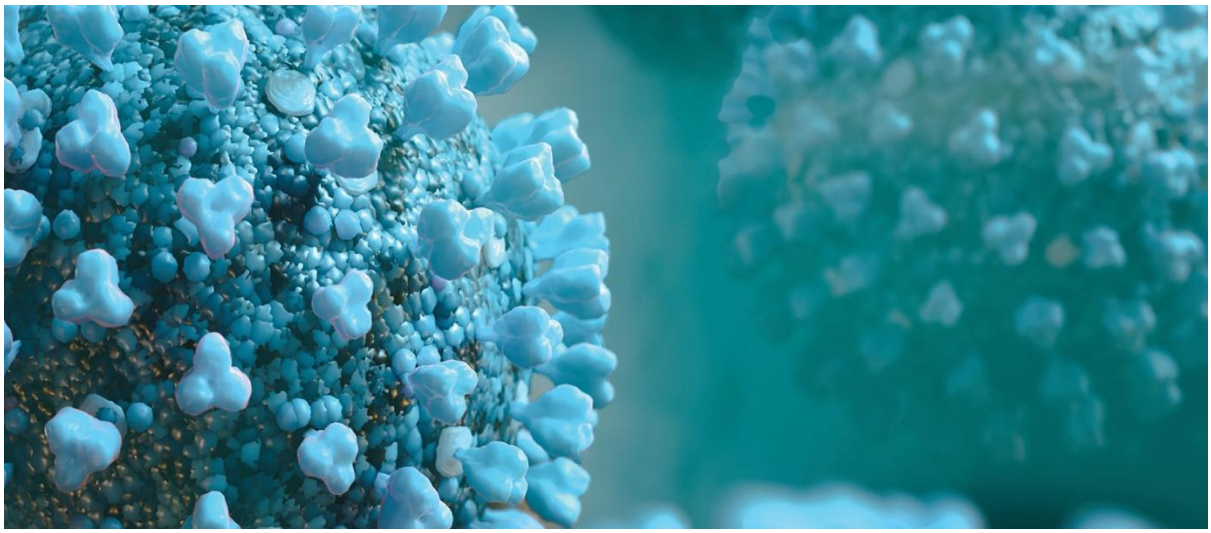
FICCI Whitepaper on ‘Economical, Accurate & Scalable Solutions for Testing’

Use of highly scalable, reliable and economic Lab-Based Immunodiagnostic Test as an approach for COVID-19



Executive Summary

Highly Reliable, Accurate, Scalable, Easy to Use and Economic Lab based Serology Test as a solution for wide scale testing

While lockdown measures so far have **proven beneficia**l for India, the COVID-19 pandemic is still continuing to evolve with numbers of cases on a rise. With nearly **70%**[1] of cases occurring in the 11 economically relevant cities which account for a high proportion of the consuming class households, economic recovery is expected to be a U-shaped curve[2,3]. The key question is whether a **protracted lockdown to save lives** is better than **worsening damage to economy and livelihoods**. Given the potential economic impact (economy will contract **by 5% in 2020-'21**)[2], there is a need for an **effective testing strategy** which will form the linchpin for saving lives and getting people back to work.

During the **lockdown**, **diagnosis** was the key focus hence molecular testing formed the backbone; however, India now requires **large scale testing** to identify the extent of **infection and immunity** to inform **containment strategy** as well as assess the **safety of returning to work.**

No diagnostic test is perfect for all uses and there are trade-offs that exist on the basis **Speed, Accuracy, Sample type and Availability and Cost.** Each platform offers its distinct advantages (e.g., Rapid Antibody & POCS tests can be easily used rural areas). Lab based immunoassays can be used as a force multiplier in sero surveillance (e.g., Chemiluminescence immunoassays, Enzyme Linked Fluorescence Assay, Enzyme-linked immunosorbent assay) . The choices we make in deploying specific diagnostics can inform both treatment and the allocation of vital but limited resources and inspire confidence.

Immunodiagnostic tests can provide information on both current and prior infection (i.e., prevalence of infection and immunity especially for asymptomatic population) and also offer **ease of sampling** and **scalability**. High sensitivity & specificity is a compelling need for Ab tests and **lab based Immunodiagnostic/Serology tests** e.g., CLIA, ELFA, ELISA) can offer **high accuracy & reliability.**

Lab based Serology tests also offer a **significant economic cost advantage**. The **analyzers** for testing are **available across small - to large-sized laboratories** (in metros, Tier I/II & beyond) and are capable of producing thousands of tests reports a day **(TAT of 10 mins- 60 mins)** with minimal human intervention due to high automation leading to **faster and reliable results** from the time of sample collection to delivery of reports.

Lab based Serology tests help determine previous exposure and potential immunity hence can be beneficial across COVID-19 impacted industries such as **healthcare, logistics**, **aviation, essential service, hospitality and MSMEs.** In the future, these tests would help identify donors for convalescent plasma therapy.

