XPRIZE RAPID COVID TESTING

COMPETITION GUIDELINES 3.0

August 21, 2020

XPRIZE Rapid Covid Testing is governed by these **Competition Guidelines**. Please send any questions or communications about them to covidtesting@xprize.org. XPRIZE may revise these Guidelines at any time during the course of the competition to provide additional information or to improve the quality of the competition. Unanticipated issues may also arise that will require modifications to these Guidelines. XPRIZE reserves the right to revise these Guidelines as it, in its sole discretion, deems necessary or desirable. All registered teams will be notified of any revisions in a timely manner.

Further details concerning the operation of the competition, such as exact dates and locations of events, specific technical thresholds for performance testing, and operational information will be published in the **Competitor Agreement**, and other documents throughout the course of the competition. The Competition Guidelines summarize the high-level requirements and rules of the competition.

NOTE: Bolded items are defined in Section 06: Glossary.

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Competition Overview

Facing the COVID-19 crisis is proving to be one of the world's most critical challenges. While imposing so-called "lockdown" measures may have been the most practical and responsible initial response for governments to take, it is clear we need a more sustainable, long-term strategy. Reopening our economies, however, is not as simple as it may seem. Many infectious carriers are asymptomatic and can quickly spread the virus. And, for a variety of reasons, safety precautions that could mitigate the spread (such as social distancing and wearing facemasks) have become contentious issues.

We need a better solution – one that's focused on testing. Current testing solutions, however, offer their own set of challenges. Many are slow to produce results (patients can easily get infected during the time in between test-taking and receiving a negative result). Others are prohibitively expensive, and can also be uncomfortable to use, which discourages people from frequently testing – or even testing at all. To safely reopen our economies and societies, we need testing that is frequent, fast, cheap, and easy to use. Some existing testing solutions might meet some of these requirements, but no test exists which meets all of them.

Together, the XPRIZE Foundation and OpenCovidScreen have partnered to launch XPRIZE Rapid Covid Testing. This prize competition will incentivize and accelerate the development of high-quality, affordable COVID-19 tests that can be used for screening proposes. With tests like this, schools, businesses, and other crucial institutions will be able to identify infected individuals before they develop symptoms. By detecting these cases early, infected individuals can seek medical attention and isolate themselves until they've recovered, allowing the rest of society to function normally.

Teams will be selected to enter the competition through the following modalities (i.e. primary or distinguishing technology): PCR, Isothermal Amplification, Next Generation Sequencing, and Antigen Detection. Testing technologies can involve one or more of these modalities. There will also be an additional modality for Open Innovation – technologies that do not fit with the abovementioned modalities, but that show high potential for impactful screening solutions.

There will be no limit to how many teams are selected to enter or win the competition for each modality. Therefore, some modalities may have multiple winning teams, while others might have no winning teams. Teams that could be placed in multiple modalities need not be concerned that any categorization will affect their chances at winning.

Over the course of roughly six months, top-performing teams will be selected through a series of rounds:

- **Semi-Finalist Round:** The first round will require the top 200 registered teams to check their solutions against a blinded proficiency test.
- **Finalist Round:** The top 20 best performing teams will then have the opportunity to gain clinical validation from two world-class laboratories based in the United States, helping to accelerate the FDA approval process.
- **Pilot Round:** Finally, the top five teams will be selected to trial their solutions on real individuals at sites around the country (possible locations include schools, offices, factories, nursing homes, and prisons). Teams will be allowed to employ pooling techniques to aid in the screening process.

These top five teams will each be awarded $1 million, with the possibility of multiple teams winning within the same modality. Each winner's testing protocol and implementation instructions will be documented in a multimedia playbook for global dissemination. In the year following the conclusion of the competition, this playbook will be used to aid testing sites around the world in the broader effort to end the pandemic.

The winning teams will:

- Develop COVID-19 tests for screening that are radically affordable compared to what is currently available on the market,
- That are comparable to commercial offerings at measuring sensitivity, specificity, and limit of detection (LoD),
- With a maximum turnaround time of 12 hours from sample to result.
- Teams must also successfully deploy and conduct a minimum of 500 tests per week at a live testing site for 60 days.

Competition Structure

This competition is structured into three rounds over approximately six months. Following the main competition, additional time and resources will be committed to scaling the impact of the winning teams' solutions, as shown in Table 1, below.

