

# XPRIZE RAPID COVID TESTING

## COMPETITION GUIDELINES 5.0

November 24, 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 purposes. 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 eight 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.
- **Winner Selection:** Finally, after clinical validation & assessment, the top five teams selected will be awarded \$500,000.00 with the option to proceed to deployment and receive an additional \$500,000.00 by demonstrating scalability, viability, and returning data and learnings for the playbook to XPRIZE.

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.

## 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**

<b>Begin</b>	<b>End</b>	<b>Milestone</b>
July 28	July 28	<b>Competition Launch:</b> Team Registration Opens, Guidelines Posted
	September 8	Registration Deadline; Qualifying Submission and Competitor Agreement Deadline
	December 22	<b>Finalist Teams Announced (up to 20 teams)</b>
December 22	February 10	Finalist Round: Clinical Validation
February 11	February 19	Finalist Judging
	February 23	<b>Winners Announced</b>
February 2021	December 2021	<b>Scaling Impact Phase</b>

### **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 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 POP. 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 deployment site testing) will be selected to compete in the competition.

### **Open Innovation Track**

Teams whose approaches that cannot be categorized as PCR, Isothermal Amplification, Next Generation Sequencing, or Antigen Detection and can not be tested through the competition rounds are eligible for the Open Innovation Track. Teams will be evaluated based on their qualifying submissions. At the discretion of the judging panel, top teams in this track will be eligible to win a share of \$500,000. These teams may choose to perform testing at a deployment site and upon successful completion are eligible to share an additional award of up to \$500,000. See Scaling Impact (Dissemination Phase) below for more details.

### **FINALS ROUND: CLINICAL VALIDATION**

Finalist Teams will have two weeks 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 roughly one week to review the results from the clinical labs and choose the five winning teams.

- The top five best performing teams (as measured by clinical validation results) will each receive a \$500,000 Award (\$2.5 million in total).

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.

### **Assay Updates**

Teams selected to advance to the Finals Round, including the top Open Innovation teams, will have a brief opportunity to update certain aspects of their Qualifying Submissions and protocols. XPRIZE will determine which aspects are appropriate for updating and will notify the top teams accordingly.

### **Investor Showcases**

The top antigen, nucleic acid, and open innovation teams will be invited to an investor showcase with the Covid Apollo Project and other potential investors. Should other investment opportunities arise additional showcases may be scheduled for the top teams.

### **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. While XPRIZE will work with all finalist teams to scale solutions, the five winners of XPRIZE Rapid COVID Testing will have additional programming moving into the scaling impact phase to receive the remainder of their prize amount.

In order to receive the remaining \$500,000, the winning teams must plan and execute a successful deployment site demonstration. These teams will be responsible for securing a site and executing the deployment site testing though XPRIZE will support teams through this process. Additionally, teams will be collecting data that must be submitted to XPRIZE, and documenting lessons learned to support the development of an implementation playbook.

Following the awards ceremony, the five winning teams will have a period of time (to be determined) to provide XPRIZE with a detailed proposal of their deployment site plans. Teams will then be eligible to receive up to \$250,000 of their remaining \$500,000. Upon completion (criteria TBD) and upon returning data and learnings for the playbook to XPRIZE, the teams will receive their final installment of \$250,000 bringing their total prize amount to \$1,000,000.

XPRIZE will oversee the development of a multimedia playbook documenting the testing protocols and plans implemented at each of the deployment sites by each of the winning 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.

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 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	Ideally cost less than \$15 per test, including all materials and reagents and amortized across capital costs.
	Deployment Period/Scaling Impact Phase: Economies of scale.



# Prizes

## Prize Purse

The total prize purse for this competition is \$6 million.

Prize Type	Amount	Prize Breakdown
Grand Prize Awards	\$ 2,500,000	<i>Awarded evenly between top five teams (\$500K/each)</i>
Deployment Awards	\$ 2,500,000	<i>Awarded evenly between the top five teams that successfully complete the deployment phase. Half to be awarded once proposal is submitted, half is awarded at completion.(\$500K/each)</i>
Open Innovation Awards	\$500,000	<i>Awarded to the winning Open Innovation teams at the Judging Panel's discretion</i>
Open Innovation Deployment Awards	\$500,000	<i>Awarded evenly to the winning Open Innovation teams that successfully complete the deployment phase.</i>
<b>Total Prize Purse</b>	<b>\$ 6,000,000</b>	

## 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. **FOUNDATIONS 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 the Scaling Impact Deployment Phase.