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/Maine CDC				
Department Contract Administrator or Grant Coordinator:	Chris Moiles / Lisa Munster				
(If applicable) Department Reference #:	CD0-20-54CAP8				
Estimated Contract or Grant Amount:	**$ 62,127.50**		Advantage CT / RQS #:	Draft RQS 10A 20200324* 1085	
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:	03/24/2020	Proposed End Date:	06/15/2020	
Vendor/Provider/Grantee Name, City, State:	Life Technologies Corporation 3175 Staley Road Grand Island, NY 14072				
Brief Description of Goods/Services/Grant:	KingFisher Flex Nucleic Acid Extractor is an approved high throughput nucleic acid extraction platform for testing of the 2019 Novel Coronavirus (COVID-19)				

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
	C. Single Source/Unique Vendor		I. Federal Agency Directed
X	D. Proprietary/Copyright/Patents		J. Willing and Qualified
X	E. Emergency		K. Client Choice
	F. University Cooperative Project	X	L. Other Authorization: COVID-19

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.

The King Fisher Flex Nucleic Acid Extractor instrument is required for the public health emergency response to COVID-19 testing.

This patented instrument, King Fisher Flex Nucleic Acid Extractor, is a distinct high throughput nucleic acid extraction platform which has been approved for the use in the CDC 2019-Novel Coronavirus (2019-nCov).

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PART III: SUPPLEMENTAL QUESTIONS

Please see attached instrument specifications and manual. This instrument has the capability to run 96 samples per run. Please see https://www.fda.gov/media/136113/download for more information. The following paragraph is copied from this 9-page document.

"This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Thermo Fisher Scientific, Inc. (Thermo Fisher) TaqPath COVID-19 Combo Kit for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The TaqPath COVID-19 Combo Kit is for use only under EUA in the United States (U.S.) in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests"

As an public health emergency response to the rapid increase in COVID-19 testing, the Health and Environmental Testing Laboratory requires a higher throughput instrument to sustain processing the volumes of samples received. Further, the laboratory will also use this instrument to conduct high-throughput testing for other infectious diseases, such as influenza.

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

Due to the COVID-19 emergency public health response, this vendor, Life Technologies Corporation, a part of ThermoFisher Scientific, is able to provide this approved patented high throughput instrument in an expedited manner, has the capability to provide a viable supply chain of consumables and reagents for this platform, and has a instrument that provides a high output capacity, thereby processing samples 3x faster per run, by processing 96 samples at one time. Further, with the purchase of this instrument, the following consumables and reagent items are required to run the protocol and are only available through this same vendor:

KingFisher™ Flex 96 Deep-Well Heating Block 24075430
KingFisher™ Deepwell 96 Plate 95040450
KingFisher™ 96 KF microplate 97002540
KingFisher™ 96 tip comb for DW magnets 97002534
MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit
(100 preparations)
MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit
components (1,000 preparations):
• MagMAX™ Viral/Pathogen Binding Solution
• MagMAX™ Viral/Pathogen Wash Solution
• MagMAX™ Viral/Pathogen Binding Beads
• MagMAX™ Viral/Pathogen Proteinase K
• MagMAX™ Viral/Pathogen Elution Buffer
TaqPath™ 1-Step Multiplex Master Mix (No ROX™)

For those required additional consumables and reagent items listed above from this vendor, a separate justification form will be completed each time for the ongoing purchases that exceed the $5,000 threshold.

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

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PART III: SUPPLEMENTAL QUESTIONS

This instrument is the only instrument that can perform the TaqPath COVID-19 Combo Kit multiplex real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2.

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

This is a one-time purchase for a piece of 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:**	3/27/20
Signature of DAFS Procurement Official:	DocuSigned by: Justin Franzose AEED9C7B3A8044E...		
Printed Name:	Justin Franzose	**Date:**	3/27/2020