Table 1: Competition Timeline

Begin	End	Milestone
July 28, 2020	July 28, 2020	Competition Launch: Team Registration Opens, Guidelines Posted
	September 8, 2020	Registration Deadline; Qualifying Submission and Competitor Agreement Deadline, Semi-Finalist Teams Announced
	October 6, 2020	Finalist Teams Announced (up to 20 teams)
October 6, 2020	October 20, 2020	Finalist Round: Qualified Teams Clinical Validation
October 20, 2020	November 2, 2020	Finalist Judging
	November 3, 2020	Pilot Teams Announced (up to 5 teams and 5 alternate teams)
November 3, 2020	November 17, 2020	Supply Chain and Pilot Site Preparation
November 17, 2020	February 8, 2021	Pilot Round: Deployment
	TBD Early February 2021	Grand Prize Winners Announced
February 2021	December 2021	Scaling Impact Phase

TEAM REGISTRATION

The first step for a team to participate in the competition is to create an account on the Prize Operations Platform (POP) – a multipurpose, online platform hosted by XPRIZE. Teams are expected to maintain their POP profiles throughout the competition, ensuring their profile is up to date with the most recent team information.

Registration Deadline & Fee

The deadline to register is September 8, 2020 18:59:59 UTC. Late entries will be admitted on a case-by-case basis at the Judging Panel's discretion. The registration fee is $100 (USD).

Competitor Agreement

After paying the registration fee, teams must sign and submit the Competitor Agreement. Teams will not be allowed to compete until they have submitted the Competitor Agreement.

Team Collaboration & Webinars
Teams and individuals are encouraged to collaborate and share skills. A team may recruit additional experts, including frontline workers, and can add new members to their team at any time throughout the competition. Teams may also merge with other teams during the competition. Teams must notify XPRIZE (via POP) of a merger before it takes place. Additional details regarding team mergers will be provided in the Competitor Agreement.

During the registration period, XPRIZE may host webinars for all Registered Teams. XPRIZE webinars will allow teams to get to know each other and also to receive important competition updates. Participation in these webinars, while not mandatory, is strongly encouraged.

SEMI-FINALIST ROUND: PROPOSAL SUBMISSION & BLIND PROFICIENCY TEST
After completing Team Registration, teams must submit the Qualifying Submission. The Qualifying Submission is a detailed questionnaire pertaining to the team's qualifications, experience, technology, and potential for scalability.

The Judging Panel will review each teams' Qualifying Submissions and assign either a 'Pass' or 'No Pass' based on the judging criteria. Up to 200 teams will receive a 'Pass' and be allowed to continue in the competition as Semi-Finalists. Teams that receive a 'No Pass' will not continue further in the competition.

Passing teams will be sent a blinded proficiency test kit and be required to accurately identify which samples contain SARS-CoV-2 material (spanning nucleic acids, contrived samples, and encapsulated virus). The kit will not contain infectious virus. Teams will have one week to submit their results to the XPRIZE Data Collaborative. Teams will be provided a template for submitting their results.

The results will be scored on specificity, sensitivity, and limits of detection. The Judging Panel will select up to 20 teams to advance to the Finals Round (Clinical Validation).

Open Innovation Modality
Teams whose approaches that cannot be categorized as PCR, Isothermal Amplification, Next Generation Sequencing, or Antigen Detection will be included in an Open Innovation modality. These teams will be asked to submit a detailed explanation of their technology and must include a video demonstration that will be viewed and evaluated by the Judging Panel. Top teams within this category that have the potential to successfully complete each round of the competition (i.e. blinded proficiency testing, clinical validation, and pilot site testing) will be selected to compete in the competition.

FINALS ROUND: CLINICAL VALIDATION
Finalist Teams will have one week to send their testing kits and protocols to two separate laboratories for clinical validation. To ensure a fair competition with comparable results, samples within each lab will be split and tested across multiple tests to generate intra-lab rankings. The

labs will follow the teams' outlined protocols, perform clinical validation, and submit the results to the Data Collaborative.

The Judging Panel will have one week to review the results from the clinical labs and choose the top five teams to advance to the Finals Round (Deployment), along with five alternate teams:

- The top five best performing teams (as measured by clinical validation results) will each receive a $500,000 Milestone Award ($2.5 million in total). **Note: The $500,000 Milestone Awards must be used for the sole purpose to further the team in the competition. If a team withdraws from the competition while they have received monies to advance to the Pilot Round, they must return the Milestone Award. Please see the Competitor Agreement for more information.**
- Five alternative teams will be identified by the Judging Panel in the event that Finalist Teams are unable to complete the pilot testing requirement in the allotted time frame.

While the goal is to have one team selected for each modality (PCR, Isothermal, Next Generation Sequencing, Antigen), some modalities may end up having more than one finalist, while others may not have any finalists, depending on the Judging Panel and a range of parameters.

