

Posting Date: May 17, 2024

Closing Date: May 28, 2024 11:30 a.m. ET

Reference Number: 24-032024

To: NCI Bid Board

From: Teferi Gebremariam
NCI CCR P-ARC
Teferi.Gebremariam@nih.gov

Subject: NCI Bid Board Posting – Reagents

The Laboratory of Pathology (LP) at the National Cancer Institute (NCI) is an integral component of the research and clinical community at the National Institutes of Health (NIH). Our goal is to be a globally recognized center of excellence in disease research, clinical diagnostics, and pathology education. The mission of the Laboratory of Pathology is to achieve the highest level of quality in research, diagnostics, and education.

The primary objective of this purchase is IGH + IGK B-Cell Clonality Assay MegaKit ABI Fluorescence, Part No. 11000041 for identification of clonal immunoglobulin heavy chain and kappa light chain gene rearrangement, which are useful for the detection of variety B-cells malignancies, lineage determination of leukemias and lymphomas, monitoring and evaluation of disease recurrence, detection and assessment of residual disease in cancer patients.

The National Cancer Institute plans to purchase IGH + IGK B-Cell Clonality Assay MegaKit ABI Fluorescence, Part No. 11000041 from INVIVOSCRIBE, INC. This is not a request for competitive quotation. However, if any interested party believes it can meet the attached requirements, it may submit a statement of capabilities. The capability statement must be in writing and must contain information and material in sufficient detail to allow NCI to determine if the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on May 28, 2024 ET. A determination by the Government not to compete this requirement based upon responses to this notice is solely within the discretion of the Government. Information received will be considered solely for the purpose of determining whether to conduct a competitive procurement.

Sole Source Justification:

Market research, competitive reagent testing, and cost/benefit analysis is performed during the Research & Development phase of all clinical tests. Once the test is validated for clinical use, reagent sources cannot be changed, and further market research is not performed unless there are significant changes in the test requirements requiring major modifications of the SOP. To maintain the consistency and reproducibility of each test, we must order the same reagent from the same company. InvivoScribes currently is the ONE provider that carry this IGH/ IGK kit that fits to the Molecular laboratory servicing to the many protocol of Clinical Center. All other vendors contacted declined service and could not render our unique need product needed for this protocol.

Attached Documents:

SF18

Statement of Work

FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (AUG 2019) is applicable and available in full text upon request.

REQUEST FOR QUOTATION <i>(THIS IS NOT AN ORDER)</i>		THIS RFQ <input type="checkbox"/> IS <input checked="" type="checkbox"/> IS NOT A SMALL BUSINESS SET-ASIDE		PAGE OF	PAGES
				1	1
1. REQUEST NUMBER	2. DATE ISSUED	3. REQUISITION/PURCHASE REQUEST NUMBER	4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1	RATING	
	05/17/2024	24-032024			
5a. ISSUED BY NIH/NCI-OA			6. DELIVER BY (Date)		
			07/05/2024		
5b. FOR INFORMATION CALL (NO COLLECT CALLS)			7. DELIVERY		
NAME		TELEPHONE NUMBER		<input checked="" type="checkbox"/> FOB DESTINATION <input type="checkbox"/> OTHER (See Schedule)	
		AREA CODE	NUMBER	9. DESTINATION	
Teferi Gebremariam, Purchasing Agent		240	760-6546	a. NAME OF CONSIGNEE	
8. TO:			Thu Pham 301-480-8929		
a. NAME		b. COMPANY		b. STREET ADDRESS	
		INVIVOSCRIBE, INC.		9000 Rockville Pike Bldg 10 RM 3S249	
c. STREET ADDRESS			c. CITY		
10222 Barnes Canyon RD STE 100			Bethesda		
d. CITY		e. STATE	f. ZIP CODE	d. STATE	e. ZIP CODE
San Diego		CA	92121-2711	MD	20892
10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS (Date)		IMPORTANT: This is a request for information and quotations furnished are not offers. If you are unable to quote, please so 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 service. Supplies are of domestic origin unless otherwise indicated by quoter. Any representations and/or certifications attached to this Request for Quotation must be completed by the quoter.			
05/28/2024					

