# AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

| 1 CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 \| 31 |

| 2 AMENDMENT/MODIFICATION NO | 3 EFFECTIVE DATE | 4 REQUISITION/PURCHASE REQ NO | 5 PROJECT NO (If applicable) |
|---|---|---|---|
| P00007 | 15-Jun-2021 | SEE SCHEDULE | |

| 6 ISSUED BY | CODE | 7 ADMINISTERED BY (If other than item 6) | CODE |
|---|---|---|---|
| ACC-APG - COVID RESPONSE - W58P05<br>6472 NTEGRITY COURT (BU LDING 4401)<br>ABERDEEN PROVING GROUND MD 21005-3013 | W58P05 | DEFENSE CONTRACT MANAGEMENT AGENCY<br>DCMA BOSTON<br>495 SUMMER STREET<br>BOSTON MA 02210-2138 | S2206A |

| 8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) | | |
|---|---|---|
| MODERNA US, NC.<br>(b) (6)<br>200 TECHNOLOGY SQ<br>CAMBRIDGE MA 02139-3578 | | 9A. AMENDMENT OF SOLICITATION NO. |
| | | 9B. DATED (SEE ITEM 11) |
| | X | 10A. MOD. OF CONTRACT/ORDER NO.<br>W911QY20C0100 |
| | X | 10B. DATED (SEE ITEM 13)<br>09-Aug-2020 |
| CODE 8PTM0 | FACILITY CODE | |

## 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

## 12. ACCOUNTING AND APPROPRIATION DATA (If required)

**See Schedule**

## 13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

| | |
|---|---|
| | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B). |
| X | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:<br>See Block 14 Continuation Page |
| | D. OTHER (Specify type of modification and authority) |

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

## 14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: (b) (6)

See Block 14 Continuation Page

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) |
|---|---|
| (b) (6) | (b) (6)<br>TEL: (b) (6) EMAIL: (b) (6) |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
|---|---|---|---|
| (b) (6)<br>(Si ) | | BY (b) (6)<br>(Signature of Contracting Officer) | 15 June 2021 |

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:
P00007
OBLIGATION AMOUNT: $3,300,000,000.00

a. The purpose of this modification (P00007) is to:

- Revise Section A (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Exercise, revise delivery schedule for, and fund Option 3 and 4 CLINs 3001, 3001AA, 3001AB, 3001AC, 3001AD, 4001, 4001AA, 4001AB, 4001AC for a total of $3,300,000,00 (Authority FAR 52.217-7)

- Update Contracting Officer (Authority FAR 43.103(b))

- Add Performance Based Payments for Options 3 and 4; and revise the table in Section G, accordingly (Authority FAR 52.232-16)

- Add clause H.19 Product Variations (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Revise Attachment 0007, Performance Based Payment (PBP) Milestone Schedule, and Attachment 0008, PBP Milestone Billing Plan (Authority FAR 52.243-1).

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total funded amount has increased by $3,300,000,000 from $4,845,591,662.60 to $8,145,591,662.60. The total contract value amount remains unchanged.

All other terms and conditions remain unchanged. Please see below for details.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $3,300,000,000.00 from $4,845,591,662.60 to $8,145,591,662.60.

The following have been modified:

**A.1** The U.S. Army Contracting Command - Aberdeen Proving Ground (ACC-APG), Natick Division has a requirement for up to 500 million SARS-CoV-2 mRNA-1273 Vaccine doses (100 µg & 50 µg, based on variation

supplied) in support of Joint Program Executive Office - Chemical Biological Radiological Nuclear Defense (JPEO-CBRND), the Assistant Secretary for Preparedness and Response (ASPR), and Biomedical Advanced Research and Development Authority (BARDA).

All doses of mRNA-1273 Vaccine to satisfy the delivery requirements of CLINs 0001, 1001, and 2001 are 100 µg doses which will be delivered in a multi-dose vial containing either 6.3mL fill volume (1260mcg) (b) (4) [redacted] or 8.0mL fill volume (1600mcg) (b) (4) [redacted] (as described in Moderna's COVID-19 Vaccine Authorized Fact Sheet and label).

Specifications of doses of mRNA-1273 Vaccine to satisfy the delivery requirements of CLINs 3001 and 4001 are described in Section H.19.

The delivery schedule for CLINs 3001 and 4001 may be concurrent with Moderna's Biologics License Application and FDA approval of the SARS-CoV-2 vaccine. Moderna agrees to continue to perform all regulatory efforts required to ensure that product delivered while the SARS-CoV-2 vaccine was under Emergency Use Authorization will remain available for use in the US.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 3001

The CLIN extended description has changed from:

The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW), and CDRLs (Exhibit A) on this contract.

To:

The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW), Clause no. H-19, and CDRLs (Exhibit A) on this contract.
.

The option status has changed from Option to Option Exercised.

SUBCLIN 3001AA

The CLIN description has changed from 33.4M Doses to 25M Doses.
The pricing detail quantity has decreased by 8,400,000.00 from 33,400,000.00 to 25,000,000.00.
The option status has changed from Option to Option Exercised.
The total cost of this line item has decreased by $138,600,000.00 from $551,100,000.00 to $412,500,000.00.

SUBCLIN 3001AB

The CLIN description has changed from 33.4M Doses to 25M Doses.
The pricing detail quantity has decreased by 8,400,000.00 from 33,400,000.00 to 25,000,000.00.
The option status has changed from Option to Option Exercised.
The total cost of this line item has decreased by $138,600,000.00 from $551,100,000.00 to $412,500,000.00.

SUBCLIN 3001AC

The CLIN description has changed from 33.2M Doses to 30M Doses.

The pricing detail quantity has decreased by 3,200,000.00 from 33,200,000.00 to 30,000,000.00.

The option status has changed from Option to Option Exercised.

The total cost of this line item has decreased by $52,800,000.00 from $547,800,000.00 to $495,000,000.00.

CLIN 4001

The CLIN extended description has changed from:

The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW), and CDRLs (Exhibit A) on this contract.

To:

The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW), Clause no. 19, and CDRLs (Exhibit A) on this contract.
.

The option status has changed from Option to Option Exercised.

SUBCLIN 4001AA

The CLIN description has changed from 33.4M Doses to 10M Doses.

The pricing detail quantity has decreased by 23,400,000.00 from 33,400,000.00 to 10,000,000.00.

The option status has changed from Option to Option Exercised.

The total cost of this line item has decreased by $386,100,000.00 from $551,100,000.00 to $165,000,000.00.

SUBCLIN 4001AB

The CLIN description has changed from 33.4M Doses to 28M Doses.

The pricing detail quantity has decreased by 5,400,000.00 from 33,400,000.00 to 28,000,000.00.

The option status has changed from Option to Option Exercised.

The total cost of this line item has decreased by $89,100,000.00 from $551,100,000.00 to $462,000,000.00.

SUBCLIN 4001AC

The CLIN description has changed from 33.2M Doses to 28M Doses.

The pricing detail quantity has decreased by 5,200,000.00 from 33,200,000.00 to 28,000,000.00.

The option status has changed from Option to Option Exercised.

The total cost of this line item has decreased by $85,800,000.00 from $547,800,000.00 to $462,000,000.00.

SUBCLIN 3001AD is added as follows:

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 3001AD | | 20,000,000 | Each | $16.50 | $330,000,000.00 |
| EXERCISED OPTION | 20M Doses<br>FFP<br>a. If executed, the option shall be awarded upon EUA or no later than (b) (4) .<br>b. The government shall provide (b) (4) notification to exercise the option.<br>FOB: Destination<br>PURCHASE REQUEST NUMBER: 0011661905<br>PROJECT: Operation Warp Speed<br>PSC CD: 6505 | | | | |

NET AMT $330,000,000.00

ACRN AM $330,000,000.00
CIN: GFEBS001166190500004

SUBCLIN 4001AD is added as follows:

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 4001AD | | 34,000,000 | Each | $16.50 | $561,000,000.00 |
| EXERCISED OPTION | 34M Doses<br>FFP<br>a. If executed, the option shall be awarded upon EUA or no later than (b) (4) .<br>b. The government shall provide (b) (4) notification to exercise the option.<br>FOB: Destination<br>PURCHASE REQUEST NUMBER: 0011661905<br>PROJECT: Operation Warp Speed<br>PSC CD: 6505 | | | | |

NET AMT $561,000,000.00

ACRN AM $561,000,000.00
CIN: GFEBS001166190500008

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

**STATEMENT OF WORK**
**LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE**

C.1 **SCOPE**. The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.

C.1.1 Background. In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Service declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

C.1.1.1 Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

C.1.2 Objective: The objective of this effort is to obtain the following:

a. Base Period: Large scale manufacturing of 100 million vaccine doses
b. Option Period 1: Large scale manufacturing of 100 million vaccine doses
c. Option Period 2: Large scale manufacturing of 100 million vaccine doses
d. Option Period 3: Large scale manufacturing of 100 million vaccine doses
e. Option Period 4: Large scale manufacturing of 100 million vaccine doses

The Base Period is 9 months, with overlapping options for a total of 20 months if all options are exercised.

C.1.3 Consistent with the Updated EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) dated 01 April 2021, up to 15 doses may be extracted from Moderna's newly authorized multidose vials with 8.0mL fill volume (1600mcg). The Government and Moderna agree that 15 doses per vial are only attainable using premium low dead volume (LDV) syringes, which are in short supply globally. Utilizing initial ancillary equipment, vaccine administration personnel can reliably extract 13 doses from these vials; however, the Government has identified needle/syringe combinations that can be used to extract 14 doses.

C.1.3.1 Given the two parties' shared interest in reducing vaccine waste and accelerating the availability of Moderna's SARS-CoV-2 vaccine doses, the Government and Moderna intend that the Moderna vaccines doses be administered with needles and syringes compatible with extraction of 14 doses when possible. Toward this end, the Government shall maintain a list of syringe and/or needle combinations which will allow extraction of 14 doses per 8.0mL vial, which list shall be updated jointly by the Government and Moderna as any additional syringe and/or needle combinations compatible with extraction of 14 doses/vial are identified. Furthermore, the Government will, to the extent that appropriate needles and syringes are available, assemble and ship kits containing sufficient quantities of syringes and needles compatible with extraction of 14 doses per vial (Kit Moderna 140) with Moderna's SARS-CoV-2 vaccine. The Government expects that these kits will be available beginning 01 May 2021 for a significant portion of Moderna's remaining deliveries. If, however, appropriate syringes and needles are not available, the Government will revert to shipping the Kit Moderna 130 with Moderna's SARS-CoV-2 vaccine.

C.2 **APPLICABLE DOCUMENTS**.

C.2.1 Federal Documents:

C.2.1.1 Title 21 Code of Federal Regulations (CFR), Food and Drugs: Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General; and, Part 211, Current Good Manufacturing Practice In Manufacturing, Processing, Packing, or Holding of Drugs; General. (https://www.ecfr.gov/cgi-bin/text-idx?SID=a95cab20f443897a400bb7e44a27cf4c&mc=true&tpl=/ecfrbrowse/Title21/21cfrv4_02.tpl#0)

C.3 **REQUIREMENTS**. Independently, and not as an agent of the USG, in accordance with the Proposal submitted by Moderna US, Inc. in response to Solicitation Number W911QY20R0043, Titled, "Advanced Procurement of mRNA-1273 Vaccine for Prevention of SARS-CoV-2 Coronavirus (COVID-19)"), dated July 10, 2020 (and any subsequent USG-approved revisions thereto), the contractor shall provide all necessary services, qualified personnel, material, equipment and facilities (not otherwise provided by the USG under the terms of this contract) to perform the specific tasks set forth below.

C.3.1 **Contract Line Item Number (CLIN) 0001 - Base Period: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.1.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million Final Drug Product (FDP) doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include, the following tasks and other activities reasonably contemplated by such task:

C.3.1.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.1.1.2 cGMP manufacturing of 100 million doses fully compliant with 21 CFR 210 and 211.

C.3.1.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.1.1.4 Coordinating with FDA to establish an approved commercial vial label, carton and packaging insert (printed or electronic).

C.3.1.1.5 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA, including "Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act" (April 2020).

C.3.1.1.6 In coordination with the USG, the contractor shall conduct a demonstration of the vaccine shipping process prior to the first delivery of FDP doses at a time mutually agreed to by the contractor and the USG. Moderna shall provide specifications and details associated with the shipping process and containers (IAW CDRL A005) to enable the USG to adequately plan and prepare for potential distribution of the vaccine.

C.3.1.1.7 Following release of product the contractor shall, promptly deliver product to the designated delivery site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. In the unforeseen event that a designated delivery site cannot receive product and the contractor provides storage beyond 20 days of product release, the contract will be subject to modification for acceptance purposes.

