COMBINED SYNOPSIS/SOLICITATION
Request for Quote (RFQ) 75F40126Q00233
Acquisition of Element Biosciences AVITI Sequencing System

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Disclaimer
This is a combined synopsis/solicitation for commercial items prepared in accordance with Part 12, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation. Offers are being requested and a separate written solicitation will not be issued.

Solicitation number 75F40126Q00233 is issued as a request for quotation (RFQ).

> The Government intends to negotiate and solicit with only one source Element Biosciences, 10055 Barnes Canyon Rd., Suite 100, San Diego, CA 92121, USA for the Acquisition of Element Biosciences AVITI Sequencing System under the authority of FAR (6.103-1). This is not a request for competitive quotes; however, any responsible offeror may submit a quote which will be given due consideration by the agency.

This acquisition is not set-aside for small business concerns. This solicitation incorporates provisions and clauses by reference. The full text of provisions and clauses may be accessed electronically at www.acquisition.gov.

- NAICS Code: 334516 – Analytical Laboratory Instrument Manufacturing. The small business size standard is 1,000 employees
- PSC Code: 6640 – Laboratory Equipment and Supplies
- Set-Aside: Sole Source
- Type of Contract: Firm Fixed Price (FFP)
- Acquisition Method: FAR 6.103-1 Only one responsible source and no other supplies or services will satisfy agency requirements.

Line Item Structure

Firm Fixed Price (FFP) Line Items

Line Item	Item Name	Quantity	Unit Price	Total Cost
1	AVITI system-includes 12 month warranty, installation and training and consumables	1	$	$
1	Freight	1	$	$
1	Individually addressable lanes enablement	1	$	$
			Total Cost	

STATEMENT OF WORK

Acquisition of Element Biosciences AVITI Sequencing System

Summary

OAMT requires a mid-throughput benchtop sequencing platform that features dual independent flowcells for running concurrent sequencing experiments for flexible and scalable metagenomic workflow management. This system is needed for methods development in metagenomics and genomics-based foodborne pathogen surveillance. The system must have a self-contained, benchtop footprint to fit within existing laboratory space and have the established capability of running two short-read flow cells simultaneously. Purchase of this system must include professional installation, operational verification, and comprehensive training on its use by OEM-authorized personnel.

Background

OAMT currently processes hundreds of bacterial isolate and metagenomic samples per month for next-generation sequencing (NGS). This work supports critical agency missions, including methods development, international surveillance of potential foodborne pathogens, and longitudinal studies of key agricultural regions to understand outbreak patterns and causes.
The Metagenomics Diversity and Ecology Branch of OAMT conducts metagenomic-based method development for pathogen detection and subtyping as well as microbiome characterization of a range of commodities. The team also supports several other OAMT and OLOAS programs by providing microbial community as well as host sample characterization and other hazard assessments. The diversity of the scope of sample and analysis activities requires a scalable and flexible sequencing platform that delivers high sequencing output quality, without template error propagation as can happen with PCR-based library preparation, for short and long-read insert libraries.
This procurement will directly support OLOAS strategic objective to explore the use of metagenomics testing as a means of identifying risk.

Technical Specifications

The mid-throughput benchtop sequencer should have the following features and capabilities:

- Non PCR-based library preparation to reduce template error amplification
- At least two independent, configurable flowcells for scalable sequencing
- Tunable sequencing output in terms of read length (2 x 75 to 2 x 300) and read counts (100 million to 2 billion)
- >85% Q30 sequencing data quality at a minimum
- Static consumable pricing over the life of the instrument
- Option to perform on board target enrichment hybridization for precision metagenomics applications

Delivery

Shipping Destination:

Dr. Christopher Grim

FDA, 5001 Campus Dr., College Park, MD 20740
The delivery or services must be during regular business hours (Monday-Friday) during the times of 8:00 AM – 4:00 PM, excluding holidays.