Scalability and accuracy of Lab based Serology tests can be tested out as a **pilot in State(s)** with high case load. State Govt. officials which are currently involved in surveillance activities can identify risky sections of the communities and map out labs and hospitals where the clinical samples will be sent. District officers can chart the plan of testing an area or looking at a profession (e.g., Healthcare followed by public-facing jobs, including food service workers, delivery drivers etc.). **Appropriate governance models** via a technology partner can offer automated **daily reporting to ICMR** so support overall monitoring objectives, like currently being mandated by ICMR. In addition, Employers can **test their employees** for safety to return back to work and to boost confidence.

ICMR & MOHFW should expand the COVID-19 Testing Strategy and select key factors that will define success include:

- Provision for inclusion of automated **Lab based Serology tests** (Chemiluminescence immunoassays, Enzyme Linked Fluorescence Assay) and Rapid ICT as a solution for COVID-19
- Inclusion of pan India **private labs and hospitals** in addition to the ICMR labs to leverage the potential of wide scale testing (network of 1000+ labs can offer a wide **scale of testing**, **higher throughput of 700-4000 tests /day/ analyzer** and an existing logistics, sample collection & support network)
- Clear guidelines on safety precautions during specimen collection, transportation, and processing

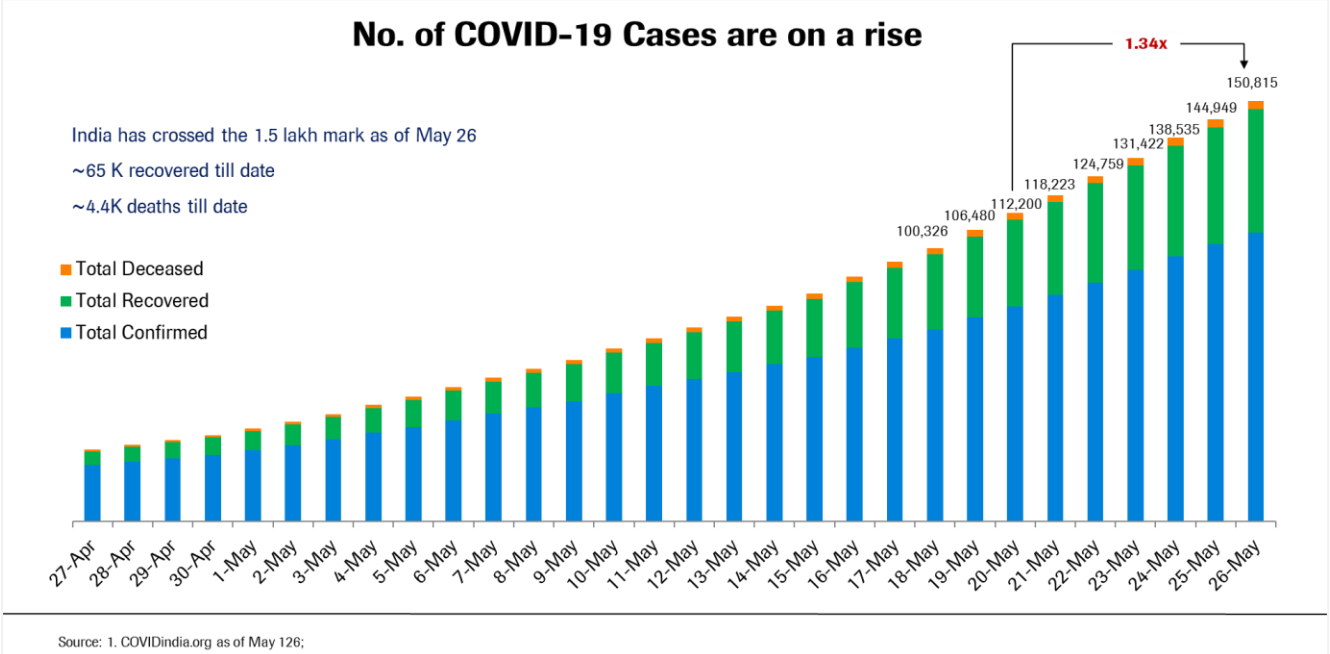
In addition, Govt. guidance around defining criteria for Antibody tests and setting thresholds of specificity and sensitivity can be explored as an option (e.g., having CDSCO approval, CE- IVD or US FDA EU authorizations). One-point approval window for ex ICMR is the need of the hour to expedite the availability and implementation of the antibody testing strategy against COVID-19. ICMR should provide a clear algorithm for Antibody based tests, indications for testing both IgM and IgG, implication of result for positive as well as negative result of each and define the frequency of retesting of IgG antibodies interval. **Lab based Serology testing** offers an opportunity to slowly kickstart the economy. **Effective scale up** can offer economic benefits to industries such as logistics, airline and hospitality that are deeply impacted by COVID-19. The challenge of curtailing the COVID-19 epidemic and 'flattening the curve' is also an opportunity for our country to script a narrative of success that would serve as a source of inspiration for us as well as the rest of the world.

