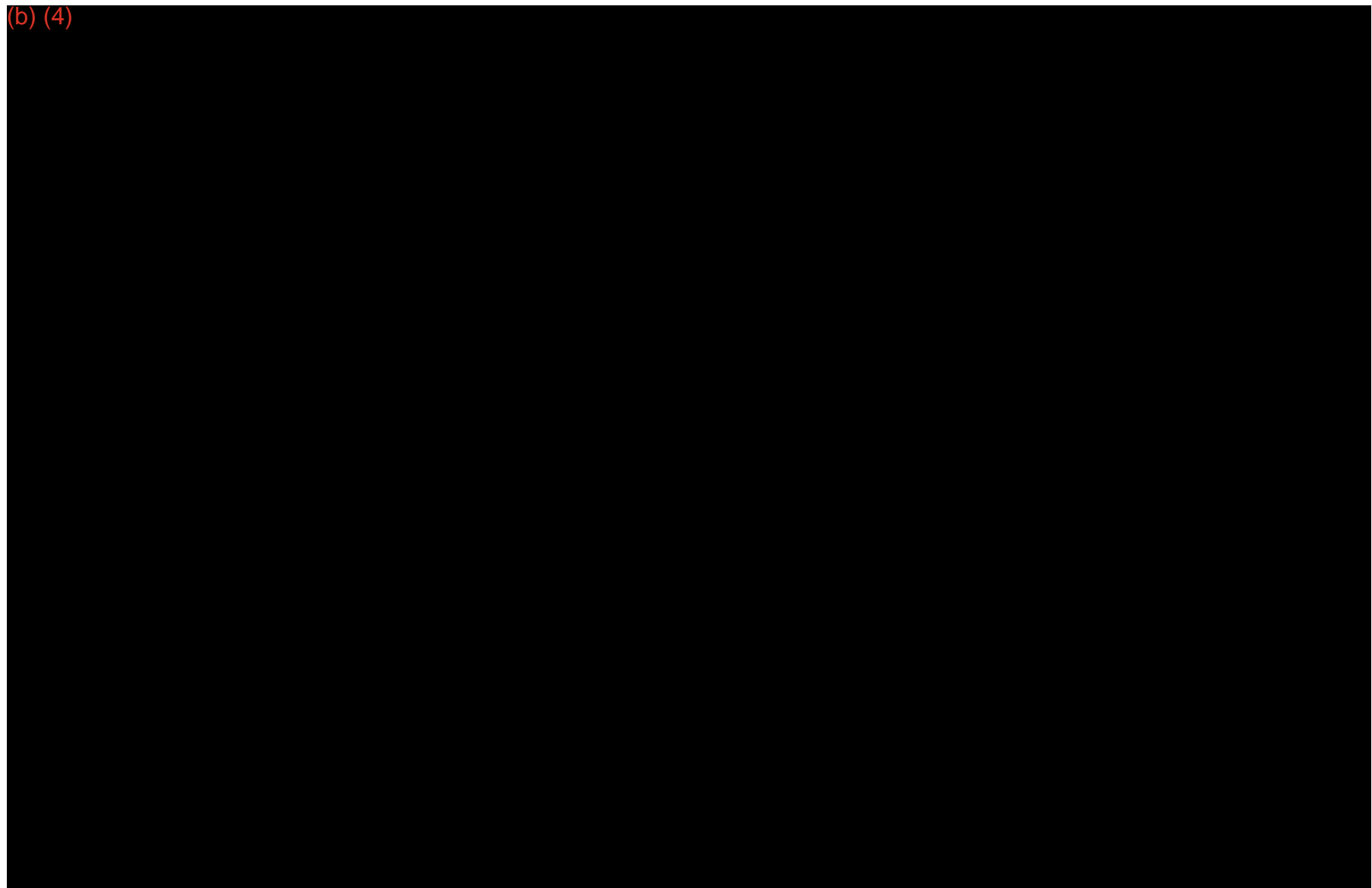
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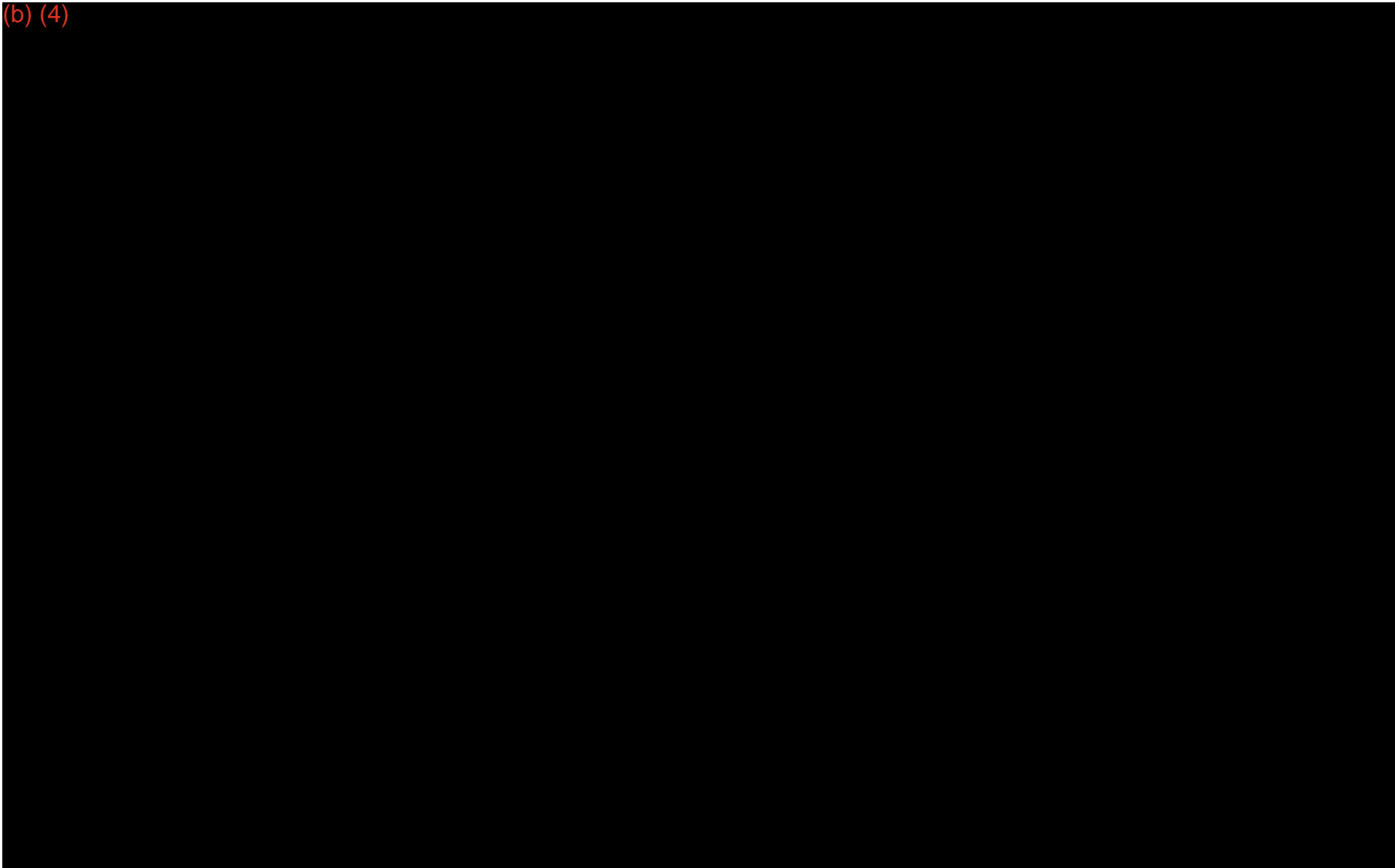
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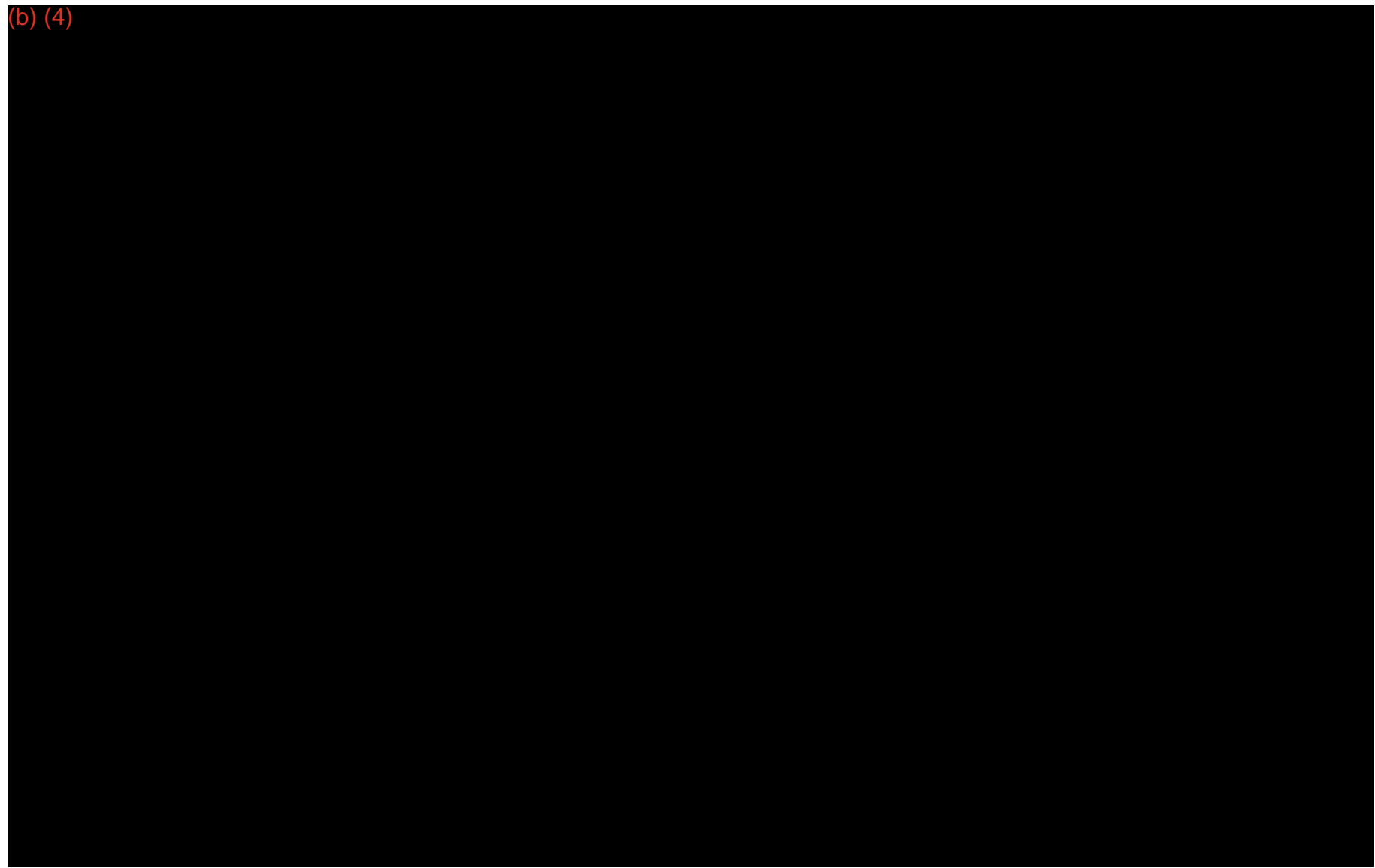




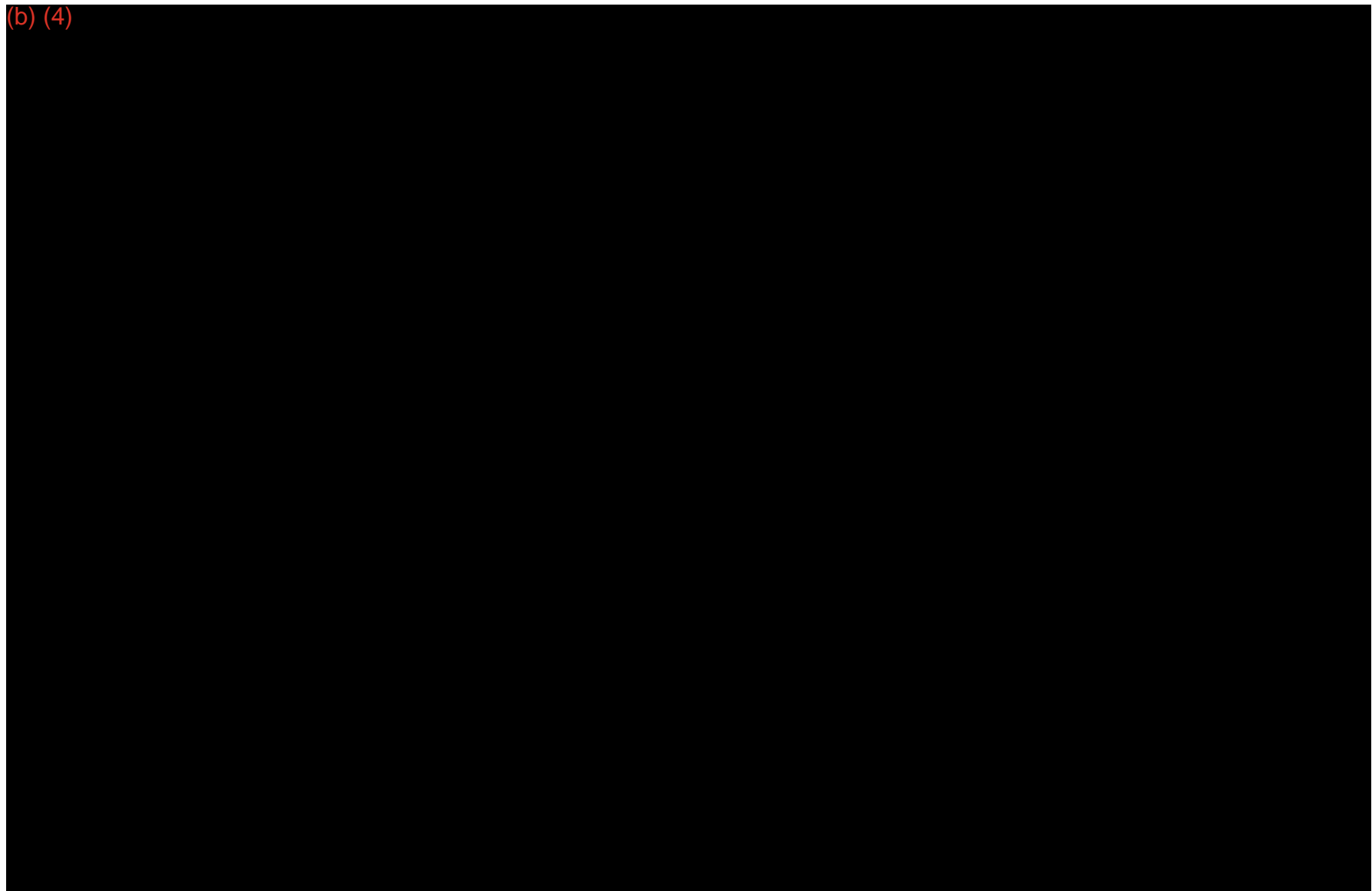
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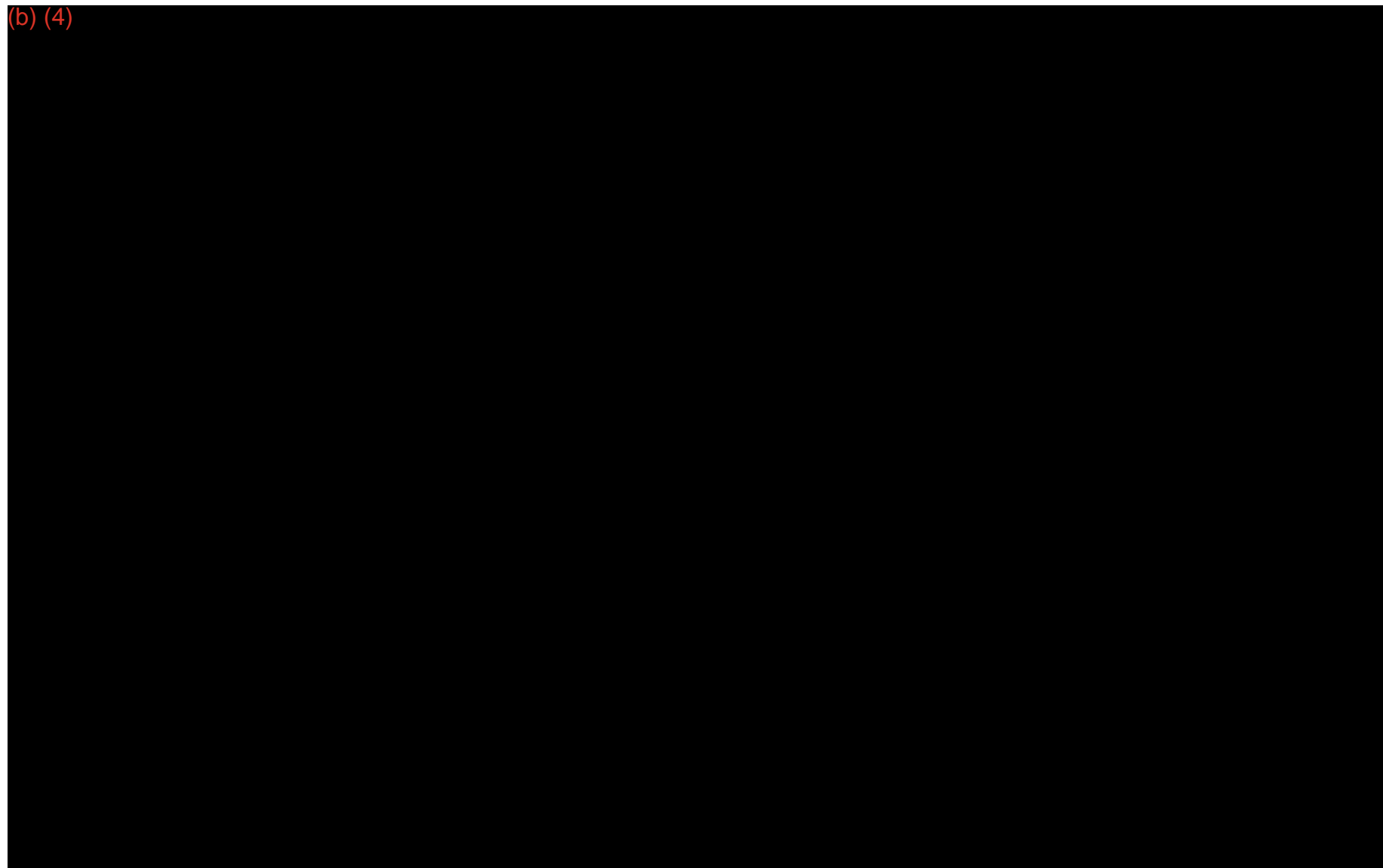


