

Posting Date: May 13, 2021

Closing Date: May 23, 2020 11:30 a.m. ET

Reference Number: 21-033945

To: NCI Bid Board

From: Tanika Crossen
NCI P-ARC Program Analyst
crossent@nih.gov

Subject: NCI Bid Board Posting – Lonza 4D-Nucleofector Core and X unit

The Laboratory of Cellular and Molecular Biology (LCMB) has a long and distinguished history in the study of signal transduction mechanisms that control normal cell growth and, when altered, lead to malignant transformation. Through the 1980s and 1990s many critical signaling molecules including growth factors, growth factor receptors and intracellular transduction molecules were first identified and characterized in the LCMB. The mission of LCMB remains focused on performing cutting-edge, world-class research in this field of biology, and important discoveries continue. The goals of the seven LCMB investigators cover a wide range of questions. They focus on defining signaling components and pathways and understanding their regulation. The relationship of signaling to cellular growth and death, transcriptional regulation, mitosis, cellular differentiation and organogenesis, cell adhesion, motility and chemotaxis are more complex topics under investigation. Alterations in signaling leading to oncogenesis, unregulated growth and metastasis are also studied. In all cases the goal LCMB hopes to achieve is outstanding, innovative and high-impact science.

To meet my group's research goals, I would like to acquire an Lonza 4D-Nucleofector system, comprised of a Core and an X unit. This instrument will enable us to deliver recombinant DNA into a variety of difficult-to-transfect cells, including the main cell line we work with, HAP1. Our lab studies WNT signaling, an important signaling pathway involved in development, tissue homeostasis and cancer. Our studies require making cell lines in which we must deliver recombinant DNA constructs to modify the genome of HAP1 cells through CRISPR-based applications, or overexpress certain genes. So far it has been very challenging to deliver such DNA into HAP1 cells through conventional transfection reagents: our typical transfection efficiency in HAP1 cells using such reagents is about 0.5%. Due to the unique nucleofection technology of the Lonza 4D-Nucleofector system (which we have tested in another lab), we have been able to improve our transfection efficiencies by nearly two orders of magnitude, obtaining transfection efficiencies of up to 40%. The Lonza 4D-Nucleofector system is the only system we are aware of capable these transfection efficiency in HAP1 as well as other difficult-to-transfect cell types.

Sole Source Justification:

Lonza is the sole company which develops and commercializes the Nucleofector™ Technology, and to date the Nucleofector™ Technology is not available from any distributor or dealer within the territory of United States.

Attached Documents:

SF18

Statement of Work

FAR Clause 52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.

FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (AUG 2020) is applicable and available in full text upon request.

| | | |
|---------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------|
| REQUEST FOR QUOTATION (THIS IS NOT AN ORDER) | THIS RFQ <input type="checkbox"/> IS <input checked="" type="checkbox"/> IS NOT A SMALL BUSINESS SET-ASIDE | PAGE 1 OF 1 PAGES 1 |
|---------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------|

| | | | | |
|-----------------------------|-----------------------------|-------------------------------------|------------------------------------------------------------|--------|
| 1. REQUEST NO. 21-033945 | 2. DATE ISSUED 5/13/2021 | 3. REQUISITION/PURCHASE REQUEST NO. | 4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1 | RATING |
|-----------------------------|-----------------------------|-------------------------------------|------------------------------------------------------------|--------|

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|--------------------------------------------------------------------|----------------------|
| 5a. ISSUED BY NCI CCR Purchasing Administrative Resource Center | 6. DELIVER BY (Date) |
|--------------------------------------------------------------------|----------------------|

| | | |
|---------------------------------------------|---------------------------------------------------------------------------------------------------------------|----------------|
| 5b. FOR INFORMATION CALL (NO COLLECT CALLS) | 7. DELIVERY <input checked="" type="checkbox"/> FOB DESTINATION <input type="checkbox"/> OTHER (See Schedule) | 9. DESTINATION |
|---------------------------------------------|---------------------------------------------------------------------------------------------------------------|----------------|