I. COVID Scenario in India

Analysis of the Spanish flu pandemic suggests that cities which went into lockdown earlier (8 days earlier) had a higher avg. employment rate compared to cities that extended the lockdown for an extra six weeks. While that was a different era, the trade-offs remain the same - a **protracted lockdown** leading to **saving lives versus worsening damage to economy** and **livelihoods**.

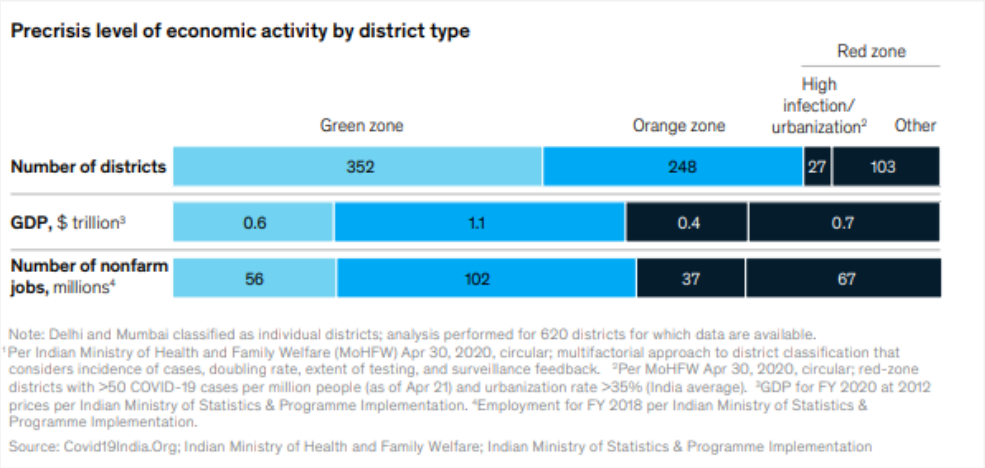
COVID-19 may continue to have an economic impact post lockdown due to residual fear, pervasive uncertainty, a lack of innovative fervour and deepened inequalities. Comparison of spending patterns in Denmark & Sweden provide an early indication of the same[2].

While lockdown measures so far have **proven beneficial** for India in terms of slowing the spread (estimates suggest 1.2 lakh – 2.1 lakh lives have been saved[28]), the COVID-19 pandemic is continuing to evolve and the numbers of cases are on a rise (avg. of **~6K daily cases per day: May 20 to May 26**[5]). Based on the current seven-days moving average of new COVID-19 cases, estimates expect a peak early July[12]. The rise in cases have strained medical capacity and overburdened health system, leading to questions about the effectiveness of an extended lockdown[2]



COVID-19 has impacted the several industries with a drop in demand, sales & profitability and is estimated to cost the Indian economy approximately $320 billion in terms of daily gross domestic product (GDP) loss after 40 days of lockdown. India's GDP growth forecasts have been revised downwards over the last few weeks[6]. This is expected to be India's fourth recession since Independence and analysts estimate the **economy to shrink by 5%** in the current fiscal due to the coronavirus lockdown[1]; few factors[1] that attribute to it include 38 million in job losses, worsening of non-performing assets crisis, drop in industrial activity with MSMEs (Micro, small medium enterprises)[2]. Additionally, the $266 B economic relief package is set majorly on reforms, most of which will have payoffs only over the medium-term[1]

With **approx. 126 M**[9] of the population living in **Metros and Tier I cities and the top 11 cities contributing to 70% of the cases**[27], this evolving situation requires constant monitoring and scenario planning to ensure a **robust mitigation strategy**.



The **case load** is high in areas of high national economic activity (such as Mumbai, Delhi, Pune, Chennai, Bengaluru, Hyderabad and Kolkata), hence economic normalcy is expected to take longer. These areas contribute to more than **50%** of India's consuming-class households[9]. A V-shape recovery may not be possible across several sectors due to demand destruction and it is anticipated that several industries will undergo a prolonged U-shaped recovery with contractions in the first two quarters of fiscal 2021[3].

As India looks at opening up the economy, precautionary measures such as social distancing, staggered workplace norms, travel restrictions, testing, containment and use of PPEs will all gain greater significance. Among these precautionary measures, testing is one of the most critical aspects, an effective testing strategy will form the linchpin for saving lives.

During the lockdown, the key focus has been on diagnosis to ensure identification, triage and remediation. Thus, molecular testing formed the backbone of the testing approach and offered effective results. However, once the lockdown is lifted, several considerations will come into play, which will warrant a different approach to ensure continued success of India's efforts towards 'flattening the COVID-19 curve'.

Almost 70% of the cases in India have been asymptomatic and with the population going back to work, this may lead to a higher risk of infection. Additionally, students going back to the academic session and return of migrant population may also add to the burden. With joint families being a commonplace paradigm for us, the elderly are at a higher risk of contracting the infection despite the measures to stay indoors. During this lockdown period, there have been several cases of healthcare workers contracting the infection while administering care. The need for a robust large-scale testing approach to identify the extent of infection and to assess the safety of returning to work is essential for revival of the economy. At this juncture, we need the ability of testing with **accuracy and capacity** to meet the needs of such large-scale testing in both **government and private sectors**.