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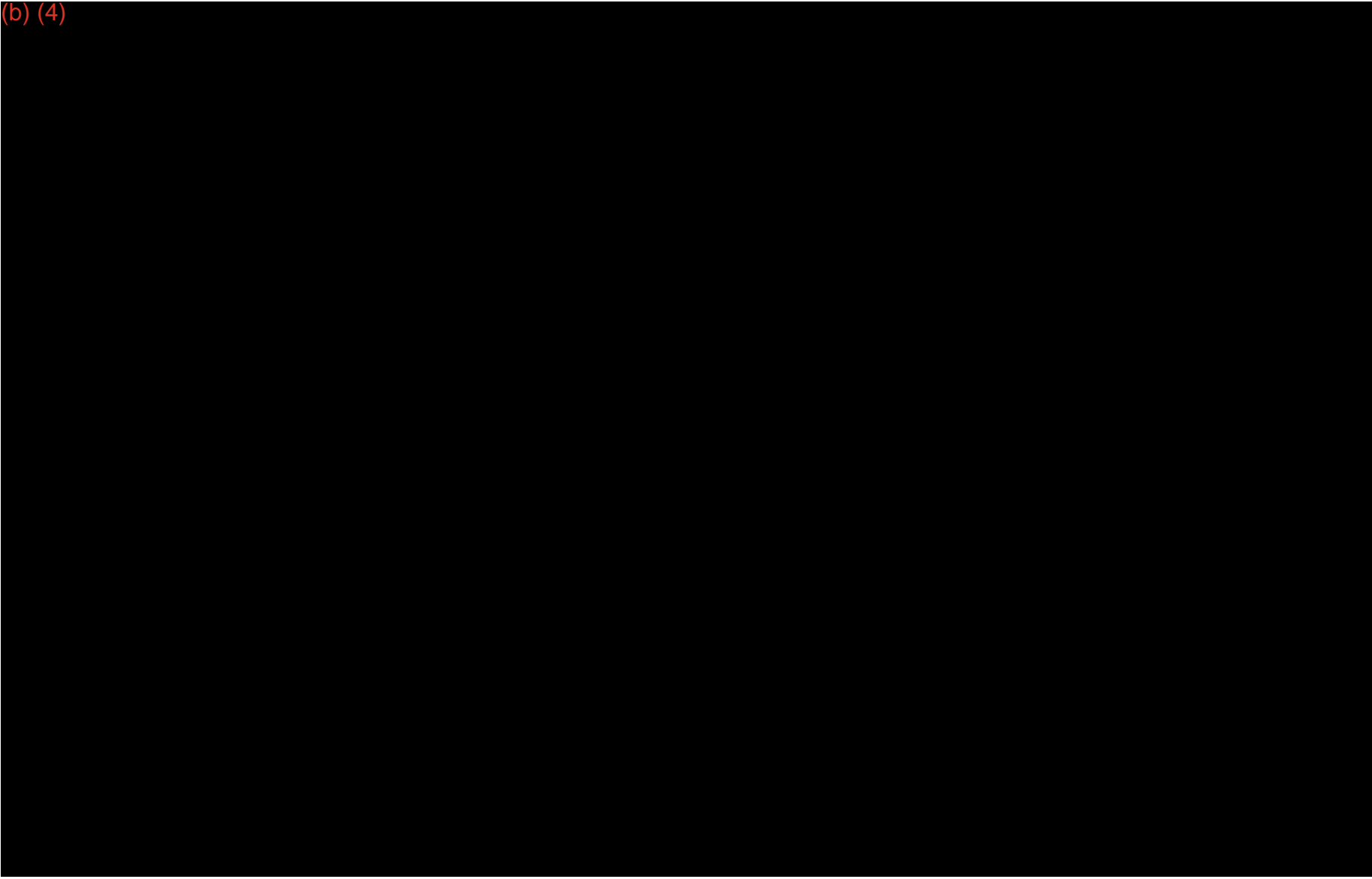
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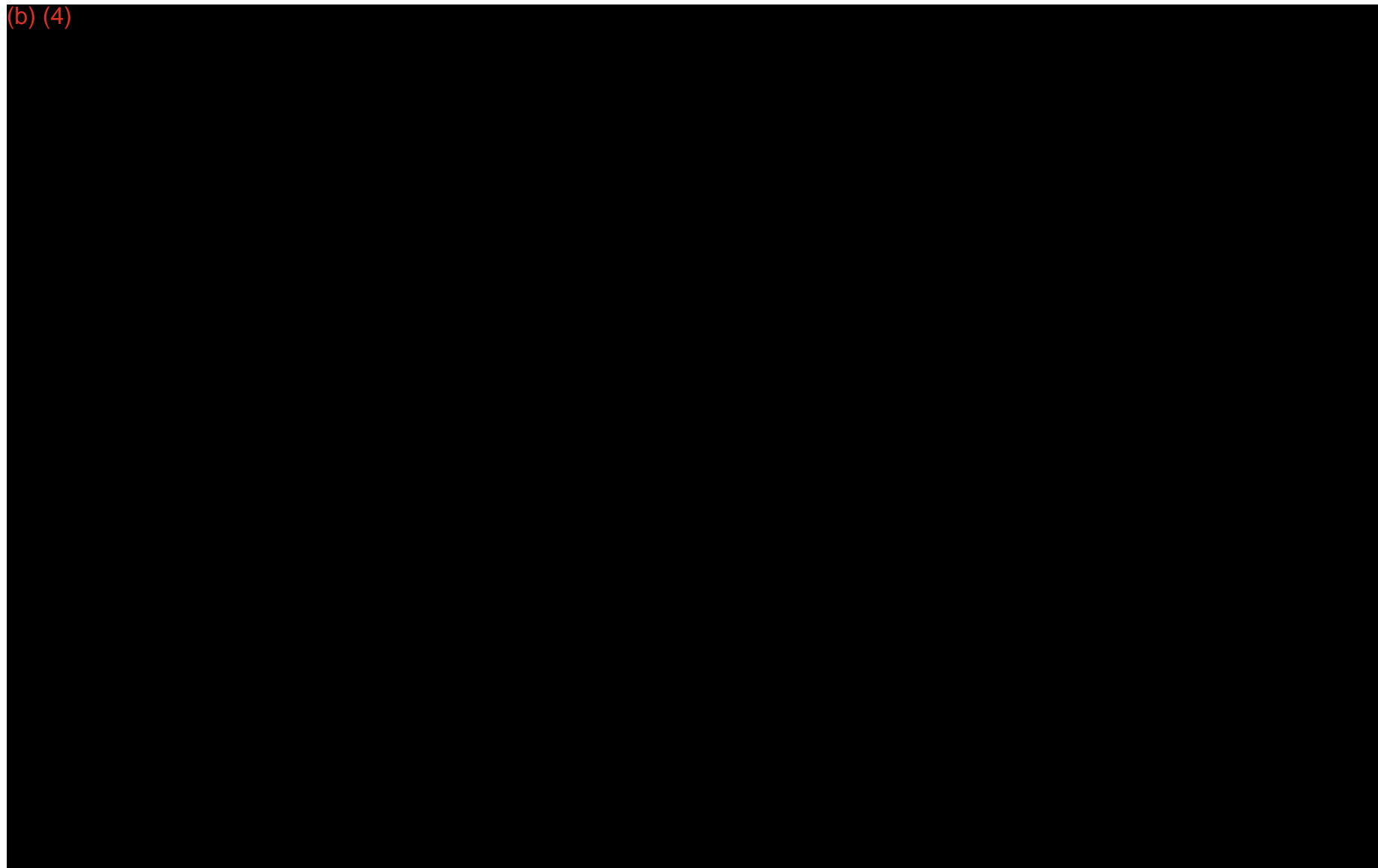
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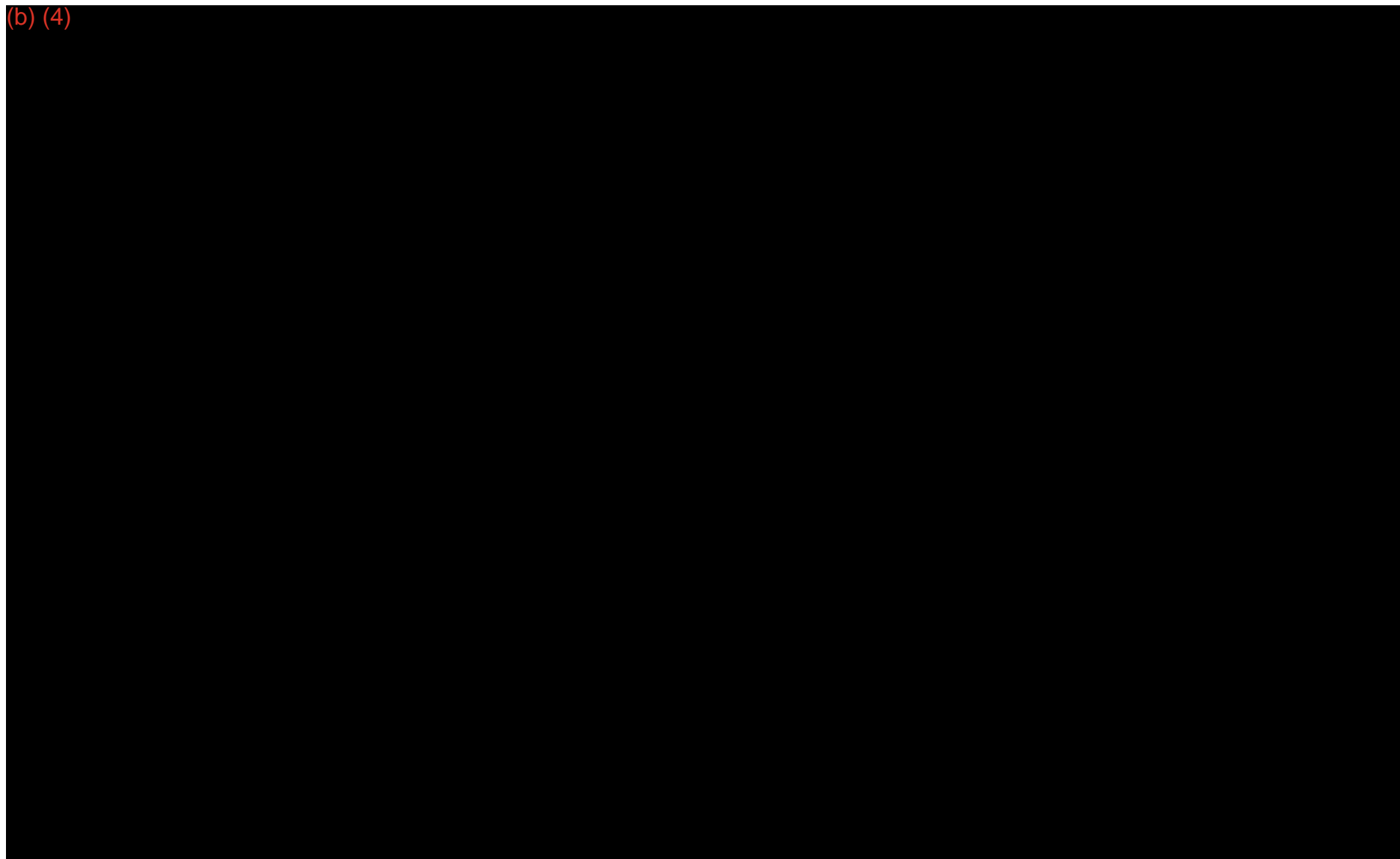
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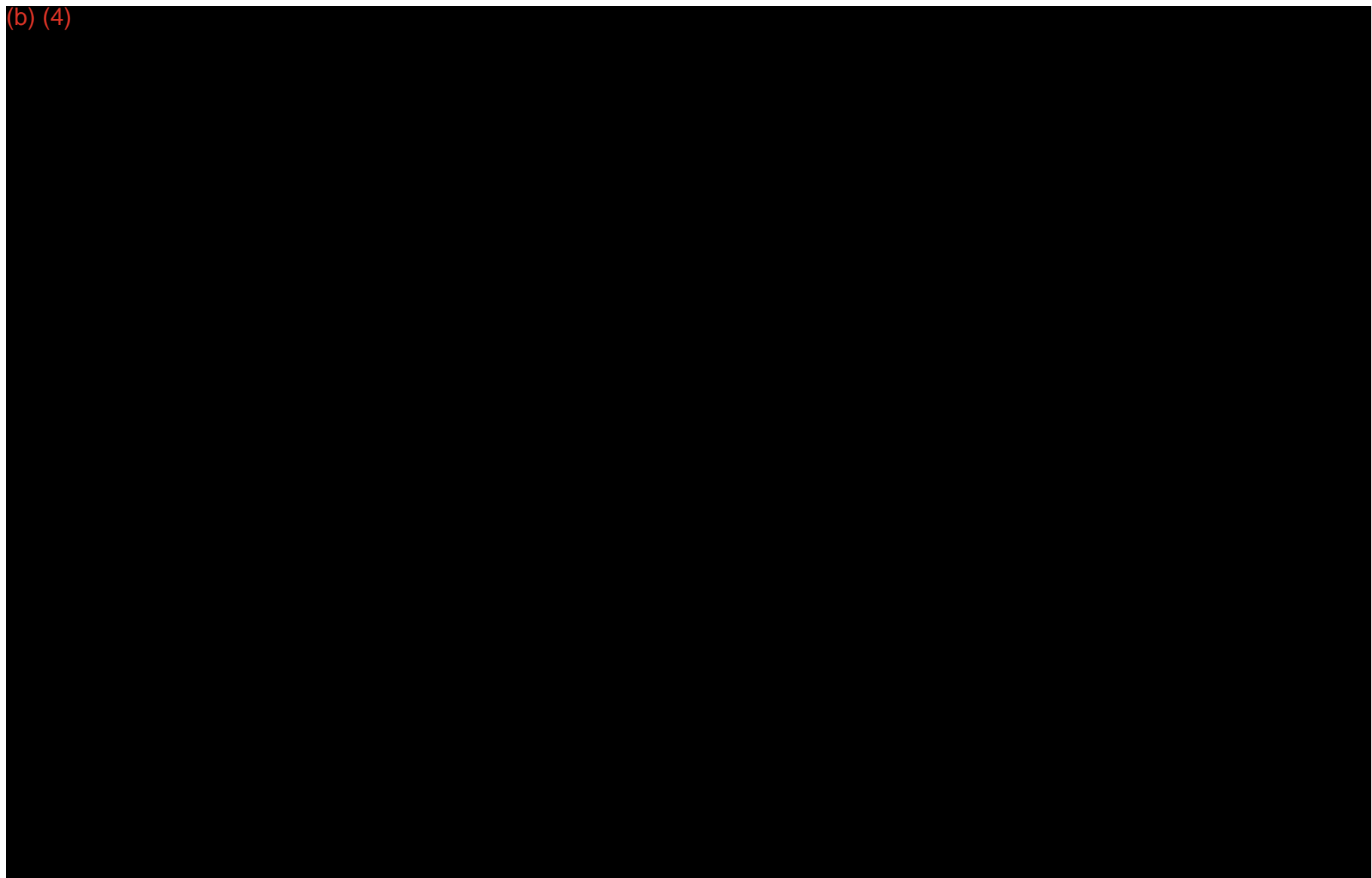
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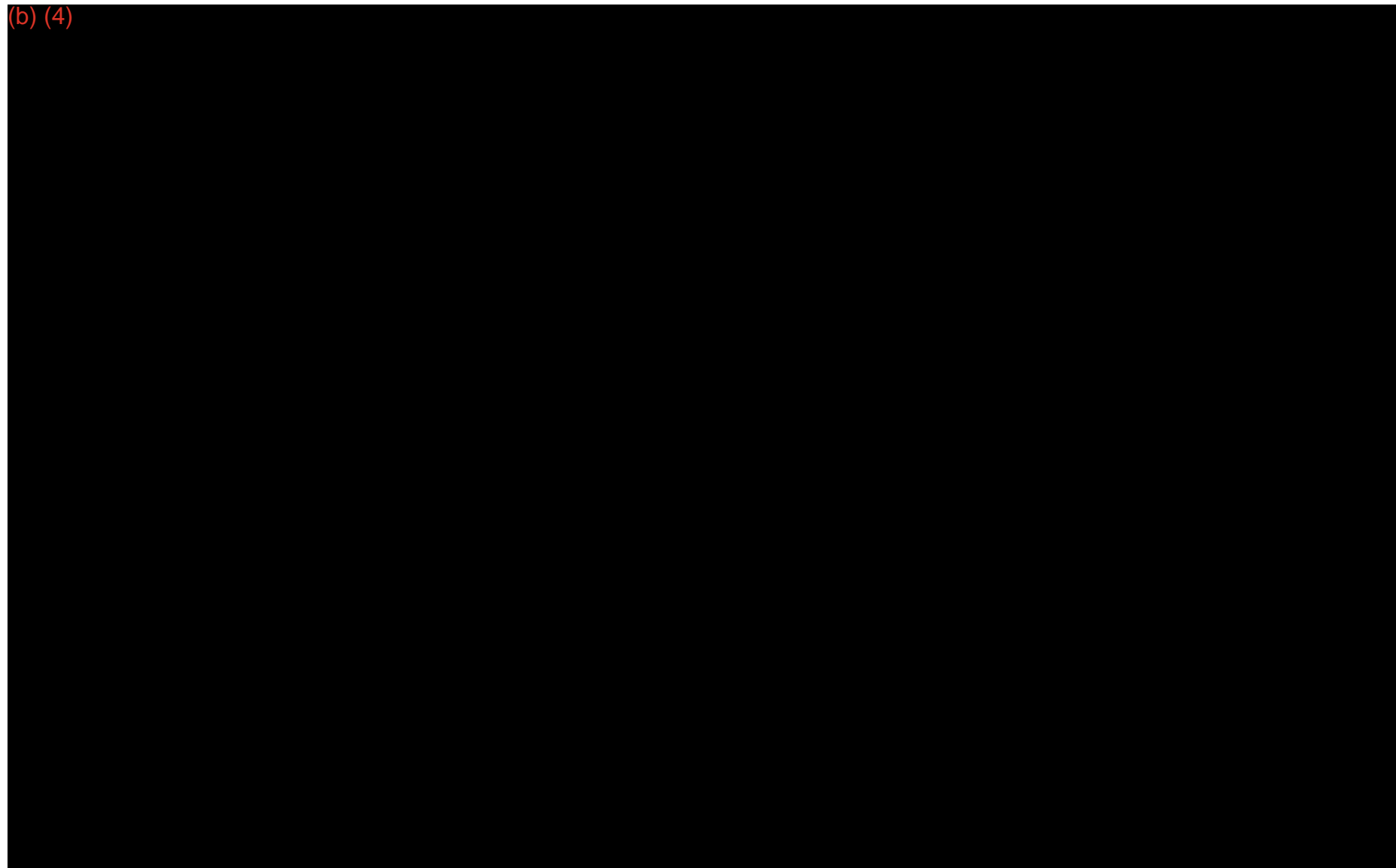
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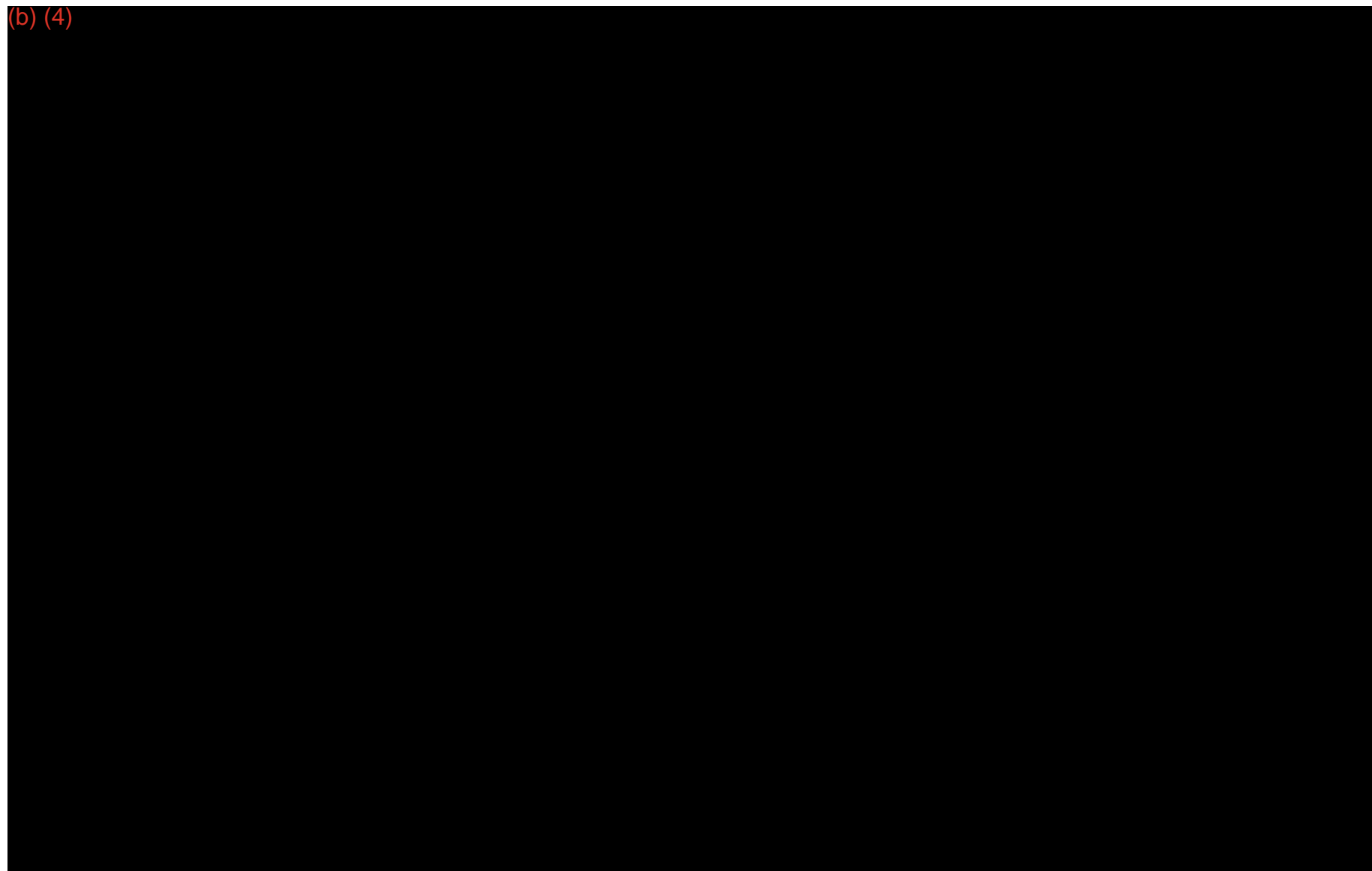
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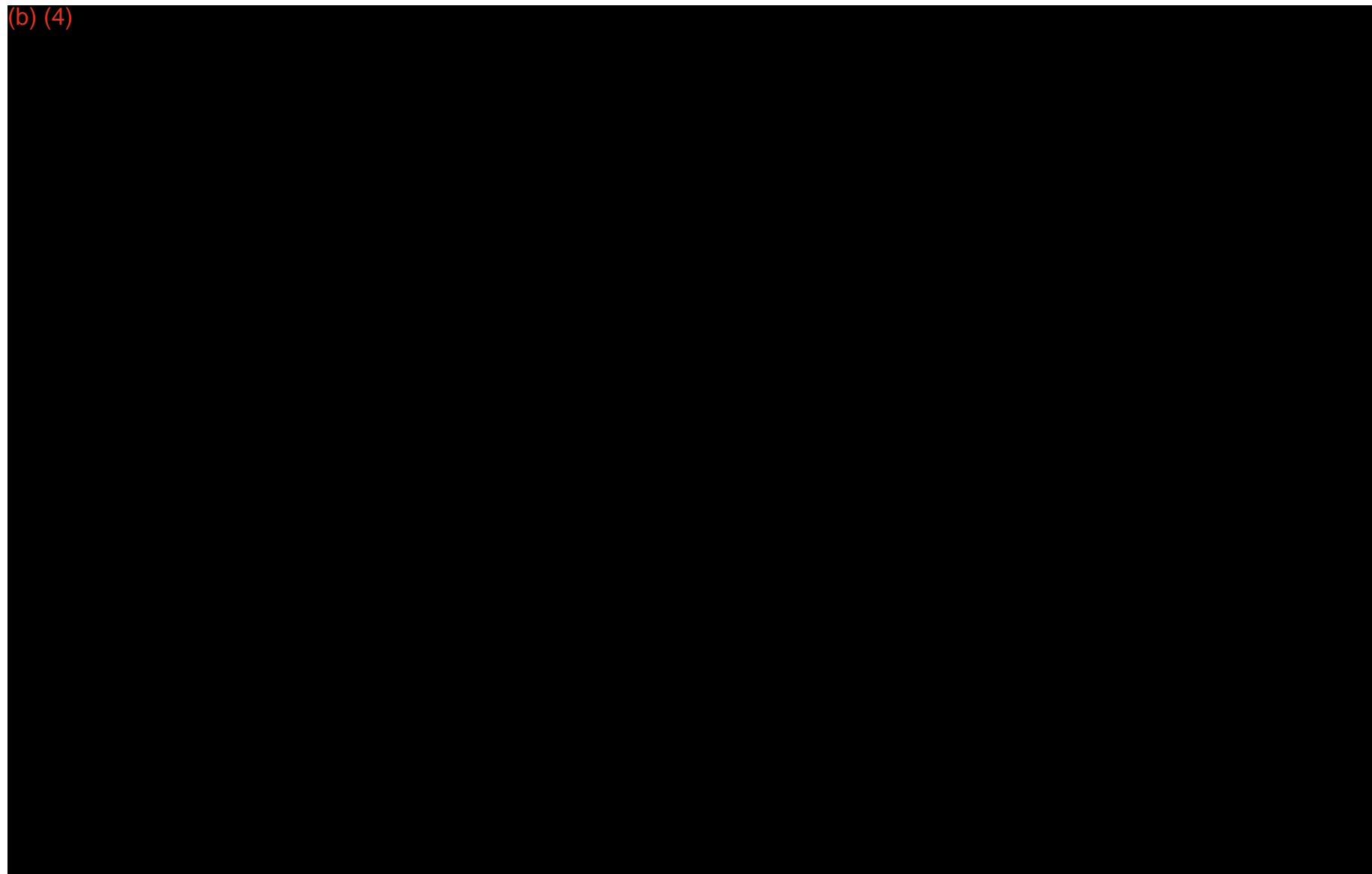
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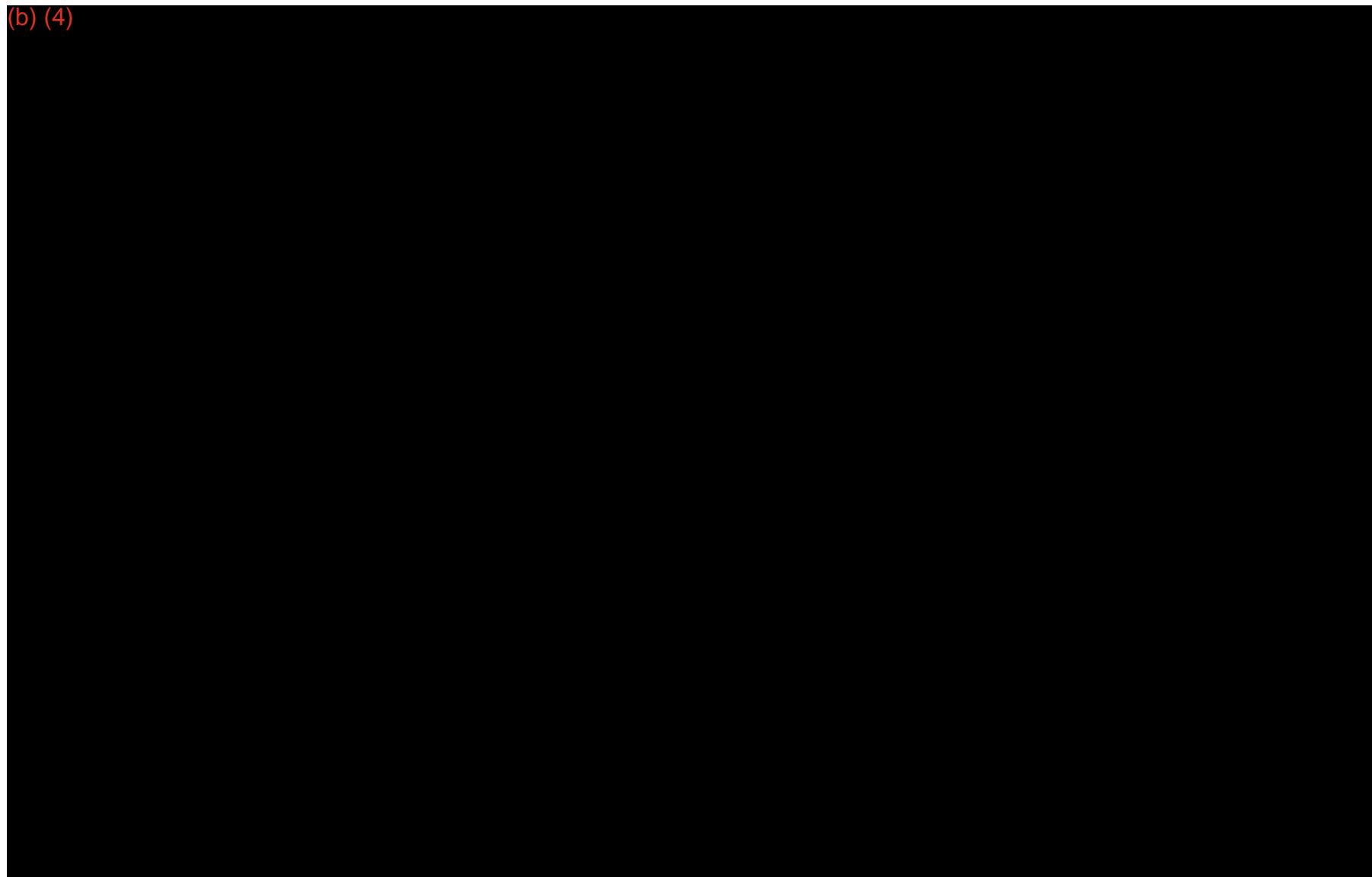


