The Four Big Misconceptions About Coronavirus Testing

January 2021
There are four big misconceptions about coronavirus testing—and very different realities

<table>
<thead>
<tr>
<th>MISCONCEPTION</th>
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<tr>
<td>1. All tests are created equal</td>
<td>Tests vary across multiple attributes and are best suited to different use cases</td>
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<td>2. Testing isn’t complicated</td>
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<td>4. Testing is less important in the wake of vaccine approval</td>
<td>The demand for testing will remain high long after widespread vaccine distribution</td>
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Source: BCG analysis.
The first misconception is that all coronavirus tests are created equal. The reality is that tests vary across multiple attributes and are best suited to different use cases. Testing must be combined with several other measures to contain the virus effectively. The demand for testing will remain high long after widespread vaccine distribution.

1. The reality is that tests vary across multiple attributes and are best suited to different use cases.

2. MISCONCEPTION: Testing isn’t complicated. REALITY: Testing entails a complex series of steps and requires coordination among multiple stakeholders.

3. MISCONCEPTION: You can test your way out of the pandemic. REALITY: Testing must be combined with several other measures to contain the virus effectively.

4. MISCONCEPTION: Testing is less important in the wake of vaccine approval. REALITY: The demand for testing will remain high long after widespread vaccine distribution.

Source: BCG analysis.
Coronavirus tests include several attributes.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
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<tr>
<td>Speed</td>
<td>The time it takes to get from sample to answer, including collection, processing, running and interpreting the test, and communicating the results.</td>
</tr>
<tr>
<td>Cost</td>
<td>The total price of the supplies, reagents, and labor needed to collect and process the samples.</td>
</tr>
<tr>
<td>Throughput</td>
<td>The rate of tests that can be analyzed in a particular time frame, given the time it takes to interpret the results and the ability to run multiple samples at once.</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>The ability to detect COVID-19 in all patients who have the disease (avoiding false-negative results for ill and asymptomatic infectious patients).</td>
</tr>
<tr>
<td>Specificity</td>
<td>The ability to distinguish SARS-CoV-2 (which causes COVID-19) from other similar viruses, avoiding false-positive results for patients who do not have the disease.</td>
</tr>
<tr>
<td>Sample type</td>
<td>The type of clinical sample, such as an oral or nasal swab, blood sample, or lower-respiratory swab.</td>
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Together, these metrics indicate the accuracy of the test.

Tradeoffs exist in diagnostic testing:
- Speed vs. sensitivity and specificity
- Cost vs. sensitivity and specificity
- Cost vs. throughput

Source: BCG analysis.
And multiple types of tests are used to detect the coronavirus

<table>
<thead>
<tr>
<th>TEST PURPOSE</th>
<th>PCR</th>
<th>LAMP</th>
<th>CRISPR-BASED</th>
<th>NGS</th>
<th>ANTIGEN</th>
<th>SEROLOGY (ANTIBODY)</th>
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<tr>
<td>EXAMPLE USE CASE</td>
<td>Detects active, acute infection</td>
<td>Confirms diagnosis for sick patients with symptoms</td>
<td>Uses enzymes to recognize and target specific RNA sequences</td>
<td>Detects specific viral sequences</td>
<td>Quickly screens for active, acute infection</td>
<td>Detects immune response</td>
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<td>DETECTION METHOD</td>
<td>Detects viral RNA after RNA is amplified</td>
<td>Detects viral RNA after RNA is amplified (more efficiently than PCR)</td>
<td>Uses enzymes to recognize and target specific RNA sequences</td>
<td>Detects specific viral sequences</td>
<td>Detects proteins on the viral surface</td>
<td>Detects human antibodies that respond to the pathogen</td>
</tr>
<tr>
<td>FALSE-NEGATIVE RATE (%)</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>20</td>
<td>3</td>
</tr>
<tr>
<td>FALSE-POSITIVE RATE (%)</td>
<td>1</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>5</td>
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<tr>
<td>KEY LIMITATIONS</td>
<td>Instrument capacity constrained worldwide; backlogs increase turnaround time</td>
<td>For high throughput, similar requirements as PCR; for point of care, additional R&amp;D is needed, and new instruments may be required in the field</td>
<td>Must run many samples at once to be cost effective</td>
<td>High false-negative rate because of low sensitivity</td>
<td>Cannot be used to detect acute infections</td>
<td></td>
</tr>
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Sources: Expert interviews; the US Food and Drug Administration; BCG analysis.
Note: PCR = polymerase chain reaction; LAMP = loop-mediated isothermal amplification; CRISPR = clustered regularly interspaced short palindromic repeats; NGS = next-generation sequencing.
### The second misconception is that testing isn’t complicated

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<td>Testing is less important in the wake of vaccine approval</td>
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Source: BCG analysis.
The testing workflow is complex, and shortages or delays at any step of the process can limit overall throughput and turnaround time.