Installation and Set-up

The Contractor must:

- Coordinate installation with the Government point of contact
- Install, calibrate, and inspect the instrument and confirm operational status following installation following OEM procedures
- Install and test a protocol of the receiving laboratory's choice, confirming its successful operation with water or expired reagents

Training and Documentation

The Contractor must provide:

- All user manuals, guides, and informational materials needed for operation and user-performed maintenance of the instrument
- Training from an OEM-trained and authorized Field Applications Specialist to a minimum of two (2) individuals from OAMT, to cover general operation of the instrument, protocol development using the software, common issues and troubleshooting, and operation of the instrument to perform the installed protocols.

Warranty and Maintenance

The Contractor must provide:

- A one (1) year warranty covering damage or failure of any portion of the instrument, including the entire instrument, to repair or replace (as needed) the affected parts and perform testing to confirm operational status of the instrument following the repair(s)
- All installation, setup, repairs, calibrations, and Preventative Maintenance must be performed by OEM-trained and authorized service personnel

Acceptance

Acceptance will occur upon successful delivery, installation, and verification that the system meets performance requirements.

Security Requirements

Any personnel participating in installation, setup, repairs, calibrations, or preventative maintenance that would bring the person into the laboratory space must be a US citizen or permanent resident, or else provide their information (name, photo of biographical page of passport) no fewer than 10 business days before the visit in order to facilitate access to the laboratory space.

The system will comply with FDA IT and cybersecurity requirements if connected to the network.

Contract Clauses and Provisions

This contract incorporates one or more clauses and provisions by reference, with the same force and effect as if they were given in full text. The full text of a clause and provision may be accessed electronically at this/these address(es):
https://www.acquisition.gov/far-overhaul
https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

Federal Acquisition Regulation (FAR) Clauses and Provisions

52.204-19 Incorporation by Reference of Representations and Certifications (Dec 2014)
52.252-2 Clauses Incorporated by Reference (Feb 1998)
52.252-6 Authorized Deviations in Clauses (Nov 2020)
52.212-4 Terms and Conditions—Commercial Products and Commercial Services (Nov 2025) (DEVIATION)
52.203-17 Contractor Employee Whistleblower Rights (Nov 2023)
52.203-19 Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017)
52.204-13 System for Award Management-Maintenance (Nov 2025) (DEVIATION)
52.209-6 Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, Proposed for Debarment, or Voluntarily Excluded (Nov 2025) (DEVIATION)
52.209-10 Prohibition on Contracting with Inverted Domestic Corporations (Nov 2025) (DEVIATION)
52.222-3 Convict Labor (Jun 2003)
52.222-19 Child Labor—Cooperation with Authorities and Remedies (Nov 2025) (DEVIATION)
52.222-35 Equal Opportunity for Veterans (Nov 2025) (DEVIATION)
52.222-36 Equal Opportunity for Workers with Disabilities (Nov 2025) (DEVIATION)
52.222-37 Employment Reports on Veterans (Nov 2025) (DEVIATION)
52.222-41 Service Contract Labor Standards (Aug 2018)
52.222-42 Statement of Equivalent Rates for Federal Hires (May 2014)
52.222-43 Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018)
52.222-50 Combating Trafficking in Persons (Nov 2025) (DEVIATION)
52.222-54 Employment Eligibility Verification (Nov 2025) (DEVIATION)
52.222-62 Paid Sick Leave Under Executive Order 13706 (Jan 2022)
52.226-8 Encouraging Contractor Policies to Ban Text Messaging While Driving (May 2024)
52.232-33 Payment by Electronic Funds Transfer-System for Award Management (Oct 2018)
52.232-39 Unenforceability of Unauthorized Obligations (Jun 2013)
52.232-40 Providing Accelerated Payments to Small Business Subcontractors (Mar 2023)
52.233-1 Disputes (Nov 2025) (DEVIATION)
52.233-3 Protest After Award (Nov 2025) (DEVIATION)
52.233-4 Applicable Law for Breach of Contract Claim (Nov 2025) (DEVIATION)
52.242-15 Stop-Work Order (Aug 1989)