C.3.1.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.1.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.1.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and Contracting Officer's Representative (COR) within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [redacted] of submittal of the audit report in accordance with CDRL A002.

C.3.1.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.2 **CLIN 1001 - Option Period 1: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.2.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.2.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.2.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.2.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.2.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.2.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.2.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.

C.3.2.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.3 **CLIN 2001 - Option Period 2: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.3.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.3.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.3.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.3.1.4 Ensuring that the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.5 Following release the contractor shall deliver product to the nearest designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.3.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.3.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.3.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice.

The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.

C.3.3.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.4 **CLIN 3001 - Option Period 3: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.4.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.4.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.4.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.4.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.4.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.4.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.4.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.

C.3.4.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding mRNA-1273 for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.5 **CLIN 4001 - Option Period 4: Large Scale Manufacturing of 100 Million Vaccine Doses**.

C.3.5.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.5.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.5.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.5.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.5.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.5.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.5.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within (b) (4) of a scheduled FDA audit or within (b) (4) of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within (b) (4) of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within (b) (4) of submittal of the audit report in accordance with CDRL A002.

C.3.5.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.4 **CLIN 0002: Data Deliverables**. The contractor shall provide the following in accordance with the Contract Data Requirements List (CDRL), DD Forms 1423, provided at Appendix A.

C.4.1 Monthly Inventory Report (CDRL A003), detailing at a minimum, raw materials, formulated LNPs, and the fill, finish, and released product.

C.4.2 Quality Management Plan. The contractor shall provide a Quality Management Plan, in accordance with CDRL A004, describing the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.

C.4.3 Shipping Documentation (CDRL A005) for all Finished Drug Product (FDP) transferring from the contractor's fill/finish facility to a USG facility. The contractor shall obtain concurrence on planned shipment protocols prior to transport.

C.4.4 Expiring Items Report (CDRL A006) for all FDP in the USG's possession.

C.4.5 Key Personnel Listing (CDRL A007).

C.4.6 Monthly Technical Progress Report (CDRL A008), to include an Integrated Master Schedule, identifying key activities and contract status.

C.4.7 Final Technical Report (CDRL A009), documenting the work performed and results obtained for the entire contract period of performance.

C.4.8 Supply Chain Resiliency Plan (SCRP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRP that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods, and key equipment suppliers and their locations, including addresses, points of contact, and work performed per location, to include subcontractors.

C.4.9 Risk Management Plan (RMP). The Contractor shall provide an RMP in accordance with CDRL A011 that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy shall capture how the corrective action will reduce impacts on cost, schedule and performance. The following RMP information shall be included in the Monthly Technical Progress Report (CDRL A008).

Risk Register content:
a. Manuf/FF -risks or possible delays. If none N/A
b. Supply chain – same as above
c. Distribution challenges – same as above
d. Regulatory – same as above

C.4.10 Manufacturing Reports and Dose Tracking. The Contractor shall provide, in accordance with CDRL A013, manufacturing reports and manufacturing dose tracking projections and actuals utilizing the USG-provided "COVID-19 Dose Tracking Template" (CDRL Attachment 0003).

C.4.11 Product Acceptance Report (for each lot of Drug Product). The contractor shall provide, in accordance with CDRL A014, pictures of the drug product with lot number, drug product lot tree, list of associated deviations (from drug substance and product), and a Certificate of Analysis.

C.4.12 Incident Report. The contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance in accordance with CDRL A016. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, shall also be reported.

C.4.13 FDA Correspondence. The contractor shall provide any correspondence between Contractor and FDA relevant to the scope of this contract and submit in accordance with CDRL A017.

C.4.14 Press Releases. The contractor shall accurately and factually represent the work conducted under this contract in all press releases. The contractor shall provide an advance copy of any press release in accordance with CDRL A018.

C.4.15 Manufacturing Development Plan. The contractor shall provide a Manufacturing Development Plan, in accordance with CDRL A025, describing the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP).

C.5 **Administration**.

C.5.1 Post Award Teleconference. The contractor shall host a Post Award Teleconference within 15 calendar days after contract award.

C.5.1.1 The contractor shall provide an Agenda, IAW CDRL A020, detailing the planned activities for the subsequent 30 calendar days and shall discuss agenda items for the Post Award Kickoff Meeting.

C.5.1.2 The contractor shall provide Meeting Minutes IAW CDRL A021.

C.5.2 Post Award Kickoff Meeting. The contracting officer may request the contractor host a contract Kick-Off Meeting within 30 calendar days after contract award via teleconference. The contracting officer shall establish the date and time of the conference and prepare the agenda to include discussion on contract activities and schedule.

C.5.3 Bi-Weekly Teleconference. The contractor shall participate in bi-weekly teleconferences (or more frequent meetings required by the USG if warranted based on contract activities) to discuss performance on the contract.

C.5.4 The contractor shall provide an Agenda, IAW CDRL A020; Meeting Minutes in accordance with CDRL A021; and, Presentation Material in accordance with CDRL A022 for each of the aforementioned teleconferences or meetings throughout the contract period of performance.

C.5.5 Daily "Check-In". The contractor shall participate in a daily "check-in" (via teleconference or email) to address key cost, schedule and technical updates. Daily updates may be shared with senior USG leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case, the contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the USG, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.

C.6 **Security**.

C.6.1 Access and General Protection/Security Policy and Procedures. The contractor shall provide all information required for background checks necessary to access critical information related to OWS, and to meet USG installation access requirements to be accomplished by the installation Director of Emergency Services or Security Office. The contractor employees shall comply with all personnel identity verification requirements as directed by the USG and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the security status of OWS change the USG may require changes in the contractor's security matters or

processes. In addition to the industry standards for employment background checks, the contractor shall be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States USG.

C.6.2 Security Program and Plan. The contractor shall implement a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the USG's requirement. The contractor's security practices and procedures shall be detailed in a Security Plan, in accordance with CDRL A019, and shall demonstrate how the contractor shall meet and adhere to the security requirements outlined in CDRL Attachment 0002. This plan shall be delivered to the USG within 45 days of award, and the USG will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Security Plan comments, and, submit a final Security Plan to the U.S. USG within thirty (30) calendar days after receipt of the comments. The Security Plan shall include a timeline for compliance of all the required security measures outlined in CDRL Attachment 0002.

C.6.3 Operational Security (OPSEC). The contractor shall develop and submit an OPSEC Standard Operating Procedure (SOP)/Plan IAW CDRL A024. The contractor shall identify in the SOP/Plan critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

C.7 **CLIN 0002 Vendor Managed Inventory (VMI)**. The Contractor shall provide the capability to store the vaccine for up to 52 weeks, up to 100M doses of mRNA-1273 vaccine, in accordance with product labeling. The contractor shall, in accordance with paragraph C.3.1.1.6, ensure the product storage of FDP doses for up to 12 months prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations . (b) (4) The contractor shall store the product to insure product quality with audible alarms and contacting. The contractor shall notify the USG within (b) (4) of detection of an incident with the potential to impact product quality, and implement corrective actions to mitigate the incident. . BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary. The contractor shall notify the USG of Corrective/Preventive actions within (b) (4) of detection of an incident with potential to impacts product quality. BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary.

C.7.1 The USG will provide the contractor advance notice of the required delivery locations for the vaccine. The contractor shall ship mRNA-1273 vaccines to designated locations (b) (4) (b) (4) in the United States. The contractor shall be responsible for shipment of all vaccine product whether acceptance is conducted at origin or destination. (b) (4)

C.7.2 The vaccine product shall be shipped and tracked by the distribution vendor's shipping tracking number, to the USG-designated sites within the continental United States.

C.7.3 (b) (4) Implementation of a Vendor Managed Inventory Plan/SOP (CDRL A012) shall be provided to the USG. (b) (4) Notwithstanding either of the foregoing sentences, the contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the USG acting within the scope of their employment.

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 3001AD:

| INSPECT AT | INSPECT BY | ACCEPT AT | ACCEPT BY |
|---|---|---|---|
| Origin | Government | Origin | Government |

The following Acceptance/Inspection Schedule was added for SUBCLIN 4001AD:

| INSPECT AT | INSPECT BY | ACCEPT AT | ACCEPT BY |
|---|---|---|---|
| Origin | Government | Origin | Government |

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for SUBCLIN 3001AA has been changed from:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

To:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

The following Delivery Schedule item for SUBCLIN 3001AB has been changed from:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

To:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

The following Delivery Schedule item for SUBCLIN 3001AC has been changed from:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

To:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

The following Delivery Schedule for SUBCLIN 3001AD has been added:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

The following Delivery Schedule item for SUBCLIN 4001AA has been changed from:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

To:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

The following Delivery Schedule item for SUBCLIN 4001AB has been changed from:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

To:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

The following Delivery Schedule item for SUBCLIN 4001AC has been changed from:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

To:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

The following Delivery Schedule for SUBCLIN 4001AD has been added:

| DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|
| (b) (4) | (b) (4) | (b) (6)<br>WASHINGTON DC 20024<br>(b) (6)<br>FOB: Destination | W56XNH |

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $3,300,000,000.00 from $4,845,591,662.60 to $8,145,591,662.60.

SUBCLIN 3001AA:

AK: 021202120222040000665654255 S.0074658.5.58 6100.9000021001 A5XAH (CIN GFEBS001166190500001) was increased by $412,500,000.00 from $0.00 to $412,500,000.00
The contract ACRN AK has been added.
The CIN GFEBS001166190500001 has been added.
The Cost Code A5XAH has been added.

SUBCLIN 3001AB:

AK: 021202120222040000665654255 S.0074658.5.58 6100.9000021001 A5XAH (CIN GFEBS001166190500002) was increased by $412,500,000.00 from $0.00 to $412,500,000.00
The contract ACRN AK has been added.
The CIN GFEBS001166190500002 has been added.
The Cost Code A5XAH has been added.

SUBCLIN 3001AC:

AL: 021202120222040000665654255 S.0074658.5.58.3 6100.9000021001 A5XAH (CIN GFEBS001166190500003) was increased by $495,000,000.00 from $0.00 to $495,000,000.00
The contract ACRN AL has been added.
The CIN GFEBS001166190500003 has been added.
The Cost Code A5XAH has been added.

SUBCLIN 3001AD:
Funding on SUBCLIN 3001AD is initiated as follows:

ACRN: AM

CIN: GFEBS001166190500004

Acctng Data: 021202120222040000665654255 S.0074658.5.58.1 6100.9000021001

Increase: $330,000,000.00

Total: $330,000,000.00

Cost Code: A5XAH

SUBCLIN 4001AA:

AK: 021202120222040000665654255 S.0074658.5.58 6100.9000021001 A5XAH (CIN GFEBS001166190500005) was increased by $165,000,000.00 from $0.00 to $165,000,000.00
The contract ACRN AK has been added.
The CIN GFEBS001166190500005 has been added.
The Cost Code A5XAH has been added.

SUBCLIN 4001AB:

AN: 021202120222040000665654255 S.0074658.5.58.2 6100.9000021001 A5XAH (CIN GFEBS001166190500006) was increased by $462,000,000.00 from $0.00 to $462,000,000.00
The contract ACRN AN has been added.
The CIN GFEBS001166190500006 has been added.
The Cost Code A5XAH has been added.

SUBCLIN 4001AC:

AN: 021202120222040000665654255 S.0074658.5.58.2 6100.9000021001 A5XAH (CIN GFEBS001166190500007) was increased by $462,000,000.00 from $0.00 to $462,000,000.00
The contract ACRN AN has been added.
The CIN GFEBS001166190500007 has been added.
The Cost Code A5XAH has been added.

SUBCLIN 4001AD:
Funding on SUBCLIN 4001AD is initiated as follows:

ACRN: AM

CIN: GFEBS001166190500008

Acctng Data: 021202120222040000665654255 S.0074658.5.58.1 6100.9000021001

Increase: $561,000,000.00

Total: $561,000,000.00

Cost Code: A5XAH

The following have been modified:

**G.1 GOVERNMENT CONTRACT ADMINISTRATION**

In no event shall any understanding or agreement, contract modification, change order, or other matter in deviation from the terms of this contract between the Contractor and a person other than the Contracting Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Contracting Officer.

