INDIA: TESTING OUR WAY OUT OF COVID

By Priyanka Aggarwal, Kshitij Vijayvargiya and Siddharth Jain

This is part of a series of short articles on combating the COVID-19 outbreak in India and covers the topic of diagnostic testing. While the responsibility for diagnosis falls primarily on the government through medical professionals and the companies that support them with equipment and supplies, business leaders need a baseline of knowledge on how testing works, what it is used for, and how it can help them restore operations and public confidence once the immediate emergency has passed.

Testing: Topic Du Jour

Diagnostic testing for COVID-19 has been the topic du jour in India – from government offices to boardrooms to social media chatrooms. There have been debates ranging from whether India is using the right testing protocols to whether India is doing enough testing. There are questions on India's testing ramp-up, there is confusion on which tests should be used when, and the accuracy of these tests. Recently, few states in India have taken a decision to reduce testing of asymptomatic contacts of patients in order to preserve test kits and enhance focus on treatment[1]. Continuous media coverage along with concerns on availability of test kits, reagents and manpower has often led to confusion on real unlocks to expand testing in India.

It is now well accepted that we are in a marathon to fight the COVID pandemic. India announced a 21-day lockdown on March 24th and then extended it till May 3rd. In doing so, India has implemented one of the most stringent measures to tackle the pandemic among the 212 countries impacted by the disease. The lock down was essential and well-timed. It has helped reduce transmission of the disease (reducing doubling rate of cases from 3.4 days prior to lockdown to 10 days currently) and provided Indian healthcare system, the much needed time to ramp up infrastructure (for example, 600+ dedicated health facilities with over 1 lac isolation beds have been set-up). In this battle between lives and livelihood, we cannot however ignore the crippling impact lock-down has had on India's econ-

omy. Already unemployment rate has risen to 23 percent[2] rising up from 8.4 percent in mid-March. Estimates from CII paint a gloomy picture, suggesting India's GDP growth will slow down to -1.9 percent to 1.5 percent for FY21.

Diagnostic testing plays a crucial part in this fight against COVID. It is obviously important to identify and treat those who are infected, and equally critical to break the chain of transmission and protect larger population from a potential exponential spread, given that large part of COVID transmission happens through asymptomatic individuals[3]. Countries like South Korea, and Germany have shown the way in using large scale testing effectively to control the disease spread without nationwide lockdown (in the case of Korea) and early staggered opening-up of economic activity (in the case of Germany starting).
(Refer to Exhibit 1).

Over time, test data provides aggregate information to understand the evolution of virus and overall level of spread of the disease in a region or segment of population. It also helps to take decisions related to easing up of lock down and enabling business continuity through bringing staff back to work safely.