II. Current testing options

The Gold standard for diagnosis of COVID-19 is based on nucleic acid amplification (NAT) using real-time reverse- transcription polymerase chain reaction (rRT-PCR) as it indicates current infection[8]. The Indian Council of Medical Research (ICMR) recommends rapid antibody tests for SARS CoV-2 in patients depicting symptomatic influenza-like illness for more than 7 days in Hotspots) and in large migration gatherings/evacuee centres (ICMR advisory, 2020). CBNAAT is also being deployed across states for COVID testing.

Several options for testing exist now compared to the situation a month ago thereby making it crucial to understand the benefits and limitations of the options to define the right test. No diagnostic test is perfect for all uses and there are trade-offs that exist on the **basis Speed, Accuracy, sample type and Availability and Cost.** The choices that we have in deploying specific diagnostics can shape and inform both treatment and the allocation of vital but limited resources and inspire confidence.

If diagnosis and triage is the need, where accuracy, rapid turnaround time, and throughput are key considerations, the most appropriate tests are IVD molecular tests. Antigen tests are currently not available; however, if reliable tests become available they could be used to diagnose when PCR is not available. Antibody tests play a crucial role if one has to check for exposure to infection and potential immunity. There are three types of Antibody tests – Rapid antibody tests, ELISA, Chemiluminescent immunoassays. The Table below (#1) highlights the key differences between the various options available

Comparison of Options Available for Testing

Parameter	Molecular Tests	Lab based Serology Tests	Rapid AbTests	Point of Care
Scalability	Automated solutions, Local Manufacturers	High, existing network of 1000 labs	High, availability of kits	Separate instruments to be bought
Sampling Ease	Throat & Nasal Swabs	Blood sample	Blood sample	Blood sample
Skill Level	High skill set	Basic	Easy to use (deployed by ASHAs and ANMs)	Basic
Throughput	~400-1000 tests/ day/instrument	1200 /day/instrument[1]	High (based on kits)	Low – Medium (based on instrument)
Specificity & Sensitivity	Very high	High[2]	High	Moderate
Cost	High	Low	Low	Variable
Infra requirement	Dedicated lab setup	Dedicated lab setup	No Infra needed	Mobile usage
Global Usage	Globally adopted as a gold standard	Widely adopted in Italy, Singapore, UK	Widely used in UK, Spain, US , Australia	Widely used in US
Potential Usage	Diagnosis & Triage	Seroprevalence, potential immunity & serosurveillance	Seroprevalence, & serosurveillance	Screening
Approval Status (India)	Allowed in ICMR approved labs for Diagnostics	ELISA allowed; CLIA, ELFA yet to be inducted	Allowed for Surveillance Only	No Clear indication for use

Note: 1. Avg. 1200 /8 hr shift/instrument (depending upon the instrument); 2. Select Chemilumiscent instruments offer accuracy close to PCR ; 3. CLIA: Chemiluminescence Immunoassay; Enzyme Linked Fluorescence Assay

Key: Very High | High | Moderate | Low | Minimal

As of May 30

From an accuracy standpoint, Immunoassays manufacturers claim high specificity of greater than 95%, with few offering >**99% specificity and 100% sensitivity** (≥14 days after PCR confirmation). Even small reductions in specificity (even by 0.5%) can increase the number of false positive results substantially leading to labelling of those unexposed to the infection as exposed. Additionally, many patients,

especially older and those with co-morbidity conditions like diabetes, hypertension, cancer, renal and other immuno-compromised conditions may not show the formation of antibodies at all.

Automation of immumoanalyzers reduces the turnaround time **(10 to 60 Minutes)** improves accuracy leading to **faster and reliable results from the time of sample collection to delivery of reports**. **Accuracy** of the assay, **speed** of delivery of results from the time of sample collection, **availability** and **accessibility** of testing platforms and the **sample type** used (accessibility and accuracy depend on it) are key considerations in selection of an assay[7].

Each platform offers its distinct advantage, rapid antibody tests and PoCs offers benefits of no sample transfer, high scalability and increased access to tier II/III and rural areas where it can be deployed by ASHA workers. On the other hand, Lab based fully automated immunoassays offer tremendous advantage in centralising testing with high throughput and high accuracy and can be used as a force multiplier in sero surveillance efforts across the country. The current installed capacity of instruments that can run a Lab based Serology test is believed to be greater than **12,000 in the country** (including private NABL accredited labs)[8] and this installed capacity in the country can run up to **8-10 lakh tests** /day (assuming inclusion of private NABL labs in addition to ICMR labs) with a higher throughput of **700-4000 tests /day, per analyser** . **Thus no new significant investments have to be made to augment Equipment capacity**. In addition, the turnaround time for tests on totally automated instruments is between **10-60 mins**, thereby reducing the manpower cost for the same. The cost of conducting **wide-scale Lab based Serology tests** significantly outweighs the **opportunity cost of an extended lockdown.**

At this stage of pandemic outbreak, India needs to pool in all potential testing platforms and for use at different healthcare levels basis the different needs each best suited for.