52.240-90 Security Prohibitions and Exclusions Representations and Certifications (Nov 2025) (DEVIATION)
52.240-91 Security Prohibitions and Exclusions (Nov 2025) (DEVIATION)
52.240-93 Basic Safeguarding of Covered Contractor Information Systems (Nov 2025)
52.244-6 Subcontracts for Commercial Products and Commercial Services (Nov 2025) (DEVIATION)

52.203-11 Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (Sep 2024)
52.203-18 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation (Jan 2017)
52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998)
52.252-5 Authorized Deviations in Provisions (Nov 2020)
52.204-7 System for Award Management (Nov 2025) (DEVIATION)
52.212-1 Instructions to Offerors — Commercial Products and Commercial Services (Nov 2025) (DEVIATION)
52.212-2 Evaluation — Commercial Products and Commercial Services (Nov 2025) (DEVIATION)

Health and Human Services Acquisition Regulation (HHSAR) Clauses and Provisions

352.239-78 Information and Communication Technology Accessibility Notice (Feb 2024) (DEVIATION)

352.224-71 Confidential Information (Feb 2024) (DEVIATION)
352.227-70 Publications and Publicity (Dec 2015)
352.237-75 Key Personnel (Dec 2015)
352.239-79 Information and Communication Technology Accessibility (Feb 2024) (DEVIATION)352.232-71 Electronic Submission of Payment Requests (APR 2026) (RFO Deviation)
FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)
(a) All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP) (see http://www.ipp.gov/vendors/index.htm).
(b) Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions-Commercial Products and Commercial Services included in commercial items contracts. The IPP website address is: https://www.ipp.gov.
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(1) The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.
(2) Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

(3) The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
(4) If your company is already registered to use IPP, you will not be required to re-register.
(5) If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.
(d) Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).
(e) Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.
(1) At a minimum the following cost information must be included, in addition to supporting documentation to substantiate costs incurred.
*Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
*Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
*Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
*Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs must also be listed;
*Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
*Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
*Fee-amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.
(f) Contractor is required to attach an invoice log addendum to each invoice which must include, at a minimum, the following information for contract administration and reconciliation purposes:
(1) list of all invoices submitted to date under the subject award, including the following:
*Invoice number, amount, & date submitted
*Corresponding payment amount & date received
*Total amount of all payments received to date under the subject contract or order, and for definitized contracts or orders only:
*Total estimated amounts yet to be invoiced for the current, active period of performance.
(g) Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments must be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.
(h) If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor must not be paid, or must be paid an amount negotiated by the CO.
(i) Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

(j) The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.
(k) Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

Submission Instructions

The offeror's quote must outline all characteristics of the requirement listed this solicitation. The contractor quote must provide sufficient information to allow the Government to evaluate that the Contractor is capable of meeting the requirement. The Government is not responsible for locating or securing any information which is not identified in the quote. Offerors may propose equivalent equipment; however, it must demonstrate that the proposed equipment meets or exceeds the minimum salient characteristics. Offerors must furnish as part of their quote all descriptive material necessary for the Government to determine whether the proposed products meet all technical requirements.

The Offeror must submit a complete pricing table for a firm fixed-price order. The Contractor must provide the price and all detailed documentation to support the total cost of the quote. The firm fixed-price proposed must be inclusive of all shipping and any other costs associated with meeting all the requirements.

Please submit any questions/clarifications regarding this requirement as soon as possible to Natalie Brown at Natalie.Brown@fda.hhs.gov.

Quote is due to Natalie Brown at Natalie.Brown@fda.hhs.gov for this solicitation no later than 8/18/2026, 2:00pm. Eastern Time.

The subject line shall read: RFQ 75F40126Q00233 Acquisition of Element Biosciences AVITI Sequencing System