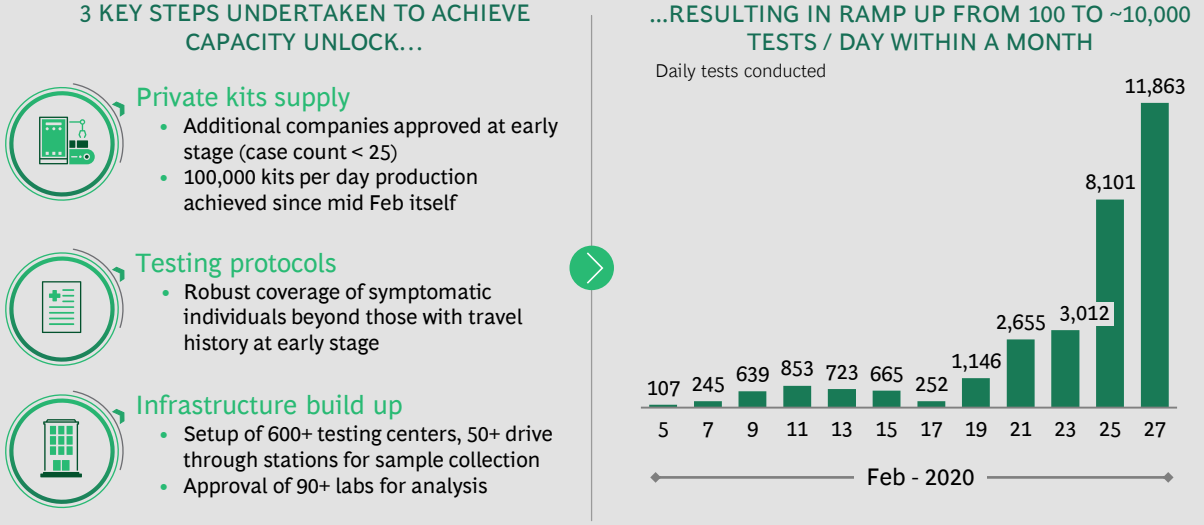
India: Current State of Testing

Till mid-March, testing in India was focused on testing only symptomatic foreign travelers or symptomatic contacts of such travelers, with the belief that disease was largely restricted to international travelers with limited local transmission. This was supported by the low positivity rates of tests even within the higher susceptible targeted population, at less than 2 percent.

With the identification of cases of local transmission[4] and increasing occurrence of positive cases (at 4.2 percent as of 27 April), the testing guidelines evolved to include symptomatic local patients, asymptomatic contacts of these confirmed cases, health care workers and other high risk categories (those in hospitals showing Influenza-like-illnesses or Systemic Acute Respiratory Illness). As it stands today, the guidelines of testing in India are consistent with those followed in South Korea and in Germany (Refer to Exhibit 2).

Since the revision in the guidelines, testing in India has gone up by over 20X over the last 2 weeks, from testing an average of 2,000 tests / day in the last week of March to above 40,000 tests / day in mid April. With scale up of testing over 20X, the positivity

EXHIBIT 1 | Case Study: South Korea has Shown Strong Focus on Testing to Ramp Up from 100 to ~10,000 Tests Per Day in A Month



Source: World Test Data, BCG analysis.

EXHIBIT 2 | India Testing Protocols in Line with Global Standards

		GERMANY	SOUTH KOREA	INDIA (20 March)	INDIA (27 April)
TRAVEL HISTORY	Symptomatic	✓	✓	✓	✓
	Asymptomatic	✗	✗	✗	✗
CONTACTS OF CONFIRMED PATIENTS (Incl. Health workers)	Symptomatic	✓	✓	✓	✓
	Asymptomatic	✓	✗	✓	✓
OTHER PATIENTS	Symptomatic - Severe Severe Acute Respiratory Illness (fever and cough and/or shortness of breath)	✓	✓	✓	✓
	Symptomatic - All ILI (fever, cough, sore throat, runny nose)	✓	✓ Hotspots only	✗	✓ Hotspots only
	Asymptomatic patients	✗	✗	✗	✗
POOL TESTING		Under evaluation		✗	✓
ACCESS		Covered by insurance	Paid by the Government		• Covered under Ayushman Bharat • Centre issuing guidelines listing for other categories of EWS[1] as well

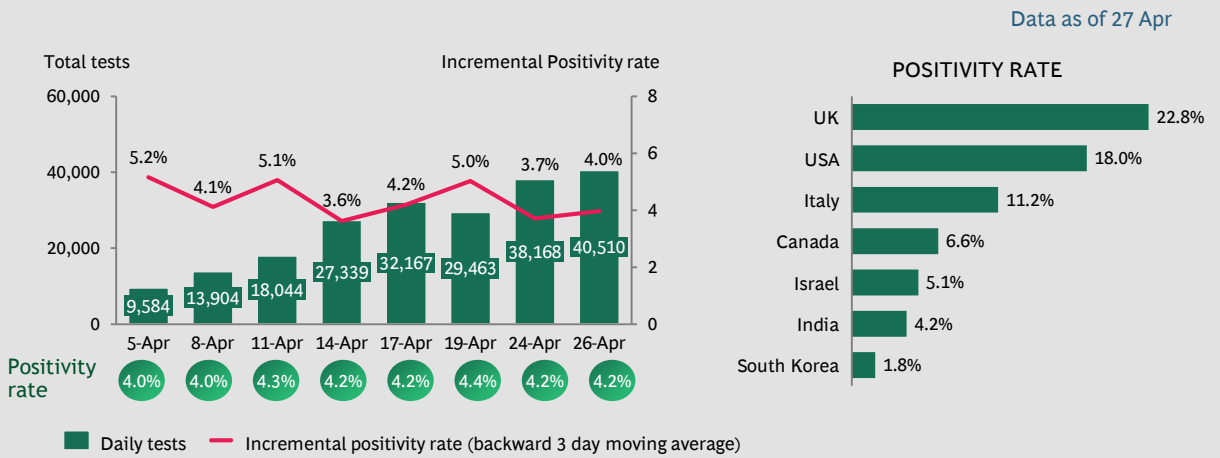
1. EWS: Economically weaker sections.
Source: ICMR, BCG analysis.

