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Request for Proposals

COVID-19 Pandemic Response:
Accelerating Coronavirus Testing Solutions (ACTS)

October 2020

Submitted by the Massachusetts Life Sciences Center

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PROJECT OVERVIEW

By any measure, Massachusetts' life sciences ecosystem is one of the most robust in the world. Whether you measure public or private investments, top research universities and academic medical centers, STEM education, R&D infrastructure, talent, or life science companies, Massachusetts leads the way in bringing healthcare innovations to patients. This life science community can positively and quickly impact the current COVID-19 pandemic, and in many ways, already has. The Massachusetts Life Sciences Center is in a unique position to accelerate this impact by identifying, supporting, and funding novel innovations and solutions for SARS-CoV-2 testing. The Center is soliciting proposals to improve testing solutions and address supply chain logistics bottlenecks during this critical time to ensure the safety of its constituents and the world.

To consider how we can return to everyday activities as safely as possible in the face of an ongoing COVID-19 pandemic, it is imperative that we rapidly identify infected individuals. Curbing the pandemic relies on the implementation of Testing, Tracing, and Supported Isolation (TTSI) strategies.

Currently, the Commonwealth is largely dependent on PCR tests, which requires analysis of specimens in an offsite laboratory. The development of a low cost "at home" test or point of care test is critical to further scaling up rapid SARS-CoV-2 testing. Additionally, supply chain bottlenecks are emerging for molecular testing. A whitepaper from McKinsey and Company¹ identifies RNA extraction kit manufacturing and laboratory capacity as the main limiting factors to large-scale testing. In the short term, the authors encourage maximizing and expanding laboratory capacity and exploring alternative testing protocols for the longer term. Specifically, supply chain logistics around upstream sample collection and processing are limiting steps to the interoperability of sample processing. Increased universality of sample collection and processing can aid in the management of testing capacity. These represent significant challenges that need to be considered as novel tests and technologies are developed.

The need for more rapid, scalable tests, and solutions for addressing the supply chain logistics, especially in the cases of high-throughput machines with proprietary plastic ware and reagents, is critical as the Commonwealth considers how to continue to reopen as safely as possible.

This project call seeks to leverage Massachusetts' research and development capabilities and innovation infrastructure to accelerate the development of improved testing modalities and address supply chain logistical bottlenecks that hinder our ability to quickly and effectively combat and contain the COVID-19 pandemic.

ORGANIZATION BACKGROUND

¹ Behnam, Mohammad, et al. "COVID-19: Overcoming Supply Shortages for Diagnostic Testing." *McKinsey & Company*, McKinsey & Company, 15 July 2020,

www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/covid-19-overcoming-supply-shortages-for-diagnostic-testing

The Massachusetts Life Sciences Center is an economic development and investment agency with a mission of supporting the growth and development of the life sciences in Massachusetts. Through public-private funding initiatives, the Massachusetts Life Sciences Center supports innovation, research and development, commercialization, and manufacturing activities in biopharma, medical devices, diagnostics, and digital health.

As a quasi-public agency, the Massachusetts Life Sciences Center's mission is to serve as the "hub" of the Massachusetts life sciences ecosystem, encourage innovation through investments in sound science and good business, strengthen and protect Massachusetts' global leadership position in the life sciences, accelerate the commercialization of promising treatments, therapies, and cures that will improve patient care, and create jobs and drive economic and STEM workforce development.

Since mid-March, the MLSC has worked with various groups to support the COVID-19 response in the Commonwealth, including the <u>Manufacturing Emergency Response Team</u>, <u>Massachusetts Consortium on Pathogen Readiness</u>, and the Massachusetts Testing, Tracing and Supported Isolation Collaborative.

ELIGIBILITY

Applicants can be Massachusetts-based for-profit companies or non-profit institutions, which includes research institutions, academic medical centers, and colleges and universities.

Municipalities or other governmental entities are NOT eligible to apply.

- Each application must be authorized by a senior leader of the applying organization (e.g., President, CEO, Executive Director, Dean, Chancellor, etc.).
- Applications should focus on developing innovative low cost "at home" or point of care testing modalities or addressing supply chain bottlenecks or logistical issues for testing SARS-CoV-2. Generally, the MLSC funds support life sciences as defined as:
 Advanced and applied sciences that expand the understanding of human physiology and have the potential to lead to medical advances or therapeutic applications including, but not limited to, agricultural biotechnology, biogenerics, bioinformatics, biomedical engineering, biopharmaceuticals, biotechnology, chemical synthesis, chemistry technology, diagnostics, genomics, image analysis, marine biology, marine technology, medical devices, nanotechnology, natural product pharmaceuticals proteomics, regenerative medicine, RNA interference, stem cell research, and veterinary science.
- Project requests must be fully justified. The requested funds can only be used to support direct labor and capital costs (e.g., equipment, supplies) related to the project.