Benefits of Lab based Serology tests

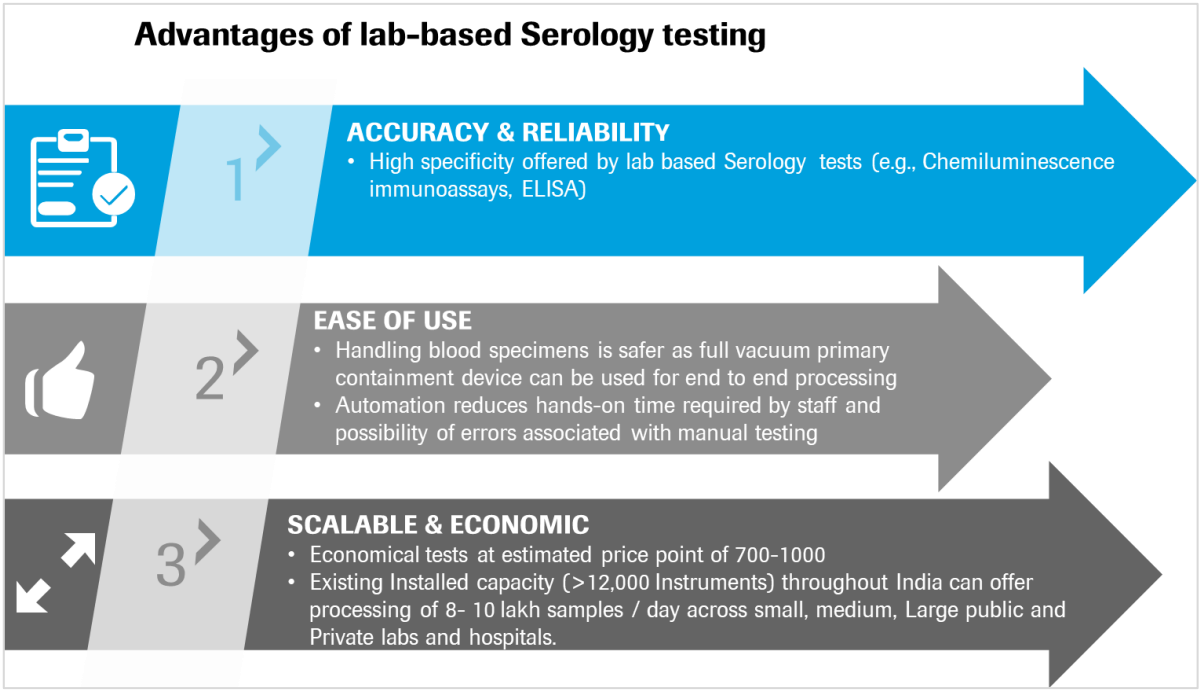
Lab based Serology tests are known to have high sensitivity and specificity and have higher accuracy and reliability.

- Lab assays use standardized reliable technologies on platforms with varying degrees of automation and offer a high degree of scalability. Existing instrument base in India in 1000+ NABL labs can offer the scale that India needs to expand testing. The analyzers are readily available across small- to medium- to large-labs. Much less sophistication is required for setting up new immunoassay facilities at labs. Lakhs of tests can be done in India per day using the existing Installed capacity in Private and Public set up.

- Blood samples are easy to collect in evacuated tubes and are routinely handled and processed in laboratories. Evacuated tubes along with safety engineered devices can ensure health care workers & patient's safety as well

- Additionally, automation reduces hands-on time required by staff and possibility of errors associated with manual testing. In addition, blood samples are routinely collected at remote locations, preliminarily processed (centrifuged), as necessary, in small lab set ups and transported across geographies.

Lab-based Serology testing has a complementary role to molecular testing. While the 'gold standard' RT-PCR test is conducted for diagnosis and discharge, antibody testing would indicate exposure to infection and potential immunity. Considering the factors above, Serology tests can help **monitor the pandemic and offer the scale that is needed at economical levels.**



Identifying the **spread on infection** in the population, burden of disease and the existence of **possible immunity** will now become important for India and Lab based Serological tests are best suited for this. As India works towards 'flattening of the COVID-19 curve', availability of standardized immunodiagnostic assays in **both government and private sectors** would be crucial to inform the right decisions for achievement of its goals.

III. Utility of antibody assays

A variety of antibody assay can help in accurate and reliable identification of SARS COV2 past exposure during the early and late phase of infection.

Healthcare Industry

Antibody assays help determine previous exposure and potential immunity. They have potential utility in screening health **care workers and first responders** to identify those who could be potentially immune and can be deployed to care for infected patients. In addition, lab based serology tests with RT-PCR can potentially be used for screening patients prior to surgery to define the right protocol for their in-hospital management.