Procuring Contracting Officer:
(b) (6)
Joint COVID-19 Response Division
US Army Contracting Command
6472 Integrity Court (Building 4401)
Aberdeen Proving Ground, MD 21005-3013

Contract Specialist:
(b) (6)
Joint COVID-19 Response Division
US Army Contracting Command
6472 Integrity Court (Building 4401)
Aberdeen Proving Ground, MD 21005-3013

**G.2 GOVERNMENT TECHNICAL POINT OF CONTACT**

(b) (6)
Biologist/Project Officer
200 C Street, SW
Washington, DC 20201

**G.3 CONTRACTOR'S CONTRACT ADMINISTRATION**

(b) (6)
Moderna US, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

**G.4 PLACES OF PERFORMANCE**

Moderna US, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

**G.5 NOTIFICATION OF REVISIONS AND CHANGE**

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO/ACO or office of the PCO/ACO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

**G.6 PERFORMANCE BASED PAYMENT**

Performance-based payments (PBP) are authorized under this contract in accordance with FAR 52.232-32. The contractor shall bill for the PBP upon achievement of the completion criteria identified in Attachment 0007, Performance-based Payment Milestone Table dated 4 May 2021. Upon achievement of the completion criteria, the contractor shall bill for the PBP for the base and each option IAW the following schedule:

| CLIN | Period | Amount |
|---|---|---|
| 0001AA | BASE | $90,210,000 |
| 0001AB | BASE | $132,308,000 |
| 0001AC | BASE | $180,420,000 |
| 0001AD | BASE | $198,462,000 |
| TOTAL | | $601,400,000 |
| (b) (4) | | |
| (b) (4) | | |

Delivery Invoicing: PBPs are a type of contract financing and are recouped by the Government through deductions of payments otherwise due to the contractor for the partial or complete delivery of contract items. The deductions are made by applying a liquidation rate to the price of delivered contract items. Attachment 0008, Performance-

based Payment Milestone Billing Plan, identifies the contractor invoicing schedule for liquidation. The contractor shall submit all invoices IAW Attachment 0008.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

**H.1 Key Personnel**

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

| Name | Title |
|---|---|
| (b) (6) | [redacted] |

**H.2 Substitution of Key Personnel**

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

**H.3 Disclosure of Information:**

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall

not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

**H.4 Publication and Publicity**

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-20-C-0100."

**H.5 Confidentiality of Information**

a. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may,

by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

**ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.**

**H.6 Regulatory Rights**

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within 30 days of award.

(b) (4) [redacted]

**H.7 Performance Based Payment Liquidated under Termination**

Performance Based Payments (PBPs) have been authorized as a method of financing under this contract. In the event the Moderna's mRNA-1273 COVID Vaccine is unsuccessful in its bid to obtain EUA or FDA approval, the Government may issue a Termination for Convenience (T4C) in whole or in part, on this contract. Upon notice of a T4C, the contractor shall submit a termination settlement proposal, IAW FAR 52.249-2, Termination for Convenience of the Government (Fixed-Price).

**H.8 Public Readiness and Emergency Preparedness (PREP) Act:**

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

(ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and

(iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act

Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Moderna prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.

(b) (4) [redacted]

(b) (4)

[redacted]

**H.10 Ensuring Sufficient Supply of the Product**

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

a. Moderna gives written notice, required to be submitted to the Government (b) (4) [redacted], of:

i. any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

ii. any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

iii. any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

(b) (4) [redacted]

[redacted]

**H.12 Transportation to Final Destination**

During the course of performance under this contract, the Government may require storage of the filled drug product (FDP) before delivery to the final government location. In these circumstances, the Government will accept FDP at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the vaccine to its final destination as identified on this contract. (b) (4) [redacted]

**H.13 Validation of IP/Data**

The Parties acknowledge that background intellectual property and technical data assertions have been made and evaluated by the parties. The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

**H.14 Novation**

Upon Moderna, US, Inc.'s registration in the System for Award Management, the Government will, at the Contractor's request, complete a novation of this Contract to recognize Moderna US, Inc. as a counterparty instead of Moderna TX, Inc. This novation will be completed through a modification executed by the Government that identifies Moderna US, Inc. as the contracting party for all purposes as if it had originally executed the Contract.

**H.15 Base & Option 1 Delivery Acceleration**

In an effort to accelerate production of the mRNA-1273 vaccine, (b) (4) [redacted] within the Option 1 period via a Modification to the contract. If these manufacturing slots are successfully utilized, (b) (4) [redacted] above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by (b) (4) for each successfully accelerated drug product fill under the Base Period (b) (4) and (b) (4) for each successfully accelerated drug product fill under Option 1 (b) (4) [redacted]

2. If the Government does not exercise Option 2 (NLT 15 May):
a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to credit the Government (b) (4) for (b) (4) and (b) (4) for (b) (4) [redacted]. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drug product

manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fill reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

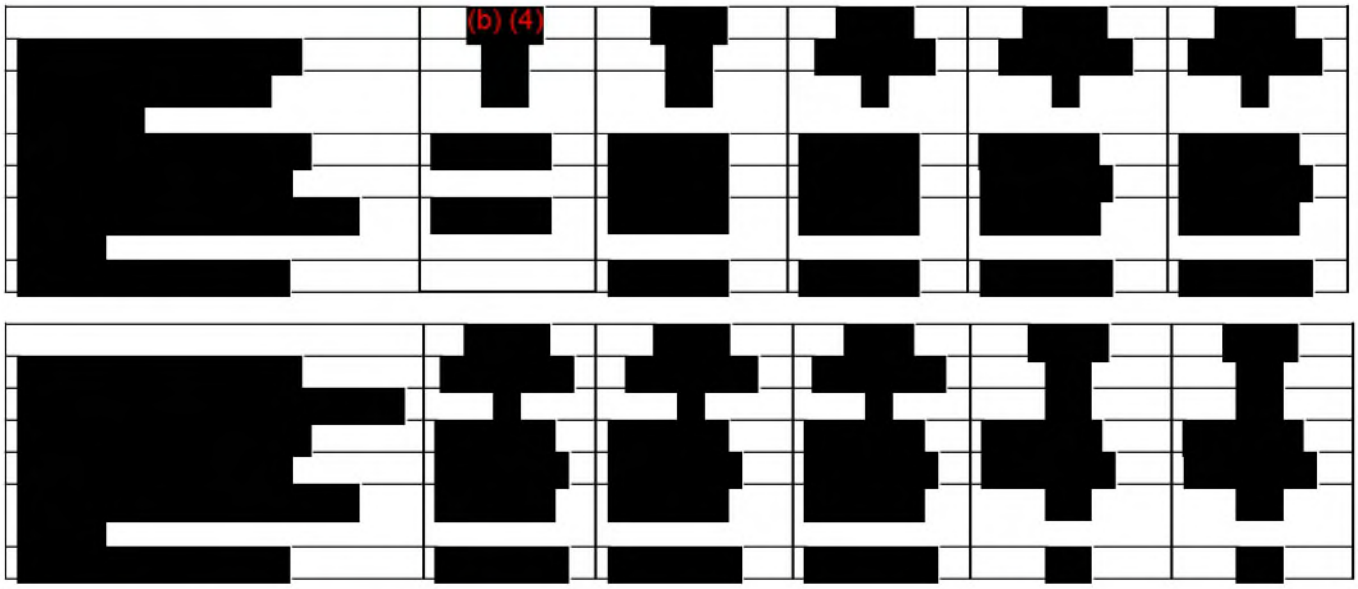
1.) Moderna shall submit documentation to the USG of the following:

i.) Cancellation notice to the subcontractor,
ii.) The basis of the cancellation. and
iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause, IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

**H.16 Delivery Schedule, as revised 11Feb2021 via modification P00004**




Moderna confirms that it will provide the USG with the first 300M doses manufactured within its US-based supply chain prior to sale or export, with the exception of doses required for clinical studies. The delivery schedule assumes that Moderna will work to further maximize fill/finish capacity by working with the FDA to increase fill volumes, thus enabling extraction of additional doses from each vial delivered. Both parties acknowledge that resulting revisions to future accounting, invoicing, acceptance and delivery of doses subject to the revised label will be implemented via a subsequent modification.

**H.17 Post-Termination Disposition of Undelivered Product**

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard

to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

(b) (4) [redacted]

In order to facilitate projections and invoicing, the Government shall provide or direct a third party (b) (4) to provide to Moderna (1) actual quantities of Moderna (b) (4) with 8.0mL vials during the reporting period; (2) actual quantities of Moderna (b) (4) with 8.0mL vials during the reporting period; and (3) the number of (b) (4) remaining in inventory and available for upcoming shipments. This information will be provided to Moderna at a frequency of at least twice monthly.

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with (b) (4) [redacted]

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with (b) (4) [redacted]

Both parties acknowledge that the delivery schedule is based on (b) (4) [redacted] 8.0mL fill volume (1600mcg) vial delivered. In accordance with the agreed approach for invoicing and counting doses toward Moderna's delivery requirement, (b) (4) [redacted] Specifically for purposes of adhering to the scheduled delivery dates set forth in this contract for the Base Period, Option 1 and Option 2, schedule shall be deemed to have been met once doses are released by Moderna and are available for order.

**H.19 Product (b) (4) (as added via P00007)**

Specific to CLINs 3001 and 4001, Moderna will deliver to the Government (b) (4) [redacted]

- mRNA-1273 Primary Series (0.2mg/mL, 100µg, 2-dose)

(b) (4) [redacted]

All doses delivered in calendar year 2021 will be delivered in multi-dose vials (b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted]

The Government and Moderna agree that total monthly delivery quantities for each of CLIN 3001 and 4001 will follow the schedule in the table below. The Government and Moderna also agree on the following points specific to product ordering:

(b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted]

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

| Document Type | Description | Page # | Date |
|---|---|---|---|
| Exhibit A | CDRLs | 15 | 11 Feb 2021 |
| Attachment 0001 | Supply Chain Resiliency Plan for CDRL A010 | 3 | 23 July 2020 |
| Attachment 0002 | Security Plan | 7 | 23 July 2020 |
| Attachment 0003 | Dose Tracking Template Draft Moderna | Excel | 15 July 2020 |
| Attachment 0004 | Data Rights | 3 | 7 August 2020 |

| | | | |
|---|---|---|---|
| Attachment 0005 | (b) (4) | 2 | 7 August 2020 |
| Attachment 0006 | ModernaTx, Inc. Background Intellectual Property | 3 | 6 August 2020 |
| Attachment 0007 | Performance Base Payment Milestone Schedule | 1 | 14 June 2021 |
| Attachment 0008 | Performance Base Payment Milestone Billing Plan | 16 | 14 June 2021 |
| Attachment 0009 | HRPAS Moderna Letter | 1 | 3 September 2020 |

(End of Summary of Changes)

# AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

| 1 CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 \| 12 |

| 2 AMENDMENT/MODIFICATION NO | 3 EFFECTIVE DATE | 4 REQUISITION/PURCHASE REQ NO | 5 PROJECT NO (If applicable) |
|---|---|---|---|
| P00008 | 16-Jun-2021 | SEE SCHEDULE | |

| 6 ISSUED BY | CODE | 7 ADMINISTERED BY (If other than item 6) | CODE |
|---|---|---|---|
| ACC-APG - COVID RESPONSE - W58P05<br>6472 NTEGRITY COURT (BU LDING 4401)<br>ABERDEEN PROVING GROUND MD 21005-3013 | W58P05 | DEFENSE CONTRACT MANAGEMENT AGENCY<br>DCMA BOSTON<br>495 SUMMER STREET<br>BOSTON MA 02210-2138 | S2206A |

| 8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) | | 9A. AMENDMENT OF SOLICITATION NO. |
|---|---|---|
| MODERNA US, NC.<br>(b) (6)<br>200 TECHNOLOGY SQ<br>CAMBRIDGE MA 02139-3578 | | 9B. DATED (SEE ITEM 11) |
| | X | 10A. MOD. OF CONTRACT/ORDER NO.<br>W911QY20C0100 |
| | X | 10B. DATED (SEE ITEM 13)<br>09-Aug-2020 |
| CODE 8PTM0 | FACILITY CODE | |

## 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

## 12. ACCOUNTING AND APPROPRIATION DATA (If required)

## 13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
See Block 14 Continuation Page

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
See Block 14 Continuation Page

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) |
|---|---|
| (b) (6) | (b) (4)<br>TEL: |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
|---|---|---|---|
| (b) (6)<br>(Signature of person authorized to sign) | June 16, 2021 | BY (b) (6) (b) (6)<br>(Signa | 16 June 2021 |

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:
P00008
OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00008) is to:

- Add H.20 Donation of Excess Product and Exhibit B (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total contract value and total funded amount remain unchanged.

All other terms and conditions remain unchanged. Please see below for details.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

**H.1 Key Personnel**

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

| Name | Title |
|---|---|
| (b) (4) | |
| | |
| | |
| | |
| | |
| | |
| | |

**H.2 Substitution of Key Personnel**

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

**H.3 Disclosure of Information:**

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

**H.4 Publication and Publicity**

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

a. Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

b. Unless authorized in writing by the CO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.

c. The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

d. The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-20-C-0100."

