

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.

DHHS/DCM Contract Administrator:	Chris Moiles	Office/Division/Program of Contract Administrator:	DHHS, MeCDC Health and Environmental Testing Lab
Est. Contract Amount:	\$162,000.00	Contract or RQS Number:	RQS 10A 20190717*057
		Purchasing Maine ID:	
		DHHS Agreement Number:	CD0-20-54MA02
Proposed Start Date:	08/01/2019	Proposed End Date:	07/31/2022
Vendor/Provider Name, City, State	Bio-Rad Laboratories Clinical Diagnostics Group 5400 E 2 nd Street Benicia, CA 94510		
Short Description of Good or Service:	Supplies and Reagents (Vendor Master Agreement)		
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.		To be completed by the Division of Procurement Services Posting dates on Division of <i>Procurement Services</i> website: From: <u>7/23/2019</u> To: <u>7/29/2019</u>	
Notice of Intent to Waive Competitive Bidding Number:		NOI# 0720191257	
1. Statutory Justification 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> Signature:	
		Printed Name:	Date:
<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: http://www.maine.gov/purchases/info/forms/govcoop.doc.</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 HETL has equipment from the vendor noted above for the purpose of testing human specimens for a variety of infectious diseases. The instruments provided by Bio-Rad require specific reagents and consumables in order to function appropriately. No other vendor can provide compatible reagents or supplies for our molecular, serology and virology equipment. Our testing protocols are based on our capability of using these particular instruments for determining the presence of specific organisms found within the specimens received in our laboratory. This agreement allows HETL to maintain their rental agreements for the Evolis and Geenius. The commodities purchased from Bio-rad also are utilized for our Bio-plex. The laboratory determined that these services are critical to the nature of the work regarding identification of pathogens of human interest, including Eastern Equine Encephalitis, West Nile Virus, and St. Louis Encephalitis. 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.

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.

- a) HETL is the reference contract laboratory that hospitals, physicians and external laboratories count on for performing complex testing in the State of Maine. Use of the appropriate kits, reagents, and supplies with these instruments is necessary in order to comply with and to follow CDC/FDA guidelines.
- b) HETL is the State Health and Environmental Testing Laboratory and the sole source of the state to provide such services.
- c) Providing rapid test results to Maine CDC is of the utmost importance in order to allow the epidemiologists to do contact investigations quickly thereby reducing the spread of the disease as well as the disease burden.

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**.

- a) The federal CDC/FDA in many cases sets the rules and guidelines in the form of Standard Operating Procedures. In order 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 run CDC/FDA approved diagnostic tests.
- b) HETL has asked manufacturers for discounts due to its status as a nonprofit, governmental organization (public health laboratory).

5. Future Competition

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

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

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.

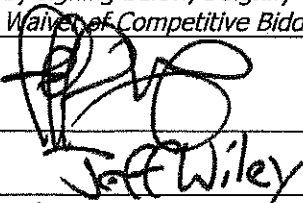
6. Uniqueness

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) The use of the Bio-Rad equipment is mandated in several Federal CDC/FDA standard operating procedures for the identification of samples or clinical specimens. HETL follows these federal CDC/FDA guidelines.
- b) The federal CDC/FDA is the governing body that sets the standards and regulations. HETL follows these federal CDC guidelines.
- c) While the federal CDC/FDA determines what standard operating procedures 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 a Diagnostic Test from Company B.
- e) HETL is required to use reagents specifically designed to work in conjunction with the instruments otherwise the warranty/guarantee of proper operation is null and void.

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.

Signature of requesting Department's Commissioner or Chief Executive (or designee within the Commissioner's Office):	<i>By signing below, I signify that my Department requests, and I approve of, this Waiver of Competitive Bidding.</i>
Printed Name:	
Date:	16 July 19