Freight & Logistics

The sector forms a backbone to all sectors and continued disruptions will impact all sectors. Half of the drivers engaged in freight movement across the country come from 14 districts[2]. Restrictions on the movement in these districts could affect the ramping up of national logistics activity. Employers

can look at screening their drivers to define they can get back to work and identify if there may be potential carriers.

Essential service personnel

Testing of at-risk front-line essential service personnel who are involved in providing essential services even beyond healthcare like security forces, police, and door to door delivery services.

Hospitality sector

With the lifting of lockdown, Lab based Serology tests can be leveraged as an option to screen staff on a regular basis at airports or hotels to identify individuals that they are ready to get back to work.

MSME Sector

Lab based Serology tests can be used for the MSMEs (especially of essential commodities) to monitor the infection and potential immunity. Common measures have already been taken into consideration by the sector which include health checks at factory entrance, provision of Personal Protective Equipment (PPEs), staggering of shift and break times to minimize congestion of people, maintain social distancing during work and compulsory use of Aarogya Setu application. Few MSMEs are considering further measures such as pre-start up fumigation of factory premises and rearrangement of work stations to maintain social distancing. Addition of Lab based Serology tests can be leveraged to monitor exposure and potential immunity and help them get back to work.

Use in convalescent plasma therapy

ICMR has initiated convalescent plasma therapy trial at multiple sites and it is hoped that the therapy will become available for clinical use in the near future. It can be extremely useful to **identify donors** for convalescent plasma therapy and evaluation of the results of **vaccine trials.**

Once COVID-19 vaccines become available, the antibody tests would be helpful to determine **immune status in order to administer vaccine to susceptible individuals**. Depending on the type of vaccine, these tests could also be potential companion diagnostics

Public health

Antibody tests are required for epidemiological studies to determine seroprevalence, the rate of asymptomatic carriage, extent of virus spread in households, communities and specific settings, mortality attributable to COVID-19 and the population still at risk of infection. **Serosurveillance** i.e. continued surveillance of **seroprevalence** through serial antibody testing would help to determine herd immunity. Antibody tests are also important for patient contact tracing.

Testing Practices across the Globe [4,14,15,22]

Select Testing Practices around the Globe

	SWEDEN	VIETNAM	GERMANY	SINGAPORE	US
ANTIBODY TESTING	YES	YES	YES	YES	YES
SOCIAL DISTANCING	Limited distancing measures	Limited distancing measures	Limited distancing measures	Limited distancing measures	Limited distancing measures
STRATEGY	• "**Herd immunity" strategy** to protect the most vulnerable populations. • To **develop a large enough pool of exposed people** (about 70 to 80 percent) to "**protect the herd.**"	• **Extensive Testing** - *800 people tested for each new confirmed case.* • Serology testing **used for Healthcare workers, Travel** etc.	• Leveraging serological tests to make **Informed decision on relaxing physical distancing** measures	• Serological tests used o **identify epidemiologic links** between cases that were not identified through traditional means	• 3-part serological testing strategy 1. Priority hot spots 2. Expanding to broader geographies 3. Specific priority populations like HCWs

IV. Scalability of lab-based Serology Tests

Scalability and accuracy of lab based Serology tests can be tested out as a pilot to help understand prevalence and need for containment measures. However, this cannot be a state or country wide strategy, the testing approach has to be localized.

i. Corporates and Commercial Hubs

With business confidence at the lowest since Jan 2020 (30 point fall[24]), and nearly 60%[25] of CEOs preparing for a U-shaped recovery, an effective testing strategy can boost **business confidence**. Across the globe several corporates (i.e., Employers) are looking to leverage Antibody tests to safety to return back to work (e.g., Amazon, General Motors etc.[25]). Leveraging Lab based Serology tests on a regular basis tests for employees could keep exposure to a minimum and **boost employees' confidence** about coming back to work and re-establishing work as a safe place.

Commercial hubs have thousands of employees which can pose a potential risk. Commercial hub or individual employers can leverage Lab based Serology tests, to test their employees. Based on the increase in number of positive antibody tests, relaxations around **containment measures, social distancing** can be modified. Urban settings have a strong network of labs which can allow employers to conduct the test at **different locations and multiple times** (as the guidance from Govt maybe). The employers can monitor results of their employees to see trends or patterns with respect to infection rates. Mandating testing in large commercial hubs in hotspot areas can be explored as an option to help return back to work.

Select countries (e.g., Singapore) have mandated testing of workers coming back across industries including construction sites, factories, restaurants or any businesses if any Covid-19 cases are detected among employees. Antibody tests are being made available to NHS and care staff, eligible patients and care residents in England to see if they have had coronavirus as part of a new national antibody testing programme[29].

Adoption of CLIA tests by other Countries

Singapore

Migrant workers

- "Aggressive testing regime" targeting the **300K migrant workers** living in dormitories
- Ab tests at sites with higher levels of infection, and individuals with Abs will be allowed to go to work
- PCR testing for individuals w/o Antibodies

United Kingdom

Mass Public Testing

- Antibody tests (CLIA) will be offered to all health and social care staff in England to determine whether they have had Covid-19
- Results will offer better understanding of the true prevalence of the virus across regions and will also improve scientific knowledge about the body's response to Covid-19.