**H.5 Confidentiality of Information**

a. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

**ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.**

**H.6 Regulatory Rights**

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within 30 days of award.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Performance Based Payments (PBPs) have been authorized as a method of financing under this contract. In the event the Moderna's mRNA-1273 COVID Vaccine is unsuccessful in its bid to obtain EUA or FDA approval, the Government may issue a Termination for Convenience (T4C) in whole or in part, on this contract. Upon notice of a T4C, the contractor shall submit a termination settlement proposal, IAW FAR 52.249-2, Termination for Convenience of the Government (Fixed-Price).

**H.8 Public Readiness and Emergency Preparedness (PREP) Act:**

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

(ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and

(iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act

Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Moderna prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.

[redacted]

**H.10 Ensuring Sufficient Supply of the Product**

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

a. Moderna gives written notice, required to be submitted to the Government (b) (4) [redacted], of:

(i) any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

(ii) any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

(iii) any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

(b) (4) [redacted]

[redacted]

**H.12 Transportation to Final Destination**

During the course of performance under this contract, the Government may require storage of the filled drug product (FDP) before delivery to the final government location. In these circumstances, the Government will accept FDP at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the vaccine to its final destination as identified on this contract. (b) (4) [redacted]

**H.13 Validation of IP/Data**

The Parties acknowledge that background intellectual property and technical data assertions have been made and evaluated by the parties. The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

**H.14 Novation**

Upon Moderna, US, Inc.'s registration in the System for Award Management, the Government will, at the Contractor's request, complete a novation of this Contract to recognize Moderna US, Inc. as a counterparty instead of Moderna TX, Inc. This novation will be completed through a modification executed by the Government that identifies Moderna US, Inc. as the contracting party for all purposes as if it had originally executed the Contract.

**H.15 Base & Option 1 Delivery Acceleration**

In an effort to accelerate production of the mRNA-1273 vaccine, (b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted]

(b) (4) within the Option 1 period via a Modification to the contract. If these manufacturing slots are successfully utilized, (b) (4) above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by (b) (4) for each successfully accelerated drug product fill under the Base Period (b) (4) and (b) (4) for each successfully accelerated drug product fill under Option 1 (b) (4)

2. If the Government does not exercise Option 2 (NLT 15 May):
a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to credit the Government (b) (4) for (b) (4) and (b) (4) for (b) (4). In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drug product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fill reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:

i.) Cancellation notice to the subcontractor,
ii.) The basis of the cancellation. and
iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause, IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

**H.16 Delivery Schedule, as revised 11Feb2021 via modification P00004**

(b) (4)

Moderna confirms that it will provide the USG with the first 300M doses manufactured within its US-based supply chain prior to sale or export, with the exception of doses required for clinical studies. The delivery schedule assumes that Moderna will work to further maximize fill/finish capacity by working with the FDA to increase fill volumes, thus enabling extraction of additional doses from each vial delivered. Both parties acknowledge that resulting revisions to future accounting, invoicing, acceptance and delivery of doses subject to the revised label will be implemented via a subsequent modification.

**H.17 Post-Termination Disposition of Undelivered Product**

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

(b) (4)

In order to facilitate projections and invoicing, the Government shall provide or direct a third party (b) (4) to provide to Moderna (1) actual quantities of Moderna (b) (4) with 8.0mL vials during the reporting period; (2) actual quantities of Moderna (b) (4) with 8.0mL vials during the reporting period; and (3) the number of (b) (4) remaining in inventory and available for upcoming shipments. This information will be provided to Moderna at a frequency of at least twice monthly.

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with (b) (4)

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with (b) (4)

Both parties acknowledge that the delivery schedule is based on (b) (4) 8.0mL fill volume (1600mcg) vial delivered. In accordance with the agreed approach for invoicing and counting doses toward Moderna's delivery requirement, (b) (4) Specifically for purposes of adhering to the scheduled delivery dates set forth in this contract for the Base Period, Option 1 and Option 2, schedule shall be deemed to have been met once doses are released by Moderna and are available for order.

**H.19 Product (b) (4) (as added via P00007)**

Specific to CLINs 3001 and 4001, Moderna will deliver to the Government (b) (4)

- mRNA-1273 Primary Series (0.2mg/mL, 100µg, 2-dose)

(b) (4)

All doses delivered in calendar year 2021 will be delivered in multi-dose vials (b) (4)

(b) (4)

The Government and Moderna agree that total monthly delivery quantities for each of CLIN 3001 and 4001 will follow the schedule in the table below. The Government and Moderna also agree on the following points specific to product ordering:

(b) (4)

(b) (4)

(b) (4)

**H.20 Donation of Excess Product**

a. If the Government determines that a quantity of doses of mRNA-1273 supplied to the Government under this contract is no longer needed by the Government, the Government may donate such doses to a foreign nation or non-governmental organization (NGO) facilitating donation to a foreign nation, subject to the remainder of this Clause H.20. The Government shall notify Contractor in writing prior to any proposed donation to a foreign nation or NGO, which notice will include (b) (4)

b. Contractor must verify in writing that all of the required conditions below are met before any such donation is made. (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

c. The Government's donations will be from supplies of vaccine delivered to and accepted by the Government. To the extent the Government commits to deliver doses that have not yet been physically delivered to the Government, such donation will not occur until such doses have been delivered to the Government. The Government will be responsible for delivery of the donated doses to, and coordination of delivery with, the receiving foreign nation or NGO, as applicable. The Government or the receiving foreign nation or NGO, as applicable, will (i) satisfy all customs shipping requirements for import and export of the product; and (ii) as the exporter, file any required FDA export notifications. To the extent not already provided to the Government, the Contractor will provide all information necessary to complete any requirements identified in this paragraph in advance of shipment.

d. When the conditions above are met for any donation, the Parties will (b) (4)

(b) (4)

f. Shipment of any donated doses under this Article does not constitute a violation of the Defense Production Act.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

| Document Type | Description | Page # | Date |
|---|---|---|---|
| Exhibit A | CDRLs | 15 | 11 Feb 2021 |
| Exhibit B | Donation of Excess Product | 1 | 16 June 2021 |
| Attachment 0001 | Supply Chain Resiliency Plan for CDRL A010 | 3 | 23 July 2020 |
| Attachment 0002 | Security Plan | 7 | 23 July 2020 |
| Attachment 0003 | Dose Tracking Template Draft Moderna | Excel | 15 July 2020 |
| Attachment 0004 | Data Rights | 3 | 7 August 2020 |
| Attachment 0005 | (b) (4) | 2 | 7 August 2020 |
| Attachment 0006 | ModernaTx, Inc. Background Intellectual Property | 3 | 6 August 2020 |
| Attachment 0007 | Performance Base Payment Milestone Schedule | 1 | 14 June 2021 |
| Attachment 0008 | Performance Base Payment Milestone Billing Plan | 16 | 14 June 2021 |
| Attachment 0009 | HRPAS Moderna Letter | 1 | 3 September 2020 |

(End of Summary of Changes)

# AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

| 1 CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 \| 2 |

| 2 AMENDMENT/MODIFICATION NO | 3 EFFECTIVE DATE | 4 REQUISITION/PURCHASE REQ NO | 5 PROJECT NO (If applicable) |
|---|---|---|---|
| P00009 | 16-JUN-2021 | SEE SCHEDULE | |

| 6 ISSUED BY | CODE | 7 ADMINISTERED BY (If other than item 6) | CODE |
|---|---|---|---|
| ACC-APG - COVID RESPONSE - W58P05<br>6472 NTEGRITY COURT (BU LDING 4401)<br>ABERDEEN PROVING GROUND MD 21005-3013 | W58P05 | DCMA BOSTON<br>495 SUMMER STREET<br>BOSTON MA 02210-2138 | S2206A |

| 8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) | | |
|---|---|---|
| MODERNA US, NC.<br>(b) (6)<br>200 TECHNOLOGY SQ<br>CAMBRIDGE MA 02139-3578 | | 9A. AMENDMENT OF SOLICITATION NO. |
| | | 9B. DATED (SEE ITEM 11) |
| | X | 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100 |
| | X | 10B. DATED (SEE ITEM 13) 09-Aug-2020 |
| CODE 8PTM0 | FACILITY CODE | |

## 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

## 12. ACCOUNTING AND APPROPRIATION DATA (If required)

## 13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
See Block 14 Continuation Page

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
See Block 14 Continuation Page

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) |
|---|---|
| (b) (6) | (b) (6)<br>TEL: (b) (6) EMAIL: (b) (6) |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
|---|---|---|---|
| (b) (6)<br>(Signature of person authorized to sign) | June 16, 2021 | BY (b) (6)<br>(Signature of Contracting Officer) | June 16, 2021 |

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00009

OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00009) is to:
   - Update Exhibit B as outlined in clause H.20 with donation information for donation to Canada (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total contract value and total funded amount remains unchanged.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

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| Attachment 0004 | Data Rights | 3 | 7 August 2020 |
| Attachment 0005 | (b) (4) | 2 | 7 August 2020 |
| Attachment 0006 | ModernaTx, Inc. Background Intellectual Property | 3 | 6 August 2020 |
| Attachment 0007 | Performance Base Payment Milestone Schedule | 1 | 14 June 2021 |
| Attachment 0008 | Performance Base Payment Milestone Billing Plan | 16 | 14 June 2021 |
| Attachment 0009 | HRPAS Moderna Letter | 1 | 3 September 2020 |

(End of Summary of Changes)

# AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

| 1 CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 \| 2 |

| 2 AMENDMENT/MODIFICATION NO | 3 EFFECTIVE DATE | 4 REQUISITION/PURCHASE REQ NO | 5 PROJECT NO (If applicable) |
|---|---|---|---|
| P00010 | 17-Jun-2021 | SEE SCHEDULE | |

| 6 ISSUED BY | CODE | 7 ADMINISTERED BY (If other than item 6) | CODE |
|---|---|---|---|
| ACC-APG - COVID RESPONSE - W58P05<br>6472 NTEGRITY COURT (BU LDING 4401)<br>ABERDEEN PROVING GROUND MD 21005-3013 | W58P05 | DCMA BOSTON<br>495 SUMMER STREET<br>BOSTON MA 02210-2138 | S2206A |

| 8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) | | |
|---|---|---|
| MODERNA US, NC.<br>(b) (6)<br>200 TECHNOLOGY SQ<br>CAMBRIDGE MA 02139-3578 | | 9A. AMENDMENT OF SOLICITATION NO. |
| | | 9B. DATED (SEE ITEM 11) |
| | X | 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100 |
| | X | 10B. DATED (SEE ITEM 13) 09-Aug-2020 |
| CODE 8PTM0 | FACILITY CODE | |

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
See Block 14 Continuation Page

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
See Block 14 Continuation

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) |
|---|---|
| (b) (6) | (b) (6)<br>TEL: (b) (6) EMAIL: (b) (6) |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
|---|---|---|---|
| (b) (6)<br>(Signature of person authorized to sign) | June 17,2021 | BY (b) (6)<br>(Signature of Contracting Officer) | June 17, 2021 |

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:
P00010

OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00010) is to:
   - Update Exhibit B as outlined in clause H.20 with donation information for donation to Taiwan (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total contract value and total funded amount remains unchanged.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

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| Attachment 0009 | HRPAS Moderna Letter | 1 | 3 September 2020 |

(End of Summary of Changes)

# Attachment 0007

# Performance Based Payment (PBP) Milestone Schedule

# 14 June 2021

| CLIN | Milestone | Severable / Cumulative | Price | Milestone Completion Verification Method |
|---|---|---|---|---|
| 0001 | Capacity and Raw Material Severable Reservation | Severable | $601,400,000 | Moderna shall provide: 1) Written confirmation from the CMO network that sufficient capacity has been reserved; and, 2) Written confirmation of reservation of sufficient raw materials along with a manufacturing schedule. |
| 1001 | | | (b) (4) | |
| 2001 | | | (b) (4) | |
| 3001 | | | (b) (4) | |
| 4001 | | | (b) (4) | |

