

# State of Maine Waiver of Competitive Bidding Request Form

**Form Instructions:** Please provide the requested information in the white boxes below. This form is to precede all contract requests that are not the direct result of a competitive bid process.

<b>DHHS/DCM Contract Administrator:</b>	Chris Moiles	<b>Office/Division/Program of Contract Administrator:</b>	DHHS, MeCDC, Health and Environmental Testing Laboratory
<b>Est. Contract Amount:</b>	\$163,638.00	<b>Contract or RQS Number:</b>	RQS 10A-20190808*0171
		<b>Purchasing Maine ID:</b>	
		<b>DHHS Agreement Number:</b>	CD0-20-54MA25
<b>Proposed Start Date:</b>	<b>9/1/2019</b>	<b>Proposed End Date:</b>	<b>8/31/2022</b>
<b>Vendor/Provider Name, City, State</b>	Qiagen, Inc Carol Stream, IL		
<b>Short Description of Good or Service:</b>	This request is to renew a master agreement for three years, for supplies and reagents to use with Molecular/Serological instrumentation, at Maine's Health and Environmental Testing Laboratory (HETL).		
<b>Please note, for transparency purposes, Waivers of Competitive Bidding will be publicly posted. Public postings are placed on the Division of Procurement Services website for a period of seven consecutive calendar days.</b>		<b>To be completed by the Division of Procurement Services</b> Posting dates on Division of <b>Procurement Services</b> website: From: <u>12/5/2019</u> To: <u>12/11/2019</u>	
<b>Notice of Intent to Waive Competitive Bidding Number:</b>		NOI# 1220191975	
<b>1. Statutory Justification</b> State of Maine statute (5 M.R.S. §1825-B(2)) allows waivers of competitive bidding only for the specific reasons listed below. Please mark the appropriate box (X) next to the justification which applies to this specific request.			
<input type="checkbox"/>	A. The procurement of goods or services by the State for county commissioners pursuant to Title 30-A, section 124, involves the expenditure of \$2,500 or less, and the interests of the State would best be served;		
<input type="checkbox"/>	B. The Director of the Bureau of General Services is authorized by the Governor, or the Governor's designee, to make purchases without competitive bidding because, in the opinion of the Governor or the Governor's designee, an emergency exists that requires the immediate procurement of goods or services;		
	<i>If citing the above justification for this Waiver of Competitive Bidding request, please have the requesting Department's Commissioner or Chief Executive (as the Governor's "designee") sign and date on the right.</i>	<i>By signing below, I signify as the Governor's designee there is an emergency that necessitates this non-competitive procurement.</i> <b>Signature:</b>  <b>Printed Name:</b> _____ <b>Date:</b> _____	
<input checked="" type="checkbox"/>	C. After reasonable investigation by the Director of the Bureau of General Services, it appears that any required unit or item of supply, or brand of that unit or item, is procurable by the State from only one source;		
<input type="checkbox"/>	D. It appears to be in the best interest of the State to negotiate for the procurement of petroleum products;		
<input type="checkbox"/>	E. The purchase is part of a cooperative project between the State and the University of Maine System, the Maine Community College System, the Maine Maritime Academy, or a private, nonprofit, regionally accredited institution of higher education with a main campus in this State involving: (1) An activity assisting a state agency and enhancing the ability of the university system, community college system, Maine Maritime Academy, or a private, nonprofit, regionally accredited institution of higher education with a main campus in this State to fulfill its mission of teaching, research, and public service; (2) A sharing of project responsibilities and, when appropriate, costs;		
	<i>If citing the above justification for this sole source request, please note that the specific approval of the Governor's Office is required, in accordance with Executive Order 26 FY 11/12, "An Order to Enhance Competitive Bidding". The approval must be documented on DAFS/BGS/Division of Procurement Services "GOVCOOP" form, found here: <a href="http://www.maine.gov/purchases/info/forms/govcoop.doc">http://www.maine.gov/purchases/info/forms/govcoop.doc</a>.</i>		

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	F. The procurement of goods or services involves expenditures of \$10,000 or less, in which case the Director of the Bureau of General Services may accept oral proposals or bids;
	G. The procurement of goods or services involves expenditures of \$10,000 or less, and procurement from a single source is the most economical, effective and appropriate means of fulfilling a demonstrated need.
	If a different authorization specifically allows for this non-competitive procurement, please provide that reference here:

**Please note that the following four points below (#2 through 5) all require a response.**

**2. Description of Specific Need**

Please identify, and fully describe, the specific problem, requirement, or need the resulting non- competitive contract would address and which makes the goods or services necessary. Explain how the requesting Department determined that the goods or services are critical and/or essential to agency responsibilities or operations.