rates have remained one of the lowest in the world at 4.2 percent (Refer to Exhibit 3)

The testing capacity of India has also rapidly been expanded with 150+ labs added in the approved list over last 3 weeks. In addition to the government labs, now ~100 private labs have also been approved to do COVID testing, taking the total to 321 laboratories. These include laboratories of large private lab players like SRL, Dr Lal's, Metropolis and hospital based labs like Apollo, Medanta and Max.

The Government has moved notifications to allow pooled testing protocols in locations with low positivity rates and has also included testing as part of the Pradhan Mantri Jan Arogya Yojana (PMJAY) package. Over 500 million people are now eligible to get tested for free if they qualify under the testing criteria.

EXHIBIT 3 | India Has Ramped Up Testing Capacity While Maintaining Lower Positivity Rate



Source: ICMR, MoHFW, Worldometer, BCG analysis.

A Complex Testing Landscape COVID testing itself is a complex landscape with many different types of diagnostic tools and processes available. Each of these have different accuracy, use case and status of approval for use in different countries. Currently, 34 test kits are approved for testing in India - 16 of these being 'Molecular Diagnostic Tests' (commonly performed on the RT-PCR platform) that test for the presence of viral genome (RNA) in the patient sample indicating current infection; while the remaining being 'Anti-body Tests' that test for presence of anti-bodies in patient sample indicating infection in the past and presence of anti-bodies in the patient that develop in response to the virus. Hence, different testing options have different use cases.

Currently, there are 4 different types of tests available in the market for testing, each with their own advantages and disadvantages.
(Refer to Exhibit 4)

- **RT-PCR tests (Viral Genome tests)**: This is the gold standard of testing. It checks for presence of actual virus RNA in the samples. This test runs in a lab using high end equipment and skilled technicians and takes 1-3 days to provide results due to the time to transport samples to lab and subsequent processing. These tests are particularly useful for diagnosis and triage of patients. These tests can detect presence of virus from 1-2 days before symptoms appear

- **RT-LAMP tests:** This is a new 'under approval' variant of the Genome tests with a shorter overall processing time and costs lower than RT-PCR tests. It however, requires installation of a separate RT-LAMP equipment in the laboratories

- **Point of Care PCR tests:** These are newly developed RT-PCR tests that can be done at a hospital or clinic setting and give results within a few hours without needing a laboratory. However, there is a trade-off between speed and accuracy with POC PCR tests being typically less accurate compared to the lab processed RT-PCR tests. While manufacturers like Abbott have FDA approved kits available globally, they are currently under validation by ICMR for usage in India.

- **Rapid Antibody tests / Serological tests:** These are blood sample based serological tests which assess the