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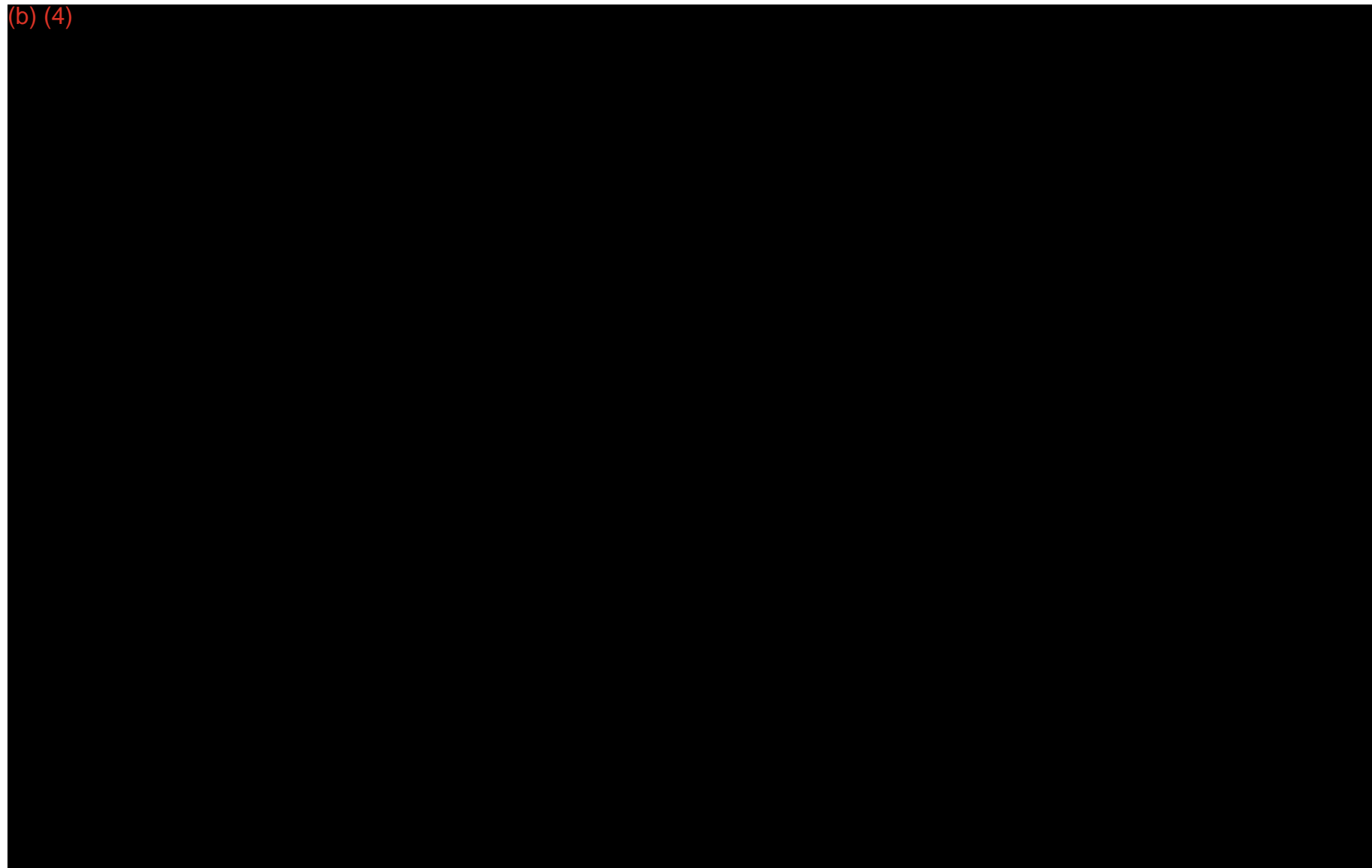
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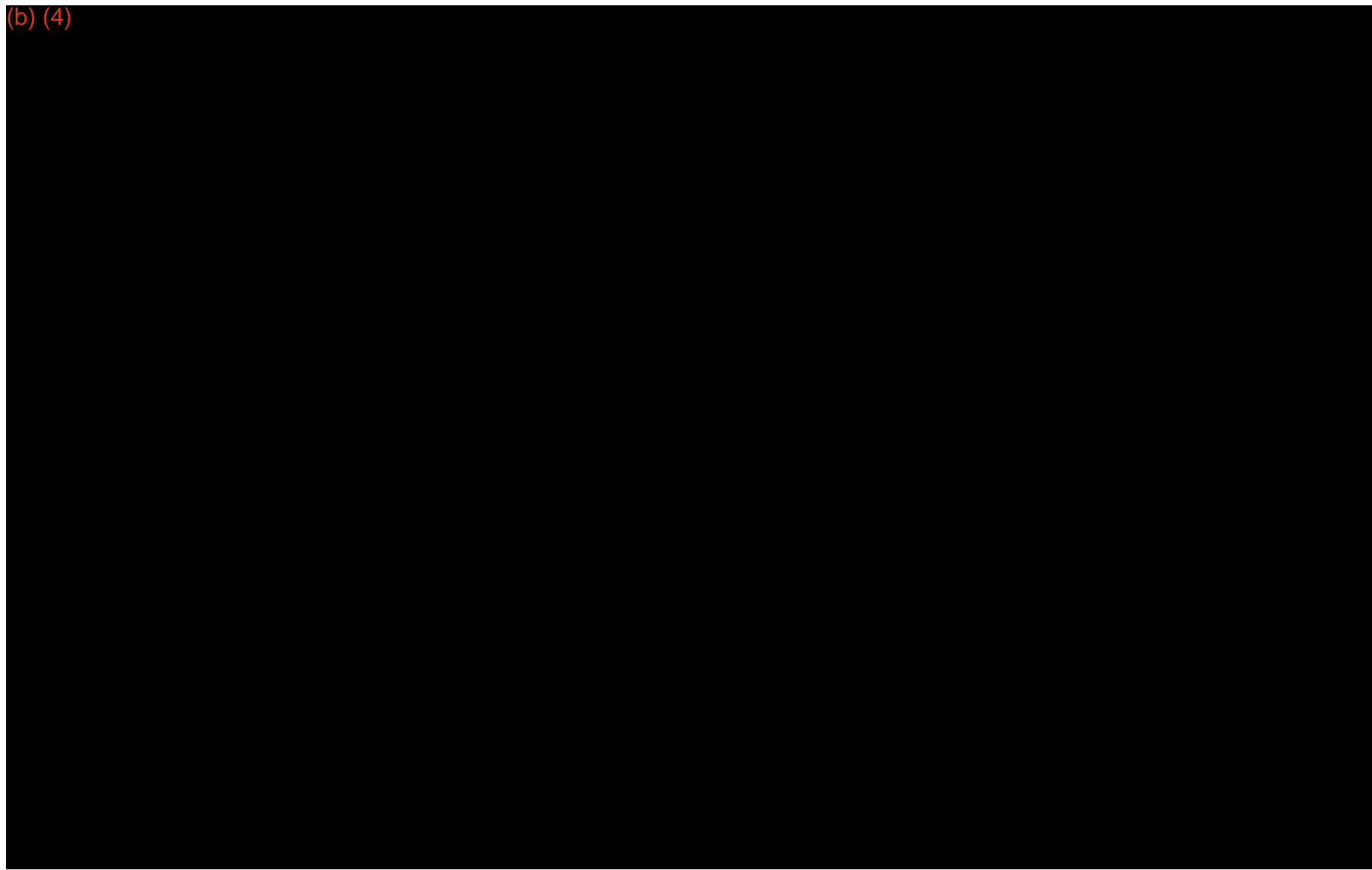
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**Listing 16.2.6-9 Plaque amount (Silness-Löe) T16 (FAS, Part 2)**

