Increasing COVID-19 testing capacity in India

Strategy to increase testing kit supply and testing capacity

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Key Ideas

India needs to significantly increase testing capacity from 100,000 to 4,50,000 samples per day for COVID-19.

To increase availability of testing kits, there is a need to incentivise indigenous manufacturing through tax exemptions and advanced purchase agreements as well as streamlining procurement from foreign sources.

Removal of price ceilings on testing will help the private sector contribute more to the testing capacity.

India has an opportunity to become a world leader as a manufacturer of testing kits and service provider for testing capabilities.

Introduction to COVID-19 testing

1a. Introduction to COVID-19 testing techniques

There are two main types of techniques used for COVID-19 detection:

a. RT-PCR b. Antibody testing

Below table summarises both techniques and their utility.

Technique	Pros	Cons	Remarks
Real Time Polymerase Chain Reaction (RT-PCR) RT-PCR detects the presence of viral genomic material in the swab sample.	Detects live infection Accurate in results [ICMR approves test kits which are 100% concordant in giving false positives and false negatives]	Time consuming (takes a few hours) Difficult to scale (Steps in protocol can become processing bottlenecks) Relatively more expensive	Considered gold standard currently for COVID-19 testing WHO-recommended method Samples from different individuals can be pooled to reduce processing time and costs.
Antibody testing Detects antibody in an infected person's body.	Rapid testing – results can be obtained within a few minutes Relatively cheaper	Cannot detect infection in early stages. May not be accurate	Several countries have announced failure of antibody rapid testing kits obtained from China. WHO does not recommend antibody testing as a diagnostic test.

1b. The aims of COVID-19 testing

Containing disease spread

The primary function of testing is to identify infected individuals and isolate them and their contacts.

Until a reliable and sensitive antibody test is designed, RT-PCR remains the gold standard for diagnosing patients.

Patients have to be tested repeatedly to determine their recovery – a patient is deemed recovered after getting two negative results.

Community testing

At a broader level, COVID-19 testing can be performed to determine the penetrance of the virus in a population. This approach can help determine the extent of the infection and facilitate policy responses.

Community testing is important for COVID-19 because there is a high proportion of asymptomatic carriers.

Pooling of samples can help reduce the time and cost of community testing – however, if positive samples are obtained, the entire sample set needs to be individually tested. Thus, pooling of samples is effective only in areas of low penetrance. Indian Council of Medical Research (ICMR) recommends pooled sampling be done in areas where <2% of population is positive for COVID-19. However, it does not specify the unit of area (i.e. district, ward, etc.) to which this advisory is applicable.

1c. Scale of COVID-19 testing

India is currently testing at 100,000 samples per day.

India's test positivity rate (TPR = Percentage of positive patients per number of tested samples) is relatively low – 4.76% as compared to 18.22% for US. South east Asian countries have used a TPR of 3% to benchmark their testing capacity.

In India's scenario, to achieve an idealistic 2% TPR, India would need to test 1.2% of its population*. At our current rate of testing, it will take at least 6 months to test even 1% of India's current population once. We recommend India should be testing 1% of its population every month for the next 12 months.

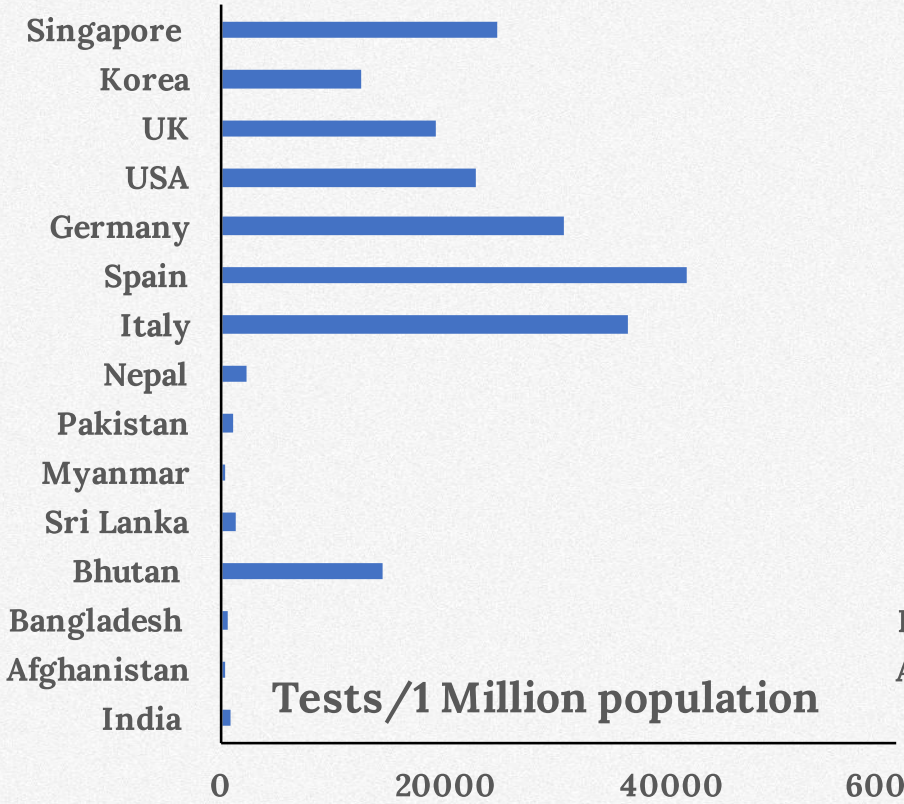
Timelines for covering 1% population at different Testing Capacities:

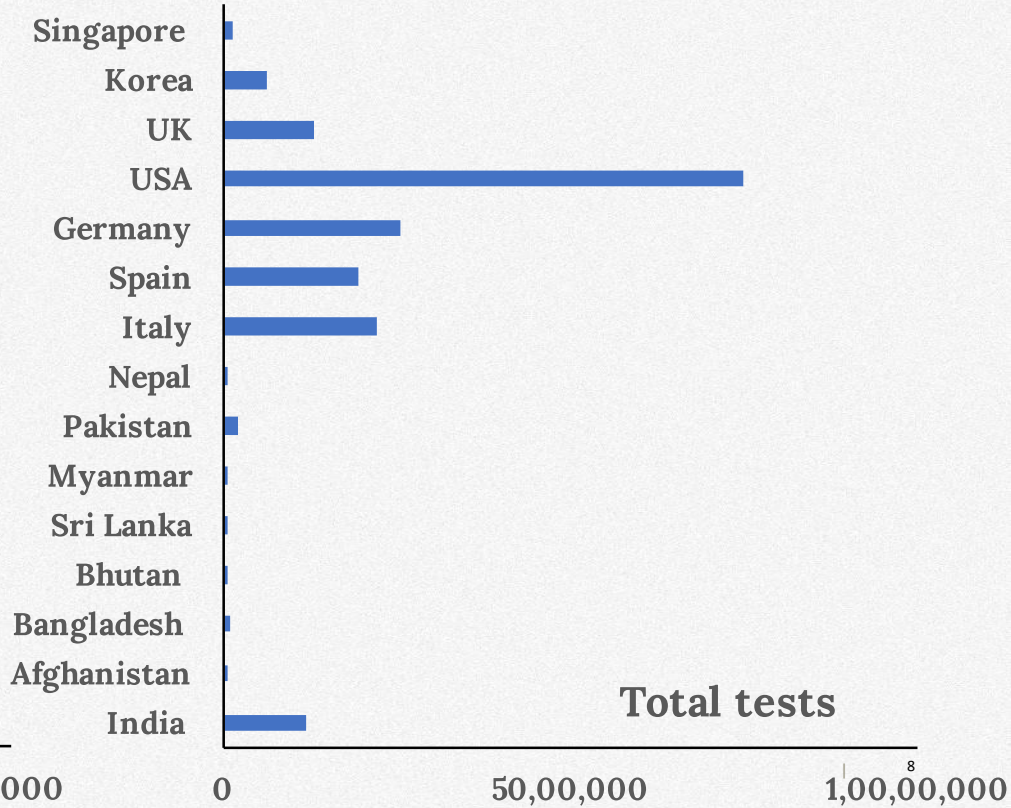
Status Quo: 100,000 samples per day	Doubling capacity: 200,000 samples per day	**Target capacity:** 4,50,000 samples per day	Exponential increase: 10,00,000 samples per day
~ 6 months	~ 3 months	~1 month	~ 13 days

* Based on Dr Deepankar Basu's calculations published in TheWire.

1d. Testing rates across the world

India rate of testing/1 million population is poor and needs to increased





2. Key Bottleneck: Lack of testing kits

2a. Key Bottleneck: Lack of testing kits

	Testing kits
Current Situation *India faces a shortage of testing kits*	• As of 23rd April 2020, ICMR had validated 37 RT-PCR tests and approved 17 kits for use. • US-FDA and/or CE-IVD approved kits can be used directly after due marketing approval from DCGI. • However there are several reports that India, particularly private laboratories are facing shortage of testing kits – both RT-PCR and RNA isolation kits. To test 1% of population once, India will need 10 million test kits at least. On May 3, India has placed an order for 6.3 million RT-PCR test kits from foreign companies.
Opportunities *India could become a leading manufacturer for testing kits*	• Increase availability of domestically manufactured kits at a reduced cost. • India could become a provider of quality and reliable testing kits to other countries facing shortage of kits. • Reduce dependence on Chinese manufacturers.
Challenges *Supply chain and regulatory issues block rapid manufacturing growth*	• Supply of reagents for manufacturing – a major bottleneck has been supply-chain of raw materials • Cheaper kits available from China – Competitive kits from China dis-incentivise indigenous manufacturing; however select kits from China have been faulty • Approval processes – Approval from ICMR for commercial kits is a slow process • Access to positive samples - for creating and testing the kits

