RAPID TESTING INNOVATION COMPETITION

New York City's Testing Need

The success of New York City's Test and Trace program has facilitated a safe and steady economic reopening; the City is seeking to significantly increase the availability, usability, and speed of testing to further reopen the economy in the period prior to broad distribution of a vaccine.

Specifically, New York City seeks point-of-care and at-home COVID tests that can deliver results in minutes, rather than hours and that may be self-administered. There are only a handful of COVID tests that have Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and are allowed in a CLIA-waived setting ("rapid tests"), however, many are in development and the FDA has recently issued guidance for at-home and over-the counter diagnostic tests.

COMPETITION OBJECTIVE

To accelerate the development and deployment of rapid tests, New York City Economic Development Corporation (NYCEDC), on behalf of the City, is seeking to identify companies developing innovative molecular or antigen rapid tests that can deliver results quickly, reliably, and at scale. Diagnostic test manufacturers, suppliers, developers, and academics are invited to submit proposals per the below guidelines. Selected respondents may have the opportunity to advance product development through access to City resources. Such resources could include, without limitation, the expertise of health agencies, City-owned real estate assets for R&D and manufacturing, or contracts for purchase of rapid tests.

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RAPID TEST CRITERIA

While existing CLIA-waived tests offer relatively quick turnaround times (TATs) of less than one hour, their reliance on a dedicated instrument limits how many such tests can be processed in any given time period. Submissions for instrument-dependent tests are permitted for this competition, but preference will be given to all-in-one solutions that are not dependent on instrumentation and healthcare personnel administration. Submissions will be assessed on how well they address the below criteria:

1. **Easily usable by individuals** – Targeting approval for use either at-home, in a non-medical setting (such as a performance venue), or a point of care; versatility with sample types and simple collection methods.

2. **Deliver quick, accurate results** – Goal for TAT of less than 15 minutes though max of 45 minutes if there are acceptable tradeoffs with other elements of test; assay performance; meets all regulatory requirements (NYS DOH CLEP, FDA, CLIA, and other applicable regulatory bodies).

3. **Inexpensive and scalable** – Eventually able to administer millions per day; price of less than $10 per test (preference for less than $5 per test); disposable, reusable, or recyclable consumables with focus on broad distribution and high throughput; minimized environmental footprint is preferred.

4. **Communicate results to patient and health agencies** – Simple visualization of results on the test (such as pictograms) to easily communicate results to multi-lingual populations; display results within a HIPAA-compliant app, website, or phone system to reach those without internet or smartphone access; data integration with health agencies.

PROPOSAL REQUIREMENTS

Respondents should include the following information in their proposals. If you are unable to provide a response for a particular section, please include explanation for omission:

Section 1: Product and Team Description

1.1. **Background and Qualifications** – Respondent's prior experience as a diagnostic test supplier and with COVID specifically. Should include details about the team, technology, and process. Note participation in NIH RADx, Xprize, or other ongoing rapid test competitions.

1.2. **Description of test steps/procedure** – Provide detailed description of the testing process including technical specifications of the test (e.g., nucleic acid sequence, chemistry, primers, and probe sets), specimen collection, analysis, and results reporting including TAT. Note intended setting for the test (i.e. CLIA-waived, medium complexity lab, home, etc.).

1.3. **Product description and technical specifications** – Include any diagrams for prototypes, all-in-one solutions, or supplementary instrumentation. Note any required consumables and/or components and how they function with one another. Include any details of supplemental instruments required (e.g., instruments, smart phones, operating systems, camera, and software requirements).

1.4. **Test result reporting (individuals and health agencies)** – Illustrate how patients receive results and any components to improve accessibility. Show how results are communicated to City, state, and federal governments. (Note how all data will be handled in a HIPAA compliant manner). Include details of any proposed software platforms.

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Section 2: Implementation & Performance

2.1. Product manufacturing – Information on manufacturing methods and partners (current and proposed), including plans for scaleup, distribution, and quality control. Procurement strategy, details of suppliers, and status of any existing orders.

2.2. Manufacturing mitigation strategies – A detailed description of how the supplier will deal with potential shortfalls in critical reagents and supplies necessary for consistent production.

2.3. Performance evaluation – Details of clinical validation, human usability, or other studies to-date, including demonstration of adequate internal control or demonstration that adequate sample was collected, limit of detection, sensitivity, specificity, cross-reactivity, successful use of QRI with individuals, mechanisms in place for invalid results, and any other pertinent performance data for consideration. Provide data at various cycle threshold (Ct) levels, for symptomatic and asymptomatic individuals for various age groups. Refer to FDA EUA guidance and NYS CLEP requirements for laboratory developed tests (LDTs)

2.4. Regulatory approvals – Any existing permits including EUA or LDT; demonstrated ability to obtain necessary federal, state, and local permits for lab and production facilities, labs performing tests, manufacturing processes, and personnel.

Section 3: Finances and Schedule

3.1. Scale and price – Current production capacity (number of tests per day and per month) and proposed capacity and maximum production. Include ramp-up schedule. Include pricing at various scales and pricing rationale (e.g. costs for different production components).

3.2. Detailed request for City support – Description of what type of support is needed from the City and proposed financial terms, including how City funding would help scaling and distribution. This support can come in the form of a purchase agreement, operating subsidy, City real estate assets, or other financial support.

3.3. Timeline for implementation – Estimated milestones such as equipment procurement, facility fit out, start, and scale up of production.

SELECTION CRITERIA

Respondents will be evaluated based on the completeness of their applications, performance (or if in development, proposed performance) and technical merit of their product, how well their product meets the stated criteria, and the evaluation of the respondent's ability to implement.

Q & A, SUBMISSION, AND SELECTION PROCESS

Q & A

Revised October 9, 2020: NYCEDC will accept questions on a rolling basis and will post answers to the website by **6 pm EST every Wednesday** as long as the competition is open. Questions may be submitted via email to rapidtesting@edc.nyc.

Submission

Revised October 9, 2020: Participants must submit digital copies of their proposals in PDF format via email to rapidtesting@edc.nyc by **6 pm on October 14, 2020** for the first cycle, and at **6 pm of the submission date of each two-week cycle**. If attachments are too large to transmit via email, please include a file transfer download link in your email to transmit your files.

Selection

Following NYCEDC's review of proposals, it will directly contact respondents it is interested in further assessing.

COMPETITION TIMELINE

Question-and-Answer Response Posting
Rolling, every Wednesday at 6 pm EST

Submission Date
First cycle, October 14, 2020 at 6 pm EST
Every two weeks thereafter, at 6 pm EST

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