

ITEM OPPORTUNITY SYNOPSIS

Scouting Number: 2023-157
Name of the item to be scouted: Benchtop Nanopore RNA/DNA Sequencer
State item to be used in: Rhode Island

Describe the Item:

Please describe the item application/the end use of the item.

We require a small benchtop DNA/RNA sequencer designed to run up to two flow cells, which allows nanopore-based long-read sequencing of both RNA and DNA while preserving epigenetic modifications.

Supplier Information:

Type of Supplier Being Sought (select from the list below):

Manufacturer x
Contract Manufacturer
Distributor
Other (Please Specify)

Reason for Scouting Submission (select from the list below)

2nd Supplier
Price
Re-Shore
Past supplier no longer available
New Product Startup x
BABA
Other (Please Specify)

Summary of Technical Specifications and Performance

Requirements:

Describe the manufacturing processes (elaborate to provide as much detail as possible)

Benchtop bio-electric DNA/RNA sequencing device

Provide dimensions / size / tolerances / performance specifications of the item

Specific characteristics of the device, initial reagents and supplies, and training that limit the availability to a sole source are as follows:

- Ability to generate long-read sequences. Long-read sequences (> 10 Mbp) are essential to enable genome assembly. Short-read sequencing technologies do not allow for the assembly of genomes due to the inability to assemble sequences with extensive homology such as repeat sequences. Furthermore, long-read sequences enable detection of copy number variation and other large-scale structural variation.
- Ability to sequence both RNA and DNA in the absence of amplification. This is simpler, faster, potentially cheaper, and preserves modified bases, which facilitates examination of epigenetic marks on the molecules.
- Ability to generate both DNA/RNA sequence and epigenetic data simultaneously. No other sequencing platform can provide information about the DNA or RNA sequence as well as the modifications that are found on the DNA or RNA. DNA and RNA base modifications that can be identified at single nucleotide resolution, include 5mC, 5hmC, 6mA, and BrdU in DNA, and m6A in RNA.
- Targeted sequencing through rejection of unwanted sequences. The platform should allow the investigator to target the regions of the genome of most interest by programming the ability to reject any sequences that are not part of those to be sequenced. No other platform provides this function.
- Ability to run two flow cells simultaneously and to reuse flow cells. The flow cells used in the technology allow the investigator to wash out the DNA/RNA in a run and add a new sample.
- Ability to assess gene sequences in real time. This feature allows the investigator to see the sequence that is being generated from a sample while the sequencing is taking place allowing the investigator to determine if the sequencing run should proceed, decreasing time to result and reducing costs. No other sequencing platform provides this feature.
- Cost for equipment, reagents, and flow cells. The cost for the equipment is priced to allow an investigator to set up a sequencing facility in their own lab at a low cost.

List required materials needed to make the product, including materials of product components, if applicable

Are there applicable certification requirements?

Yes
No x
Please explain:

Are there any applicable regulations that apply to the production of this item?

Yes
No x
Please explain:

Are there any other standards / requirements?

Yes

No

x

Please explain:

Additional Comments:

Additional technical comments:

Volume and Pricing:

Estimated Potential Business Volume (i.e. #units per day, month, year):

1 device with initial reagents and training

Estimated Target Price / Unit Cost Information:

Approximately \$40,000

Delivery Requirements:

When is it needed by? (Immediate, 30 days, 6 months, etc)

6-12 months

Describe packaging requirements (i.e. individually / group packaging, etc)

Components wrapped and shipped as needed for intact delivery

Where will this item be shipped?

27 Tarzwell Drive Narragansett, RI 02882

Additional Comments:

Is there other information you would like to include?

- "Vendor/company must be registered or will register in SAM.gov (<https://sam.gov/content/home>)." - "This inquiry does not guarantee award of a contract." - "EPA requires a commercial off the shelf instrument that is immediately available that meets the technical specifications attached. Vendors shall provide documentation that their proposed product meets or exceeds the technical specifications attached."

Market Narrative for Benchtop RNA/DNA Sequencing Device

Market Research:

ACESD/CEMM is seeking a benchtop sequencing device to perform high throughput, low cost sequencing of RNA and DNA to support ongoing research in SHC (SHC 409.1.1 Methods and Measures for Characterizing Restoration Effectiveness). The goal of this work is to evaluate innovative genomic approaches as markers of ecological condition to characterize restoration effectiveness, and to develop methods to use these approaches that can be broadly applied by stakeholders. This requires several things: 1) genomic (DNA) long-read sequencing and/or targeted genotyping of large numbers of individual fish from field sites of concern 2) sequencing of eDNA or eRNA from field sites of concern, and 3) the development of methods with a low price point of entry so they can be used by a wide variety of stakeholders.