EXHIBIT 4 | Different Types of Tests Currently Available for Covid-19

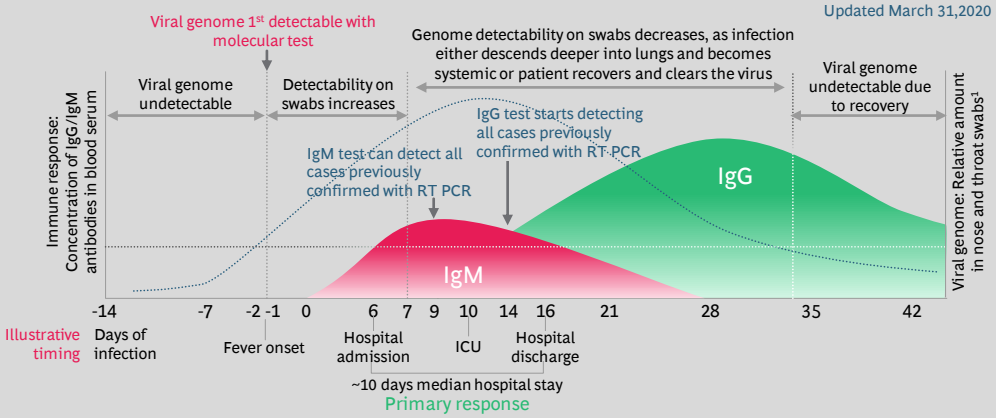
	RT / PCR	RT-LAMP	Point of Care PCR	Rapid antibody
METHODOLOGY	Swab based	Swab based	Swab based	Serological
TEST LOCATION	Lab	Lab	Point of care / lab	Point of care / lab
TIME FOR RESULT	1-3 days	1 day	1-3 hours	1-3 hours
COSTS (INR)	2,500 – 4,500	1,000 (Prelim. Pricing)	500 – 1,000	500 – 1,000
USE CASES	• Diagnosis • Monitor spread	• Diagnosis • Monitor spread • Screening & confirmation	• Diagnosis • Monitor spread	• Monitor spread • Test infection status • Vaccine screening
EXAMPLES OF APPROVED KITS FOR INDIA (Non-exhaustive)	MyLab, Altona, ADT	-	-	Abbott, Alpine, BioMedomics

Source: BCG analysis

development of immune response to virus in patients by detecting the presence of two antibodies (IgG and IgM) in the body, thereby confirming past infection. These tests don't achieve the same detection rate as viral-genome diagnoses as immune response is activated only 9-12 days after the infection. While they are less useful in immediate response (and thus cannot and should not be used to diagnose infected patients who need care), they can be used to track disease development in a segment of population and can help detect the immunity of an exposed population to help take decisions for government actions at district or ward level on social activities and restrictions in an area. They also can help identify individuals who are already immune and can safely return to the workplace[5]. These tests can give results within a few minutes or hours. As of now, we have 18 antibody tests approved in India.

See Exhibit 5 and 6 for details on stages when different tests are most effective, and their performance comparison

Exhibit 5 | Viral Genome Test Detects COVID-19 1-2 Days Before Symptoms, Immune Response (IgG/IgM) Tests Achieve Similar Detection Rate 9-12 Days Later



1. Current tests detecting presence of viral genome are qualitative and are not meant to measure absolute amount or viral genome present (ie viral load)
Note: Detectability of viral particle not shown as test currently does not exist
Source: Wang et al., JAMA (2020); IgG/IgM product insert materials; Expert interviews; BCG analysis

Exhibit 6 | Performance and Accuracy Need Careful Assessment When Choosing A Test To Deploy in Various Applications (Scenario with 4% Disease Prevalence)

ANALOGS FOR COVID-19 TESTING

Due to rapid development, Covid-19 test performance could vary significantly

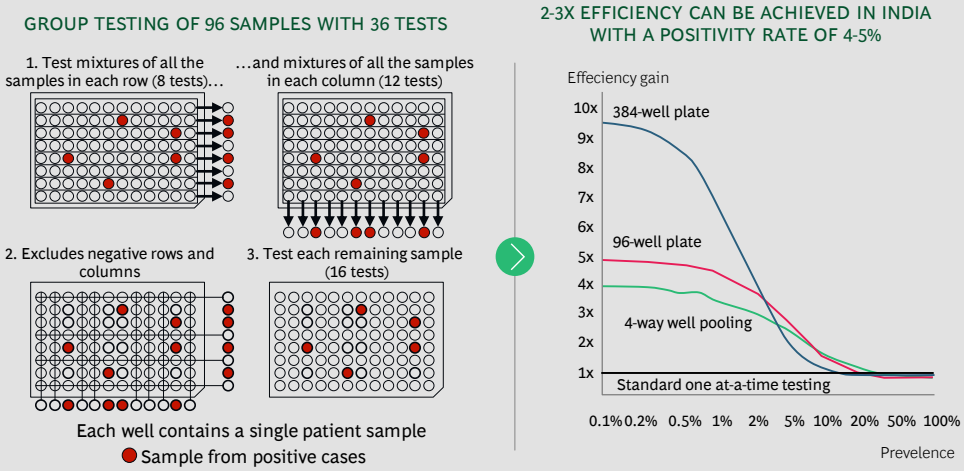
Scenario: 100,000 tests performed Disease prevalence: 4%		Sick patients = 4,000 True positive	Sick patients = 4,000 False negative		Healthy patients= 96,000 True negative	Healthy patients= 96,000 False positive	Observations & implication
Gold standard RT PCR tests	Sensitivity 98%	3,920	80	Specificity 99%	95,040	960	• Very few sick pts missed, ~1% need 2nd confirmatory test (done on the same sample
Anti-body tests	Sensitivity 80%	3,200	800	Specificity 90%	86,400	9,600	• 10x more cases missed vs RT PCR; most effective as part of combination screening and risk reduction strategy
Low quality anti-body tests (COVID-19 Shenzhen Bioeasy example)	Sensitivity 30%	1,200	2,800	Specificity 60%	57,600	38,400	• Tests with this performance level will quickly lose in the market. Misses more cases than it detects, very large number of people seek unnecessary care