PILOT ROUND: DEPLOYMENT and LAUNCH

In the Pilot Round, each of the top five teams will be assigned to one of five pilot test sites around the United States in order to demonstrate the effectiveness of their testing solutions in a real world scenario. The Pilot Round is split into two distinct phases, as explained below.

Phase 1: Pilot Site Preparation and Scaling Supply Chains

In order to complete the pilot site testing, each team must be able to successfully perform at least 500 tests per week for a period of two months (a minimum of 4,000 tests needed per team). Teams will be responsible for planning and building out their own supply chains in order to accomplish this task. Teams should plan to produce a sufficient amount of additional tests to account for product damage/loss/shrinkage, onsite mishaps, and other issues.

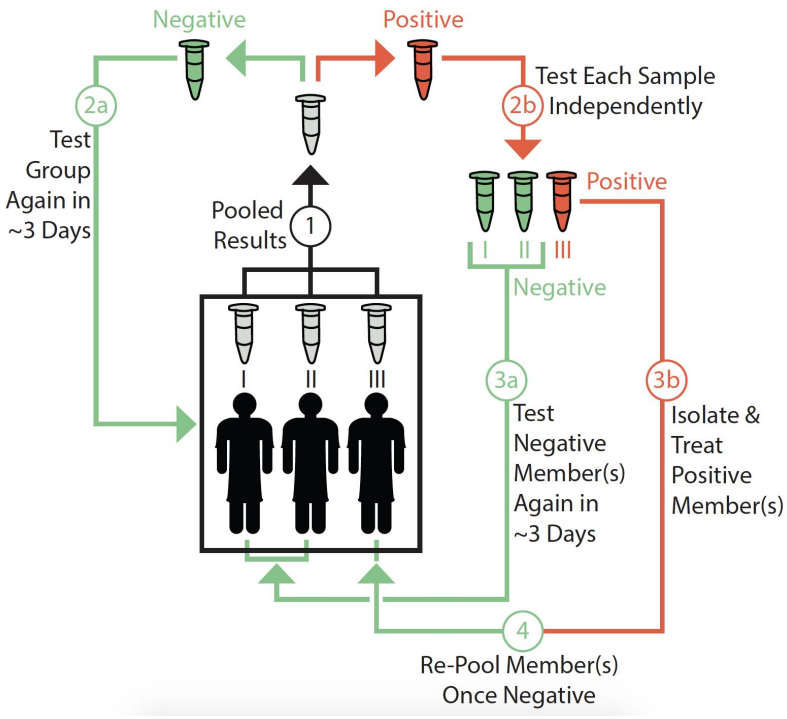
Prior to this phase, XPRIZE will have identified five optimal pilot test sites. While the five teams are building their testing supply chains, XPRIZE will pair them with one of the five test sites. Pilot sites and teams will collaborate to determine specific requirements, including those related to site-specific logistics, infrastructure, refrigeration, contact persons, guidelines, and special protocols. Pilot sites will be responsible for any/all costs associated with preparing for testing. Teams will be responsible for any/all costs associated with their tests, reagents, and other materials.

Phase 2: Pilot Site Testing

Teams will either travel to their pilot site, or work remotely with local teams to implement their protocols. Each week, teams must conduct a minimum of 500 tests.

Individuals that test positive for COVID should be reflexed (i.e. referred) to a clinical testing partner for official diagnosis.

Pooling
In order to increase testing capacity, test sample results from multiple people can be "pooled" together in groups of two or more. When a given "pool" tests ***positive*** for COVID-19, the entire pool must be reflexed to a clinical testing partner in order to isolate the positive sample(s). See Figure 2 below for a diagram explaining the pooling process.
Figure 1: Pooling Process Overview



Teams must send their pilot site test results to the Data Collaborative on a regular basis. Teams will be provided a template for submitting their results.

REGULATION COMPLIANCE AND FINAL JUDGING
Once the 60 day pilot test has concluded, the teams' results will be validated for regulation compliance. The Judging Panel will ensure that test results are in compliance with any/all regulations, including those related to the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR).

The Judging Panel will have two weeks to review the results. Teams that meet the judging criteria will be awarded a final prize of $500,000 each, totalling $2.5 million if all teams are successful.

SCALING IMPACT (DISSEMINATION PHASE)
Following the announcement of the winners, the remainder of the year will be devoted to accelerating the adoption of the solutions that emerge from the competition on a massive scale. XPRIZE will oversee the development of a multimedia playbook documenting the testing protocols and plans implemented at each of the five test sites by each of the Finalist teams.

