



PROCUREMENT JUSTIFICATION FORM (PJF)

This form must accompany all contract requests and sole source requisitions (RQS) over \$5,000 submitted to the Division of Procurement Services.

INSTRUCTIONS: Please provide the requested information in the white spaces below. All responses (except signatures) must be typed; no hand-written forms will be accepted. See the guidance document posted with this form on the Division of Procurement Services intranet site (Forms page) for additional instructions.

PART I: OVERVIEW

Department Office/Division/Program:		DHHS/Maine CDC	
Department Contract Administrator or Grant Coordinator:		Chris Moiles / Melanie Boucher	
(If applicable) Department Reference #:		CD0-23-5470	
Amount: (Contract/Amendment/Grant)	\$8,404.00	Advantage CT / RQS #:	RQS 10A 20221017*0537
CONTRACT	Proposed Start Date:	11/1/2022	Proposed End Date: 10/31/2023
AMENDMENT	Original Start Date:		Effective Date:
	Previous End Date:		New End Date:
GRANT	Project Start Date:		Grant Start Date:
	Project End Date:		Grant End Date:
Vendor/Provider/Grantee Name, City, State:		Qiagen LLC Germantown, MD	
Brief Description of Goods/Services/Grant:		An IQOQ (Installation Qualification and Operational Qualification) for laboratory instrumentation (Qiacube extraction platform) serial numbers 5191 and 6935 that are used for the extraction of DNA and RNA used in the rapid identification of infectious agents.	

PART II: JUSTIFICATION FOR VENDOR SELECTION

Check the box below for the justification(s) that applies to this request. (Check all that apply.)

<input type="checkbox"/>	A. Competitive Process	<input type="checkbox"/>	G. Grant
<input type="checkbox"/>	B. Amendment	<input type="checkbox"/>	H. State Statute/Agency Directed
<input checked="" type="checkbox"/>	C. Single Source/Unique Vendor	<input type="checkbox"/>	I. Federal Agency Directed
<input type="checkbox"/>	D. Proprietary/Copyright/Patents	<input type="checkbox"/>	J. Willing and Qualified
<input type="checkbox"/>	E. Emergency	<input type="checkbox"/>	K. Client Choice
<input type="checkbox"/>	F. University Cooperative Project	<input type="checkbox"/>	L. Other Authorization

Please respond to ALL of the questions in the following sections.

PART III: SUPPLEMENTAL INFORMATION

1. Provide a more detailed description and explain the need for the goods, services or grant to supplement the response in Part I.

This one-time service is for 2 Qiagen Qiacube DNA/RNA extraction instruments (serial numbers 5191 and 6935) to receive an installation qualification and operational qualification at the new laboratory at 47 Independence Drive. This service ensures that the instruments are working according to the manufacturer's specifications, and enables the lab to comply with quality standards and ensures the accuracy and precision of the instrument.

The laboratory determined that these services are critical to the nature of the work regarding identification of pathogens of human interest, including Zika virus, *Neisseria meningitidis*, influenza A and B, novel strains of influenza, enteric pathogens, Bordetella specimens, Herpes simplex virus, norovirus, SARS-CoV-2, and enterovirus as well as several respiratory pathogens. This work allows physicians and public health workers to make timely and crucial decisions for their patients with an unknown illness and to assist in outbreak detection and disease tracking. The MA allows us to meet all accreditation requirements set forth by the Clinical Laboratory Inspection Amendments, by maintaining proper instrument functionality.

2. Provide a brief justification for the selected vendor to supplement the response in Part II. Reference the RFP number, if applicable.

Qiagen (Original Equipment Manufacturer), is the only organization that provides maintenance and repair of the QIACube in accordance with the equipment warranty.

- QIAGEN Field Service is the only organization certified by QIAGEN to Repair, Qualify, Calibrate, Upgrade, Maintain, and Move QIAGEN instrumentation.
- Attempts to perform any Repairs, Calibration, Preventive Maintenances or Moves by organizations or individuals other than QIAGEN Field Service or those directed by QIAGEN Field Service, immediately and irrevocably void any QIAGEN Warranties or QIAGEN Support Agreements.
- QIAGEN manufactures, calibrates, certifies, and stocks all parts necessary for the Repair, Calibration and Maintenance of QIAGEN instrumentation. The specifically developed parts and as such are not available from any other source, or vendor.

3. Explain how the negotiated costs or rates are fair and reasonable; or how the funding was allocated to grantee.

The service amount is similar to the annual preventative maintenance agreements that have been formalized or are also in the system to be signed. The service agreement ensures that all maintenance, repairs, parts, and travel time for the field service technician are covered, with no additional cost to the lab.

If the instrument failed or needed routine preventative maintenance to stay in compliance with regulatory standards, the HETL would be liable for payment at a higher cost, without a service agreement in effect.

4. Describe the plan for future competition for the goods or services.


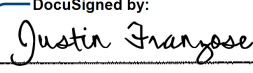
The department does not intend to RFP this service at this time.

PART IV: AMERICAN RESCUE PLAN ACT (ARPA) / MAINE JOBS & RECOVERY PLAN (MJRP)

Does this request utilize ARPA/MJRP funds?

Yes – If Yes, please attach the approved Business Case(s).

No – If No, proceed to Part V.

PART V: APPROVALS			
The signatures below indicate approval of this procurement request.			
Signature of requesting Department's Commissioner (or designee):			
Typed Name:	Ben Murray	Date:	11-3-22
Signature of DAFS Procurement Official:	DocuSigned by: 		
Typed Name:	Justin Franzose <small>AEFD9C7B3A8044E</small>	Date:	11/14/2022