**PRETEST SCREENING**
- A patient feels ill or suspects exposure to COVID-19...
- ...and seeks a test or goes to see a health care provider (HCP)...
- ...which (unless it is a POC test) is sent to a lab, possibly offsite
- ...to be prescreened for COVID-19

**SAMPLE COLLECTION**
- Manufacturers ship the specialized testing components to the HCP...
- ...and the HCP collects a patient sample...
- ...then the test is prepared and run

**SAMPLE PREPARATION AND ANALYSIS**
- Manufacturers ship the specialized testing components to the test site...
- ...and are logged in the electronic health record and sent to the HCP, insurance, and others...

**RESULTS RECORDING AND ALERTING**
- The results are recorded in-house...
- ...and the patient is notified of the results

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**Shortages or delays**
- The lack of a centralized integrated platform that supports questionnaires, health record integration, and other elements
- Limited test locations
- A lack of swabs or PPE
- Sample transport logistics burdened
- Shortages of components needed to run tests
- Administrative obstacles to integrating health records for new labs

The availability of trained staff is a key constraint throughout the process.

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Note: This information is illustrative, not exhaustive. This workflow may not apply to all health systems, and simpler workflows can be found in more-integrated markets. POC = point-of-care; PPE = personal protective equipment.
Optimizing the diagnostic-testing ecosystem requires the coordination of heterogeneous stakeholders.

Supplying end users with the needed components is a complex process run by many manufacturers.

Note: PPE = personal protective equipment.
The third misconception is that you can test your way out of the pandemic

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Source: BCG analysis.
Testing is just one measure, among many, that ensures effective containment of COVID-19 outbreaks

Implement coronavirus testing:
- Molecular diagnostic testing can identify the current presence of the virus
- Antigen testing can be used for population screening
- Serological (antibody) testing can identify previous (or current) exposure

Deploy contact-tracing and communication procedures

Leverage tracking technologies, such as contact-tracing and notification systems

An integrated system to ensure safe reopenings

Establish social-distancing guidelines, including public distancing and limited gathering sizes

Provide and mandate the use of personal protective equipment, especially in high-risk environments

Institute targeted lockdown measures, which may include mandatory quarantine rules for individuals arriving from high-risk areas

Promote symptom screening, such as temperature scans and self-reported symptom checks

Source: BCG analysis.
Because of the time it takes for the coronavirus to incubate, testing can’t eliminate the risk of transmission

Sources: “Variation in False-Negative Rate of Reverse Transcriptase Polymerase Chain Reaction-Based SARS-CoV-2 Tests by Time Since Exposure,” Annals of Internal Medicine; Johns Hopkins University; American College of Physicians; BCG analysis.

Note: The data and information are accurate as of October 7, 2020.

Context
Jane travels each week for work, and her team takes high-quality rapid tests every Sunday and Thursday to reduce the risk of infection.

Timeline
- **Friday**: Jane is exposed to the coronavirus by an infected neighbor in her condo building.
- **Sunday**: Jane takes a rapid test, which comes back negative. She travels to her work site for the week.
- **Monday/Tuesday**: Jane feels fine but reaches peak contagiousness while working onsite with her team.
- **Wednesday**: Jane feels a little tired and has a slight cough. She works from her hotel to err on the side of caution.
- **Thursday**: Jane takes another rapid COVID-19 test. This one is positive. Her employer initiates contact tracing.

Contagious
- Days since exposure: 0-10

Symptomatic
- Days since exposure: 0-10

Detectable through testing
- Days since exposure: 0-10

>95% chance of false-negative result if tested within 48 hours of exposure

Days since exposure
- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10

Contagious
- Days since exposure: 0-10

Symptomatic
- Days since exposure: 0-10

Detectable through testing
- Days since exposure: 0-10
Examples can be found worldwide of how to combat COVID-19 by using testing in conjunction with containment measures.