Testing Criteria

Testing Modalities

Teams are allowed to compete in one of the following four modalities (i.e. primary or distinguishing technology):

- PCR
- Isothermal Amplification
- Next Generation Sequencing
- Antigen

Testing Categories

During the Deployment Round, teams will be grouped into the following testing categories, depending on the type of test they develop:

- **At Home:** Tests that individuals can administer themselves. Single use, includes disposable use testing kits.
- **Point of Care:** Tests that can be easily administered by trained, non-health care workers (for example, a school nurse). Can perform several dozens/hundreds of tests per week.
- **Distributed Lab:** Testing solutions that require results to be sent off to an offsite laboratory. Has capital costs below $10,000 and can perform around 1,000 tests per week.
- **High-Throughput Lab:** Testing solutions that can produce results onsite using advanced automated laboratory equipment. Has capital costs above $10,000 and can perform several thousands of tests per week.

Judging Criteria

The winning teams will:

- Develop COVID-19 tests for screening that are radically affordable compared to what is currently available on the market,
- That are comparable to commercial offerings at measuring sensitivity, specificity, and limit of detection (LoD),
- With a maximum turnaround time of 12 hours from sample to result.
- Teams must also successfully deploy and conduct a minimum of 500 tests per week at a live testing site for 60 days.

The following judging criteria may be used to determine which teams win the competition.

Category	Measurement
Performance	Sensitivity: Results must be greater than or equal to clinical sensitivity results posted by current market offerings.
	Specificity: Results must be greater than or equal to clinical specificity results posted by current market offerings.
	Limit of Detection (LoD): Results must be greater than or equal to clinical LoD results posted by current market offerings.
Speed	Maximum turnaround time of 12 hours, from sample to result.
Frequency	Ability to conduct at least 500 tests per week (4,000 over the two month pilot period) and scalable to thousands per week by replicating the configuration.
Ease of Use	Must use a minimally invasive collection method (buccal swab, anterior nasal swab, or saliva sample).
Cost	On Site Pilot Test Period: Ideally cost less than $15 per test, including all materials and reagents and amortized across capital costs. Post-Pilot Period/Scaling Impact Phase: Economies of scale (cost per test should be less than what it was during on site pilot test period due to scaled production).

Prizes

Prize Purse

The total prize purse for this competition is $5 million.

Prize Type	Amount	Prize Breakdown
Milestone Awards	$ 2,500,000	*Awarded evenly between top five teams ($500K/each)*
Finalist Awards	$ 2,500,000	*Awarded evenly between top five teams ($500K/each)*
Total Prize Purse	**$ 5,000,000**	

Open Science

This competition adopts an ethos of knowledge sharing and collaboration. To this end, a multimedia playbook will be assembled by the end of the competition, which can then be used to scale rapid testing solutions to sites around the world. The contents of the playbook will include the following information pertaining to the top five teams:

- Protocols and standard operating procedures for testing (similar to what is required for FDA EUA authorization).
- Results from the blind proficiency test and clinical validation rounds.

Teams will not be required to release intellectual property secrets or other information that gives them a competitive advantage regarding the commercialization of their innovations. However, teams must include the cost of any and all proprietary components into the cost of their testing solution.

Roles and Responsibilities

ADVISORY BOARD

A. **SELECTION OF ADVISORS.** XPRIZE and its Partners and Sponsors will collaborate to appoint a panel of subject matter experts, and big-picture thought leaders to serve as the Advisory Board for the competition. The Advisory Board will remain in place throughout the competition to advise XPRIZE regarding the scientific and other elements of the competition.

B. **INDEPENDENCE.** The Advisory Board will be independent of XPRIZE, Sponsors, and all teams and team members. No Advisor, nor any member of the Advisor's immediate family, shall participate, nor have any financial or other material interest, in XPRIZE, the Sponsor(s), and/or any team or team member. All members of the Advisory Board shall promptly disclose to XPRIZE any such current, former, or expected future conflict of interest with XPRIZE, the Title Sponsor, or any team or team member.

C. **ROLE OF ADVISORY BOARD.** The duties and responsibilities of the Advisory Board may include, but not be limited to: (i) assisting with the establishment of qualifications for prospective Judges; (ii) recommending members of the Judging Panel; (iii) assisting with development of testing protocols and judging criteria; (iv) and providing input toward the development of these Competition Guidelines.

JUDGING PANEL

A. **SELECTION OF JUDGES.** The Judging Panel (as defined in the Competitor Agreement) will be composed of highly-qualified subject matter experts across a diversity of fields, selected and vetted by XPRIZE, Sponsors, and the competition Advisory Board.