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**Listing 16.2.6-10 Plaque amount (Silness-Löe) T21 (FAS, Part 2)**

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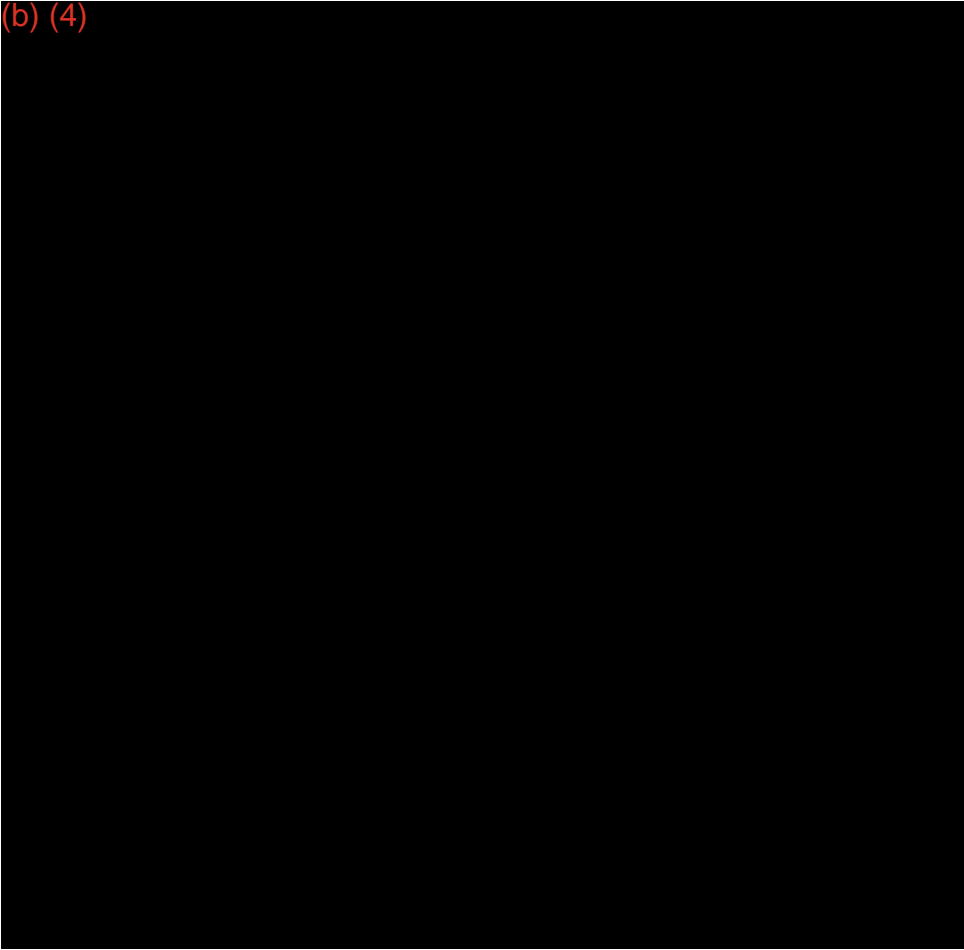


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**Listing 16.2.6-11 Plaque amount (Silness-Löe) T24 (FAS, Part 2)**

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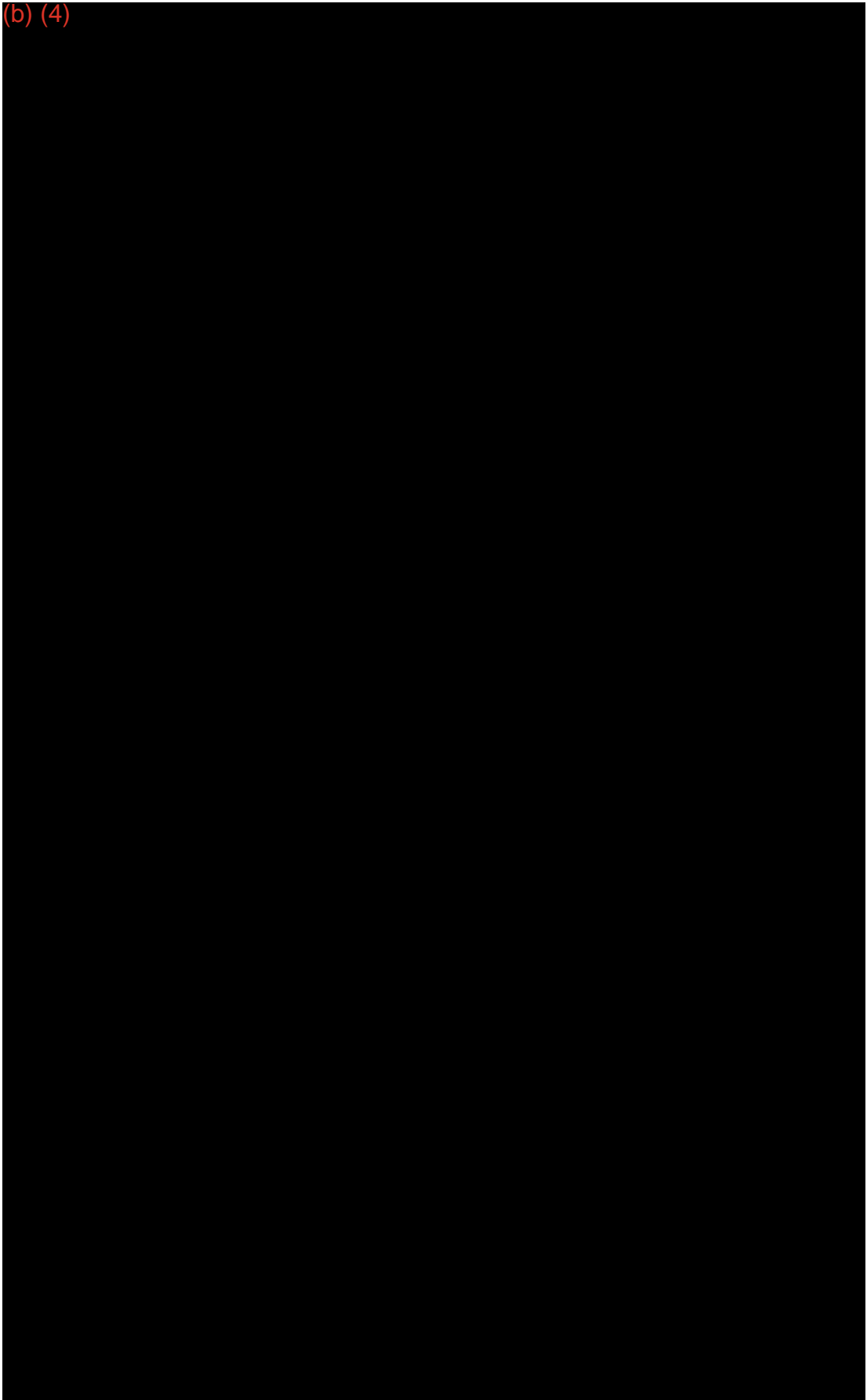