Searches of the literature and queries to other US EPA and academic researchers revealed others with similar goals either paid for the work via individual outside contracts at high cost per sample or used a benchtop sequencing device such as the Oxford Nanopore Technologies devices or an Illumina miSeq. Internet searches and conversations with colleagues and collaborators revealed that the pricing for the Oxford Nanopore technology was by far the lowest price point of entry. Furthermore, the base technology and methods used by the higher throughput Oxford Nanopore devices could be scaled all the way down to be used in a similar lower throughput device that is completely portable, could be used at a field station or in simply equipped lab, and costs under \$10,000 (MinION Mk 1). While this device does not provide the throughput needed for our work, we can develop methods that stakeholders could use with that level of capital investment, helping to meet requirement 3 above.

We therefore made a market research inquiry to Oxford Nanopore Technologies about the types of long-read sequencing devices available, and their capabilities. After a discussion, they replied with a market research quote. The quote demonstrated a price (PromethION 2 Solo device itself ~\$15,000) and capabilities (meeting requirements 1 & 2 above) that cannot be matched by other options.

For example, Illumina offers several benchtop sequencing devices. The standard for comparable capabilities is the miSeq. The Illumina miSeq device is capable of most of the things required for this work, but is far more expensive (approximately \$125,000). Furthermore, the miSeq can still not perform long-read sequencing. Their cheapest devices are the iSeq 100 and the miniSeq, which start at about \$20,000-\$30,000 (<https://emea.illumina.com/systems/sequencing-platforms/iseq/order.html#:~:text=%2419%2C900&text=Be%20among%20the%20first%20researchers,harness%20the%20power%20of%20NGS.>) However, the iSeq 100 is not capable of the 16S metagenomic sequencing required for many eDNA applications and neither is capable of untargeted transcriptomic sequencing. (<https://www.illumina.com/systems/sequencing-platforms.html>).

PacBio does not offer similarly priced bench-top type sequencers. They do offer a long-read capable sequencing platform called Revio, however the list price is \$779,000. This is the type of device that would be used by a contract company that customers would pay to run samples at a higher per sample cost and via an individual contract.

Suggested source comparison:

Oxford Nanopore Technologies (ONT), Inc
101 Avenue of the Americas
New York, NY 10013, USA
POC: Melissa Cabral, Melissa.Cabral@nanoporetech.com

Illumina
iSeq 100 or miniSeq - start at \$20,000-\$35,000 (device alone); have some of required capabilities
miSeq - ~\$125,000 (device alone); most of the needed capabilities
(<https://www.illumina.com/systems/sequencing-platforms.html>)



New York Genome Center,
 101 Avenue of the Americas
 New York
 NY 10013, USA
 Tel: +1 (646)846 4446
support@nanoporetech.com

Dear Bryan,

Thank you for your interest in our products. Please find below your quotation.

Billing Address

Accounts Payable
 US Environmental Protection Agency,
 Office of Research and Development
 27 Tarzwell Drive
 Narragansett
 Rhode Island
 US,02822
 T: 401-782-3032

Quote reference Quote-59840 / SFDC
Valid Until 27-Nov-2023
Account No. C086341
Currency USD

Product Name	Description	Qty	Pack Size	Unit Price	TOTAL
PromethION 2 Solo CapEx	1 x License and warranty - P2 Solo; SLW12M-P2S 1 x PromethION 2 Sequencing Unit Solo; PRO-SEQ002	1		\$15445.00	\$15445.00
PromethION Advanced Training	RSD006	1	1	\$19980.00	\$19980.00
Flow Cell Wash Kit XL	EXP-WSH004-XL	1	1	\$432.00	\$432.00
PromethION Flow Cell Packs (R10.4.1)	FLO-PRO114M	1	3	\$3420.00	\$10260.00
Native Barcoding Kit 96 V14	SQK-NBD114.96	2	1	\$799.00	\$1598.00

Total	\$47715.00
Number of Shipments	4
Device Carriage	\$0.00
Carriage	\$200.00
Additional Charges	\$-5994.00
Tax(VAT/GST, excludes import duties – Incoterms DAP)	Tax will be applied upon placement of your order
Quote Total	\$41921.00

**Additional
Comments /**

Shipping Address: Bryan Clark
US Environmental Protection Agency, Office of Research and Development
27 Tarzwell Drive
Narragansett
Rhode Island
US,02822
T: 401-782-3032

Yours sincerely,
Melissa Cabral
Nanopore Account Specialist
Tel: +44 (0) 845 034 7900
support@nanoporetech.com

