

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, DS, HETL, Sue Dowdy
Est. Contract Amount:	\$ 16,000	Contract or RQS Number:	RQS 10A 20190621*1371
		Purchasing Maine ID:	VC1000009175
		DHHS Agreement Number:	CD0-19-5420
Proposed Start Date:	8/1/2019	Proposed End Date:	3/31/2022
Vendor/Provider Name, City, State	BioSearch Technologies Genomic Analysis by LGC 3600 Minnesota Street, Alexandria MN 56308		
Short Description of Good or Service:	This request is for a 3-year Master Agreement with BioSearch Technologies. This vendor provides primers and probes, with Analyte Specific Reagents (ASRs), which are defined as "antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification.		
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 Procurement Services website: From: <u>7/3/2019</u> To: <u>7/9/2019</u>	
Notice of Intent to Waive Competitive Bidding Number:		NOI# 0720191155	
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.

A molecular probe is a small DNA or RNA fragment that recognizes the complementary sequences in DNA or RNA and allows identification of the target sequence. Primer is a small stretch of DNA or RNA which serves as a starting point for DNA synthesis. Primers and probes hybridize with the complementary nucleotides of the template DNA or the target DNA. However, the key difference between probe and primer is that primers are necessary for DNA replication while probes are necessary for detection of specific sequences in the sample DNA. Primers and probes are utilized for our polymerase chain reaction (PCR) procedures where a single copy or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a DNA sequence are amplified. PCR allows for rapid and highly specific diagnosis of infectious diseases, including those caused by bacteria or viruses.^[32] PCR also permits identification of non-cultivable or slow-growing microorganisms such as mycobacteria, anaerobic bacteria, or viruses from tissue culture assays and animal models. The basis for PCR diagnostic applications in microbiology is the detection of infectious agents, and the discrimination of non-pathogenic from pathogenic strains by virtue of specific genes.

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 for the State of Maine. Use of the appropriate kits, reagents, and supplies with the specific instruments is necessary, to comply with, and to follow CDC/FDA guidelines.
- b) HETL is the State of Maine's 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, to allow epidemiologists to conduct contact investigations quickly, thereby reducing the spread of the disease, as well as the disease burden. Rapid test results, for operating under the influence (OUI) program, allows for convictions to occur, in a timely manner.

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**.

The CDC protocols, HETL's current Standard Operating Procedures (SOPs), and current validation reports all use BioSearch primers and probes.

To change vendors, and not use BioSearch would cost HETL \$198,880 to validate the new primers and probes. According to HETL's regulatory body, CLIA, §493.1255 Standard: Calibration and calibration verification procedures; (i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. §493.1256 Standard: Control procedures. (6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced.

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The total estimated cost for the 3-year duration of the Master Agreement is based on purchasing history with this vendor and anticipated need.

5. Future Competition

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

There are no future opportunities to foster competition for these goods, or services, unless HETL re-validates the sets of primers and probes, utilized by the laboratory.

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.

BioSearch primers and probes are lyophilized, which give them a longer shelf life and can be stored in a refrigerator. In comparison, IDT primers and probes are liquid, which gives them a shorter shelf life, and need to be stored in a freezer.

When requesting quotes from BioSearch and IDT for: 5' Cal Fluor Red 610-CAGTCGGCCTTGCGTGAGTGGG-BHQ2 3', IDT was unable to provide a quote, as they do not have required licensing to provide a quote for Cal Fluor Red 610.

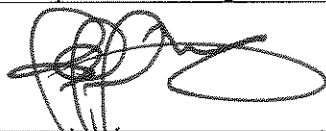
7. Timeframe (Complete only if B. is the Statutory Justification marked on Page 1)

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:

Jeff Wiley

Date:

17 MAY 2019