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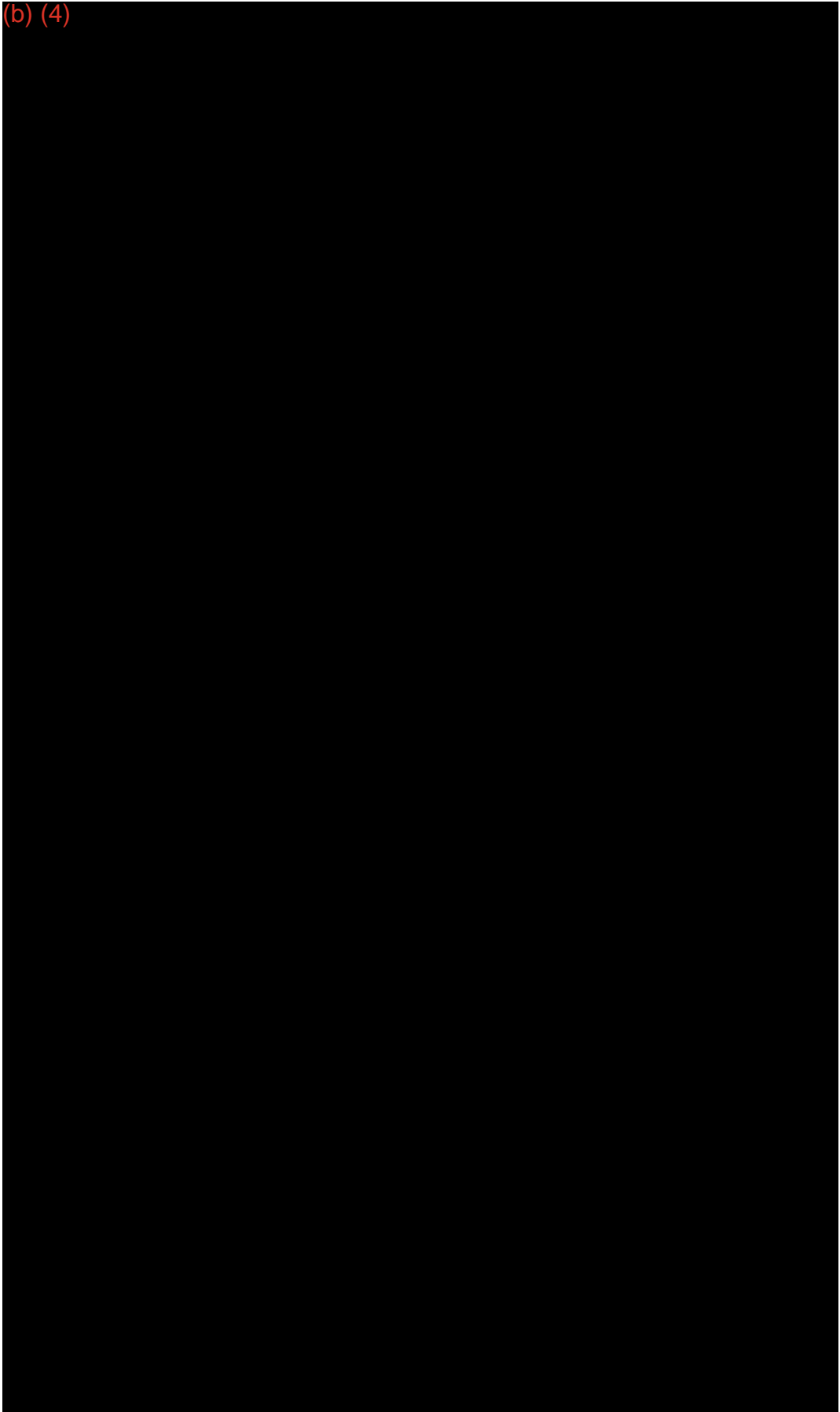
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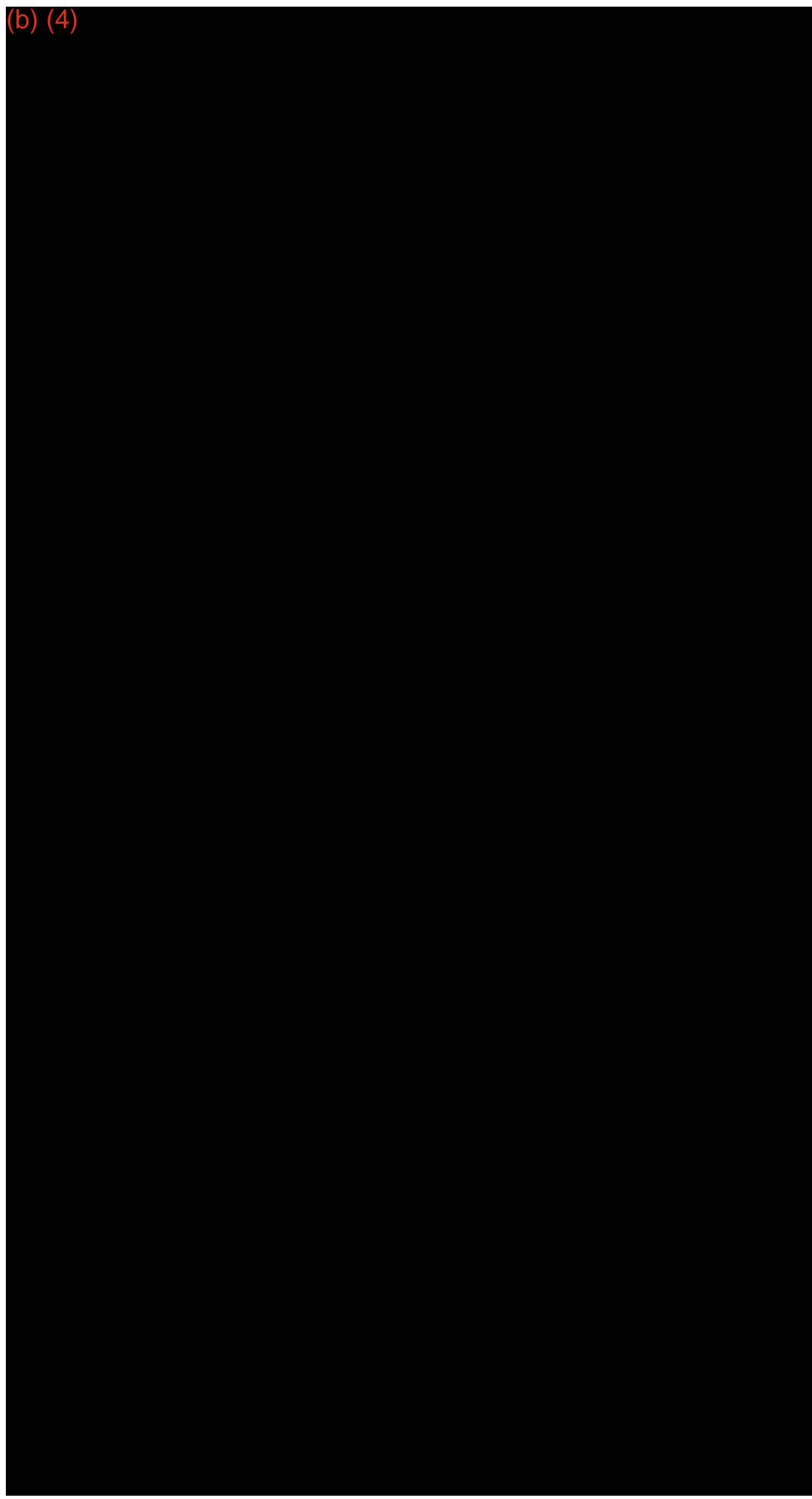
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**Listing 16.2.6-12 Plaque amount (Silness-Löe) T36 (FAS, Part 2)**

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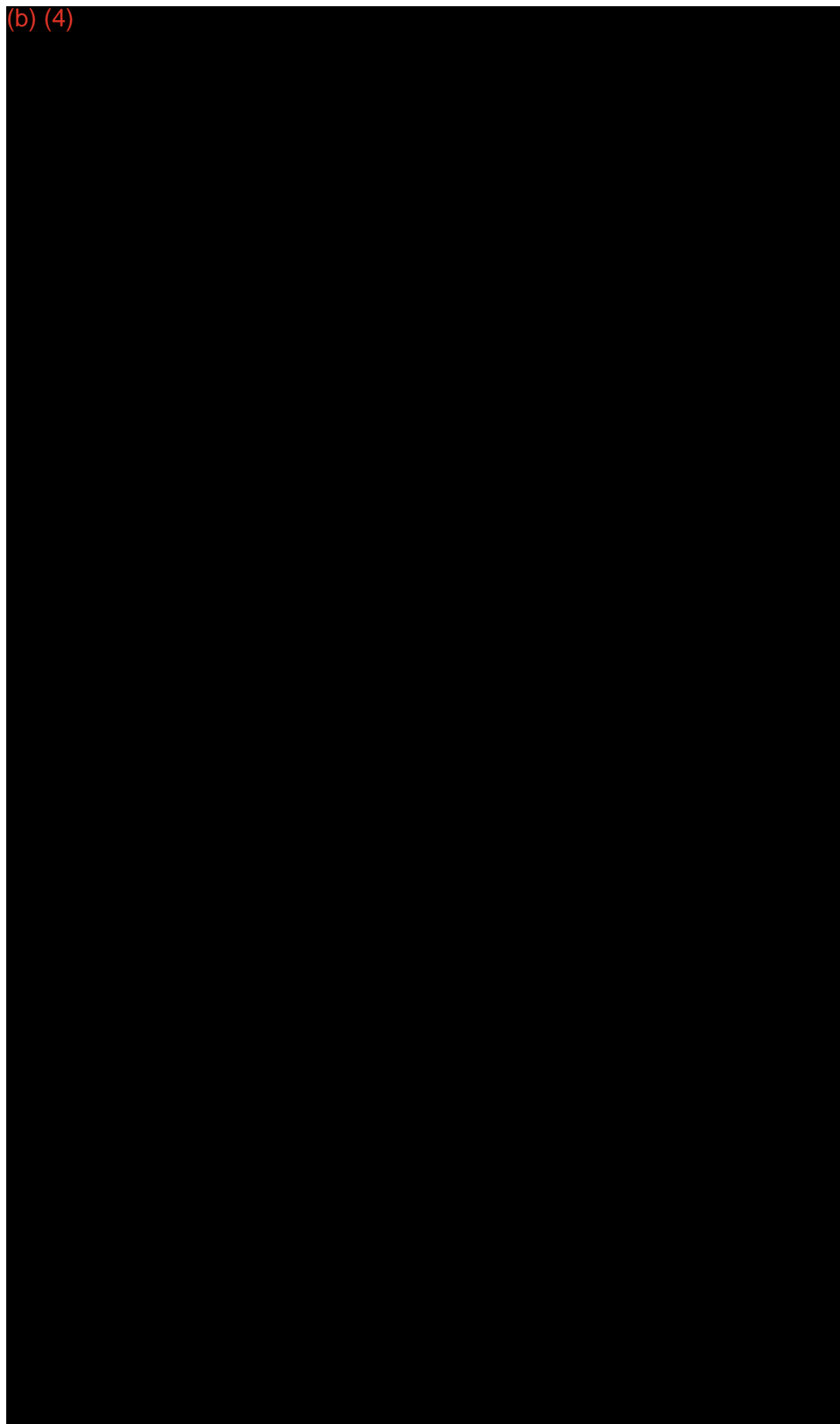
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**Listing 16.2.6-13 Plaque amount (Silness-Löe) T41 (FAS, Part 2)**

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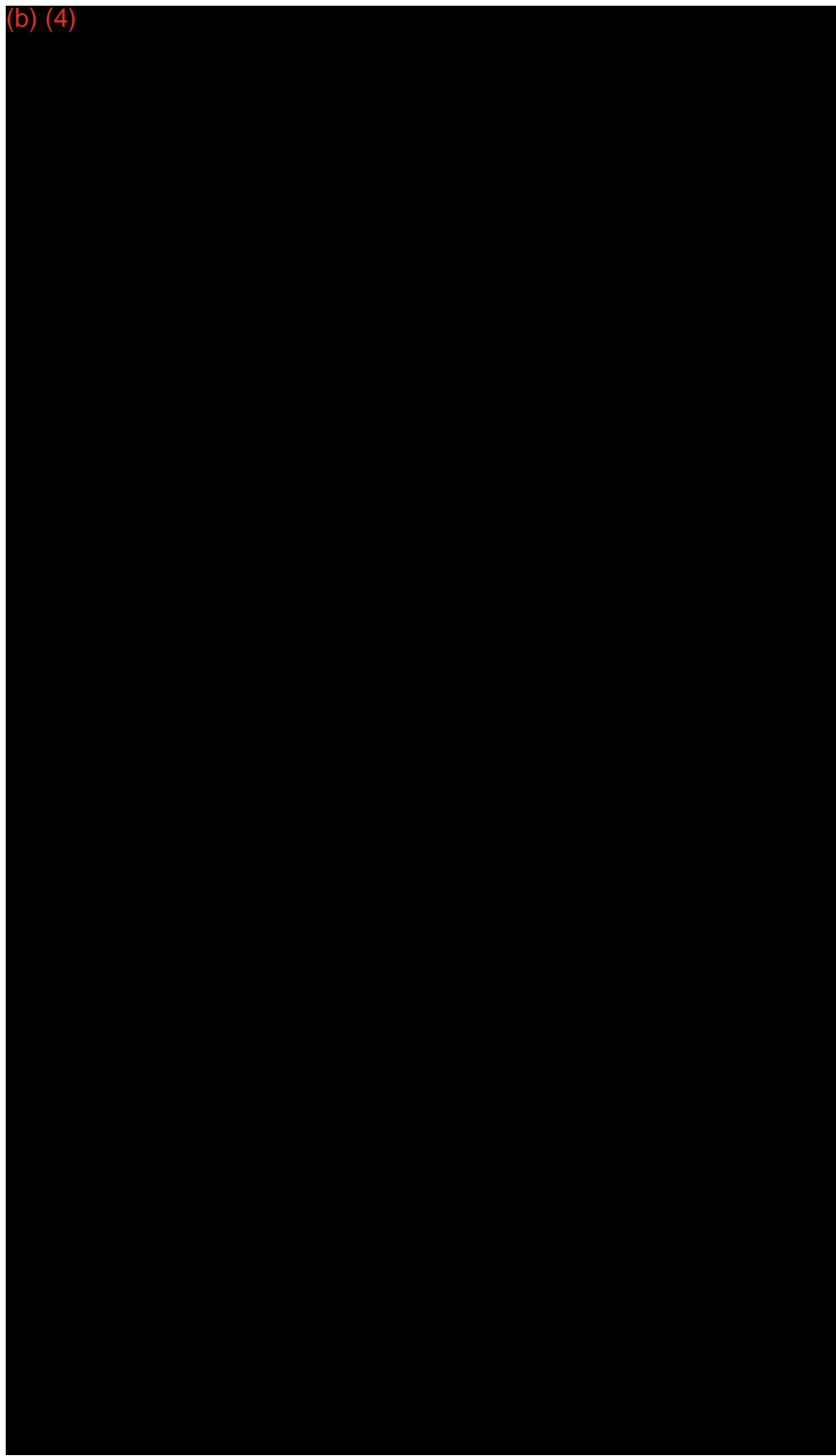
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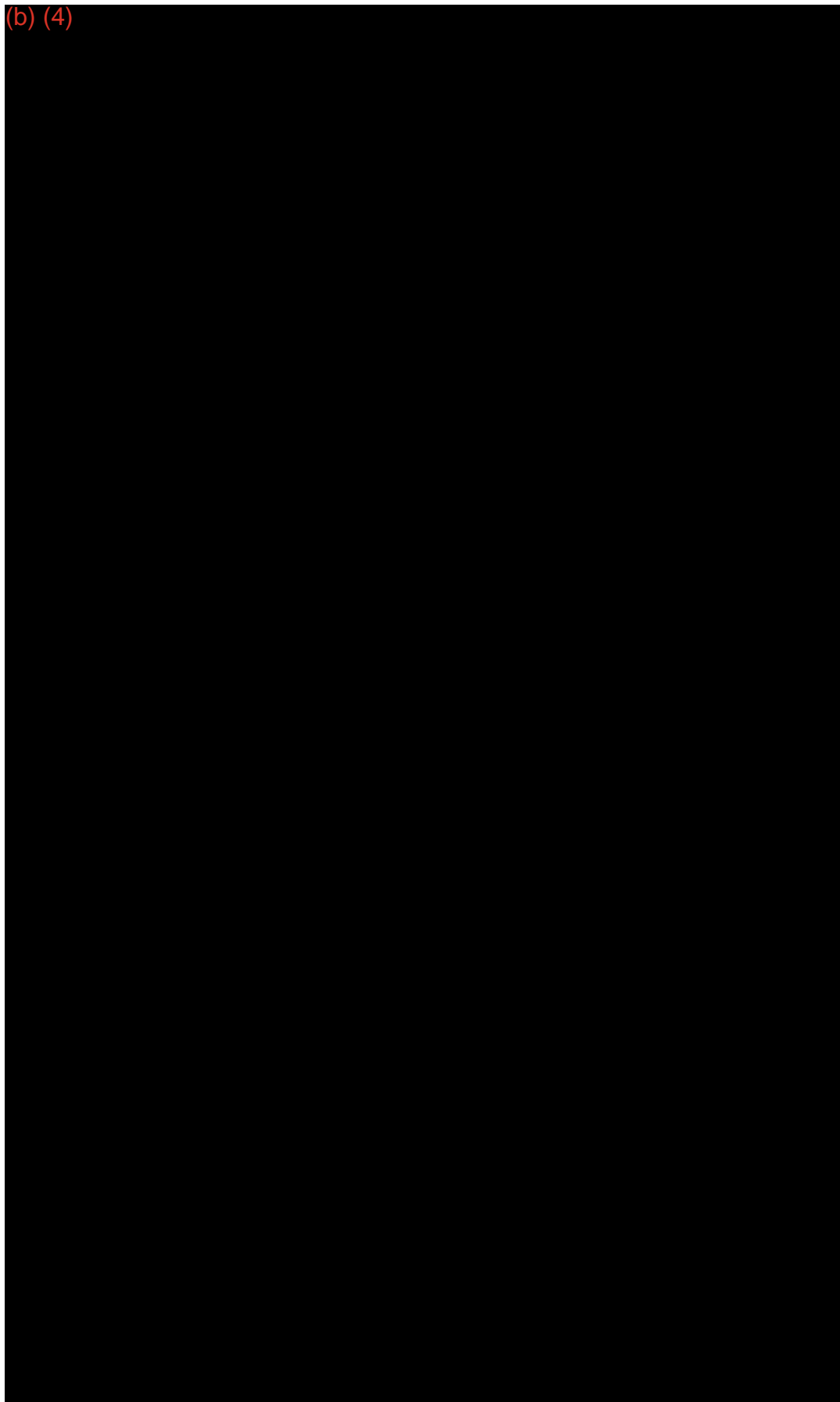
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**Listing 16.2.6-14 Plaque amount (Silness-Löe) T44 (FAS, Part 2)**