Oxford Nanopore Technologies

Information about this quotation

This quotation is provided in conjunction with the following conditions:

- Minimum order quantities apply, as described in the conditions of sale
- Quotations provided are valid until the date specified
- Customers shall remain responsible for all shipping and freight charges incurred by shipment.
Any charges included within the quotation are for illustration purposes only and are subject to change
- In the event of any questions related to this quotation, please email us at support@nanoporetech.com
- Pricing for consumables applies only to the products specified herein
- The tax and shipping figures shown are based on the information you provided and may be subject to change
- Unless otherwise agreed with Oxford Nanopore, payment terms are 30 days from invoicing.
- By submitting an order, Customer accepts and agrees that the Terms and Conditions and policies displayed on https://nanoporetech.com/commercial_information is the sole and exclusive agreement between Customer and Oxford Nanopore Technologies with respect to the Oxford Nanopore Technologies products and/or services as described above and accepts all other terms of this quotation. Any additional or different terms, provisions or conditions proposed by the Customer in any current or future purchase order, invoice, acknowledgment, acceptance or other business form that the parties may use in connection with the current or future orders for the purchase of the products and/or services will have no effect on the rights, duties or obligations of the parties under, or otherwise modify, these Terms and Conditions and policies, regardless of any failure of Oxford Nanopore Technologies to object to such (further) terms, provisions or conditions. Notice of objection to them is hereby given and any such proposed terms, provisions and conditions shall be void.

NOTWITHSTANDING THE FOREGOING, IF OXFORD NANOPORE TECHNOLOGIES AND CUSTOMER HAVE ENTERED INTO A VALID AND ENFORCEABLE AGREEMENT GOVERNING THE OXFORD NANOPORE TECHNOLOGIES PRODUCTS AND/OR SERVICES DESCRIBED ABOVE ("THE AGREEMENT"), THE ORDER OF PRECEDENCE BETWEEN THE AGREEMENT AND THE TERMS AND CONDITIONS SHALL BE AS FOLLOWS: IN THE EVENT OF A CONFLICT BETWEEN THE TERMS OF THE

AGREEMENT AND THE TERMS AND CONDITIONS, OR IF THE AGREEMENT INCLUDES ADDITIONAL TERMS NOT ADDRESSED IN THE TERMS AND CONDITIONS, THE AGREEMENT SHALL GOVERN WITH RESPECT TO SUCH TERMS

Early access declaration

By accepting this quotation, you agree that:

- You are able to receive an early access device and understand this will have passed internal safety testing but will not be fully CE certified. You understand that Oxford Nanopore will either provide a CE certified device or other relevant labelling/documentation for any existing device once the CE certification process is complete. The CE certification process is expected to complete in late 2022 (subject to change).*
- Early access programs can include delivery of free trial consumables. You agree that you can receive free materials.*
- You have samples that are ready to sequence before your P2 will arrive in the provided timelines and would like an Oxford Nanopore account manager to get in touch to discuss ways to complete your project earlier.

Delivery information and shipping

Whilst shipping information varies dependent on your location, there are some uniform rules that can be applied to all deliveries

- All orders placed must have a defined ship schedule, for at least the first 90 days of the period of the contract
- Shipments associated with bulk orders should be split over the period of the contract and should be complete before expiry
- Any changes to shipping schedules must be communicated to Oxford Nanopore with a minimum notice period of 28 days. ONT accepts no responsibility for any losses caused by such changes inside of this period
- Orders received without ship schedules will have a shipping schedule defined for them by Oxford Nanopore, for which the above terms will apply to
- We have four distribution hubs located in the UK, US, and The Netherlands, from which your order will be fulfilled

**SOLE SOURCE JUSTIFICATION FOR
ACQUISITIONS UNDER THE SIMPLIFIED ACQUISITION THRESHOLD**

1. In accordance with Federal Acquisition Regulation 13.106-1(b)(1), I hereby determine that the items below, listed on **<insert purchase request number>** are available from only one source, and competition is precluded for the reasons indicated below. There are no substitutes available.
 - a. PromethION 2 Solo Sequencing Unit
 - b. Flow Cell Wash Kit XL
 - c. PromethION Flow Cell Packs (R10.4.1)
 - d. Native Barcoding Kit 96 V14
 - e. PromethION Advanced Training

2. This acquisition is restricted to the following source:

Company: Oxford Nanopore Technologies (ONT), Inc
Company Address: 101 Avenue of the Americas, New York, NY 10013, USA
Company Point of Contact and Phone Number: **<insert name and phone number>**

3. The Oxford Nanopore PromethION 2 Solo device, initial reagents and supplies, and training are estimated to cost \$41,921 and is required to be **<delivered/performed>** by **<insert date>**

The Oxford Nanopore PromethION 2 Solo device is a small benchtop DNA/RNA sequencer designed to run up to two PromethION flow cells, which allows nanopore-based long-read sequencing of both RNA and DNA while preserving epigenetic modifications.