Note: Serology tests detect active COVID-19 infection starting ~7-12 days after it was contracted (IgM earlier, IgG later), or previous exposure to the virus (IgG only)
Source: Expert interviews, BCG analysis

The Added Benefit from Pooled Testing

Recently, many countries, including India, have started a protocol of pooled testing wherein samples from multiple people are mixed together and tested collectively in order to test at scale. A test with -ve result could be used to clear infection in all the people thus tested in the pooled sample. When a result comes +ve, further testing would be required to identify the exact person with the infection. This method of testing is highly effective for testing at scale in locations with low positivity rates and could give a bump up of 2-3x to the overall testing capacity using the same kits and equipment. See Exhibit 7 for details.

EXHIBIT 7 | Testing kits: Pooled testing could be used to scale up capacity upto x3 times



Source: Evaluation of Group Testing for SARS-CoV-2 RNA, Research Paper https://t.co/ysXUFJLXBU?amp=1

Shifting to the Next Gear

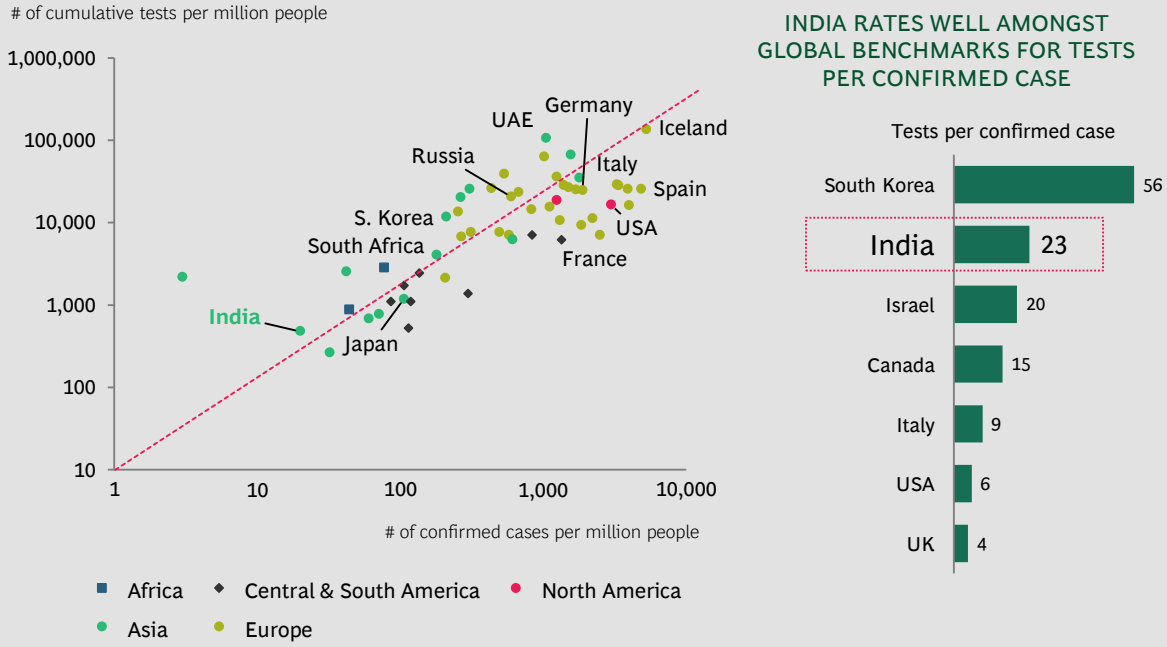
With these steps, the total testing rate in India has climbed from 10 tests per million in mid-March to up to 519 tests per million as of 28th Apr. While this is below other nations, it is pertinent to note that the positivity rate in India has been steady and stayed at a low number of 4.2 percent. Even the incremental positivity rate (defined by new positive cases / new tests done) is not too much higher. With ramp up in testing, India has maintained a position consistent with the global benchmarks trends (Refer to Exhibit 8).