2b. Issues in Procurement of Testing Kits

Approval from ICMR/ US-FDA/CE-IVD

- Long waiting times for approval

Indian Manufacturer

- Competition with foreign manufacturers
- Start-ups lack high manufacturing capacity

Intermediary Supplier (May be multiple)

- Profiteering/ Information asymmetry. In one case, commissions for 2 intermediaries contributed to 61% of the total costs of kit

End Consumer (Govt./pvt. company)

- Government does not process advance payments.

2c. Recommendations for procuring testing kits

Sector	Recommendations
Improve Indigenous Manufacturing	• Easing of approval process: appoint more institutions such as CCMB, NCBS or industry organisations such as ABLE to certify testing kits • Incentivise partnerships between research institutions/small to mid-size startups and manufacturers • Set advanced purchase agreements with local manufacturers of approved RNA isolation and RT-PCR kits
Streamline Import of kits	• Remove price ceiling on actual cost. • Identify and source directly from manufacturers • States sourcing kits were offered different prices. Aggregate sourcing as much as possible. Creating a central repository of kits from which states could purchase their requirements could help reduce costs and streamline supply chain.

3. Key Bottleneck: Lack of testing capacity

3a. Key Bottleneck: Lack of testing capacity

	Testing Capacity
Current Situation *India faces a shortage of testing capacity*	• Allowed in NABL accredited private labs and select Government labs • Requires BSL2/3 facilities for testing • Private labs across the country have a testing average of 16 per cent to 18 per cent • National Testing capacity is at 100,000 samples/day
Opportunities *India could become a service provider, particularly to countries in Africa*	• Improve real-time surveillance in India • India could become a provider for testing capacity to other countries without sufficient infrastructure to optimally test their own populations.
Challenges *Supply chain and regulatory issues*	• Approval process • Availability of automatic RNA extraction equipment • Access to RTPCR kits • Availability of trained labour

3b. Cost of testing samples

Sampling

Kits/Reagents

INR 1200-3000/kit of 96 RTPCR reactions

Accreditation costs

INR 1000 - 2,40,000/year depending on lab size

PPE

INR 1000/kit/ person/day

Salaries

Utilities

Logistics

*approximate costs for some sub-components as are publicly available. Accreditation costs are for NABL

3b. Recommendations for Increasing Testing Capacity

	Recommendations
Lowering regulatory hurdles for private sector	Easing of approval process; allow industrial organisations to assess and grant testing approvals
Financing	Exemption on purchase of specialised equipment Payment of utilities (include sunset cost limited to COVID-19 pandemic)
Stockpiling of nasal swabs and Personal Protection Equipment (PPE)	Union and state governments could maintain a stockpile of sampling equipment and PPE to prevent any supply bottlenecks
Pricing of tests The Government offers tests free of cost to users. Tests offered by Private labs are capped at INR 4500. The Supreme Court of India announced that tests should be made free and the government could reimburse private labs later. Several states have put their own price caps - Karnataka has fixed the cost at INR 2,250. Uttar Pradesh has fixed it at INR 2,500 and the BMC has been paying INR 3,500 for testing in private labs. There have been several calls to enable free testing in India.	"Free test" is a misnomer. Government sponsored tests come with an opportunity cost – that money could be used for other purposes. Private labs can add massive testing capacity if allowed to work at a profit. Current price caps deter smaller companies from contributing to the testing capacity. Thus, private labs should be allowed to run tests and subsidise testing for those belonging to lower economic groups.

4. Summary of Recommendations

4. Summary of Recommendations

Increasing the manufacture of testing kits	*Increasing the supply of testing kits*	*Increasing testing capacity*
• Easing of approval process: convert more labs into approval testing labs • Removal of price ceilings • Partnerships between research institutions/small to mid-size startups and manufacturers • Set advanced purchase agreement with local manufacturers of approved kits	• Identify sourcing partners for vetting and purchasing kits • Remove price ceiling on actual cost • Identify and source directly from manufacturers • Aggregate sourcing as much as possible. Create a central repository of kits from which states could purchase their requirements could help reduce costs and streamline supply chain.	• Easing of approval process; allow industrial organisations to assess and grant testing approvals • Exemption on purchase of specialised equipment • Payment of utilities (short term for COVID-19) • Remove price ceiling for private labs or allow dual pricing. Subsidise testing for weaker economic sections.

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