NIH NATIONAL CANCER INSTITUTE

Posting Date: April 29, 2025

Closing Date: May 08, 2025 11:30 a.m. ET

Reference Number: 25-021882

To: NCI Bid Board

From: Christine Buntz
NCI CCR P-ARC
christine.buntz@nih.gov

Subject: NCI Bid Board Posting – Purchase of IGH + IGK B-Cell Clonality Assay MegaKit for the Laboratory of Pathology.

The National Cancer Institute Division of 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 is to purchase InvivoScribe IgH +IgK B-cell clonality MegaKit Assays 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 MegaKits from InVivoscribe Technologies Inc from San Diego, CA to perform this work. 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 is the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on May 08, 2025, 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:

Invivoscribe Technologies Inc is the only company that sells the clonality MegaKit Assays due to having proprietary data. Invivoscribe IgH + IgK B-cell clonality assays Kit is for identification of clonal immunoglobulin heavy chain and kappa light chain gene rearrangement. The assays work with the lab's current Genetic Analyzer system, provide a result within 24hrs, and have been a tool in assisting clinicians in cancer patient care. These are "direct replacement" parts/components for existing equipment. Regulatory oversight requires development of Standard Operating Procedures (SOP) using defined reagents in CLIA laboratory. To maintain the consistency and reproducibility of each test, the lab must order the same reagent from the same company. Other companies contacted did not have the patent rights therefore, could not supply kits needed for our lab. Market research was conducted, and vendors were contacted, but due to proprietary data, there were no other vendors that were able to meet the requirement.

Attached Documents:
SF18
Statement of Need

52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.
FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (AUG 2019) is applicable and available in full text upon request.

REQUEST FOR QUOTATION
(THIS IS NOT AN ORDER)

THIS RFQ ☐ IS ☒ IS NOT A SMALL BUSINESS SET-ASIDE

PAGE 1 OF PAGES 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
	04/29/2025	25-021882	▶	

5a. ISSUED BY
NIH/NCI-CCR P-ARC

6. DELIVER BY *(Date)*
06/08/2025

5b. FOR INFORMATION CALL *(NO COLLECT CALLS)*

NAME	TELEPHONE NUMBER	
	AREA CODE	NUMBER
Christine Buntz, Purchasing Agent	240	760-6456

7. DELIVERY ☐ FOB DESTINATION ☒ OTHER *(See Schedule)*

9. DESTINATION

a. NAME OF CONSIGNEE
Thu PHAM 301-480-8929

8. TO:

a. NAME	b. COMPANY	b. STREET ADDRESS
	Invivoscribe Inc	9000 Rockville Pike Bldg 10 RM 3S249

c. STREET ADDRESS	c. CITY
10222 Barnes Canyon Road Bldg 1	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)*
05/08/2025

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.

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 #: 1100041 Notice of Intent: If submitting a capability statement, please e-mail only 1 copy of the technical capability statement to: Christine Buntz @ christine.buntz@nih.gov See attached statement of need. 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	d. CALENDAR DAYS 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		
b. STREET ADDRESS	16. SIGNER	
	a. NAME *(Type or print)*	b. TELEPHONE AREA CODE
c. COUNTY		NUMBER
d. CITY / e. STATE / f. ZIP CODE	c. TITLE *(Type or print)*	

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition not usable

STANDARD FORM 18 (REV. 6/1995)
Prescribed by GSA-FAR (48 CFR) 53.215-1(a)

STATEMENT OF NEED (SON)

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 indentify the amplifiable fragmented DNA in the sample, which is useful to derteminate 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 taget 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.

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 one time after items have been received and confirmed by the lab. 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.
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.
   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.