Viewed this way, the overall picture does not seem as grim as many have claimed. However, reviewing the state wise status of testing, it is seen that there are wide disparities across the average national numbers which implies the need for urgent segmented action (Refer to Exhibit 9):

- States like West Bengal and Madhya Pradesh are seeing low testing rates despite high positivity. They have an immediate need to ramp up testing to understand the true spread of disease
- States like Delhi and Maharashtra show a high spread while having high testing rates, at above 500 tests / million population. These geographies have shown many disease 'hotspots' or outbreaks in clusters linked by an event, or geographical region and need to continue large scale testing to identify patients and treat them actively
- States like Bihar have done very little testing, and while they currently see low positivity, they need to enhance testing as a way for mass surveillance and identification of areas of potential outbreaks early; and for taking decisions to open up gradually after lock-down and rebound of economic activity.

Exhibit 8 | While, India has Tested Less than Global Benchmarks, It Is on The Same Curve Of Incidence Rates

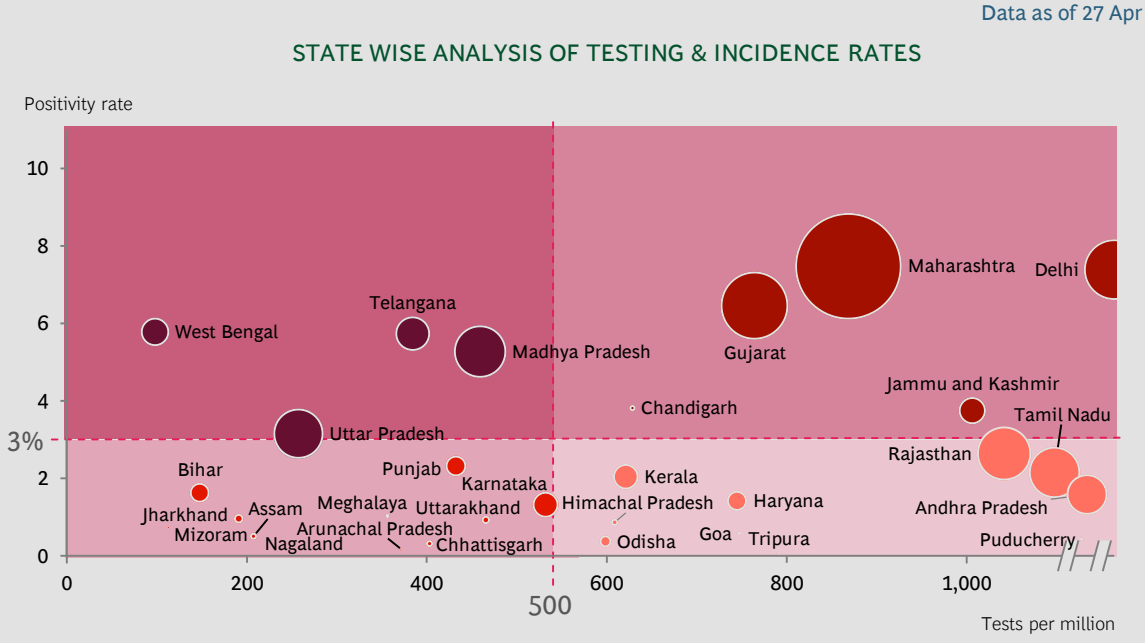
Data as of 27 Apr



Source: ICMR, MoHFW, BCG analysis

Exhibit 9 | State Wise View Indicates Need of Focused Segmented Action to Ramp Up Testing