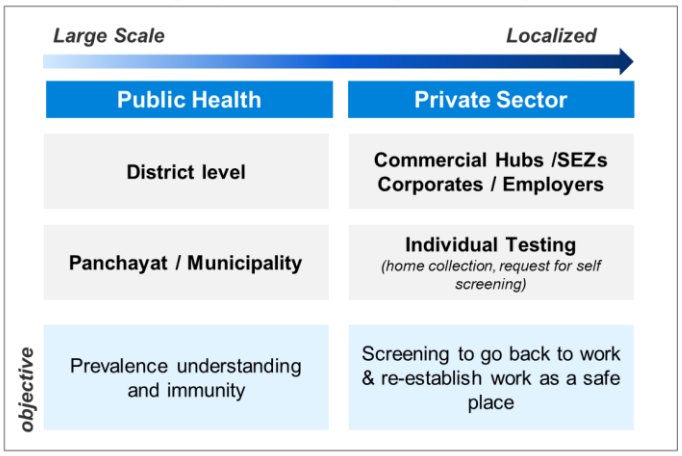
Source: https://www.straitstimes.com/singapore/health/major-effort-under-way-to-determine-extent-of-infection; https://asia.nikkei.com/Spotlight/Coronavirus/Singapore-to-test-all-300-000-plus-migrant-workers-for-coronavirus; https://news.sky.com/story/coronavirus-new-100-accurate-covid-19-antibody-test-approved-for-use-in-uk-11987924

ii. Testing at District, Municipal & ward levels

Selection of states with high case load/low testing (e.g., West Bengal) or high load / high testing (e.g., Maharashtra) or states that are close to flattening the curve can offer an opportunity to understand epidemiology and prevalence. These tests have a potential for expanding Access to tier 2 -3 cities and if required post the pilot.

Wide scale testing can be done either by prioritization of hotspots where individuals can go back to work or by prioritization of individuals by occupation in an area. For example, healthcare workers (including staff) can be prioritized, followed by essential public-facing jobs, including food service workers, delivery drivers, and grocery.

Screening objective can vary basis Segments



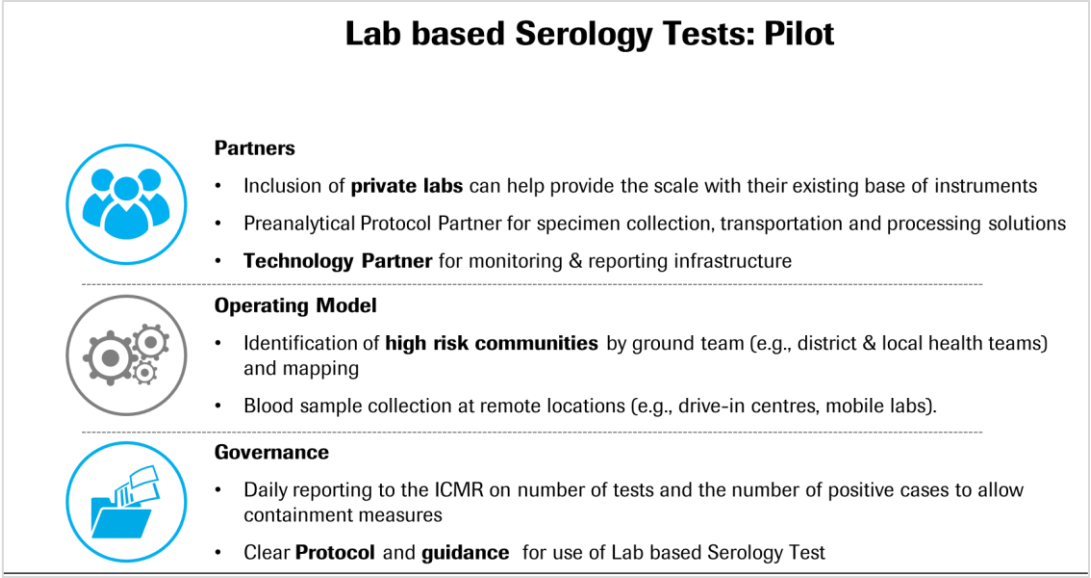
Assumption that Private sector will fund itself

There are three essential levers to ensure success of a wide scale testing approach:

a) Partners:

- **Lab partners**: Inclusion of private labs and hospitals in the prioritized State(s) can help provide the scale to conduct the tests in addition to the ICMR labs.
    - COVID-19 assay would run on the immunoassay analyzers that routinely perform various serology tests every day. The analyzers are readily available across small- to medium- to large-labs with a **higher throughput** of **700-4000 tests /day /analyzer**
    - Trained staff for operating the analyzers is already available which can conduct the blood collection in a safe & effective manner