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**Listing 16.2.6-15 Plaque amount (Silness-Löe) mean of all sites (Part 2)**

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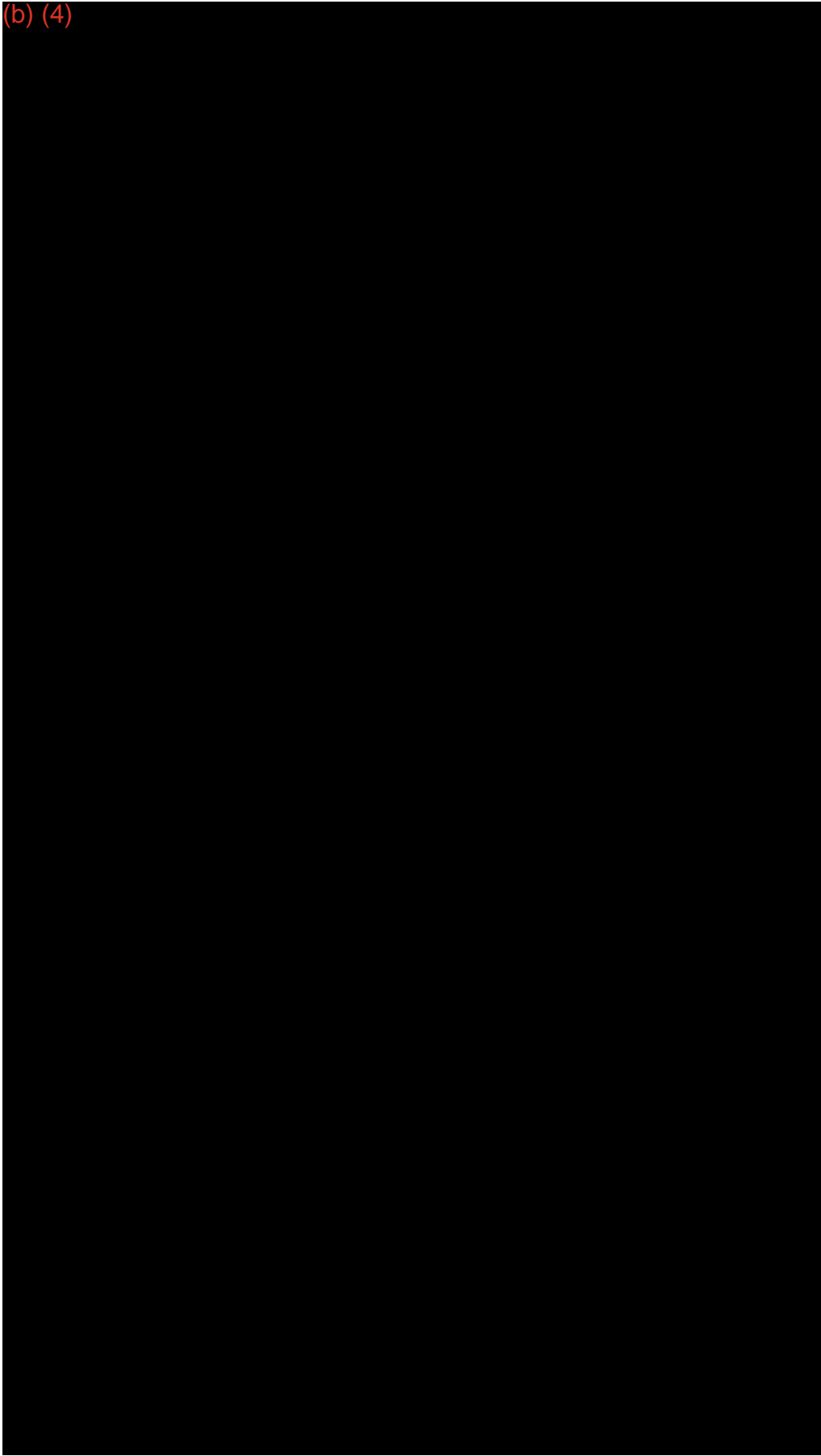
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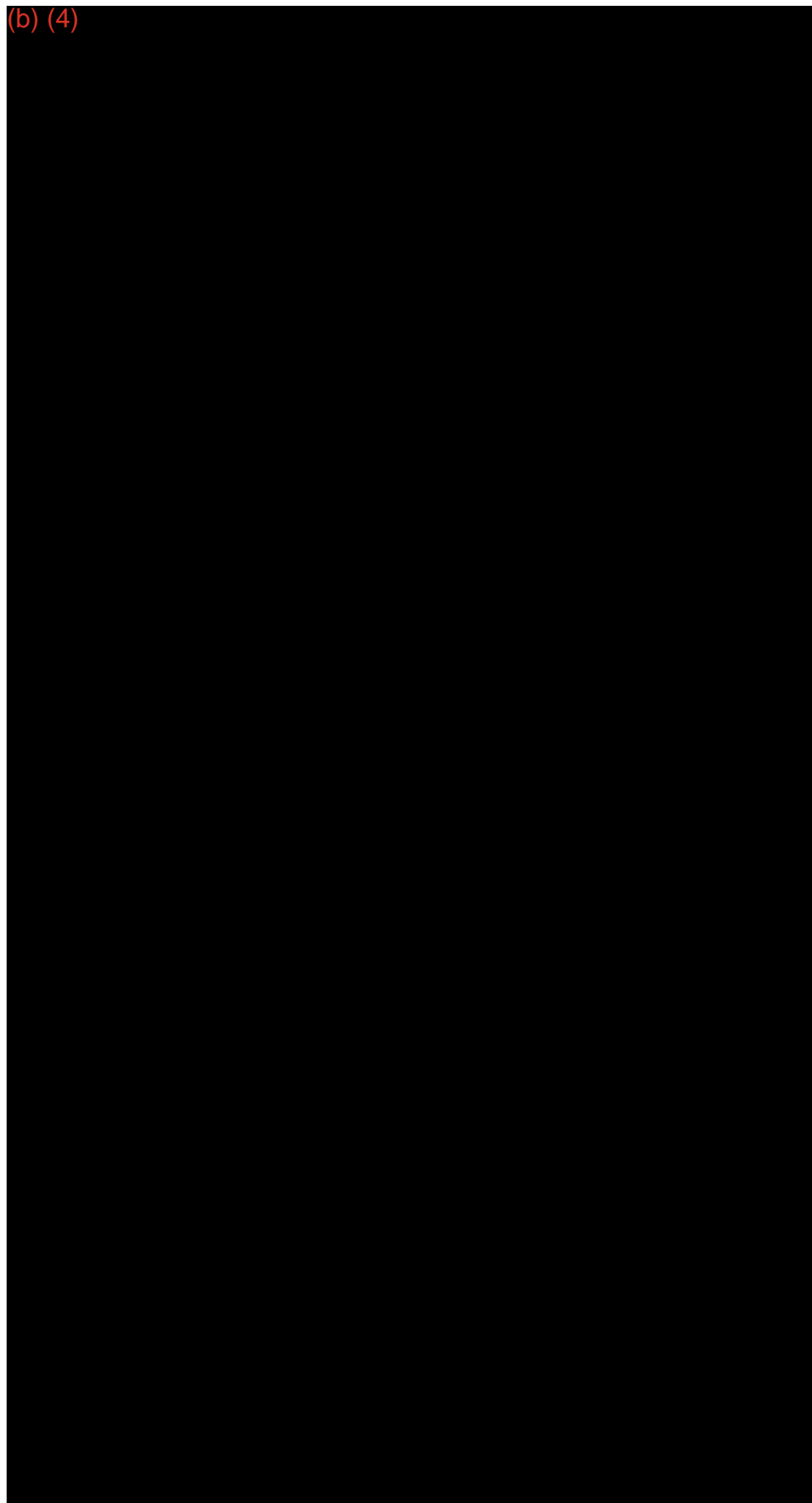




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**Listing 16.2.6-16 Oral microflora (FAS, Part 2)**

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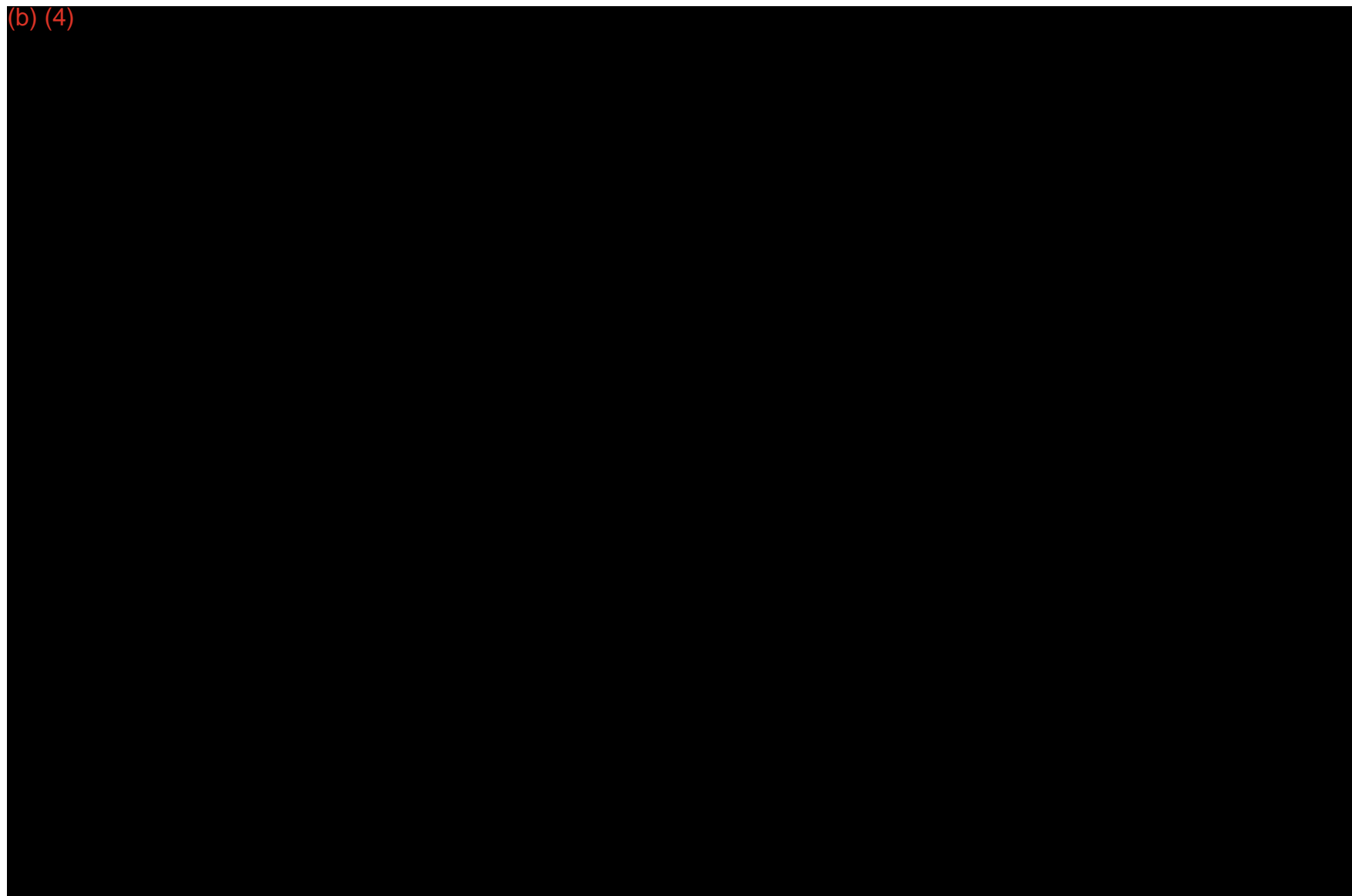
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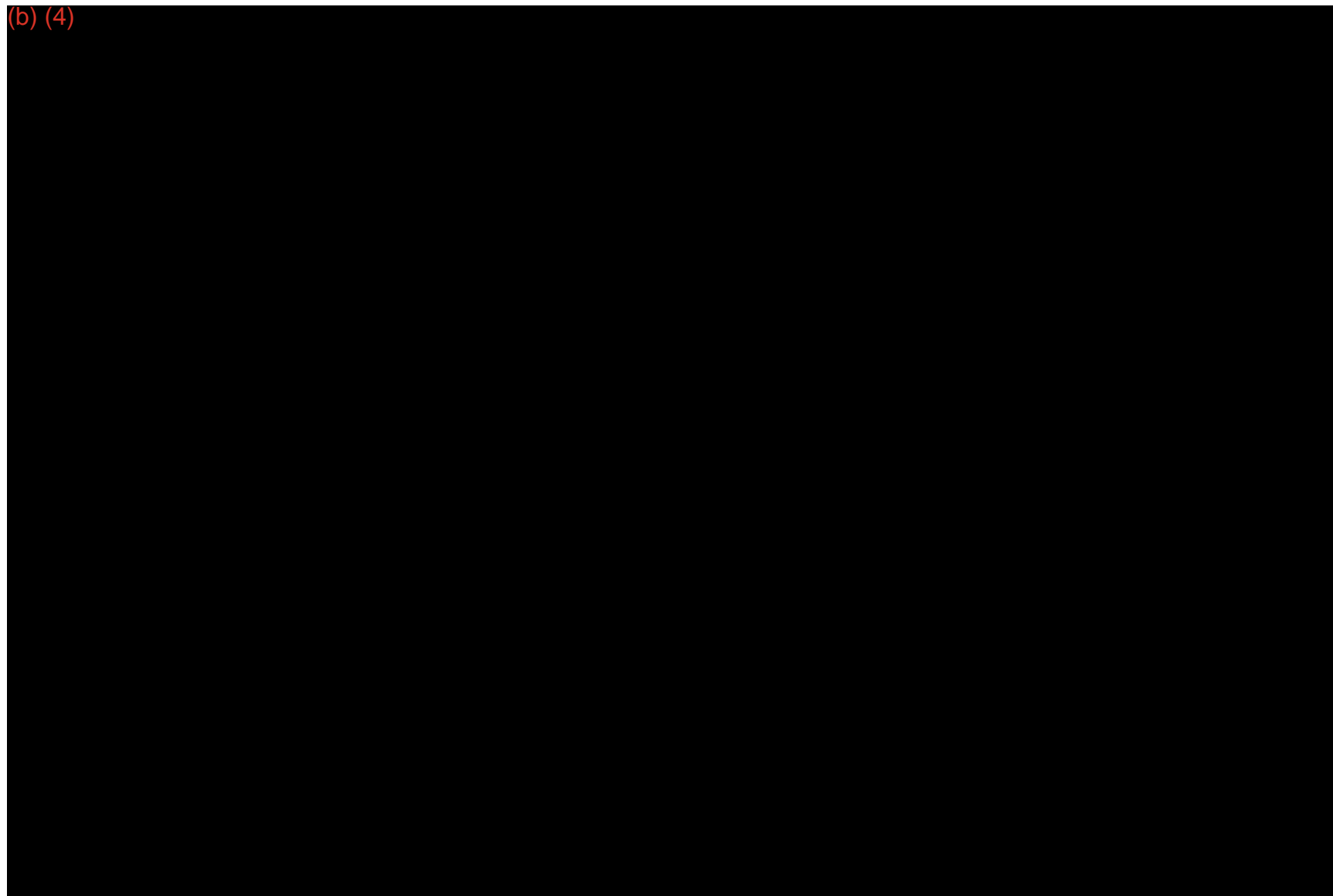