Data as of 27 Apr



Telangana updated on 19 Apr, Tripura on 22 Apr, Goa & Mizoram on 23 Apr, Chattisgarh & Karnataka on 24 Apr, Arunchal Pradesh, Bihar, Haryana, Jammu & Kashmir, Kerala, Maharashtra, Odisha & Tamil Nadu on 26 Apr, Andhra Pradesh on 27 Apr and rest on 25 Apr
Source: ICMR, COVID 19 India, BCG analysis.

While cumulative cases in India have exceeded 20,000, a granular review at district level shows wide variation in the level of spread. 8 cities contribute to over ~45 percent of cases, while there are still 250+ districts with no reported COVID cases.

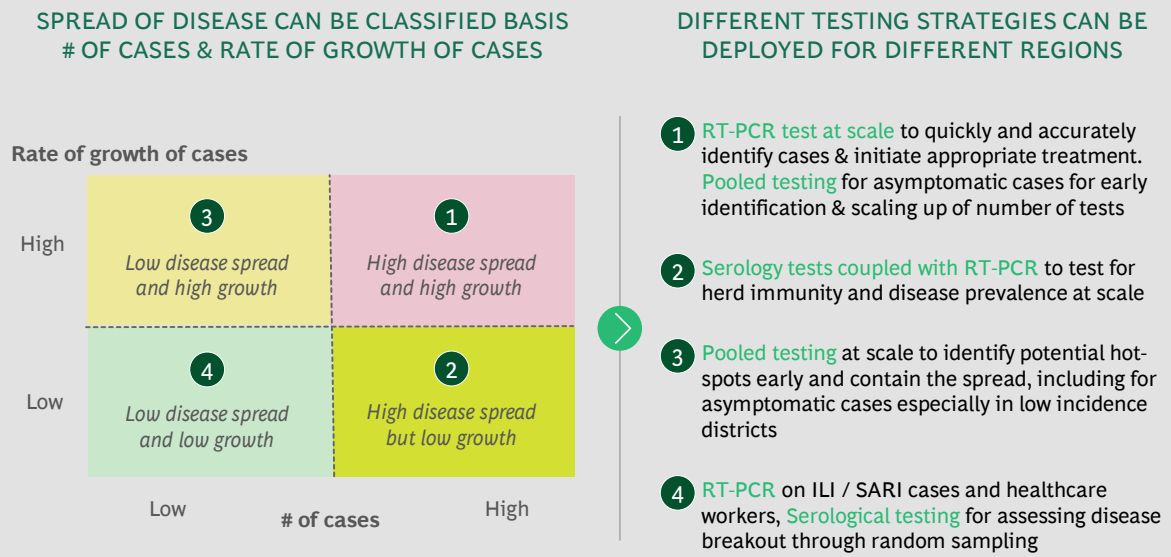
This along with the fact that there is high concentration of growth of COVID in particular areas, allows for a regional review to decide on lifting lock-down restrictions. Ramp up of testing, therefore, is critical in India in order to control the disease spread and enable a thorough risk assessment on spread of disease to take informed decisions on opening up social and economic activities beyond the lock down.

With the different testing options available in front of India, and the current disease progression dynamics, it is imperative to deploy a segmented approach for testing in India, which is customized for each region / geography depending on the current level of disease spread and the level of positivity from the region. While the first level of decision could be made at a state by state level, further classification of regions could be done basis districts and then subsequently basis wards within the district to accelerate testing

As highlighted in Exhibit 10, different regions would need to develop a customized testing solution:

- High disease spread and high growth rates: Need continued large scale PCR testing to support accurate and timely identification of cases. Rapid testing could also be used and deployed in hotspots to quickly assess community immunity which could have built in
- High disease spread but low growth rates: Leverage combination of Rapid antibody tests to test development of mass scale immunity coupled with PCR tests as a way for diagnosis
- Low disease spread and High growth rates: Leverage pooled testing at scale to quickly identify new hotspot developments
- Low disease spread and low growth rates: Leverage RT-PCR tests for all ILI /SARI cases and for healthcare workers while deploying serological testing for random sampling as a way to monitor disease surveillance

EXHIBIT 10 | Stratified Testing Strategy Could be Used at District Level to Decide Course of Action



Locations could move from one classification to another basis evolution of cases

Source: BCG analysis.