11. SCHEDULE (Include applicable Federal, State and local taxes)

ITEM NUMBER (a)	SUPPLIES/SERVICES (b)	QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)
001	IGH + IGK B-Cell Clonality Assay MegaKit™ ABI Fluorescence Part Number 11000041	1	EA	0.00	\$0.00
002	Shipping and handling Notice of Intent: If submitting a capability statement, please e-mail only 1 copy of the technical capability statement to Teferi Gebremariam at Teferi.Gebremariam@nih.gov See attached statement of work. This will be awarded as a Firm-Fixed Price Contract	1	EA	0.00	\$0.00

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.

13. NAME AND ADDRESS OF QUOTER			14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION		15. DATE OF QUOTATION	
a. NAME OF QUOTER			16. SIGNER			
b. STREET ADDRESS						
c. COUNTY			a. NAME (Type or print)		b. TELEPHONE	
d. CITY			c. TITLE (Type or print)		AREA CODE	
e. STATE		f. ZIP CODE			NUMBER	

STATEMENT OF NEED (SON)

Instructions: This document should be used for the acquisition of PRODUCTS. Instructions for completion are in red, and should be excluded in the completed document.

1.0 TITLE

Clinical Laboratory Molecular Diagnostics Cancer Test using inVivoScribe reagents kit.

2.0 BACKGROUND

The Molecular Diagnostics Laboratory of the Laboratory of Pathology performs molecular testing to assist in the diagnosis of a variety of cancers. The laboratory develops tests that assist in pathologic diagnosis, predict prognosis and identify potential targets for rational personalized therapies. It is currently the only CLIA and College of American Pathology approved clinical laboratory within the NCI certified for performing molecular oncology testing on materials from NIH patients.

In InvivoScribe IgH +IgK B-cell clonality Assays is for identification of clonal immunoglobulin heavy chain and kappa light chain gene rearrangement, which are useful for the detection of variety B-cells malignancies, lineage determination of leukemias and lymphomas, monitoring and evaluation of disease recurrence, detection and assessment of residual disease in cancer patients.

Specimen Size Control Ladder is for identify the amplifiable fragmented DNA in the sample, which is useful to determine the quality of each patient DNA sample.

3.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

4.0 SPECIAL ORDER REQUIREMENTS

4.1 PRODUCT FEATURES/SALIENT CHARACTERISTICS

The following product features/characteristics are required for this requirement: InvivoScribe IgH +IgK B-cell clonality Assays is for identification of clonal immunoglobulin heavy chain and kappa light chain gene rearrangement, it work with our current Genetic Analyser system, provide a result within 24 hrs, and have been a tool in assisting clinicians in cancer patient care.

The InvivoScribe IGH+IGK Clonality kit includes the following:

- IGH tubes A, B and C target framework 1, 2 and 3 regions within the variable region and joining region of the IGH locus.
- IGK tubes A and B target the variable, intragenic and joining regions of the IGK locus.
- Specimen Control Size Ladder generates a series of amplicons ensuring the quality and quantity of input DNA is adequate to yield a valid result.

STATEMENT OF NEED (SON)

4.2 DELIVERY / INSTALLATION

- Deliver to : TINA PHAM
- Delivery Address :

***National Institutes of Health
10 Center Drive, Building 10, Room 3S249
Bethesda, MD 20892***

- Item shall be delivered within 10 business days of purchase order award, and should be delivered during government business days.

4.3 TRAINING

Not Applicable

5.0 PAYMENT

Payment shall be made during order

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).

STATEMENT OF NEED (SON)

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.
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:

STATEMENT OF NEED (SON)

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.
 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.