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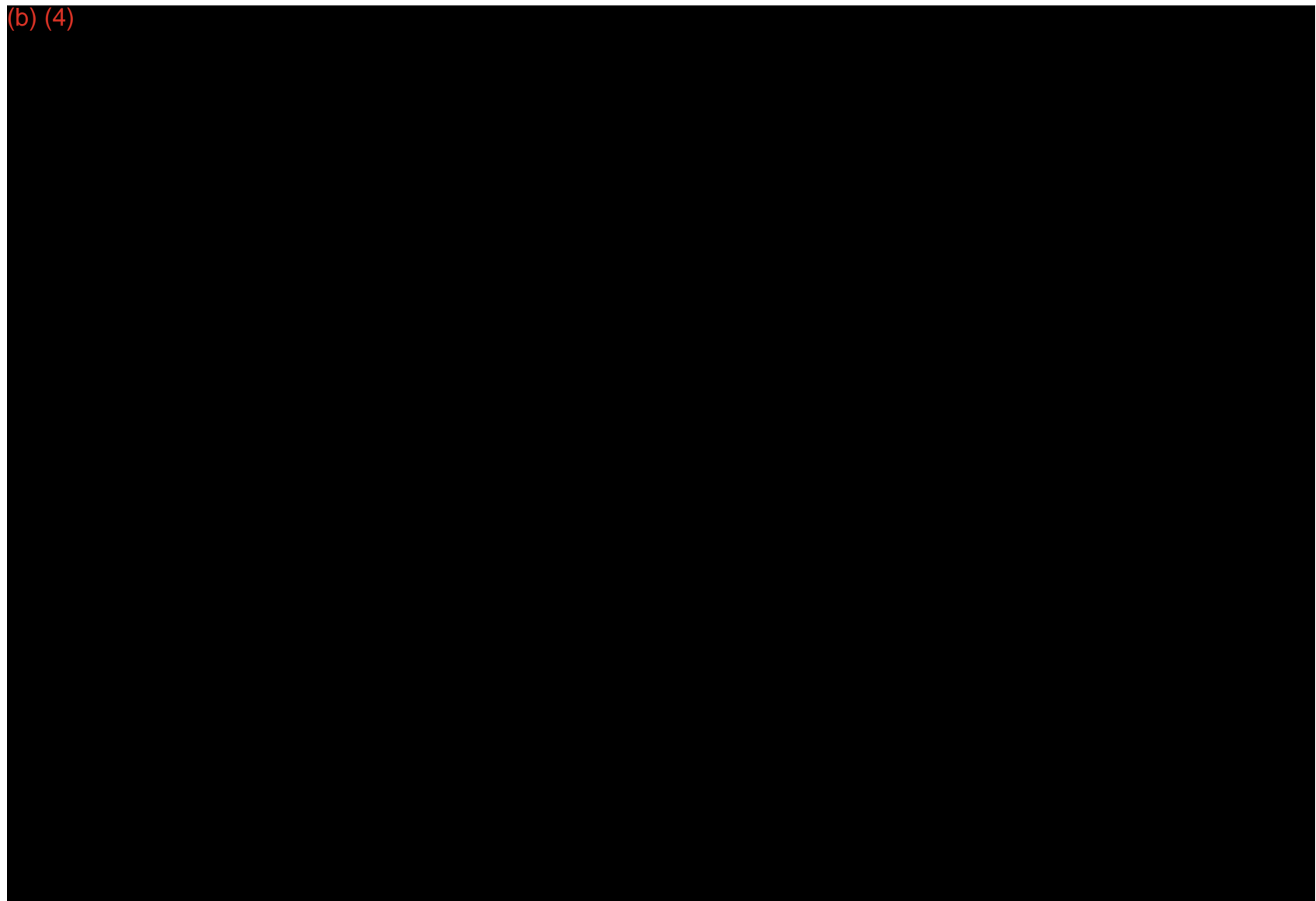
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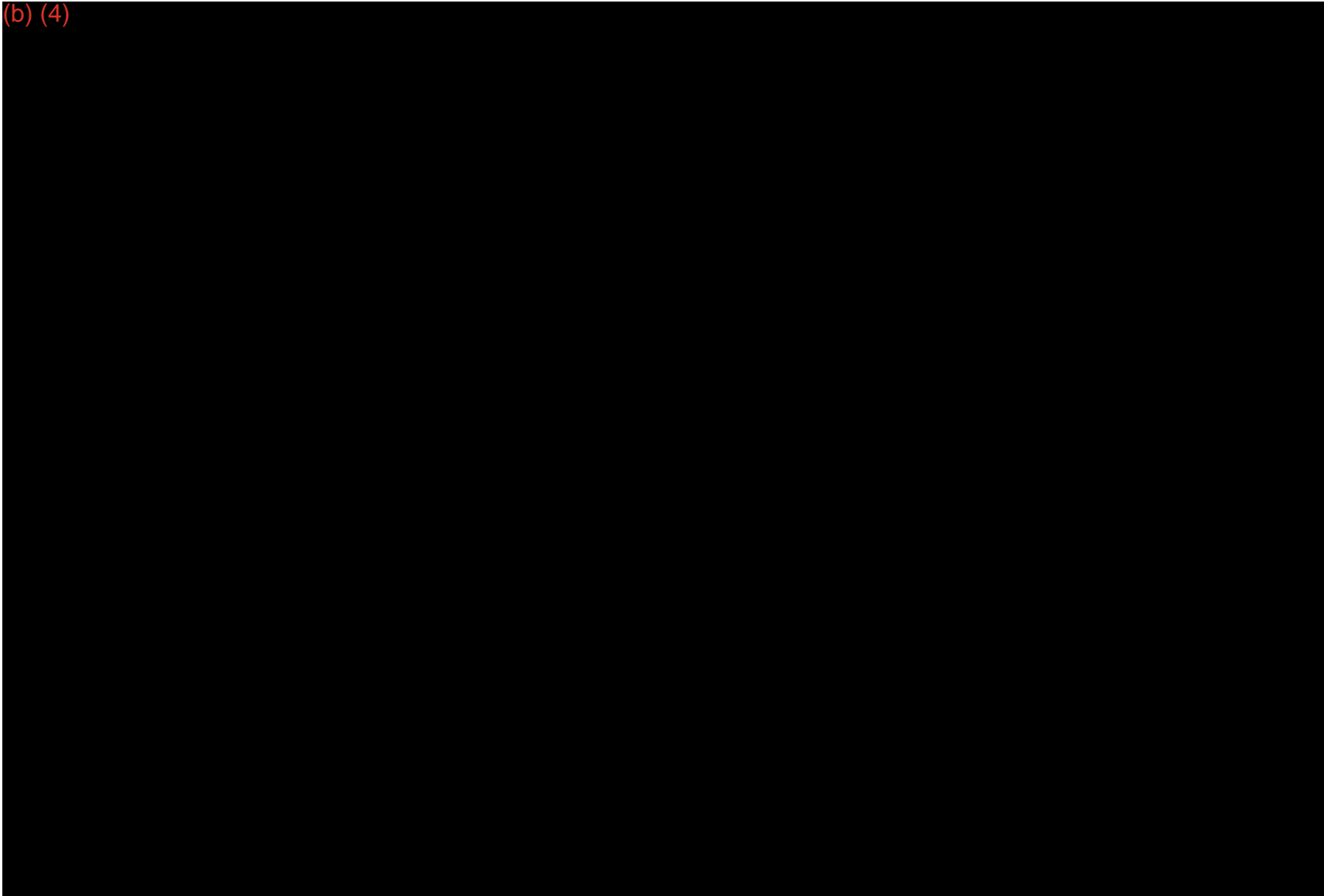
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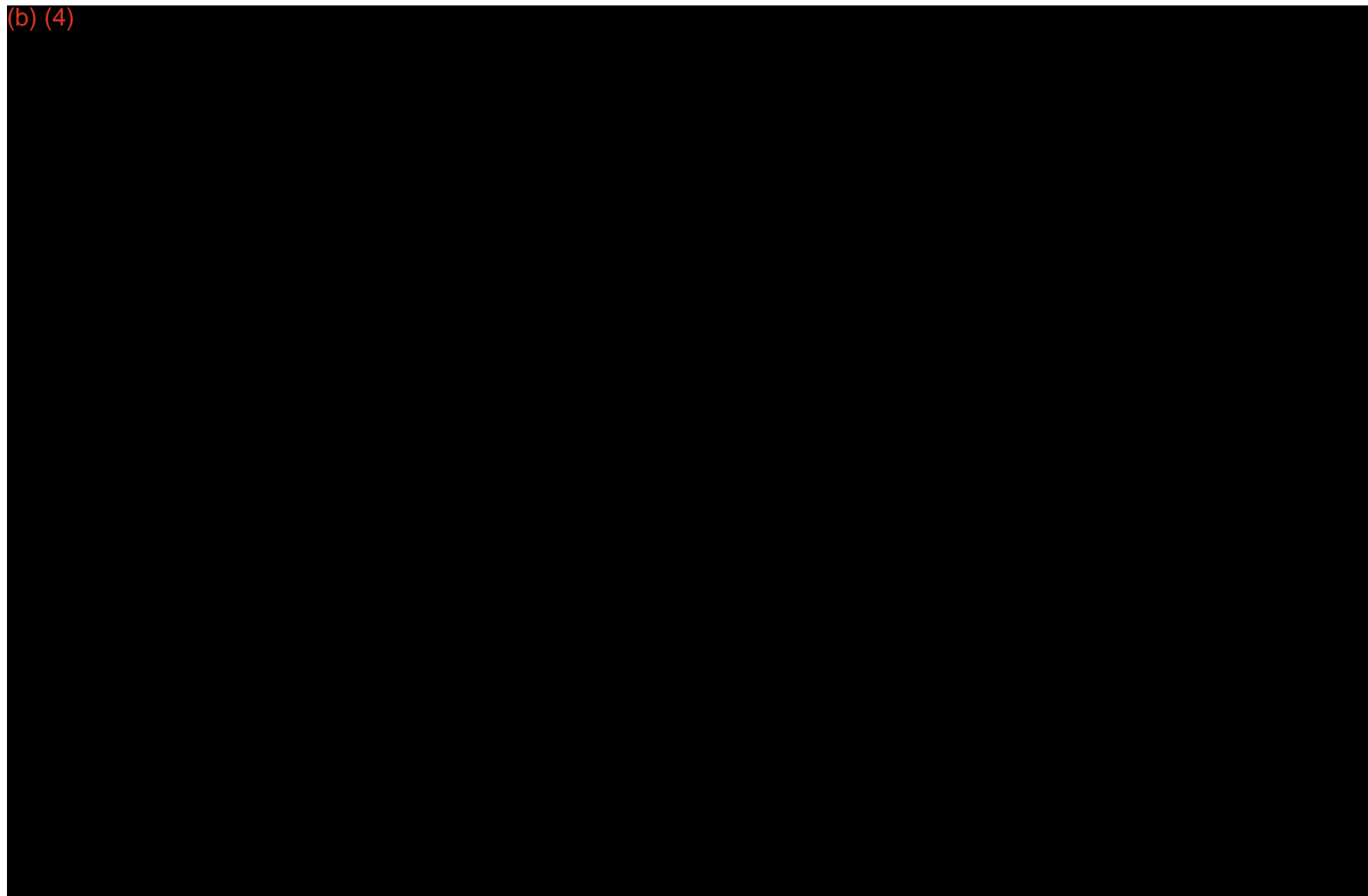
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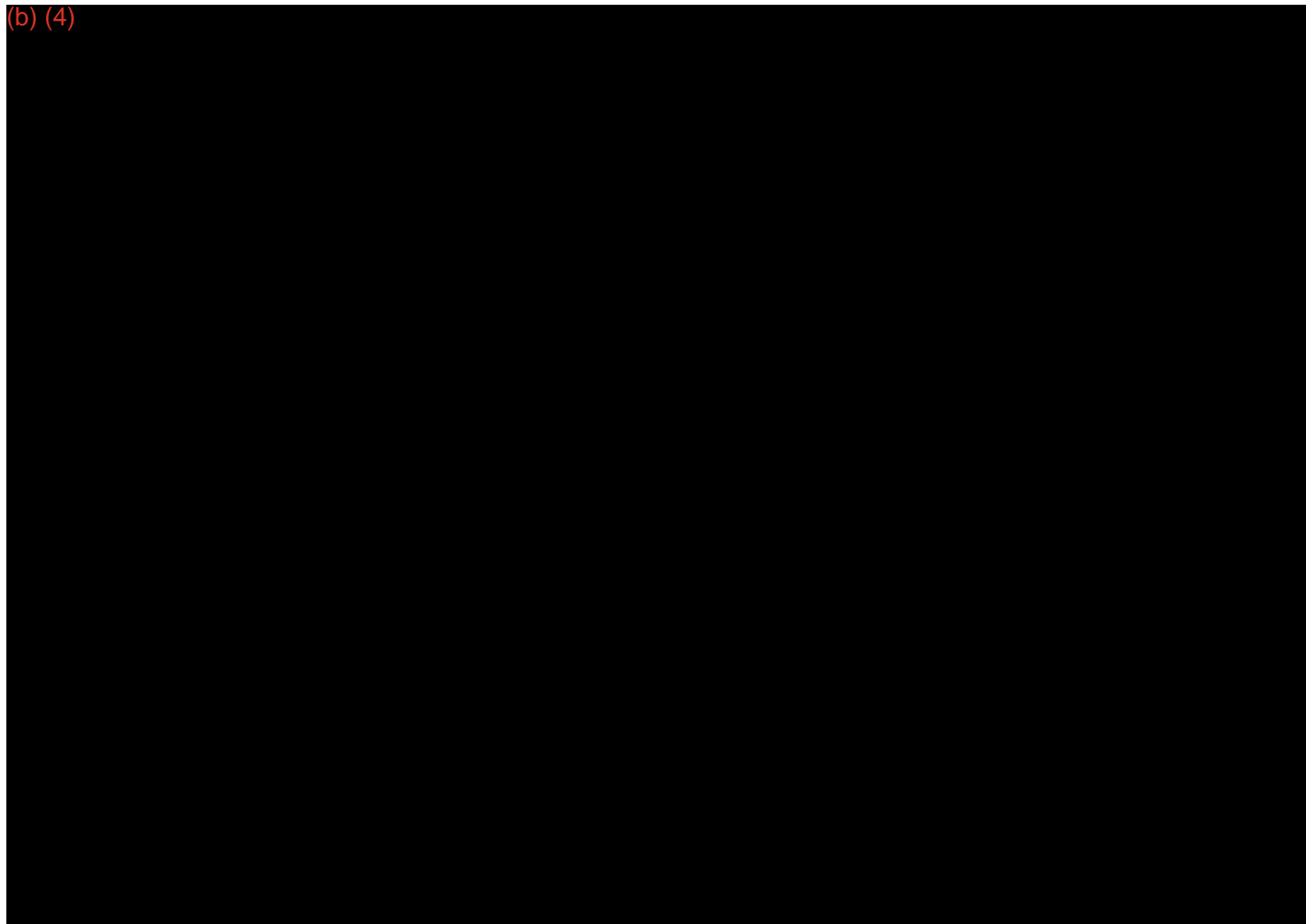
(b) (4)