<table>
<thead>
<tr>
<th>Geographic area and testing capabilities</th>
<th>Rapid and robust disease eradication</th>
<th>Technology-enabled contact tracing</th>
<th>Coordinated state-level response</th>
<th>Effective use of limited resources</th>
</tr>
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<tbody>
<tr>
<td>Hallmark feature</td>
<td>New Zealand</td>
<td>Taiwan</td>
<td>Germany</td>
<td>Senegal</td>
</tr>
<tr>
<td>1,322 tests per confirmed case</td>
<td>236 tests per confirmed case</td>
<td>91 tests per confirmed case</td>
<td>35 tests per confirmed case</td>
<td></td>
</tr>
<tr>
<td>An island with a sizable rural demographic and a mixed public-private health care system</td>
<td>A densely populated island with high levels of government authority and single-payer health care</td>
<td>Shared borders and a moderate degree of government authority</td>
<td>Rural, with limited health care infrastructure and little experience with prior diseases</td>
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<tr>
<td>Containment measures</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>• Disease elimination strategy</td>
<td>• Widespread technology use for case tracking</td>
<td>• Large-scale lockdown and widespread case tracking</td>
<td>• Curfews and travel restrictions imposed early in the pandemic</td>
<td></td>
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<tr>
<td>• Government lockdown in place before first death</td>
<td>• Centralized ramp-up and distribution of PPE</td>
<td>• Extensive community testing</td>
<td>• Mobile testing centers set up with &lt;24-hour response times</td>
<td></td>
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<tr>
<td>• Aggressive, extensive testing from the beginning</td>
<td>• Strict penalties for quarantine violation</td>
<td>• State-by-state decision making and coordination</td>
<td>• Government beds promised for every positive patient</td>
<td></td>
</tr>
<tr>
<td>Outcomes (cumulative, per 1 million people)</td>
<td>300 cases</td>
<td>20 cases</td>
<td>3,600 cases</td>
<td>900 cases</td>
</tr>
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Sources: Government announcements; Our World in Data; BCG analysis.
Note: The containment policies described here include policy initiatives that are currently or have previously been implemented. All information is illustrative, not exhaustive, and based on data that is accurate as of October 7, 2020. Population and outcome figures are rounded. PPE = personal protective equipment.
The fourth misconception is that testing is less important in the wake of vaccine approval

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The reality is that testing demand will remain high long after widespread vaccine distribution

Source: BCG analysis.
Various factors limit the ability of vaccines to eradicate the coronavirus completely—and create the potential for high testing demand through 2021

Multiple approved vaccines offer high levels of efficacy, above 90%, but efficacy can differ among demographic groups (e.g., children, the elderly, pregnant women)

Some vaccines (e.g., those from Moderna and Pfizer-BioNTech) require multiple doses, and the time required between doses will extend the timeline for reaching herd immunity

It remains unclear how long immunity will last; some vaccine producers claim that immunity lasts from one to two years

Limited data is available, but at least three months of immunity has been observed in recovered patients

Rapid transportation and distribution to the highest-risk populations will require extensive coordination across governments, manufacturers, and care sites

Leading vaccines from Moderna and Pfizer-BioNTech require specific transportation and storage requirements (such as cold storage at temperatures as low as –80°C)

The population’s willingness to receive a coronavirus vaccine has dropped because of safety concerns about the rushed vaccine approval processes

Polls from autumn 2020 show that only 50% of Americans would be willing to get vaccinated, a 15% drop since May

Sources: CNN poll conducted in October 2020 (regarding public adoption); “Functional SARS-COV-2-Specific Immune Memory Persists After Mild COVID-19,” University of Washington (regarding immunity observed); BCG analysis.

Note: Percentage figures are rounded.

Russia claims that its recently registered vaccine, Sputnik V, will provide immunity for up to two years.
COVID-19 Disclaimer

The situation surrounding COVID-19 is dynamic and rapidly evolving, on a daily basis. Although we have taken great care prior to producing this presentation, it represents BCG’s view at a particular point in time. This presentation is not intended to constitute medical or safety advice, nor be a substitute for the same, or be seen as a formal endorsement or recommendation of a particular response. As such, you are advised to make your own assessment as to the appropriate course of action to take, using this presentation as guidance. Please carefully consider local laws and guidance in your area, particularly the most recent advice issued by your local (and national) health authorities, before making any decision.