State of Maine
Procurement Justification Form

This form must accompany ALL contract requests and sole source requisitions submitted to the Division of Procurement Services.

INSTRUCTIONS: Please provide the requested information in the white spaces below.

PART I: OVERVIEW					
Department Office/Division/Program:	DHHS/MECDC/Health Environmental Testing Laboratory (HETL)				
Department Contract Administrator or Grant Coordinator:	Chris Moiles				
(If applicable) Department Reference #:					
Estimated Contract or Grant Amount:	$53,823.62	Advantage CT / RQS #:	Draft RQS 10A 20200212*916		
AMENDMENT	Original Start Date:		New Start Date:		
	Original End Date:		New End Date:		
GRANT	Project Start Date:		Grant Start Date:		
	Project End Date:		Grant End Date:		
ALL OTHER	Proposed Start Date:	02/12/2020	Proposed End Date:	06/30/2020	
Vendor/Provider/Grantee Name, City, State:	Qiagen, 19300 Germantown Road, Germantown, MD 20874-1415				
Brief Description of Goods/Services/Grant:	Qiagen EZ1 Advanced XL is the only nucleic acid extraction platform approved for the detection of the 2019 novel Coronavirus				

PART II: JUSTIFICATION FOR VENDOR SELECTION			
Mark an "**X**" before the justification(s) that applies to this request.			
	A. Competitive Process		G. Grant
	B. Amendment		H. State Statute/Agency Directed
x	C. Single Source/Unique Vendor		I. Federal Agency Directed
	D. Proprietary/Copyright/Patents		J. Willing and Qualified
x	E. Emergency		K. Client Choice
	F. University Cooperative Project		L. Other Authorization

PART III: SUPPLEMENTAL QUESTIONS

Please respond to ALL of the following questions.

1. Provide a more detailed description of the goods, services or grant to supplement the response in Part I.

This instrument, the EZ1 Advanced XL from Qiagen, is the only nucleic acid extraction platform which has been approved for use in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. CDC-006-00019, Revision: 01 CDC/DDID/NCIRD/ Division of Viral Diseases Effective: 2/4/2020.

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PART III: SUPPLEMENTAL QUESTIONS

For FDA Emergency Use Authorization (EUA) documents related to Coronavirus please see the following attached documents sent along with this Procurement Justification Form; CDC-2019-nCoV-Authorization.pdf, Emergency-Use-Authorization-of-Medical-Products-and-Related-Authorities---Printable-PDF.pdf, and 20200204_PHE FDC Determination_508.pdf

The documents detail the FDA's general EUA authority, the FDA authority to issue this Coronavirus test, and the FDA's EUA Determination and Declaration of a public health emergency.

There are two ways to extract viral nucleic acid from clinical specimens using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. CDC-006-00019, Revision: 01 CDC/DDID/NCIRD/ Division of Viral Diseases Effective: 2/4/2020. For Emergency Use Only test. One way is a slow manual method which may result is a delay in reporting patient results if there are large numbers of samples pending.

As a side note: This instrument is also FDA EUA approved for the use our Influenza Real-Time rtPCR clinical diagnostic test. This instrument will also be used to replace our 15-year old nucleic acid extraction platform which we currently use to conduct Influenza Real-Time rtPCR clinical diagnostic testing as well as other viral identification. This model has been discontinued by the manufacturer so parts for repair may be more difficult to obtain.

2. Provide a brief justification for the selected vendor to supplement the response in Part II.

CBRN: chemical, biological, radiological, and nuclear; MCMs: medical countermeasures

Verbatim from the FDA Emergency Use Authorization (EUA) website:

"The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN threats by facilitating the availability and use of MCMs needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

Section 564 of the FD&C Act was amended by the Project Bioshield Act of 2004 and was further amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), the 21st Century Cures Act of 2016, and Public Law 115-92 of 2017."

This instrument, the Qiagen EZ1 Advanced XL is the only extraction platform the FDA has approved for use in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. CDC-006-00019, Revision: 01 CDC/DDID/NCIRD/ Division of Viral Diseases Effective: 2/4/2020. For Emergency Use Only test.

The original novel Coronavirus protocols released by the Federal CDC at the end of January 2020, listed many different types of nucleic acid extraction platforms. For unbeknownst reasons, the FDA only accepted the Qiagen EZ1 Advanced XL as the only extraction platform to be used.

Per the FDA EUA, a laboratory may not modify the approved diagnostic test, which includes the nucleic acid extraction instrument.

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PART III: SUPPLEMENTAL QUESTIONS
3. Explain how the negotiated costs or rates are fair and reasonable; or how the funding was allocated to grantee.
The federal CDC/FDA in many cases set the rules and guidelines in the form of Standard Operating Procedures. To provide diagnostic testing to the State of Maine, HETL must follow the guidelines instituted by the federal CDC/FDA. Therefore, HETL has purchased and currently maintains the equipment required to conduct CDC/FDA approved diagnostic testing. HETL requested a discount from this manufacture due to its nonprofit status, as well as a governmental organization (public health laboratory).
4. Describe the plan for future competition for the goods or services.
None. This is a one-time purchase for a piece a scientific laboratory equipment that is allowed to be used for the FDA EUA approved test for the clinical detection of 2019-Novel Coronavirus (2019-nCoV).

PART IV: APPROVALS			
Signature of requesting Department's Commissioner (or designee):	*By signing below, I signify that I approve of this procurement request.*		
Printed Name:	Ben Mann	**Date:**	2/13/20
Signature of DAFS Procurement Official:	DocuSigned by: Justin Franzose AEED9C7B3A8044E...		
Printed Name:	Justin Franzose	**Date:**	2/26/2020