| | | |
|-----------------------------------------|------------------------------------------------------|----------------------------------|
| NAME Tanika Crossen, Program Analyst | TELEPHONE NUMBER AREA CODE NUMBER 301 480-0602 | a. NAME OF CONSIGNEE NIH, NCI |
|-----------------------------------------|------------------------------------------------------|----------------------------------|

| | | |
|-------------------|---------------------|-------------------|
| 8. TO: a. NAME | b. COMPANY Lonza | b. STREET ADDRESS |
|-------------------|---------------------|-------------------|

| | |
|-------------------|---------------------|
| c. STREET ADDRESS | c. CITY Bethesda |
|-------------------|---------------------|

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|----------|-----------------|-----------------------|-----------------|----------------------|
| d.. CITY | e.. STATE MD | f.. ZIP CODE 20892 | d.. STATE MD | e. ZIP CODE 20892 |
|----------|-----------------|-----------------------|-----------------|----------------------|

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|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS (Date) 5/23/2021 11:30 EST | IMPORTANT: This is a request for information, and quotations furnished are not offers. If you are unable to quote, please indicate on this form and return it to the address in Block 5a. This request does not commit the Government to pay any costs incurred in the preparation of the submission of this quotation or to contract for supplies or services. Supplies are of domestic origin unless otherwise indicated by quoter. Any representations and/or certifications attached to this Request for Quotations must be completed by the quoter. |
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11. SCHEDULE (Include applicable Federal, State and local taxes)

| ITEM NO. (a) | SUPPLIES/SERVICES (b) | QUANTITY (c) | UNIT (d) | UNIT PRICE (e) | AMOUNT (f) |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-------------|-------------------|---------------|
| | Lonza 4D-Nucleofector Core and X unit Notice of Intent: If submitting a capability statement, please e-mail only 1 copy of the technical capability statement to Tanika Crossen @ crossent.mail.nih.gov See attached statement of work This will be awarded as a Firm-Fixed Price Contract. | 1 | | | |

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|---------------------------------|-------------------------|-------------------------|-------------------------|------------------------------------|
| 12. DISCOUNT FOR PROMPT PAYMENT | a. 10 CALENDAR DAYS (%) | b. 20 CALENDAR DAYS (%) | c. 30 CALENDAR DAYS (%) | d. CALENDAR DAYS NUMBER PERCENTAGE |
|---------------------------------|-------------------------|-------------------------|-------------------------|------------------------------------|

NOTE: Additional provisions and representations are are not attached.

| | | |
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| 13. NAME AND ADDRESS OF QUOTER | 14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION | 15. DATE OF QUOTATION |
|--------------------------------|------------------------------------------------------|-----------------------|

| | | |
|-------------------|------------|--|
| a. NAME OF QUOTER | 16. SIGNER | |
|-------------------|------------|--|

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|-------------------|-------------------------|------------------------|
| b. STREET ADDRESS | a. NAME (Type or print) | b. TELEPHONE AREA CODE |
|-------------------|-------------------------|------------------------|

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|-----------|----------|-------------|--------------------------|--------|
| c. COUNTY | e. STATE | f. ZIP CODE | c. TITLE (Type or print) | NUMBER |
|-----------|----------|-------------|--------------------------|--------|

STATEMENT OF NEED (SON)

1.0 TITLE

Acquisition of Lonza 4D-Nucleofector Core and X unit

2.0 BACKGROUND

Federal Agency:

Program Office: DHHS/NIH/NCI Division
Laboratory of Cellular and Molecular Biology
Dr. Andres Lebensohn
Building 37, Room 2056C
Phone: 240-760-7799
andres.lebensohn@nih.gov

Proposed Contractor:

Lonza Walkersville, Inc.
8830 Biggs Ford Road
Walkersville MD 21793
USA
Main: 1-800-638-8174
Email: order.us@lonza.com
Sales person:
Celio Duarte
Direct phone number: 1-301-378-1509
celio.duarte@lonza.com