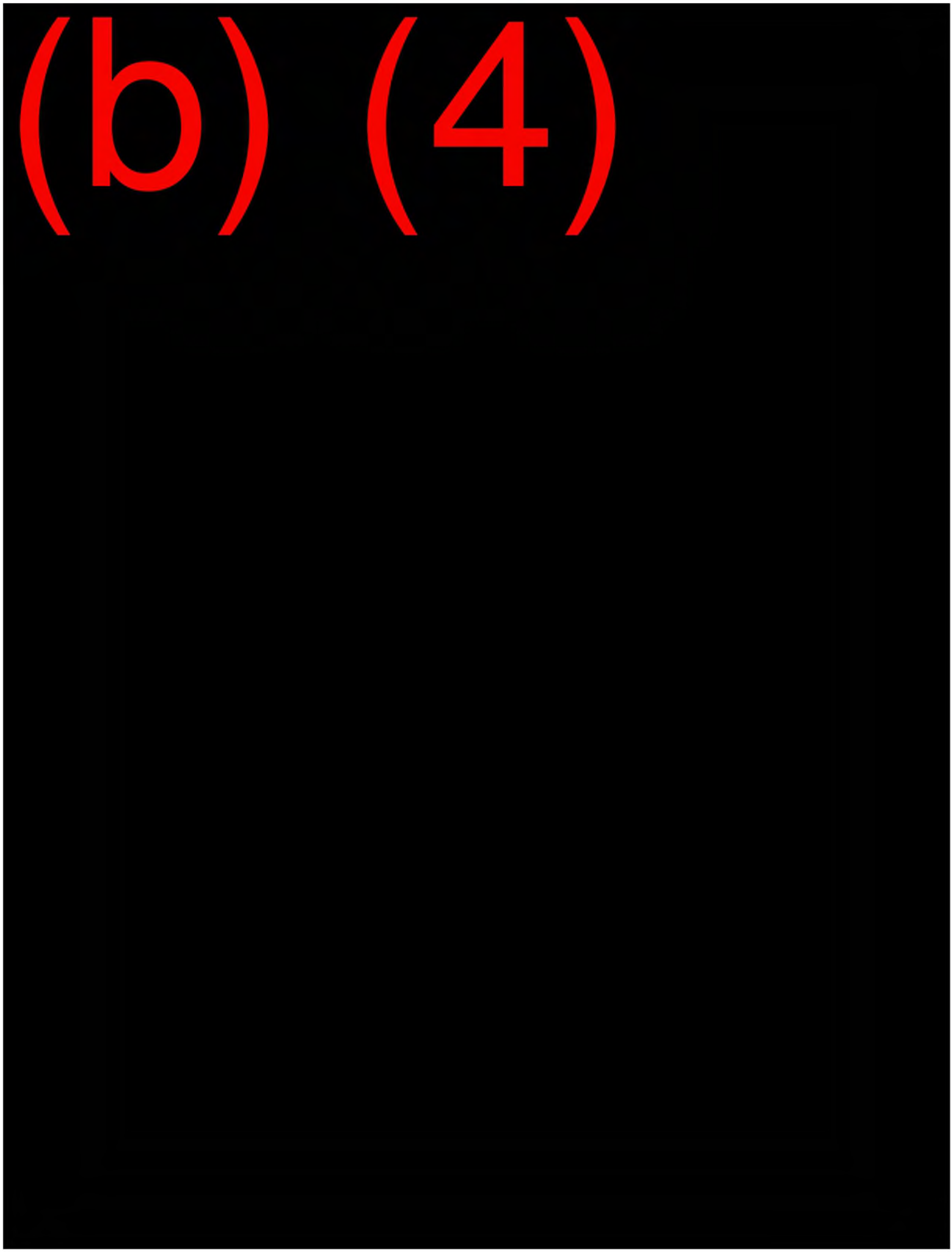
Attachment 0008

Performance Based Payment (PBP) Milestone Billing Plan

14 June 2021

Pages 16


(b) (4)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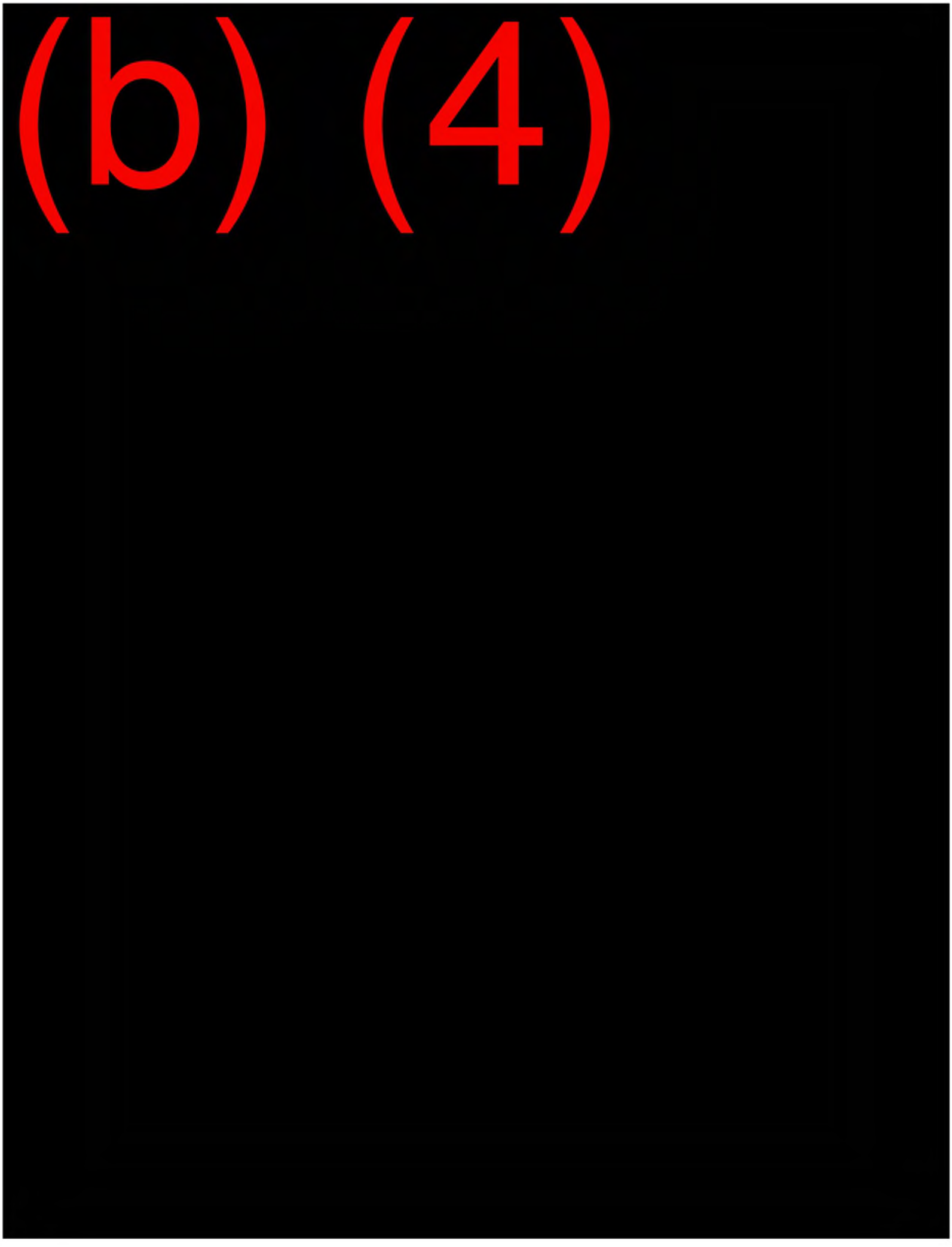
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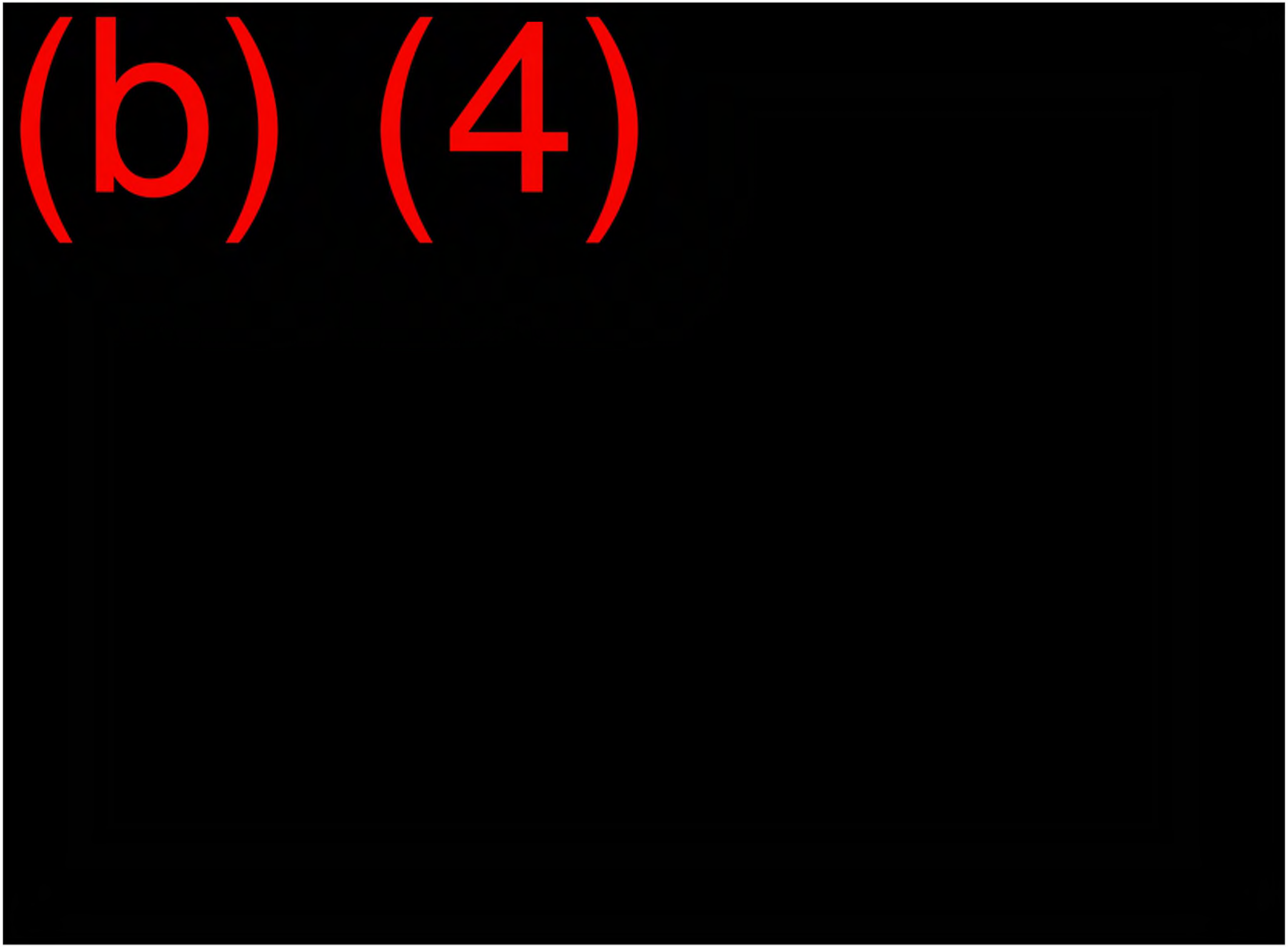
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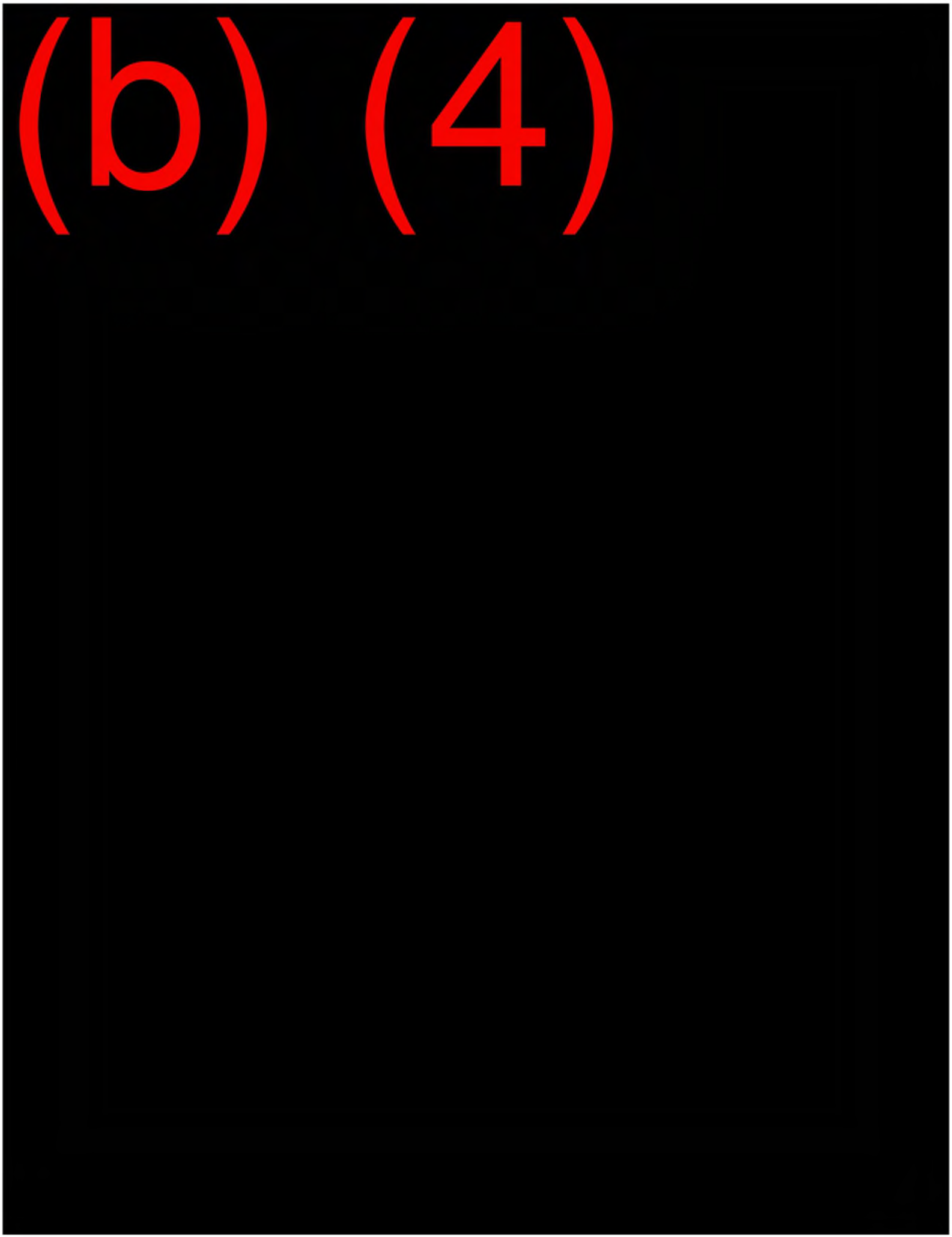
