RAPID TESTING INNOVATION COMPETITION

Question & Answer

Updated 10/14/2020

Testing Product Type

1. **Are you only considering molecular and/or antigen tests, or will other testing technologies (such as VOC measurements) be considered as well?**

   Yes, we are open to all testing technologies that will deliver rapid, accurate results and receive all regulatory approvals.

2. **Are you open to proposals that do not meet all the requested criteria? Such as tests that are undergoing study but are not immediately able to be commercialized?**

   We are open to proposals that are early in development and there may be opportunity to partner with other participants. Proposals should have a path identified to commercialization in the near future.

3. **Is the competition open to sensor-based solutions?**

   Yes, we are open to all testing technologies that will deliver rapid, accurate results and receive all regulatory approvals.

4. **Do tests need a digital component for reporting to the various health agencies?**

   We cannot provide definitive guidance, but preference is for all tests to allow for reporting to local, state, and federal health agencies. For up to date guidance, please refer to current FDA guidelines for at-home tests.

5. **We would be applying for funding for assay optimization, clinical validation, and app development for results reporting. Is this in line with what the call could fund?**

   There is no defined prize pool, and respondents may propose various types of City support such as, direct funding, utilization of City-owned real estate, assistance from health agencies, etc. for support, including, without limitation, for test development, commercialization, and deployment.

6. **The test we have developed could be run in a lab as an automated high throughput assay that is highly sensitive, equally cheap, with processing time of 1–2 hours and time from sample collection to results communication of 8–24 hours. Would this competition consider funding for such a test?**

   This competition is seeking to identify tests that do not require offsite processing in a moderate or high complexity laboratory, however we understand that there are many use cases for different types of tests and welcome submissions that will dramatically reduce turnaround time and increase throughput.

7. **Is it a requirement that the test ultimately receive an FDA EUA? To the extent an EUA is required, can the NYC EDC help with the political challenges (those beyond the merits of the test) in securing an EUA.**

   The test should ultimately receive the necessary regulatory approvals for use, whether federal or state are appropriate can be case specific. NYCEDC may be able to help with certain aspects of a submission.

8. **Would we be eligible without clinical or preclinical studies aside from ELISA?**

   We understand applicants will be at different phases of development and would expect to see plans laid out to make progress from current state to broad use commercially. As part of that, the test should ultimately receive the necessary regulatory approvals for use, whether federal or state.

9. **I noticed the 45-minute limit on turnaround time. I assume that is per test. Our technology takes around 1-2 hours, but it would be anything from 1 sample to 100 and then about 1 hour extra for every additional 100 samples. Would you consider that?**

   The preference is for tests that return results as quickly as possible, however we understand that there are many use cases for different types of tests and welcome submissions that will dramatically reduce turnaround time and increase throughput.

Applicant Criteria

1. **Is the competition open to submissions from outside NYC?**

   This is a global competition. Applicants from outside NYC and across the international community are invited to apply.

2. **Will proposals that involve building a production facility in (or near) NYC vs. already having a high capacity supply chain in place, be given preference?**

   Applicants are encouraged to include information about how test development and manufacturing may directly benefit the New York City economy; the preference is for rapid deployment.

3. **Can a small startup of 5 people apply?**

   Yes, there are no restrictions on team size.

4. **We don't have prior experience with FDA, will this be an issue?**

   The test should ultimately receive the necessary regulatory approvals for use. Prior experience with the FDA does not matter to our competition as long as necessary approvals are obtained.

5. **We are a group of biotech scientists, and don't have any software development experience. Section 1.4 requires the results to be communicated to the city/state/federal agencies. We currently don't have this ability. Will this be an issue?**

   It is a requirement that results are communicated to the relevant agencies. If your team does not currently have that ability, you should detail what steps and resources are required to accomplish that goal in the future.

Deployment

1. **Will the tests be used primarily in NYC or also in NY State or elsewhere?**

   This is a NYC-focused competition. Please only include information that is pertinent to deployment of your product in New York City.

City Resources

1. **Is there a budget ceiling? Is there a budget template that should be used?**

   There is no maximum amount of funding request, however respondents should provide reasonable justification for their funding need, whether funding will be available for any, or none, of the submissions will be in the City's sole discretion.

2. **Please provide additional detail on the city resources that will be made available in the competition.**

   Submissions may propose ways the City could support the development and deployment of the subject test. Some examples of City support could include Health and Hospitals Corporation (HHC) or Department of Health and Mental Hygiene (DOHMH) staff providing guidance on validation study structure, leases at City-owned real estate assets, or advance purchase agreements. These are all illustrative examples, specific support that will be made available, if any, will be determined, in the City's sole discretion, after proposals are assessed.

Application Process

1. **Will submissions remain confidential? Our test is currently under development and uses proprietary technology.**

   Application materials will only be available to competition reviewers and will not be posted publicly, however NYCEDC and/or the City could have obligations to disclose materials under the Freedom of Information Law (FOIL), unless such information falls into one of FOIL's exceptions, such as being a trade secret. Applicants should include as much information as possible in order for an informed assessment to be made of the proposal, however if applicants choose to exclude any pertinent pieces of information to protect against breaching confidentiality, please include an explanatory note.

2. **Is it a requirement to disclose details of raw material suppliers at this stage of the competition?**

   No, this is not a requirement, however if this is an important part of your proposal you should provide as much detail as possible to allow for a complete proposal evaluation.

3. **Is there a page limit for the application?**

   There is no page limit, but applicants are encouraged to make their proposals concise.

4. **What does "successful use of QRI with individuals" mean?**

   QRI stands for quick reference instructions. Your proposal should show any studies that illustrate effective use of QRI with individuals (if applicable).

5. **What does "Provide data at various cycle threshold (C_t) levels" mean for tests that do not involve any florescence generation or detection?**

   We would like to understand performance at varying degrees of viral load. Please show data, whether at varying C_t levels or via other metrics, to address a range of infection.

6. **What volume tiers should the proposal include test pricing for and what delivery frequency (per week, month, quarter, etc.)?**

   There is no preferred frequency, please present what is most applicable to your proposal.

7. **Please provide any Indemnification Agreements that will be required in any contracts that are going to be executed in accordance with this agreement. Please provide exact Insurance requirements for any and all insurance that will be required. Will any Surety Bonds be required? If so, describe type and amount.**

   To the extent contracts are entered into, if any are entered into, requirements will be based on the details of each such contract.

8. **Could you please explain the time scale of this announcement? My lab might be interested, but we would need more time.**

   Revised October 9, 2020: NYCEDC will now accept applications on a **rolling basis,** in two-week cycles. Applications for the first cycle will close on **October 14, 2020 at 6pm EST**. Subsequent cycles will close every two weeks after that point, with the new submission date updated on the competition website. Cycles will continue on a rolling basis until NYCEDC posts the final submission date on the competition website, at which point there will be one final, two week cycle for submissions. NYCEDC will also accept questions on a rolling basis and will post answers to the website by 6pm EST every Wednesday as long as the competition is open. The city intends to move quickly with the most promising submissions, so we highly encourage applicants to submit as soon as possible.

9. **Should we submit one application if we have multiple technologies that are applicable? Or should we submit multiple applications?**

   Each technology should have its own application in order to facilitate accurate review. However, sections that will be identical across applications such as team structure or experience may be reused across the individual applications.