The Maine Health and Environmental Testing Laboratory (HETL) uses instruments from the vendor, noted above, to test human specimens for a variety of infectious diseases, including multi-drug resistant TB, novel influenza and Zika virus. The instruments provided by Qiagen require specific reagents and consumables to function appropriately. No other vendor can provide these specific compatible reagents or supplies. Our testing protocols are based on our ability to use these instruments, to determine the presence of TB antigens, or extracting nucleic acids from specimens received in our laboratory.

- a) The two (2) Qiacubes instruments are used for the high-throughput extraction of nucleic acid (DNA, RNA) from clinical samples. Extracted nucleic acid is then used in several diagnostic tests to determine if clinical samples received from hospitals, Primary Care Providers, and/or external laboratories are positive for specific infectious diseases.
- b) The Pyrosequencer instrument is used to determine the exact sequence of a short strand of DNA to determine antiviral resistance within the influenza genome. This machine can also be used for other sequencing needs.
- c) The Evolis system is used to process blood samples for tuberculosis antigen which determines if a patient has active TB or is harboring a latent infection.
- d) These machines are used at HETL. It is the responsibility of HETL to perform these functions for the State of Maine. If these machines did not have proper reagents and supplies to use, several of the tests performed at HETL would be delayed, or no longer offered.

**3. Availability of other Public Resources**

Please explain how the requesting Department concluded that sufficient staffing, resources, or expertise is not available within the State of Maine's government, or other governmental entities (local, other state, or federal agencies) external to the requesting Department, which would be able to address the identified need more efficiently and effectively than the identified vendor.

Sufficient staffing, resources, or expertise is not available within the State of Maine's government.

**4. Cost**

Since a waiver of competitive bidding is being requested for this procurement, please explain how the requesting Department concluded the negotiated costs, fees, or rates are **fair and reasonable**.

Qiagen has agreed to a 5% discount in consideration of HETL's status as a non-profit governmental organization (public health laboratory).

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## 5. Future Competition

Please describe potential opportunities which may be available to foster competition for these goods or services in the future.

The department does not intend to RFP these services.

**Please note that only one of the two points below ("Uniqueness" or "Timeframe") requires a response. Requesting Departments are not required to respond to both points.**

## 6. Uniqueness

Please explain if the goods or services required are unique to a specific vendor. Describe the unique qualifications, abilities, and/or expertise of the vendor and how those particular unique factors address the specific need identified above. If the vendor has unique equipment, facilities, or proprietary data, also explain the necessity of these particular unique assets.

- a) HETL must use the Qiacubes and Pyrosequencer, per Federal CDC/FDA standard operating procedures for the extraction of nucleic acid from a pure bacterial sample or clinical specimen. HETL follows these federal CDC/FDA guidelines.
- b) The federal CDC/FDA is the governing body that sets the standards and regulations.
- c) While the federal CDC/FDA determine what standard operating procedure to follow, it is up to HETL to purchase and maintain all equipment that is needed to perform said tests.
- d) It must be stated that when performing a specific diagnostic test, the user is immediately 'locked-in' to that one sole-source for that specific diagnostic test. A diagnostic test from Company A is in no way compatible with the diagnostic test from Company B.
- e) HETL is the only laboratory in the state to conduct genetic analyses of influenza samples for antiviral resistance mutations.

## 7. Timeframe (Complete only if B. is the Statutory Justification marked on Page 1)

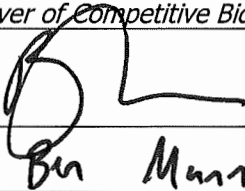
Please explain if time is of the essence and an emergency exists which requires the immediate procurement of goods or services. Describe the nature of this emergency, provide the date by which the goods or services must be delivered, and explain how that date was determined and its significance (i.e. impact if delayed beyond this date). Also, provide information as to how it was determined this vendor is the best option to address this time-sensitive procurement.

N/A

**Signature of requesting Department's Commissioner or Chief Executive (or designee within the Commissioner's Office):**

*By signing below, I signify that my Department requests, and I approve of, this Waiver of Competitive Bidding.*

**Printed Name:**



**Date:**

12/2/19