Applicants must explore all options for funding and equipment requests (e.g., loaning equipment from a neighboring institution or partner, internal funding, etc.).

- Projects will be evaluated, in part, based on the level of support and funds already identified and raised by the Applicant for the project. In general, the more MLSC dollars are leveraged by other funds, the stronger the application will be.
- All funds must be spent before June 30, 2021. The applicant will forfeit any funds not spent by this date.
- The Applicant must be in compliance with all other MLSC agreements they are a party to, if any.

SCOPE OF WORK

The MLSC is requesting proposals to increase SARS-CoV-2 testing capacity. Projects funded under this grant may fall into one of two priority response areas:

- Development of Rapid, Innovative "at home" or Point of Care Testing Modalities: We aim to support testing innovations that are easier and quicker to perform and can be done by patients outside of a healthcare practitioner's office.
 - O Solutions that provide a low cost, surveillance testing technology that can be deployed independent of CLIA approval or medical personnel are encouraged to apply. Solutions that cost less than \$10 per test are of particular interest.
 - O Solutions that will provide a low cost test with greater than 75% sensitivity and ideally 95% specificity are encouraged to apply.
- Addressing Supply Chain Bottlenecks: Innovations or increased or novel manufacturing capacity that can address the supply chain bottlenecks for existing platforms are encouraged to apply. The MLSC is aiming to support the development of novel technologies to address the lack of specialized plastic ware and development of generic reagents and supplies to allow labs across the Commonwealth to fully utilize and leverage their existing high throughput testing platforms. To the extent that applicants are proposing supply chain solutions to a closed system, which involves proprietary technology, applicants will need to demonstrate that they have taken into consideration the requirement for any necessary approvals from the manufacturer of the proprietary system.

An application may address a well-defined issue beyond the priority areas identified above but needs to clearly articulate the positive impact on SARS-CoV-2 testing. Applicants are encouraged to provide solutions that significantly increase testing capacity across the Commonwealth.

APPLICATION

Applications will be accepted online via the MLSC's application system: https://mlsc.smartsimple.com/. Applicants will be asked to provide the following:

- Application Narrative: Five pages maximum narrative outlining the proposed project. Applicants will be asked to address the following:
 - What is the unmet need or gap in SARS-CoV-2 testing the proposed project aims to address?
 - O Describe the proposed novel testing modality or supply chain solution.
 - What community and institutional support does the proposed project have?
 - What equipment, capabilities, and research currently exist and what additional work needs to be done to develop the solution?
 - O What needs to be done to implement the solution here in Massachusetts (e.g., manufacturing, adoption of method or process)?
 - Who are the target beneficiaries of the proposed project?
 - O What partners are involved in the project? What are their roles? For novel tests, manufacturing and distribution partners, and/or reasonable scaling plans are required.
 - O What additional support will be leveraged to contribute to this effort? (Funds, in-kind contributions, loaner equipment, staff, etc.)
 - O What are the milestones and timeline that will bring the proposed solution to the community?
- Budget: Applicants will be asked to provide an itemized list for all equipment to be purchased through the MLSC funds. Please see the awards section below for more information about allowable costs. In addition, applicants will be asked to provide a onepage budget narrative that covers the following topics:
 - The overall budget for the proposed project and what fraction will be covered by MLSC funds vs. other funds
 - Support or justification for budget estimates
 - Outline of the financial support being provided by the Applicant's institution or organization
 - O Describe what financial contribution project partners will provide
 - Provide a high-level timeline for the expenditure of funds

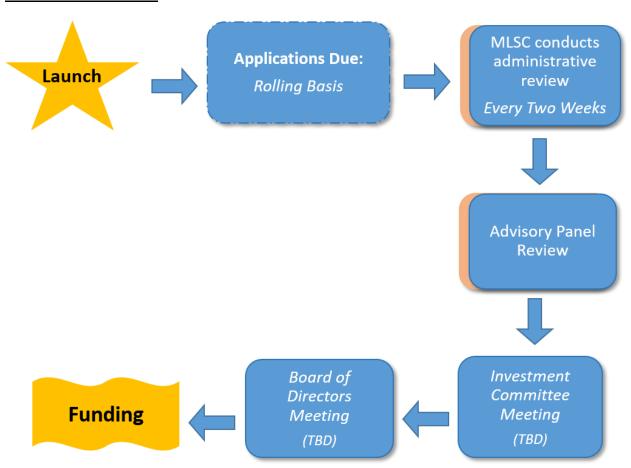
EVALUATION CRITERIA

The following criteria will be considered in determining the competitiveness/strength of an application:

- Ability to address a priority area as identified in the RFP
- The team's capability to execute the project within the funding period; time to patient and/or implementation will be significantly considered
- Ability to leverage additional resources (funding, supplies, equipment) to supplement the eligible expenditures covered by the MLSC grant

- Probability of both scaling here in the Commonwealth and positively impacting the health of its constituents
- Potential for driving economic development in Massachusetts
- Contributions to the Massachusetts life sciences ecosystem, its culture of innovation, and workforce

APPLICATION PROCESS



After the program's launch, the application and review cycle is anticipated to take at least four weeks. Typically reviewing and making funding decisions take several months, but in light of the global pandemic, the MLSC will make best efforts to expedite review and decisions.