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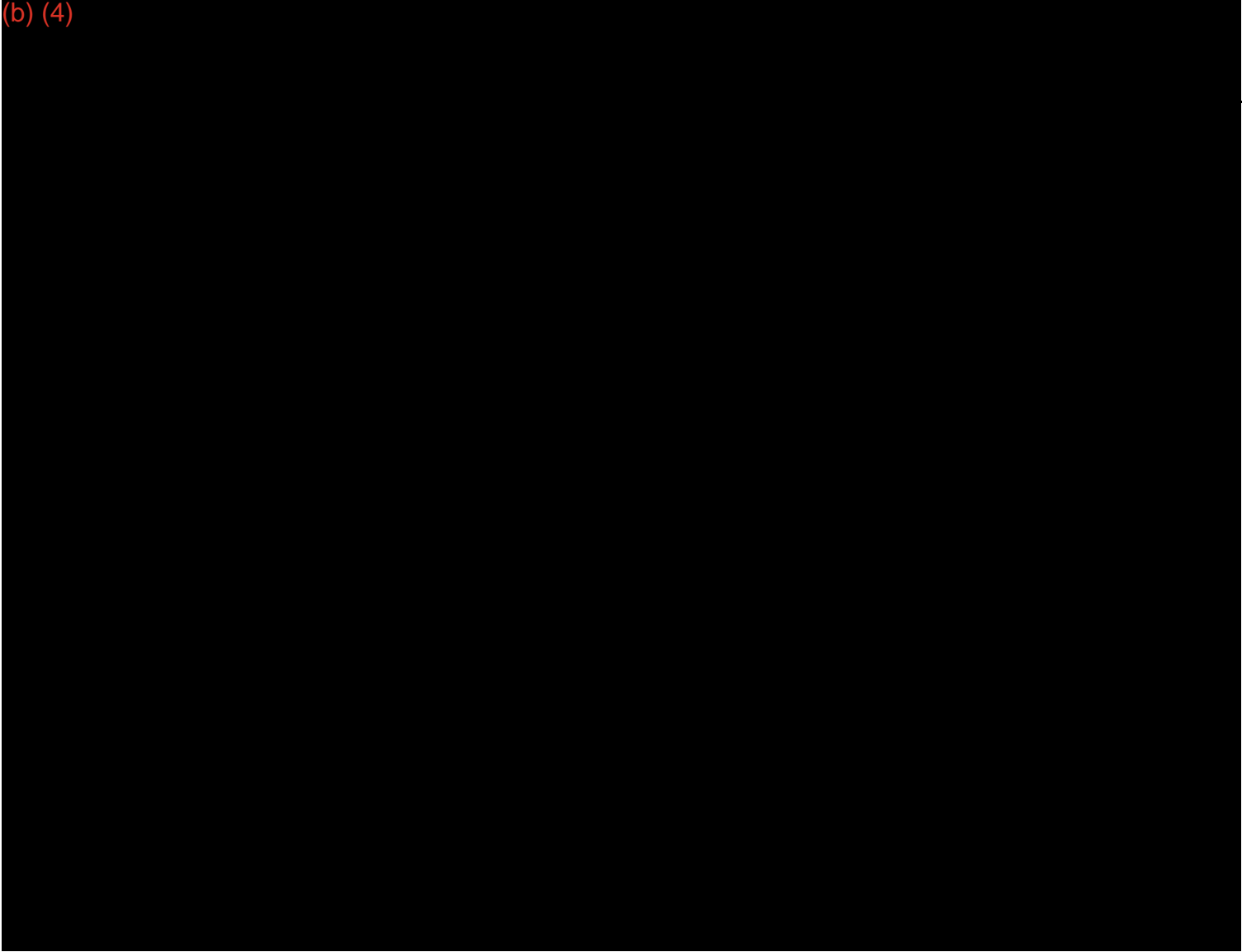
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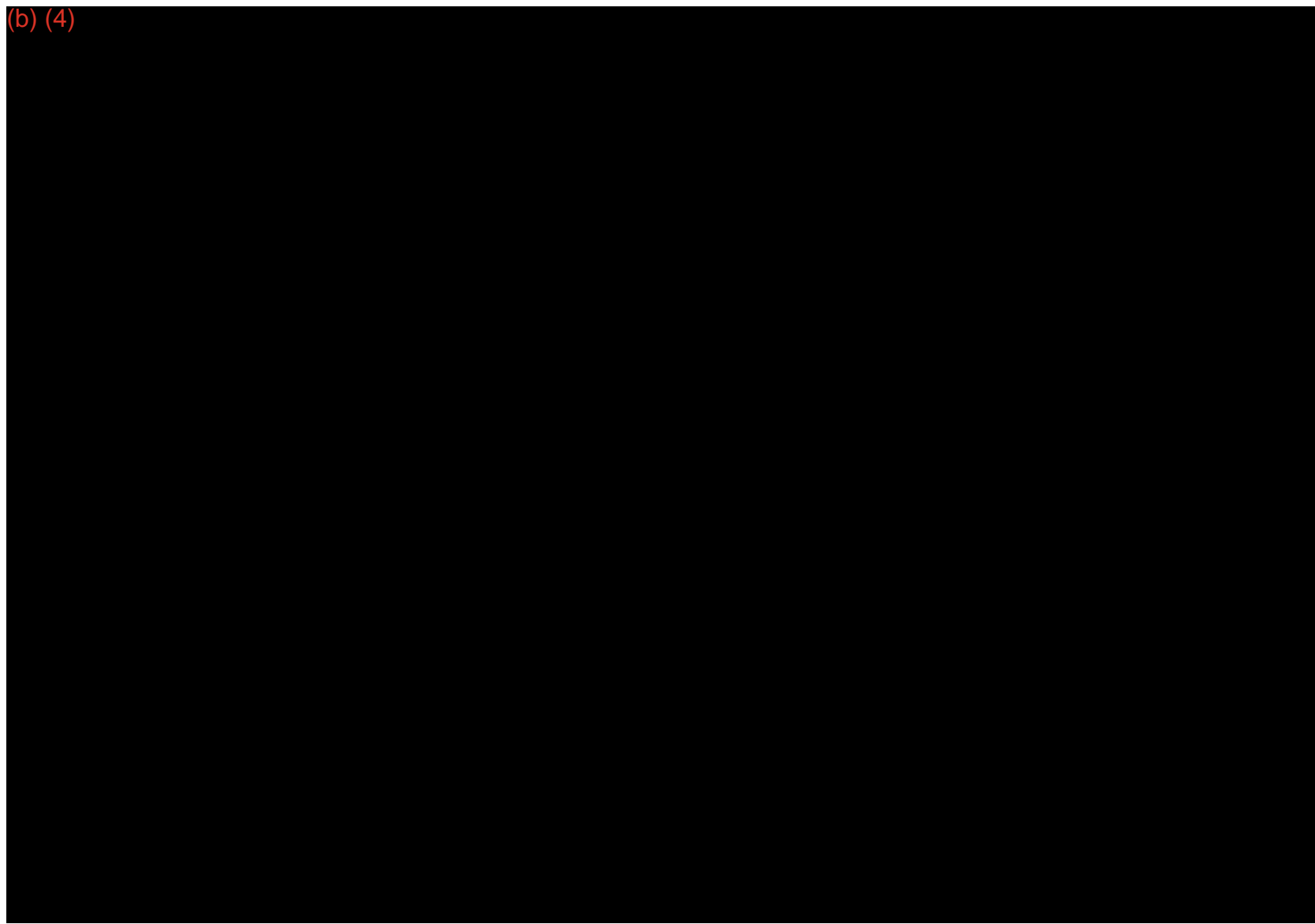
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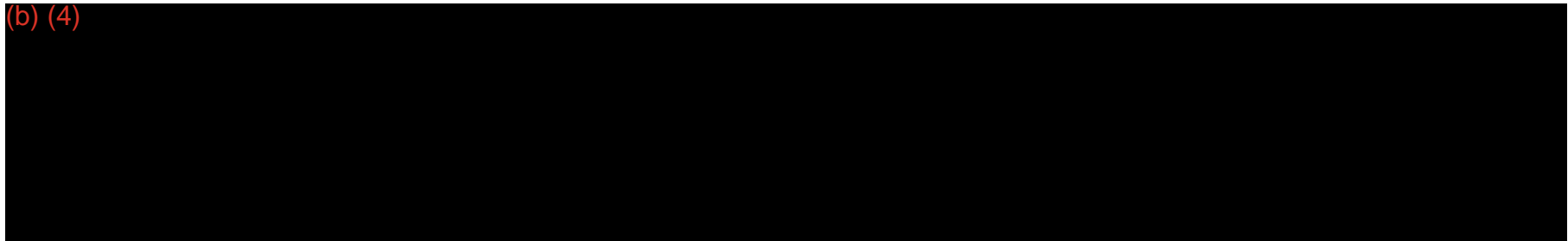
## 16.2.7 Adverse Event Listings

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Listing 16.2.7-1      Adverse events, duration (FAS, Part 1)  
Listing 16.2.7-2      Adverse events, coding and severity (FAS, Part 1)  
Listing 16.2.7-3      Adverse events, duration (FAS, Part 2)  
Listing 16.2.7-4      Adverse events, coding and severity (FAS, Part 2)  
)

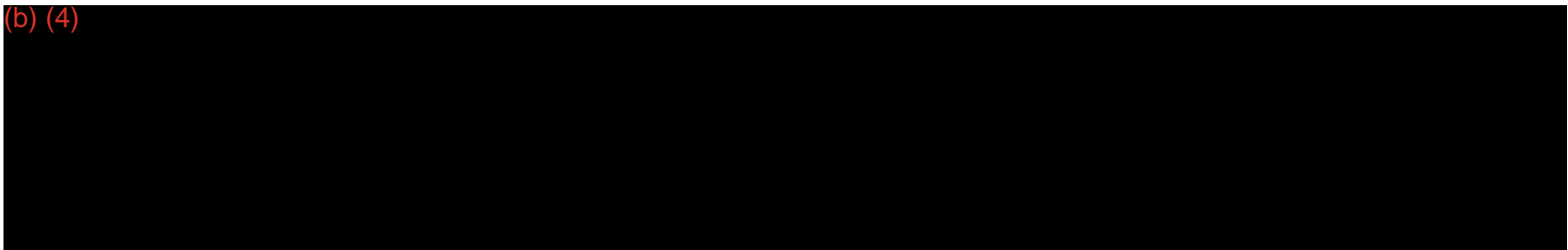
**Listing 16.2.7-1 Adverse events, duration (FAS, Part 1)**

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A large black rectangular redaction box covering the entire content area of Listing 16.2.7-1.

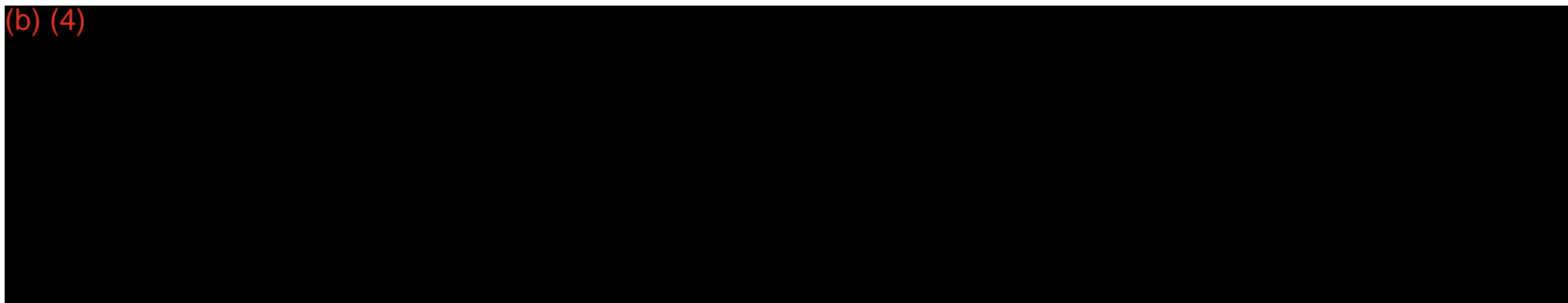
**Listing 16.2.7-2 Adverse events, coding and severity (FAS, Part 1)**

(b) (4)

A large black rectangular redaction box covering the entire content area of Listing 16.2.7-2.

**Listing 16.2.7-3 Adverse events, duration (FAS, Part 2)**

(b) (4)

A large black rectangular redaction box covering the entire content area of Listing 16.2.7-3.

(b) (4)



**Listing 16.2.7-4 Adverse events, coding and severity (FAS, Part 2)**

(b) (4)



### **16.2.8 Listing of Individual Laboratory Measurements by Subject**

Not applicable.

## 16.2.9 Subject disposition

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Listing 16.2.9-1	Disposition events (FAS, Part 1)
Listing 16.2.9-2	Disposition events (FAS, Part 2)
Listing 16.2.9-3	Subject visits (FAS, Part 1)
Listing 16.2.9-4	Subject visits (FAS, Part 2)
Listing 16.2.9-5	Subject elements (FAS, Part 1)
Listing 16.2.9-6	Subject elements (FAS, Part 2)



**Listing 16.2.9-1 Disposition events (FAS, Part 1)**

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**Listing 16.2.9-2 Disposition events (FAS, Part 2)**

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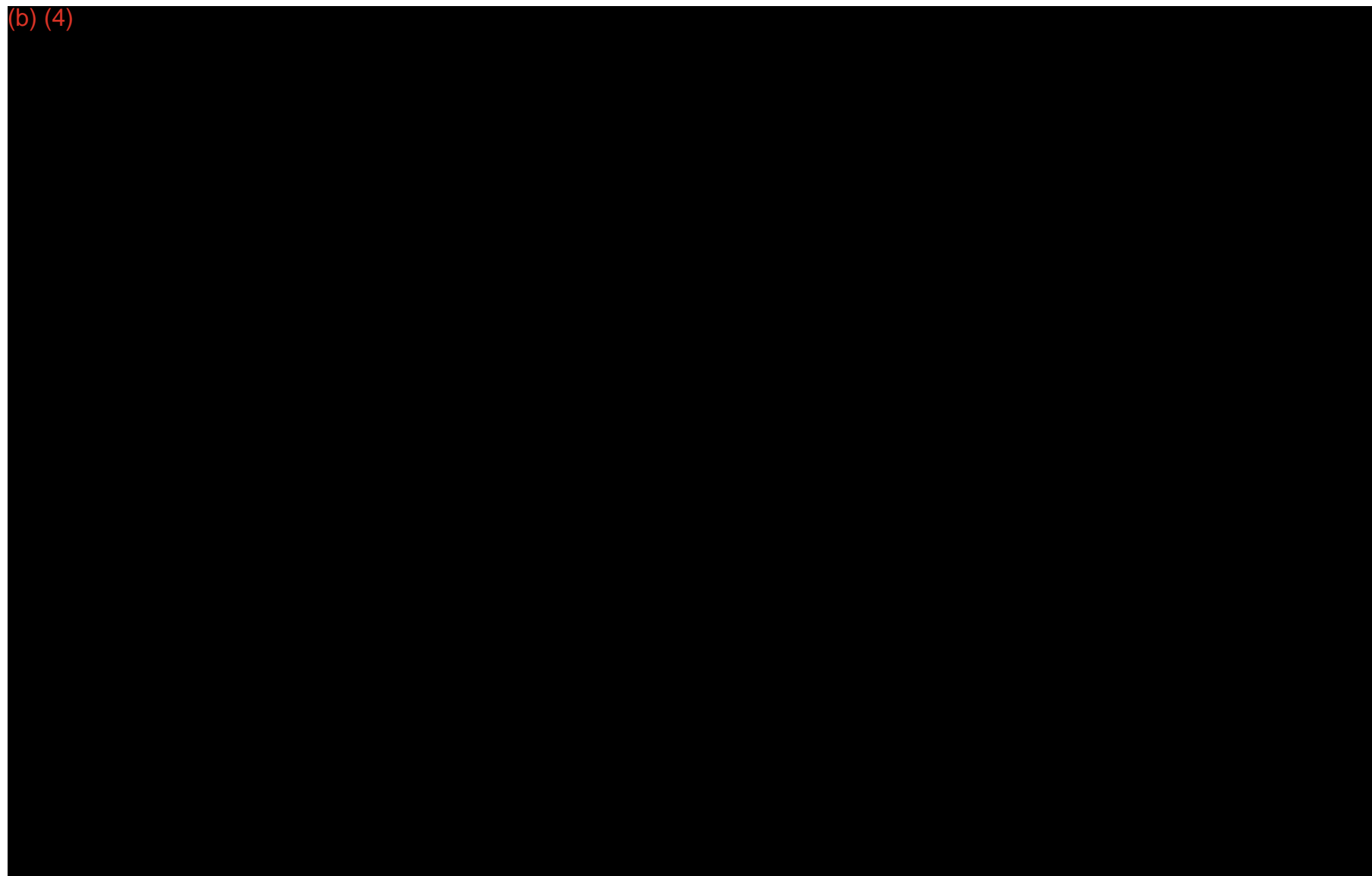
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**Listing 16.2.9-3 Subject visits (FAS, Part 1)**

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**Listing 16.2.9-4 Subject visits (FAS, Part 2)**

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**Listing 16.2.9-5 Subject elements (FAS, Part 1)**

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