Operationalizing the Ramp Up

Delivering the tests would require multiple different capacities to come together. As already mentioned, there has been efforts to create capacity for the testing kits and for labs in the recent past. As the testing ramps up, new bottlenecks are likely to emerge in the entire process. This needs a holistic look at the current state of supply and unlocks to move to the next trajectory. Some key focus areas that need to be kept in mind are:

- **Lab Capacity:** While lab capacity has been increased in recent past, there are regional disparities in availability of labs. States like Jharkhand, Chattisgarh and J&K have less than 5 labs and UP has only 2 approved private labs. Furthermore, capacity of labs in states like Gujarat is reaching the limit with the current spread of the epidemic. There is a need to review the regional availability of capacity and ramp it up. Private sector collaboration could help in plugging the gap here

- **Sample collection:** Sample collection and ensuring availability of phlebotomists will continue to be a challenge as capacity ramps up. While labs and kits might be available and further ramp up through pooled testing, the samples need to be collected at an individual patient level. Here, taking learnings from South Korea and other countries, India should set up drive-through sample collection booths at scale to enable sample collection

- **Equipment:** PCR machines are the most critical equipment needed in the current molecular testing regime. Current capacities of PCR machines in approved labs (~400 machines) should support 70,000-80,000 tests in public sector and 30,000-40,000 tests in private sector. However, India has a pool of 1200+ installed machines and the focus needs to be on addition of more labs with PCR machines or temporarily shifting PCR machines to approved labs

- **Kits:** While significant progress has been made on kits (with enough stock to conduct ~100,000 tests / day for next 2 months), ramping up beyond this will need accelerated procurement and mass adoption of innovations like pooled testing

Closing Note

INDIA HAS COME a long way in testing over the last 3 weeks. The journey ahead is however likely long and arduous. There is an urgent need to balance the dual objectives of securing public health and restarting economic activity. With increasing unemployment rates, it is critical to evaluate lifting of sanctions in non-affected and green zones to rebuild the economy. Initiating activities in certain sectors like construction and infrastructure will go a long way towards helping resolve issues related to daily wage population.

In this environment, testing at scale seems to be the single most effective solution for appropriate surveillance and control till a vaccine is available at the right price and in sufficient quantity to tackle the COVID challenge.

Note: *The overall COVID situation is evolving quite fast. This article is intended to provide the current understanding of the testing situation in India and does not intent to be a comprehensive representation of all the facts and solutions.*

NOTES:

1. BMC amends testing strategy https://economictimes.indiatimes.com/news/politics-and-nation/mumbai-to-first-test-high-risk-contacts-with-symptoms/articleshow/75169149.cms?from=mdr
2. Centre for Monitoring Indian Economy (CMIE)
3. Diamond Princess study https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.10.2000180, Obstetrics study https://www.nejm.org/doi/full/10.1056/NEJMc2009316, China daily case count study https://www.bmj.com/content/369/bmj.m1375
4. News articles: https://timesofindia.indiatimes.com/india/india-still-in-local-transmission-stage/articleshow/74903148.cms
5. Assuming sustained immunity in patients who have previously been infected although this is still under investigation

About the Authors

Priyanka Aggarwal is a Managing Director and Partner in the New Delhi office of Boston Consulting Group. She is a leader in the Healthcare practice in BCG. You may reach her at Aggarwal.Priyanka@bcg.com

Kshitij Vijayvargiya is a Partner in the New Delhi office of Boston Consulting Group. He is a leader in the Healthcare practice in BCG India. You may reach him at Vijayvargiya.Kshitij@bcg.com

Siddharth Jain is a Project Leader in the New Delhi office of Boston Consulting Group. You may reach him at Jain.Siddharth@bcg.com

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