Application Period: Responses to this RFP will be accepted on a rolling basis and will be evaluated in two week cycles. Applications for the first cycle will close on October 16, 2020 at 12 pm EST and subsequent cycles will close every two weeks after that point. Applications will only be accepted through the MLSC's online application system, found here.

After submitting, applicants may be asked to provide additional information or answer questions about the proposal at any point during the review cycle.

After the initial application and evaluation period, the MLSC may reopen the program for additional applications based on the availability of funding and the quality of applications.

EVALUATION AND AWARDS

Evaluation:

- The MLSC's staff will conduct an initial screening of each application.
- Members of an external review panel, including entrepreneurs, clinicians, scientists, public health experts, and individuals from academia and industry, may be assigned to evaluate applications based on their expertise.
- Upon invitation, an applicant may be invited to virtually meet with the review panel to
 present their proposal and address questions for clarification. The MLSC will notify such
 applicants in advance and provide additional instructions.
- The review panel and MLSC staff will recommend awardees to the MLSC's Board of Directors.
- The MLSC reserves the right to ask the applicant to provide more information or clarification at any stage of this process.

Awards:

- Allowable costs for the MLSC funds include software/technology, equipment and research supplies, and direct labor. Costs for this project are to be spent by the primary applicant.
 - Non-fundable expenses include legal expenses, travel, paying off debt, paying board members, paying for operating costs such as rent and utilities, and activities funded by other funding sources.
- After the MLSC's Board of Directors confirms Awardee(s), the Awardee will be expected
 to enter into a Grant Agreement (the "Agreement") with the MLSC that contains certain
 standard provisions. The MLSC reserves the right to amend the standard form of
 Agreement at any time without reissuing this Solicitation. The MLSC will not seek to
 procure any intellectual property rights in the agreement.
- Following execution of the Agreement, funds will be provided based on an appropriate reimbursement structure relative to the award amount.
- The MLSC reserves the right to include periodic deliverables based on the duration of the Grant.
- The MLSC reserves the right to adjust the requested amount of funding for each proposal.

CONFIDENTIALITY

MLSC is subject to the requirements concerning disclosure of public records under the Massachusetts Public Records Act, M.G.L. c. 66 (Public Records Act), which governs the retention, disposition and archiving of public records, such as written materials, financial statements, statistical tabulations, and other documentary materials or data. As a result, applicants should

be aware that any information submitted to MLSC is subject to public disclosure as set forth in the Public Records Act.

There are, however, exceptions. "Public records" do not, for example, include documents containing trade secrets, such as commercial or financial information regarding the operation of any business conducted by a company or other institution or regarding the competitive position of a company or other institution in a particular field. In the event that an applicant wishes to submit certain documents to MLSC and believes such a document or documents may be proprietary in nature, the applicant should identify such materials in its application as Confidential. MLSC's General Counsel is the sole authority within MLSC for making determinations on the applicability and/or assertion of an exemption to the Public Records Act. All documents submitted by the applicant, whether designated as "Confidential Information" or not, are not returnable.

General Conditions

Contractual Requirements

The MLSC intends to enter into an Agreement with the Awardees containing certain standard provisions. The MLSC reserves the right to amend the Agreement without further issuance of another solicitation. Please be advised that this standard Agreement must be executed in substantially the form provided and the terms and conditions therein are non-negotiable.

Waiver Authority

The MLSC reserves the right, at its sole discretion, to waive minor irregularities in submittal requirements, to request modifications of the application, to accept or reject any or all applications received, and/or to cancel all or part of this solicitation at any time prior to awards.

Disclaimer

This solicitation does not commit the MLSC to award any funds, pay any costs incurred in preparing an application, or procure or contract for services or supplies. The MLSC reserves the right to accept or reject any or all applications received, negotiate with all qualified Applicants, cancel or modify the solicitation in part or in its entirety, or change the application guidelines, when it is in its best interests. An application does not constitute an award.

Changes/Amendments to Solicitation

This solicitation has been distributed electronically using the MLSC's website. It is the responsibility of Applicants to check the MLSC's website for any addenda or modifications to the

Solicitation to which they intend to respond. The MLSC, the Commonwealth of Massachusetts, and its subdivisions accept no liability and will provide no accommodation to Applicants who submit an application based on an out-of-date solicitation document.

Please direct any questions about this RFP to Covid@MassLifeSciences.com