B. **INDEPENDENCE.** The Judging Panel will be independent of XPRIZE, the Title Sponsor, any other prize sponsors, and all teams and team members. No Judge, nor any member of Judge's immediate family, shall participate, nor have any financial or other material interest, in XPRIZE, the sponsor(s), and/or any team or team member. All members of the Judging Panel shall promptly disclose to XPRIZE any such current, former, or expected future conflict of interest with XPRIZE, the sponsor, and/or any team or team member.

C. **ROLE OF JUDGING PANEL.** The duties and responsibilities of the Judging Panel will include, but not be limited to: (i) evaluating teams' compliance with the Competitor Agreement as they relate to prize operations, these Competition Guidelines, and the Rules and Regulations for the purposes of the competition; and (ii) the awarding of points and selection of teams that will proceed to each subsequent round of the competition.

D. **GROUNDS FOR JUDGING PANEL DECISIONS.** Official decisions made by the Judging Panel will be approved by a majority of the Judges that vote on each such decision after careful and impartial consideration of the testing protocols, procedures, guidelines, rules, regulations, criteria, results, and scores set forth in the Competitor

Agreement, these Competition Guidelines, Rules and Regulations, and all other applicable exhibits to the Competitor Agreement. If any vote of the Judges results in a tie, then the Judging Panel shall determine, in its sole and absolute discretion, the mechanism to settle the tie. Similarly, if one or more teams are tied at any stage during the competition, the Judging Panel shall have the sole and absolute discretion to settle the tie.

E. **DECISIONS OF JUDGING PANEL ARE FINAL.** The Judging Panel shall have sole and absolute discretion: (i) to allocate duties among the Judges; (ii) to determine the degree of accuracy and error rate that is acceptable to the Judging Panel for all competition calculations, measurements, and results, where not specified in the Rules and Regulations; (iii) to determine the methodology used by the Judging Panel to render its decisions; (iv) to declare the winners of the competition; and (v) to award the prize purses and other awards. Decisions of the Judging Panel shall be binding on XPRIZE, teams, and each team member. XPRIZE and teams agree not to dispute any decision or ruling of the Judging Panel, including decisions regarding the degree of accuracy or error rate of any competition calculations, measurements, and results. Teams shall have no right to observe other teams' testing or evaluation, or to be informed of other teams' calculations, measurements, and results, unless such information is made publicly available by XPRIZE.

Glossary

Advisory Board: A select group of prominent advisors who contribute their wisdom, knowledge, and guidance to various aspects of the prize.

Competition Guidelines: Document for the public and for teams that describes the requirements and parameters of the competition.

Competitor Agreement: A legal and binding document that details the responsibilities of competitors for the prize.

Data Collaborative: The XPRIZE Data Collaborative is a collection of exclusive datasets and AI capabilities spanning multiple domains. It democratizes access to data and the tools needed to develop solutions, thus enabling teams and collaborators to use these valuable assets to solve the world's most immediate challenges.

Impact: Impact describes the change in peoples' lives. It is most often the result of the immediate work of the teams involved in a certain prize, as well as the long-term results of the competition. It is measured according to the goals of a particular prize or activity, but an XPRIZE competition is expected to have an impact on at least millions of peoples' lives.

Judging Panel: The subject matter and technical experts who serve as an impartial and independent evaluation team for all aspects of this prize. Judges score the team submissions and make the final award determinations in both the Semifinals and the Finals Competitions.

Limit of Detection (LoD): Measure of the test's precision. The lowest concentration of the virus that can be reliably detected.

Prize Operations Platform (POP): The standard internal XPRIZE portal for teams to input data, documents, and other information for use in this competition.

Prize Purse: This refers to money offered, won, or received as a prize. It also refers to the overall amount of funds allocated to all prizes in this competition.

Sensitivity: A test's ability to detect a positive case of COVID. Also known as positive agreement.

Specificity: A test's ability to detect a negative case of COVID. Also known as negative agreement.

Team Definitions:

- **Interested Team**: A team or individual that is interested in participating in the competition and has created a profile in the XPRIZE POP system.

- **Registered Team**: A team that has completed all necessary registration activities, paid the required registration fee (if applicable) and is eligible to submit a Qualifying Submission for the Judging Panel's review.

- **Semifinalist Team (up to 200 teams)**: A team that has been selected by the Judging Panel from the pool of Registered Teams based on the strength of their Qualifying Submission and results of their Blinded Proficiency Test.

- **Finalist Team (up to 20 teams)**: A team that has successfully completed the Blinded Proficiency Test and is approved by the Judging Panel to participate in the Final Round Clinical Validation Test.

- **Winning Team (up to 5 teams)**: A team that has successfully completed the Final Round Clinical Validation Test and is approved by the Judging Panel to participate in Pilot Site Deployment.