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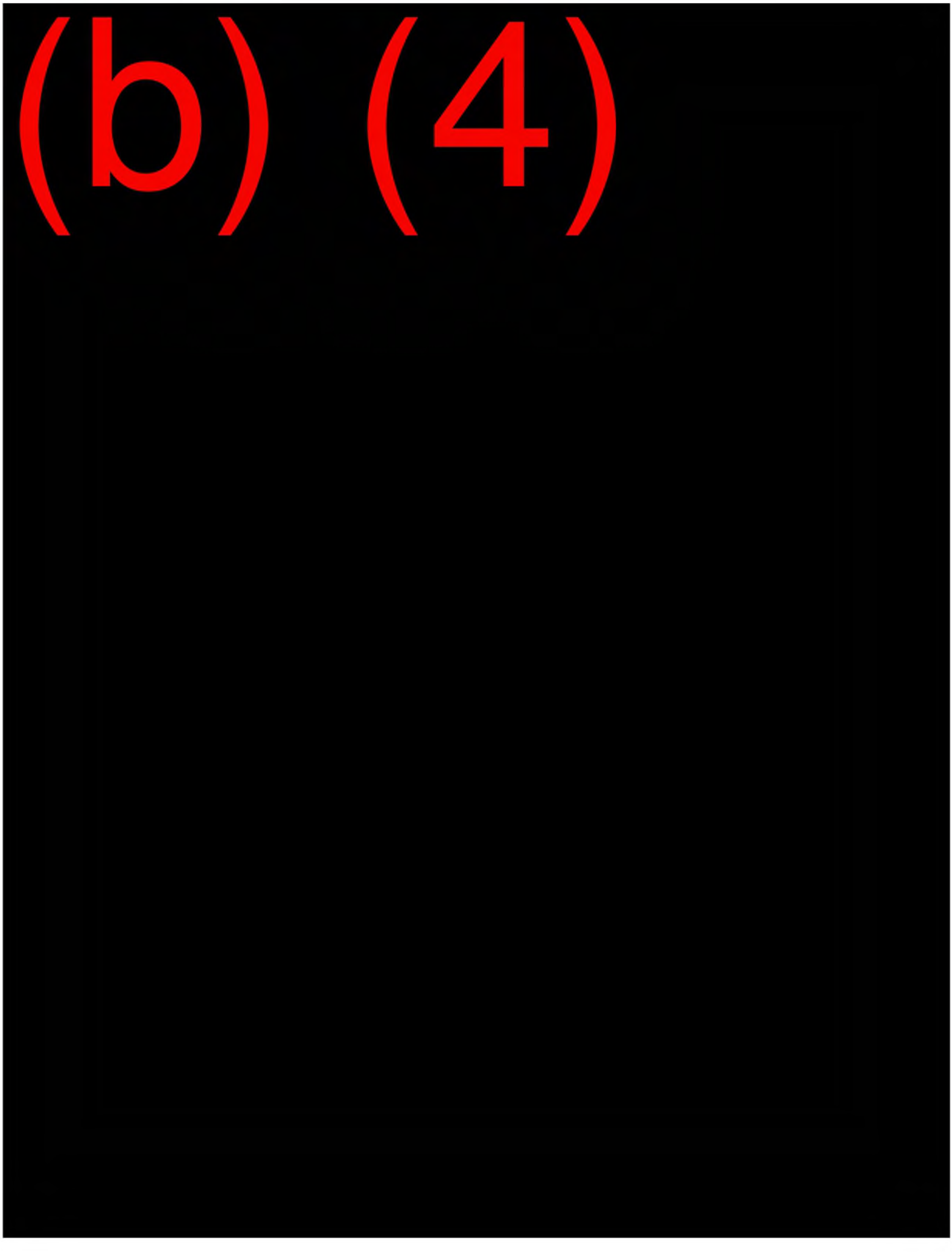
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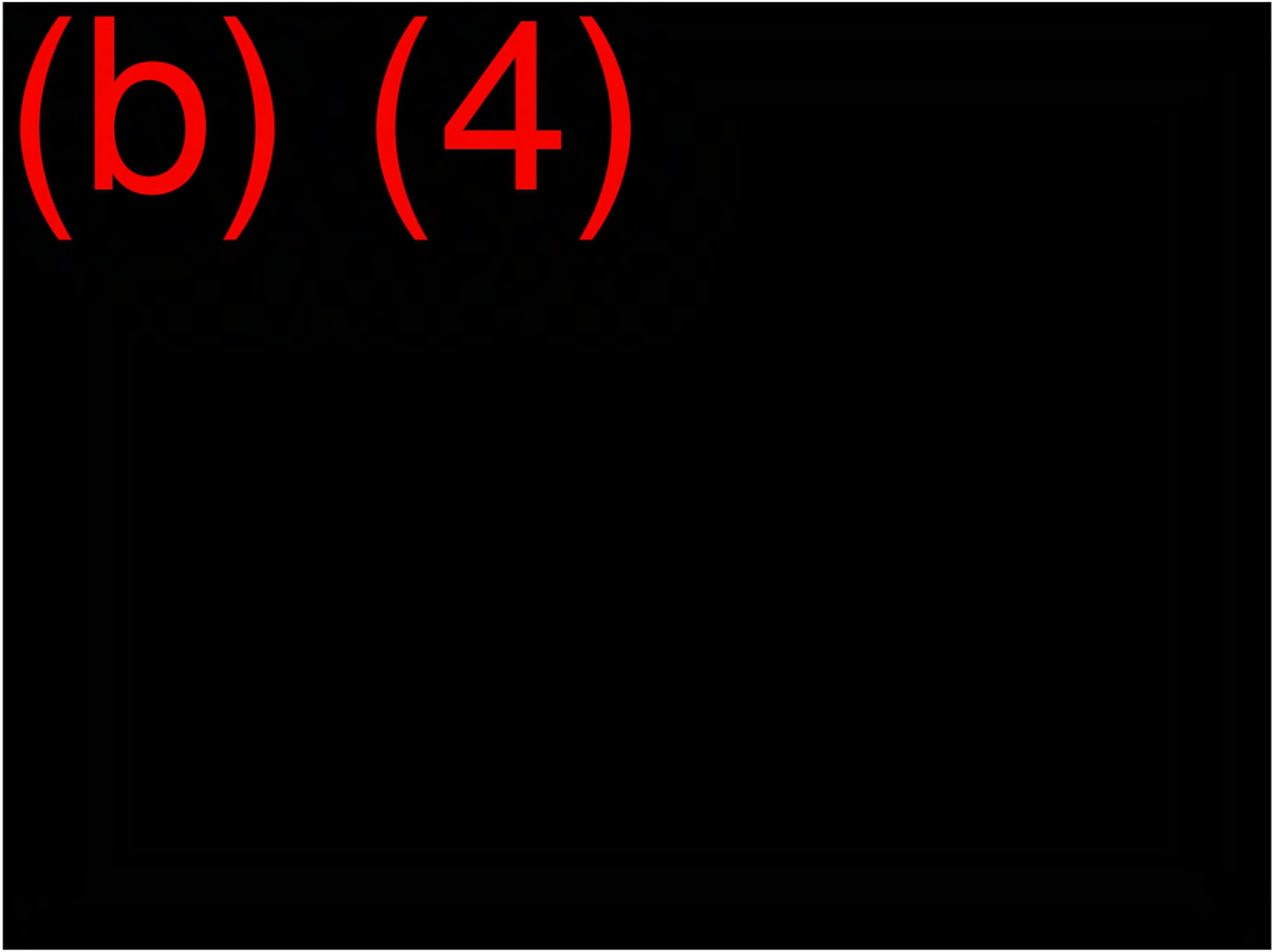
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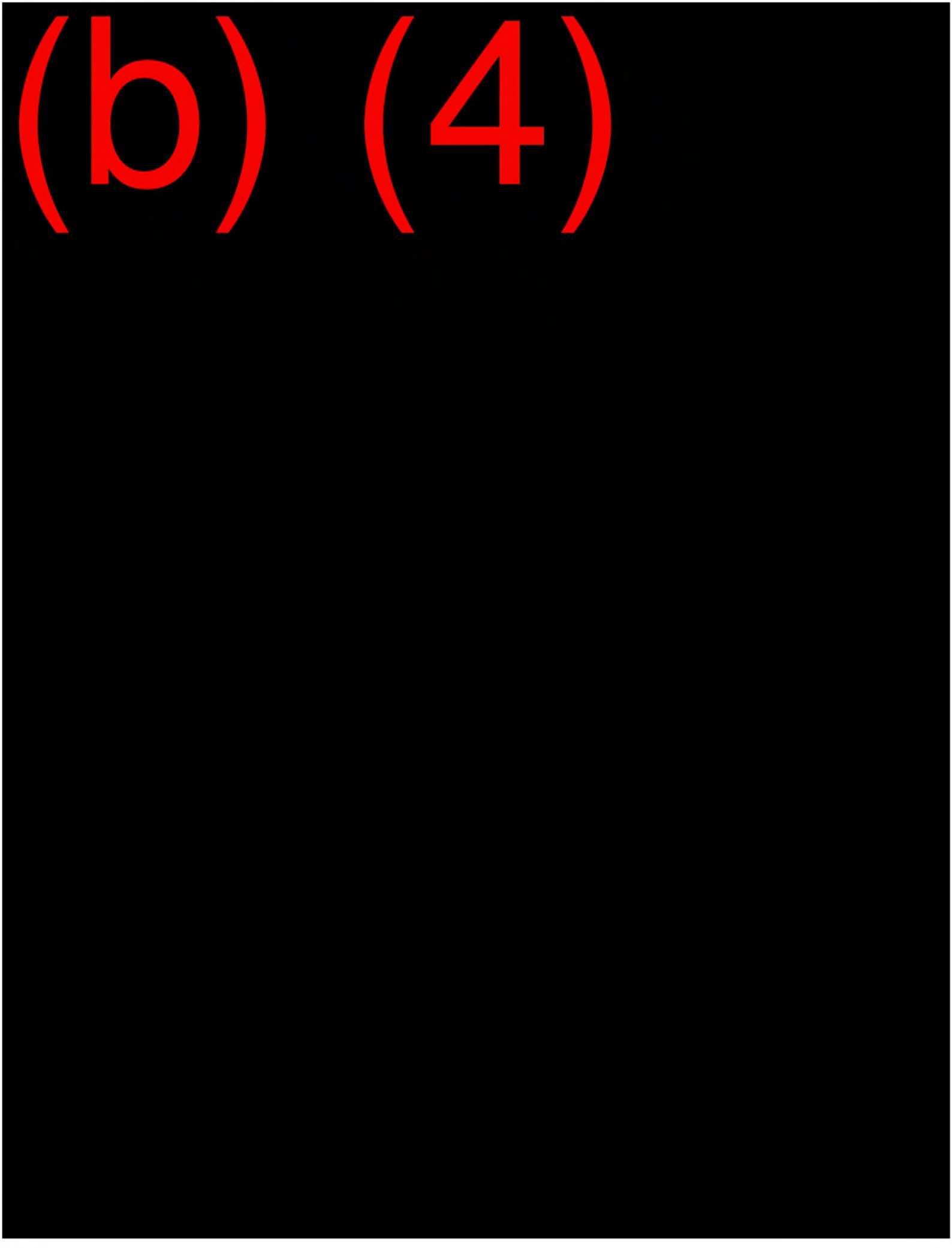
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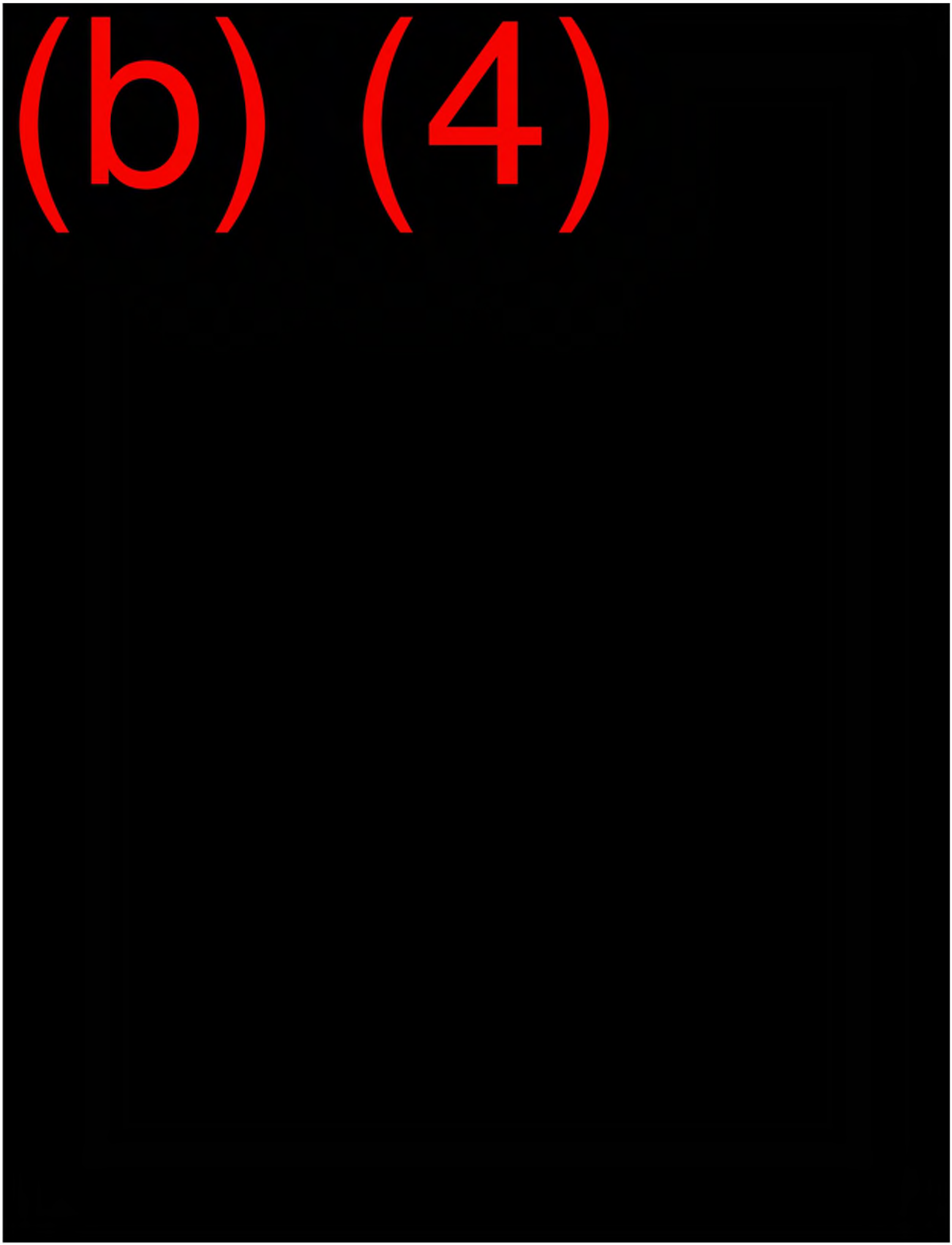