4. *[Insert one of the paragraphs listed below, depending on the justification]*

Specific characteristics of the Oxford Nanopore PromethION 2 Solo device, initial reagents and supplies, and training that limit the availability to a sole source are as follows:

- **Ability to generate long-read sequences.** Long-read sequences (> 10 Mbp) are essential to enable genome assembly. Short-read sequencing technologies do not allow for the assembly of genomes due to the inability to assemble sequences with extensive homology such as repeat sequences. Furthermore, long-read sequences enable detection of copy number variation and other large-scale structural variation. Only two other companies provide long-read sequencing platforms (PacBio and Illumina), but neither meets other requirements (listed below).
- **Ability to sequence both RNA and DNA in the absence of amplification.** No other company allows the sequencing of RNA or DNA in the absence of amplification steps. This is simpler, faster, potentially cheaper, and preserves modified bases, which facilitates examination of epigenetic marks on the molecules.
- **Ability to generate both DNA/RNA sequence and epigenetic data simultaneously.** No other sequencing platform can provide information about the DNA or RNA sequence as

Commented [BC1]: Need to ask purchasing - we don't have to have it immediately. Any time in next 6-12 months would be acceptable, but not sure if that's ok to put

well as the modifications that are found on the DNA or RNA. DNA and RNA base modifications that can be identified at single nucleotide resolution, include 5mC, 5hmC, 6mA, and BrdU in DNA, and m6A in RNA.

- **Targeted sequencing through rejection of unwanted sequences.** The ONT platforms allow the ability of the investigator to target the regions of the genome of most interest by programming the ability to reject any sequences that are not part of those to be sequenced. No other platform provides this function.
- **Ability to reuse flow cells.** The flow cells used in the technology allow the investigator to wash out the DNA/RNA in a run and add a new sample. All other technologies do not allow the reuse of the flow cells.
- **Ability to assess gene sequences in real time.** This feature allows the investigator to see the sequence that is being generated from a sample while the sequencing is taking place allowing the investigator to determine if the sequencing run should proceed, decreasing time to result and reducing costs. No other sequencing platform provides this feature.
- **Cost for equipment and flow cells.** The cost for the equipment is priced to allow an investigator to set up a sequencing facility in their own lab at a low cost. Costs for Illumina and PacBio instruments are up to 10-20 fold higher than the ONT instruments. The flow cells used in the ONT sequencers, because they can be reused allow lower sequencing costs than the other companies.

Only this suggested source can furnish the requirements, to the exclusion of other sources, because market research revealed no evidence of equal or similar instruments capable of meeting the attributes described above. The PromethION 2 Solo is only manufactured by Oxford Nanopore Technologies, and associated software, flow cells, sample preparation reagents and kits are manufactured, produced and made available under license exclusively by Oxford Nanopore Technologies for components used in nanopore detection technology, as well as for methods performed by the same technology. Oxford Nanopore Technologies plc. provides its products exclusively to registered users. These users may only obtain Oxford Nanopore Technologies devices and consumables directly, or from authorized distributors in certain countries. ONT's products are manufactured in the United Kingdom; however, many ONT products contain significant proprietary components purchased from and created by a US company and leverage significant intellectual property created through investment in research and development that occurred in the United States.

5. Check and fill in all that are applicable:

The material or service must be compatible in all aspects (form, fit, and function) with existing systems presently installed. The current equipment is *<insert description of current equipment>*, and the new item/service must coordinate, connect, or interface with the existing system by *<insert description of how the new item/service must coordinate or interface>*.

A patent, copyright, proprietary data, or licensing agreement limits competition. The

proprietary data are described as follows:

<Insert description>

These are "direct replacement" parts/components for existing equipment.

Other information to support a sole-source buy:

<Insert any additional information that supports this sole-source acquisition>

Commented [BC2]: This? They're the only ones who do long read nanopore technology?

Commented [BC3]: Also this, but just repetitive of what's above in attributes?

CERTIFICATION

I certify that statements checked and information provided above are complete and correct to the best of my knowledge. In accordance with FAR 13.106-1(b)(1). The facts of this acquisition preclude the use of full and open competition.

<Insert Name>
Contracting Officer

Date

Kathryn P. Barton, Chief
Simplified Acquisitions Branch

Date