

6 APRIL 2020

Testing scenarios: Potential challenges at different levels of testing

	Laboratories	PCR machines ¹	Laboratory manpower	Collection: manpower, PPE and logistics ²	Kits (incl reagents) ³
Current status (approval)	Public: 136 labsPrivate: 56	 Public: ~200 Private: ~80 Capacity of ~50-60K tests/ day at 1 shift 	Currently running 1 shift to deliver both COVID & non-COVID test requirement	Respective labs sending their manpower, with PPE	 Current capacity: ~15k samples/ day Near term visibility of ~50k samples/ day
Current status (installed base)		 1000+ machines Public: ~600 Private: ~400 			 CE approved MNC supplies could ramp up
30,000 tests a day		Current approved capacity can handle ~50K tests / day ¹		Need to refine collection approach + logistics	
60,000 tests a day	State level access	Need to enhance utilization of PCR machines	Train/ pool manpower to run addn shifts		Visibility of 50-60K kits / day
100,000 tests a day	State level access	Need to enhance PCR machines deployed for COVID	Train/ pool manpower to run addn shifts	ca	Expand testing / extraction kit pacity, and improve # samples/ kit

Assuming 3 runs/ shift and 96 samples/ run. 50% of machine capacity in identified labs for COVID
 Currently deployed ~1000 phlebotomists for sample collection

3. Kits include reagents for extraction, amplification, primer and probe. Can be procured individually if required

action

Limited challenges Need for coordination

Need for structured

Key recommendations to enhance capacity to 60,000 tests a day

Collection process - including transportation

- Enhance collection capacity by exploring innovative collection means; e.g. collection booths (e.g. being used in Kerala)/ movable vans/ COVID fever clinics etc. to address collection capacity
- Set up a district specific sample drop off and transportation point. The labs (if in different district/ state) to be linked with this point through daily, scheduled transport connection (e.g. through India Post/ dedicated ambulance) for ease in logistics
- PPE kit availability (in line with testing requirements) ensured at this district point

PCR machines

- Optimize capacity of 280 approved machines ramp-up shift operations to enhance capacity by 1.5X-2X
- Tap into pool of additional private sector PCR machines through
 - (a) Move under utilized equipment to approved labs, getting scale advantage and availability of manpower
 - (b) Accreditation of additional labs (over 600 machines across unapproved labs currently, atleast 20-30 additional labs with right capabilities can be added)

Laboratory manpower

- Leverage staff to conduct low skill work (e.g. data entry)
- Pool lab technicians across labs in the same geography to enhance utilization

Laboratories

- Expand approval process for labs to allow for bringing in samples from any part of country. Enable creation of centers of excellence with high benefits of scale (e.g. staff availability, support work like documentation etc)
- Expand lab network in selective states where lab density is low
- Approve additional labs of already approved laboratory chains

Key recommendations to enhance capacity to 100,000 tests a day

PCR Machines

- Clearly defined protocol for PCR + Serology based testing to reduce load on PCR
- Continue to tap into private sector machines through (a) temporary relocating to approved labs (b) Enhancing accredited labs

Laboratory manpower

- Leverage skilled technicians currently in teaching roles / in other labs upskill if needed
- Rapid training of students in their final weeks/months in major institutes across the country

Kits (and reagents)

- Explore dis-bundling the kits e.g. leverage primer and probe from Roche with extraction and amplification reagents from other manufacturers
- Explore pooled testing: Pilot phase in Germany showing potential to ramp-up capacity by 4-5 (will also reduce PCR machine requirement)

Key recommendations on Governance measures



Guidelines and procedures

- Enforce ICMR testing advisory at state level - following different norms leading to issues in home collection and data reporting
- Data management: Data around Covid+ cases should be monitored and released by central ICMR task force (and not by states)
- Allow interlab comparison with other labs/hospitals in the same city for private labs
- Widen category of testing to include symptomatic non hospitalized patients who have no history of contact



Empowered state-level taskforce

- Create a state level taskforce to make state level customizations and recommendations on the operating model involving 3 key stakeholders:
 - State Health Department
 - ICMR
 - Lead designate Private sector representative



Planning and operational norms

- Support with clear projections of volumes by the centre to private labs to enable due investment planning
- Develop clear SOP for payments
 process
- One window helpline for private labs to bring forth daily challenges and find a resolution

Appendix

Testing kits: Current capacity at ~17k samples /day, could ramp up to 50-60k samples /day with measures underway

Capacity per day	Current	Near term visibility	Potential run rate
MYLABS, India	5,000	20,000	50,000
Altona Diagnostics, Germany	1,500	4,000	4,000
KILPEST, India	-	1,500	1,500
Siemens ¹	-	16,000	16,000++
Seegene and SD Biosenser, South Korea	-	NA	NA
Thermo Fisher ¹	-	16000	16,000
Abbott	-	NA	NA
Roche	1,500	1500-5000	10,000
Stock at ICMR ²	9,000	9,000	9,000
Total	17,000	50,000 - 60,000	90,000++

1. 1Mn kits being imported by Siemens and ThermoFisher; spread over 2 months to arrive at 16,000 2. 5.5 lakh kits as of 1st April 2020 spread over 2 months

PCR Machines: While installed capacity at ~300k tests/day, deployed capacity at ~55-60k tests/ day (max. at dedicated state)

India has a large installed capacity of RT-PCR machines

	Not comprehensive	
	RT-PCR	
Public	400	
Private	600	
Total	1,000	
Tests capacity @ 1 shift	~300 / day (96 every 3 hours)	
Installed capacity	300K tests / day	

Installed capacity of ~300K tests / day

However, COVID approval is limited; in private sector only ~20% of installed base is under use

		Public	Private
machines in approved labs	Approved labs (#)	136	56
	Installed machines	~200	78
	Tests capacity @ 1 shift	60k	25-30k
dedicated for COVID	PCR machine capacity in COVID (approx. assuming 70% of installed capacity is for COVID)	~140	~56
	Max capacity at 8 hour shift	40k	15-20k

COVID capacity of ~55-60k tests / day

Lab network: Needs to be strengthened to enable access



Enhance lab capacity for testing

- Ensure a lab within a 250 KM radius for plains and within 100 KM radius in hilly areas
- Enable approved lab chains to set up an alternate testing facility with the trained manpower to conduct testing
- Accelerate approval for already accredited labs
- Enable movement of samples across different states to build large COVID labs

Innovations to improve phlebotomists and PPE: Global best practices on testing booths to increase accessibility with minimal transmission risk









Best practices from South Korea

Testing Booths

 No touch screening and testing booths, reducing risks of human to human

Drive Through

- Set up in parking lots; helps minimize contact with health workers
- Stringent hygiene norms in place - eg air circulation in car has to be set to internal
- Can collect 350-400 samples
 / day

Kerala has already started implementation



Testing booths in Ernakulam, Kerala