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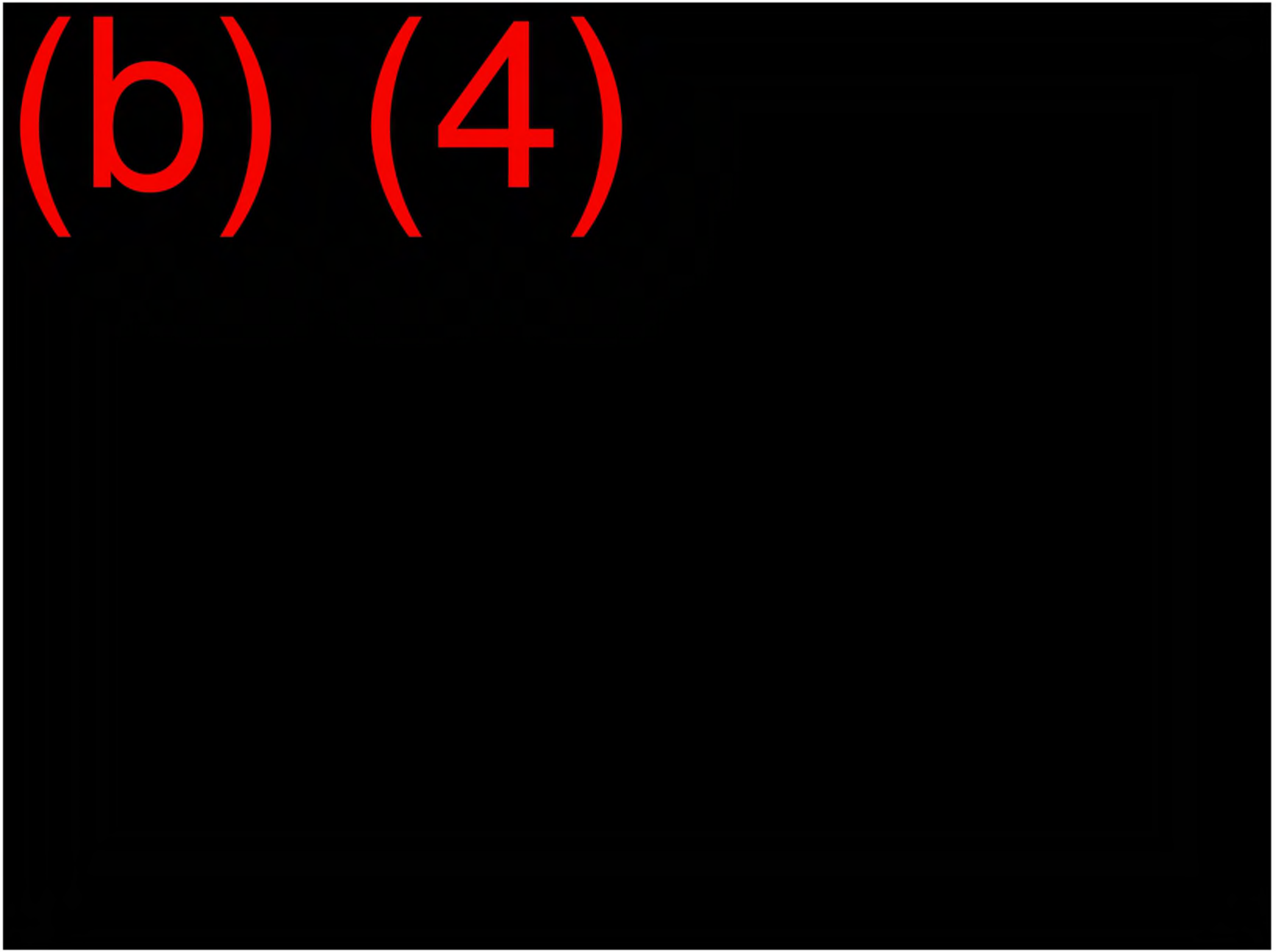
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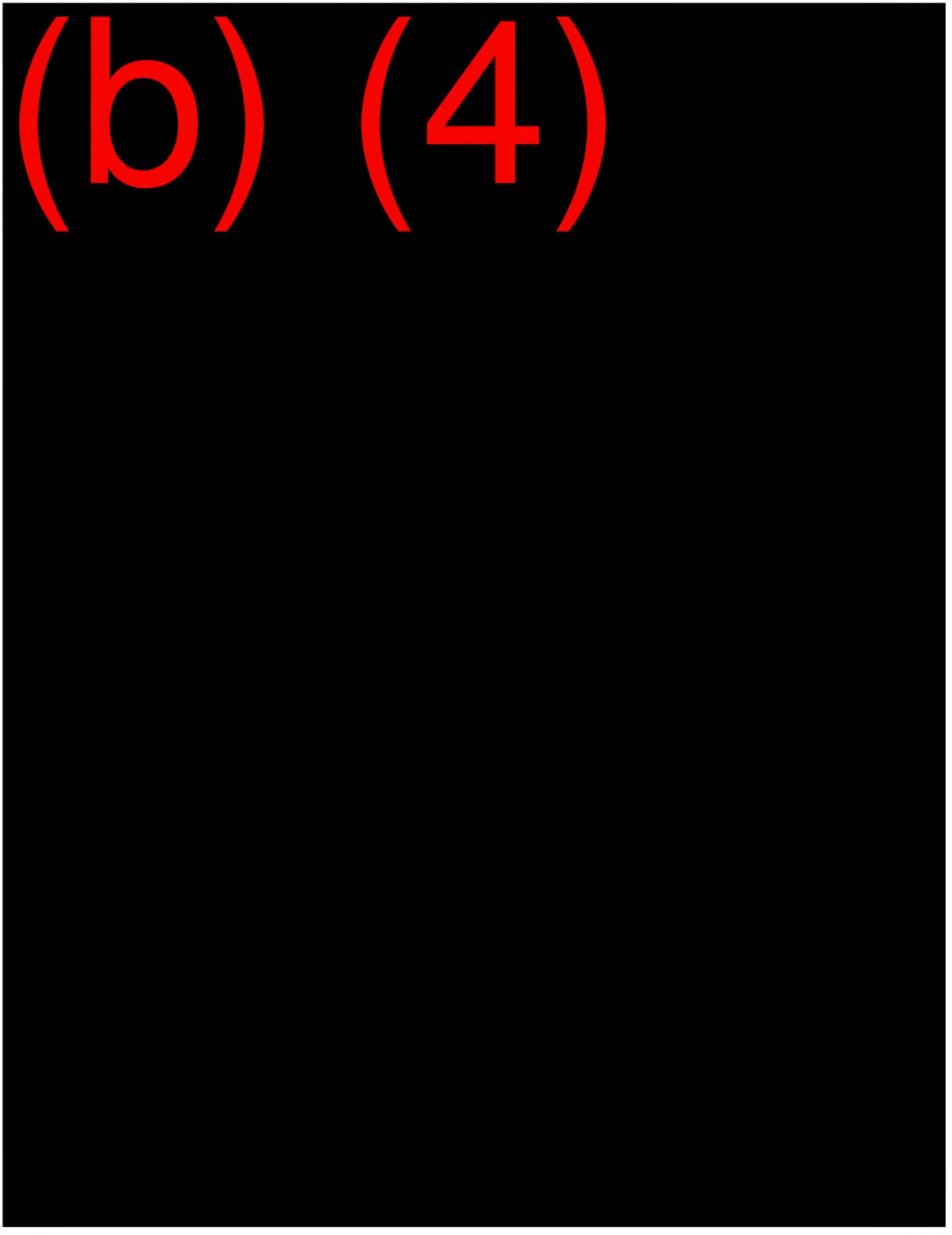
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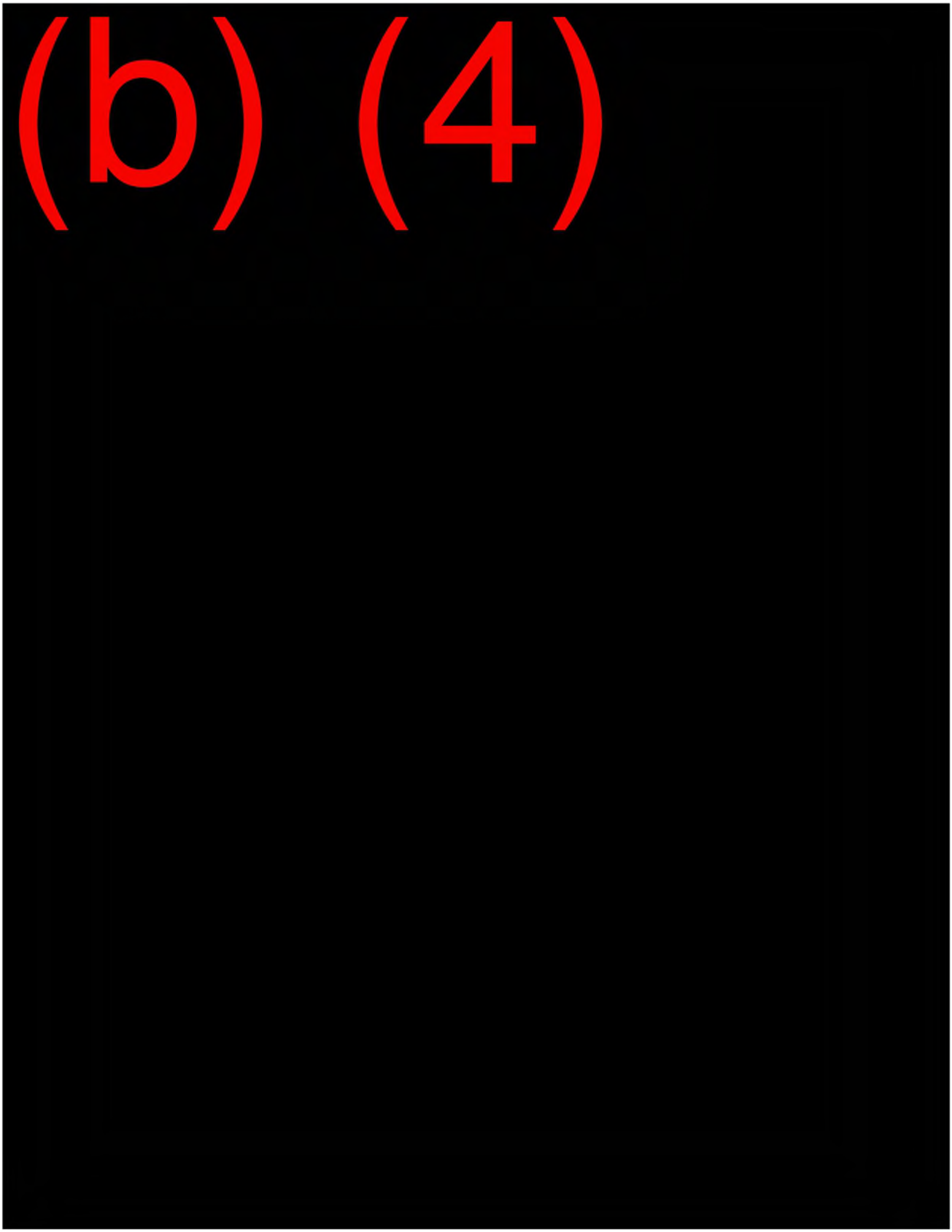
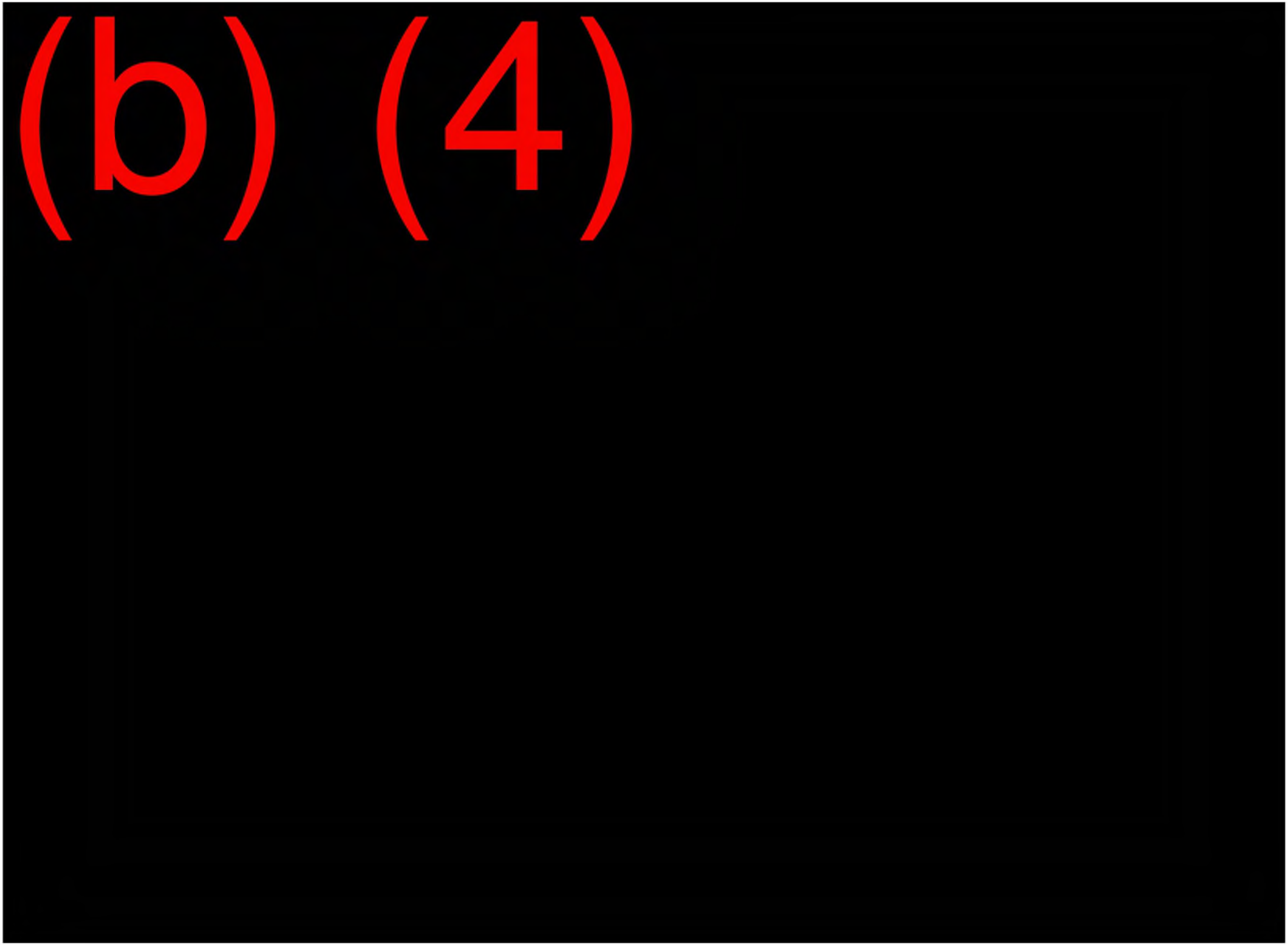
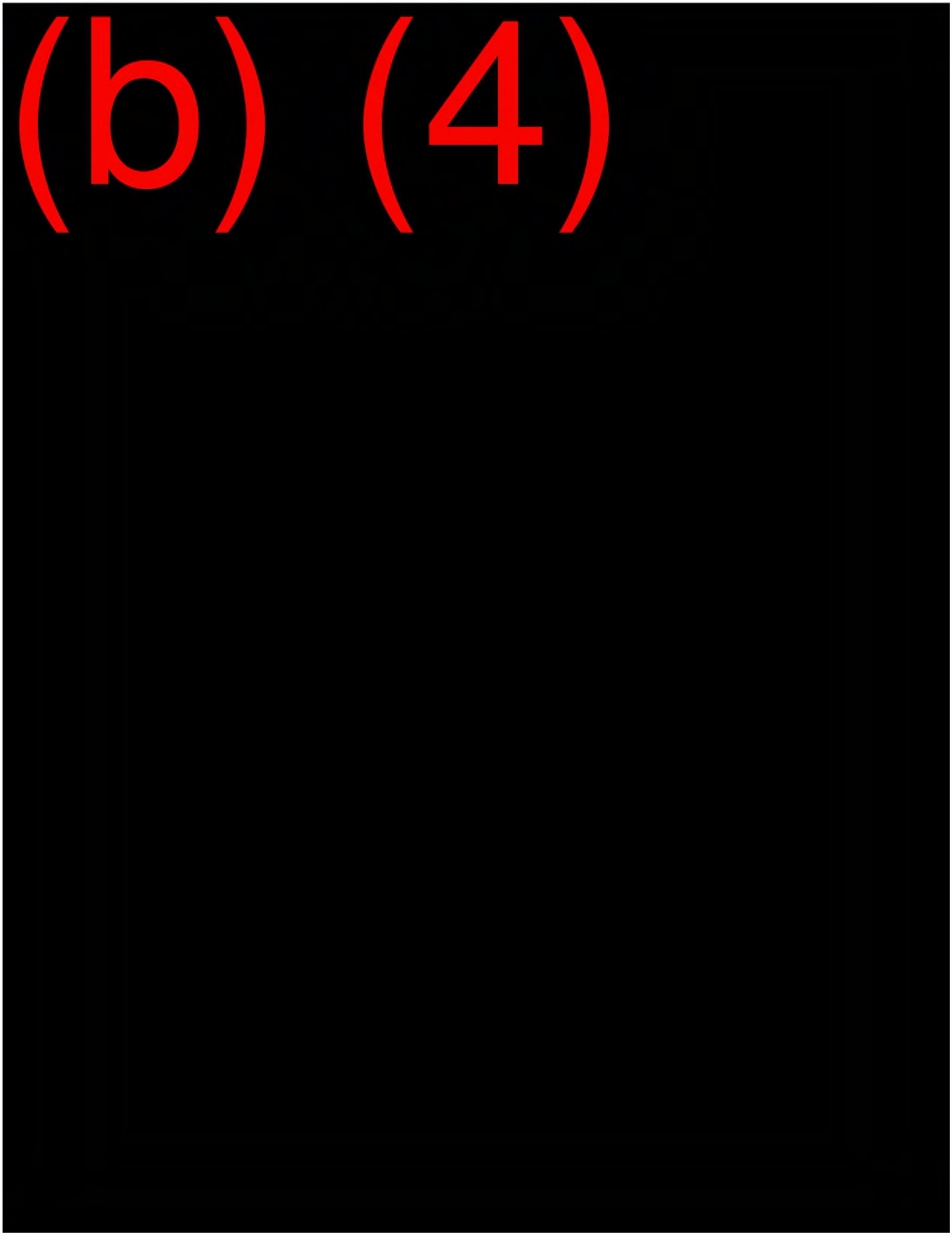

