SOURCE JUSTIFICATION FORM

Bureau of Procurement

The objective of this form is to capture all relevant documentation an Agency may have to assist the Department of General Services ("DGS"), Bureau of Procurement, in expediting the source justification review process. This form must be completed electronically, signed, and submitted with all relevant documentation to DGS. If a question is neither mandatory nor applicable, please indicate "N/A". Please use standard terminology and define acronyms.

SECTION A

1. Agency Name:	Department of Health				
2. Procurement Description: This description will appear on the eMarketplace website for public viewing	Reagents, consumables, instrumentations and cloud services as required for the instrumentations.				
Materials Description:					
Services Description:					
3. Materials Shopping Cart # or	12761013	Estimated Cost:	\$250,001 - \$500K		
Services SPR#		Initial Contract Term:	5 years		
		Renewals:	NA		
4. Supplier - Name:	Illumina, Inc.				
Full Address:	5200 Illumina Way, San Diego, CA 92122				
Contact Name:	Andres Rondon				
Telephone:	858-245-2801	FAX:	858-245-2801		
E-mail:	arondon@illumina.com				
SRM Supplier #:	408689				
5. Delivery or service location:	PA Department of Health Bureau of Laboratories				

SECTION B

1. Sole Source: Only known source - Not available from another supplier.

2. *Material/Repair/Maintenance*: Material or service MUST be compatible with existing equipment. Documentation must be provided from the manufacturer.

3. Used Equipment: Value set by 2 independent 3rd party appraisals.

4. *Professional Expert*: Describe in detail in Section C.

5. Exempt (*Law*): A federal or state statute or regulation exempts the procurement from the competitive procedure. Any applicable information precluding the procurement from competitive procedures must be attached.

6. Feasibility: Clearly not feasible to award the contract on a competitive basis.

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SECTION C

1. Describe the unique features of this procurement that prohibit a competitive environment. If applicable, attach a Statement of Work ("SOW").

2. Document and attach the research that has been conducted to date to verify the supplier is the only known source.

3. Does the supplier utilize distributors, dealers, resellers, etc.? If "Yes," please identify.

4. Are there compatibility requirements or compliance requirements with a warranty or service agreement? If "Yes." please explain.

5. How has the material or service been procured in the past? Please provide previous source justifications, contracts, & PO's for this material or service.

6. If procured through the IT ITQ process, please provide original \$ amount and contract period of order. Is this the final phase of the project?

7. If this is an upgrade, addition, alteration, etc., to an earlier procurement, please describe in detail.

This sequencing-based testing program as detailed in this application is required by the CDC as the only instrumentation that they will support for Public Health Laboratories' participation in the CDC's PulseNet Foodborne Disease program using state-of-the-art Whole Genome Sequence (WGS) analytical technologies. The CDC surveyed similar instruments and found that only Illumina's platforms had the required minimal error rates in analysis and could produce draft genome sequences that have >90% probability of containing full-length genome sequences of clinically relevant proteins. The standardization of the protocols and testing systems is required across the nation's public health laboratories in providing comparable data for outbreak detection.

The Illumina equipment was purchased and installed in 2017, we currently own five Illumina sequencing platforms. To continue operations and maintain performance metrics for the CDC PulseNet, WGS reagents, and consumables, supporting equipment and analysis data transfer from Illumina are required. No other manufacturer makes reagents required for this instrumentation.

NA

Yes. The current sequencing instrumentation includes all the necessary compatible equipment and software as well as necessary service and maintenance agreements to ensure the continued operation of the equipment. Service needs to be performed only by Illuminia's technical support.

The first implementation of Whole Genome Sequence (WGS) analysis at the Bureau of Laboratories (BOL) was accomplished via an emergency sole source authorization purchase of the MiSeq in 2017. Materials and reagents are currently obtained through the previous five-year contract.

NA

This is not an upgrade.

Department of General Services

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8. What are the consequences of not approving this procurement?	Failure to approve this contract will result in the inability of the Bureau of Laboratories (BOL) to participate in the CDC PulseNet foodborne surveillance program. BOL will lose federal funding for this program. The BOL has been participating in the PulseNet system since at least 2001. The PulseNet system is a critical Public Health Resource for monitoring foodborne and other infectious disease reporting and monitoring systems utilized in most major food-related outbreaks and recalls. It is relied upon by Epidemiologists, the FDA, USDA, etc., in identifying and managing food-related outbreaks and contamination investigations. This will impact the safety of our PA citizens.
9. If timing is a factor, what is the time factor and why?	In order to have an uninterrupted testing service and not lose any grant funding for foodborne and COVID-19 sequence testing, this contract renewal is needed to be in place by the end of the five-year cycle by the end of this contract 4400020005. Currently, there is no contractual avenue through which to purchase the critical supplies and materials needed. This results in lost efficiency in specimen processing and throughput. It critically limits our ability to utilize the equipment and technology to meet the expected performance goals.
10. List any other information relevant to the acquisition of this procurement here or as an attachment.	Lobbying Cert due to federal funds being used for this procurement.
11. For requests > \$100,000, has the supplier signed cost or pricing data certification and is the pricing breakdown attached?	No. DGS is currently working with the vendor to establish.

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SECTION D

IMPORTANT*: The printed names on this form shall constitute the signatures of these

individuals. Agencies must insure that these individuals review the completed form and give their consent to apply their printed name on this form. No handwritten signatures shall be required in order for the form to be considered "signed" by those individuals whose names appear in the signature section of the form.

Shopping Cart Contact Person (Person whom DGS will contact regarding the Shopping Cart):							
Name:	Joann Maluulu	P-Group:	HC9	Date:	04-10-23		
Title:	Purchasing Agent	Telephone:		Fax:			
Agency Contact Person: Person in your agency that DGS can contact for additional information, etc.							
Name:	Lisa Dettinger	Title:	Public Health Division Director	Date:	04-10-23		
Telephone:		Fax:		Email:	ldettinger@pa.gov		
Approving Authority (Agency Head or Deputy reviewing and approving this request): Approving Authority connotes approval of the source justification and the cost or pricing data certification.							
Name:	Rebekah Greorowicz	Title:	Director, Procurement Specialist	Date:	04-18-23		
Telephone:		Fax:					
Additional Approvals (if required by Agency):							
Name:		Title:		Date:			
Telephone:		Fax:		Email:			
Name:		Title:		Date:			
Telephone:		Fax:		Email:			
Name:		Title:		Date:			
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Name:		Title:		Date:			
Telephone:		Fax:		Email:			
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Name:		Title:		Date:			
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