To meet my group's research goals, I would like to acquire an Lonza 4D-Nucleofector system, comprised of a Core and an X unit. This instrument will enable us to deliver recombinant DNA into a variety of difficult-to-transfect cells, including the main cell line we work with, HAP1. Our lab studies WNT signaling, an important signaling pathway involved in development, tissue homeostasis and cancer. Our studies require making cell lines in which we must deliver recombinant DNA constructs to modify the genome of HAP1 cells through CRISPR-based applications, or overexpress certain genes. So far it has been very challenging to deliver such DNA into HAP1 cells through conventional transfection reagents: our typical transfection efficiency in HAP1 cells using such reagents is about 0.5%. Due to the unique nucleofection technology of the Lonza 4D-Nucleofector system (which we have tested in another lab), we have been able to improve our transfection efficiencies by nearly two orders of magnitude, obtaining transfection efficiencies of up to 40%. The Lonza 4D-Nucleofector system is the only system we are aware of capable these transfection efficiency in HAP1 as well as other difficult-to-transfect cell types.

3.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

4.0 SPECIAL ORDER REQUIREMENTS

None.

STATEMENT OF NEED (SON)

4.1 PRODUCT FEATURES/SALIENT CHARACTERISTICS

I need a recombinant DNA delivery system capable of attaining high transfection efficiencies in difficult-to-transfect cell lines, such as HAP1, while maintaining cell viability.

The Nucleofector™ concept uses a unique combination of electrical parameters and specific Nucleofector™ solutions. Based on this combination, the Nucleofector™ Technology is the first efficient routine method for non-viral gene transfer into primary cells and hard-to-transfect cell lines. In addition, the Nucleofector™ Technology to date is unique in its ability to transfer DNA directly into the cell nucleus on a routine basis.

With the development of unique conductive polymer electrodes for the most recent generation of Nucleofector Systems (4D-Nucleofector, HT Nucleofector and 96-well Shuttle), additional benefits have been added like:

- capability of parameter transfer from low to high cell numbers
- transfer of protocols between the platforms
- no aluminium ion release during Nucleofection process
- modular system features addition of other functional transfection units (X or Y-unit)

The Nucleofector™ Technology thus enables gene transfer into medically highly relevant cell types with in many cases unprecedented efficiencies.

Lonza Cologne GmbH, a corporation organized under the law of the Federal Republic of Germany, having its principal office at Nattermannallee 1, 50829 Koeln, Germany, (hereinafter referred to as “Lonza”) hereby declares the following:

Lonza is the sole company which develops and commercializes the Nucleofector™ Technology, and to date the Nucleofector™ Technology is not available from any distributor or dealer within the territory of United States.

4.2 DELIVERY / INSTALLATION

Deliver to:

Dr. Andres Lebensohn
National Cancer Institute
Laboratory of Cellular and Molecular Biology
Bldg.37, Room 2056
37 Convent Drive
Bethesda, Maryland 20892
Phone 240-760-7799
andres.lebensohn@nih.gov

The items will be delivered approximately 8 weeks after receipt of the purchase order. Installation of the equipment will be scheduled with Lonza.

4.3 TRAINING

A local representative will provide one training session at the time of installation at no extra cost.

5.0 PAYMENT

STATEMENT OF NEED (SON)

Payment shall be made in one payment from Dr. Andres Lebensohn's CAN. Payment authorization requires submission and approval of invoices to the COR and NIH OFM, in accordance with the payment provisions listed below:

The following clause is applicable to all Purchase Orders, Task or Delivery Orders, and Blanket Purchase Agreement (BPA) Calls: PROMPT PAYMENT (JUL 2013) FAR 52.232-25. Highlights of this clause and NIH implementation requirements follow:

I INVOICE REQUIREMENTS

- A. An invoice is the Contractor's bill or written request for payment under the contract for supplies delivered or services performed. A proper invoice is an "Original" which must include the items listed in subdivisions 1 through 12, below, in addition to the requirements of FAR 32.9. If the invoice does not comply with these requirements, the Contractor will be notified of the defect within 7 days after the date the designated billing office received the invoice (3 days for meat, meat food products, or fish, and 5 days for perishable agricultural commodities, dairy products, edible fats or oils) with a statement of the reasons why it is not a proper invoice. (See exceptions under II., below.) Untimely notification will be taken into account in the computation of any interest penalty owed the Contractor.
1. Vendor/Contractor: Name, Address, Point of Contact for the invoice (Name, title, telephone number, e-mail and mailing address of point of contact).
 2. Remit-to address (Name and complete mailing address to send payment).
 3. Remittance name must match exactly with name on original order/contract. If the Remittance name differs from the Legal Business Name, then both names must appear on the invoice.
 4. Invoice date.
 5. Unique invoice #s for all invoices per vendor regardless of site.
 6. NBS document number formats must be included for awards created in the NBS: Contract Number; Purchase Order Number; Task or Delivery Order Number and Source Award Number (e.g., Indefinite Delivery Contract number; General Services Administration number); or, BPA Call Number and BPA Parent Award Number.
 7. Data Universal Numbering System (DUNS) or DUNS + 4 as registered in the Central Contractor Registration (CCR).
 8. Federal Taxpayer Identification Number (TIN). In those exceptional cases where a contractor does not have a DUNS number or TIN, a Vendor Identification Number (VIN) must be referenced on the invoice. The VIN is the number that appears after the contractor's name on the face page of the award document.
 9. Identify that payment is to be made using a three-way match.
 10. Description of supplies/services that match the description on the award, by line billed.*
 11. Freight or delivery charge must be billed as shown on the award. If it is included in the item price do not bill it separately. If identified in the award as a separate line item, it must be billed separately.

STATEMENT OF NEED (SON)

12. Quantity, Unit of Measure, Unit Price, Extended Price of supplies delivered or services performed, as applicable, and that match the line items specified in the award.*

* NOTE: If your invoice must differ from the line items on the award, please contact the Contracting Officer before submitting the invoice. A modification to the order or contract may be needed before the invoice can be submitted and paid.

B. Shipping costs will be reimbursed only if authorized by the Contract/Purchase Order. If authorized, shipping costs must be itemized. Where shipping costs exceed \$100, the invoice must be supported by a bill of lading or a paid carrier's receipt.

C. Mail an original and 1 copy of the itemized invoice to:

National Institutes of Health
Office of Financial Management, Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

For inquiries regarding payment call: (301) 496-6088

In order to facilitate the prompt payment of invoices, it is recommended that the vendor submit a photocopy of the invoice to the "Consignee" designated for the acquisition in blocks 6A – 6E of the face page of the Order/Award document.

II. INVOICE PAYMENT

A. Except as indicated in paragraph B., below, the due date for making invoice payments by the designated payment office shall be the later of the following two events:

1. The 30th day after the designated billing office has received a proper invoice.
2. The 30th day after Government acceptance of supplies delivered or services performed.

B. The due date for making invoice payments for meat and meat food products, perishable agricultural commodities, dairy products, and edible fats or oils, shall be in accordance with the Prompt Payment Act, as amended.

III. INTEREST PENALTIES

A. An interest penalty shall be paid automatically, if payment is not made by the due date and the conditions listed below are met, if applicable.

1. A proper invoice was received by the designated billing office.
2. A receiving report or other Government documentation authorizing payment was processed and there was no disagreement over quantity, quality, or contractor compliance with a term or condition.

STATEMENT OF NEED (SON)

3. In the case of a final invoice for any balance of funds due the contractor for supplies

delivered or services performed, the amount was not subject to further settlement actions between the Government and the Contractor.

B. Determination of interest and penalties due will be made in accordance with the provisions of the Prompt Payment Act, as amended, the Contract Disputes Act, and regulations issued by the Office of Management and Budget.

IV. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (DEC 2013)

a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b) The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.