(b) (4)


(b) (4)


(b) (4)

(b) (4)

**Exhibit B - Donation of Excess Product**

**As of 16 June 2021**

| Country | Mod No | Batch | Exp Date | COVID Vaccine Type | DS Source | Fill Finish Site | Dose Total |
|---|---|---|---|---|---|---|---|

**Exhibit B - Donation of Excess**

**Product As of 16 June 2021**

| Country | Mod No | Batch | Exp Date | COVID Vaccine Type | DS Source | Fill Finish Site | Dose Total |
|---|---|---|---|---|---|---|---|
| Canada | P00009 | (b) (4) | (b) (4) | mRNA-1273 (b) (4) | (b) (4) | (b) (4) | 1,000,020 |

**Exhibit B - Donation of Excess Product**

**As of 17 June 2021**

| Recipient | Mod No | Batch | Exp Date | COVID Vaccine Type | DS Source | Fill Finish Site | Dose Total |
|---|---|---|---|---|---|---|---|
| Canada | P00009 | (b) (4) | (b) (4) | mRNA-1273 (b) (4) | (b) (4) | (b) (4) | 1,000,020 |
| Taiwan | P00010 | (b) (4) | (b) (4) | mRNA-1273 (b) (4) | (b) (4) | (b) (4) | 960,680 |
| Taiwan | P00010 | (b) (4) | (b) (4) | mRNA-1273 (b) (4) | (b) (4) | (b) (4) | 955,780 |
| Taiwan | P00010 | (b) (4) | (b) (4) | mRNA-1273 (b) (4) | (b) (4) | (b) (4) | 333,620 |