Nextseq 2000 Sequencing System
Request for Information
FDA-RFI-115872

MARKET RESEARCH PURPOSES ONLY
NOT A REQUEST FOR PROPOSAL OR SOLICITATION

The U.S. Food and Drug Administration (FDA), Office of Acquisitions and Grants Services (OAGS) is issuing this request for information announcement on behalf of the National Center for Toxicological Research (NCTR), Division of Microbiology in order to determine if there are existing small business sources capable of providing a "Brand Name or Equal" Illumina Nextseq 2000 Sequencing System (part # 20038897) for direct purchase or lease.

The appropriate NAICS code for the acquisition is 334516 – Analytical Laboratory Instrument Manufacturing; Small Business Size standards – 1,000.

Background:
The Division of Microbiology serve a multipurpose function including evaluating the impact of antimicrobial agents, food contaminants, food additives, nanomaterials, and FDA-regulated products on the microbiome; developing methods to detect and characterize microbial contaminants; determining antimicrobial resistance and virulence mechanisms; conducting research to aid FDA in the areas of women's health, tobacco products, and nanotechnology; and improving risk assessments. Multiple projects within the Division requires sequencing across all available methods (RNA-Seq, Whole Genome Sequencing, Metagenomics, Microbiota sequencing, etc.).

Minimum Technical Requirements:
The sequencer shall:

1. Have Q30 reads for over 80% of the bases at the largest amplicon size.
2. Have amplicon ranges from 50 to 300 bp.
3. Produce a minimum of 40 GB of data in 13 hours for 50 bp amplicons and 180 GB of data in 44 hours for 300 bp amplicons.
4. Multiplexed, high throughput with options that allow for more sequencing depth and coverage with newer kits.
5. Has a simplified workflow that is fast and reliable, and well published.
6. Has bioinformatics workflows that are reliable and validated in the literature.
7. Be a desktop sequencer due to space requirements.
8. Be established in the literature for refining long-read sequencing technologies.
9. Have a service contract available, either added to the lease agreement or if a direct purchase is decided upon, added to that purchase for the first year.

Installation, Training and Warranty Requirements:

1. The system and its associated accessories shall include operations and maintenance manuals covering proper operation, routine maintenance, and troubleshooting for the instrument and controlling software. All manuals and documentation on the instrument shall be provided in hard copy and/or electronic format.

2. The offeror shall install the equipment and provide all labor, travel, kits and tools, etc., to install the equipment at the address provided below, to include inside delivery.
3. The offeror shall provide training for proper operation of the instrument.
4. The offeror shall warrant the entire system for a period of at least one (1) year from acceptance by FDA. The warranty shall include: unlimited telephone/e-mail support for questions regarding operation, onsite visits for diagnosis of problems and repairs inclusive of all parts, labor, and travel expenses at no additional cost to the FDA.

Place of Delivery:
U. S. FDA – NCTR
Division of Microbiology
3900 NCTR Road
Bldg.62, Rm. 205
Jefferson AR 72079

Though the target audience is small business vendors or small businesses capable of supplying a U.S. service of a small business vendor or producer, all interested parties may respond. At a minimum, responses shall include the following:

1. Business name and bio, SAM UEI number, business address, business website, business size status (i.e., SB, VOSB, SDVOSB, HUBZone SB, SDB, WOSB, LB), point of contact name, mailing address (if different from business address), phone number and email address. Provide this same information again if responding to provide a service offered by another firm.

2. The offeror shall furnish capability statements with sufficient technical information necessary for the Government to conclusively determine experience and qualifications of the firm for the minimum technical requirements identified above. As well as, descriptive literature, brochures, marketing material, etc. detailing the nature of the product and service the responding firm is regularly engaged in manufacturing and/or selling. Annotate in your capability statement if your company provide the option to lease; if applicable, include details.

3. Past Performance information shall include recent (within the last 3 years) and relevant (prior experience information for the manufacturer and/or sale of same or substantially similar product and service or similar brand instruments). For each past performance reference include date of sale, description, dollar value, client name, client address, client contact name, client point of contact mailing address (if different from that provided for client), client point of contact phone number, client point of contact email address, and name of the manufacturer (to include SAM UEI number and size status) if not the respondent.

4. Post-warranty service/maintenance agreement plans available.

5. Though this is not a request for quote, informational pricing for the system (direct purchase and lease) would be helpful.

6. If applicable, identification of the firm's GSA Schedule contract(s) by Schedule number and SINs that are applicable to this potential requirement are also requested.

7. If applicable, identification of Best in Class (BIC) contract information.

8. If a large business, provide if subcontracting opportunities exist for small business concerns.

9. Standard commercial warranty.

10. Provide place of product manufacture or service performance and any other applicable information to enable review and analysis pertaining to the Buy American statute and requirements relating to Made in America.

The Government is not responsible for locating or securing any information, not identified in the response.

Interested Parties shall respond with capability statements which are due by email to the point of contact listed below on or before **February 14, 2023, by 12:00 PM (Central Time in Jefferson, Arkansas)** to jennifer.johnson3@fda.hhs.gov, and reference: FDA-RFI-115872.

Notice of Intent:
Responses to this request for information/source sought announcement will assist the Government in determining whether any future requirement similar to this one should be set aside for small business, made available to full and open competition or procure through sole-source acquisition procedures.

Disclaimer and Important Notes:
This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work.

Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in SAM.gov. However, responses to this notice will not be considered adequate responses to a solicitation.

Confidentiality:
No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).

Additional Notes:

If the stated requirements appear restrictive, please submit comments detailing the concern.