- **Diagnostic Manufacturers:** Production of the antibody assays is easily scalable with numerous manufacturers with the ability to offer high quality kits.
- **Technology Partner:** Tie up a technology partner to support the infrastructure for daily reporting of tests and maintain a registry of individuals tested as individuals may be tested multiple times. Hence a registry of individuals, who have been tested, would have to maintained and managed by an organization capable of handling that data securely and without conflicts of interest. Patient confidentiality and privacy would be especially important considerations for any test.
- **Preanalytical Protocol Partner**: Tie up with a national pre-analytical brand which can provide robust, accurate & safe solutions for specimen collection, transportation and processing



b) Operating Model:

State Govt. can enlist district officers in every district to identify risky sections of the communities. Segmentation of high risk communities can vary basis **number of cases** and **growth rate of cases** in a community**.** The task force in the State can map out labs where the clinical samples will be sent basis the sample collection points that have been identified. This will allow seamless transfer of samples to the network lab. Collection of blood samples can easily be done at the remote locations (such as drive-in centres, mobile labs).

Public health workers, social sector workers can be enlisted as volunteers to support the logistics and execution of the program on ground

Samples can be preliminarily processed (centrifuged), as necessary, in small lab set ups or can be routinely transported across easily with a lowered risk of infection across geographies.

Sampling Approach for Serosurvey: Govt. is currently looking to conduct a Serosurvey in select districts with **400 cases /district.** Screening a wider population base (top 5 districts basis case load[c]) can offer better understanding of seroprevalence, rate of asymptomatic infections, spread in high-risk groups. Crosssectional survey of selected districts using stratified random sampling:

- **Two strata approach:** Hotspots/ containment zones and Non-containment areas in red zones
- **10,000 samples/district** (5,000/stratum/district) of the total could be sampled in the survey
- **Expansion**: Serosurveillance applied across all red zones. In parallel, serosurvey for selected orange and green zone districts can be conducted followed by a state-wide expansion of serosurveillance

c) Governance:

To understand the changing patterns of spread of infection and to monitor the level of exposure of the population, continued surveillance i.e. testing at regular intervals will be required.

- Private labs can upload a report on a daily basis with details on the number of tests conducted in a day and the number of positive cases. This would allow ICMR to monitor the macro level trends and patterns
- RT-PCR testing can give further information on presence of active infection in an antibody positive case

Post pilot at select State(s), Lab based Serology tests can be scaled to include mass public testing in the country to identify the spread of disease, prevalence of potential immunity and determine need for intermittent lockdowns in the coming days. Cost effectiveness of the kits offers an opportunity to reduce the overall economic burden on a state.

V. Conclusion

In the past two months, India has functioned at 49-57% of its full activity level; the economic costs of continued lockdown may not sustainable[3]. The economy will have to be managed with the risk of infection and there exists a possibility of intermittent lockdowns that we are witnessing in other parts of the world. India, with its vast epidemiological and social-cultural diversity, cannot have a singular testing approach going forward and the only way to come out of the lockdown by expanding testing, tracing, and treatment capacity, strengthening public & private health system, and ensuring a socioeconomic safety net.

Surveillance must be expanded, through a combination of household surveillance for influenza-like illness and an expanded package of testing. State governments should engage **local communities** by linking **district and local health teams** with community leaders and volunteers. The State Govt. can evaluate reinforcing the principle of locking down only the containment zones and not the entire districts, in line with MHA guidelines. With adequate support and supervision, local communities can play a key role in contact tracing, monitoring social distancing, shielding the vulnerable, and encouraging people to seek treatment when they need it. Laboratory-based Serology will address the gaps of the current solutions and fulfil the unfolding needs by pooling in capacity available in the private labs. At this stage of pandemic outbreak India needs to pool in all potential testing platforms and use them to their advantage at different healthcare levels and for different needs each best suited for.

Key factors that will define success with this approach include:

- Provision for inclusion of automated **Lab based Serology tests** (Chemiluminescence immunoassays, Enzyme Linked Fluorescence Assay) and Rapid ICT as a solution for COVID-19
- Inclusion of **private labs and hospitals** in addition to the ICMR labs to leverage the potential of wide scale testing. The Non - NABL can be considered for the rapid antibody tests
- Clear guidelines on safety precautions during specimen collection, transportation and processing

In addition, Govt. guidance around good quality tests and setting thresholds of specificity and sensitivity can be explored as an option. **Lab based Serology testing** offers an opportunity to slowly kickstart the economy. Speed and scalability are critical to understand seroprevalence & serosurveillance and **CLIA** should be given an **equal opportunity** as it can act **as a force multiplier**. **Effective scale up** can offer economic benefits to industries such as logistics, airline and hospitality that are deeply impacted by COVID-19. The challenge of curtailing the COVID-19 epidemic and 'flattening the curve' is also an opportunity for our country to script a narrative of success that would serve as a source of inspiration for us as well as the rest of the world.

Appendix: Sources

1. First post health/covid-19: India to face the worst recession, May 22, 2020; COVID India perspective: BCG Analysis, Apr 24, 2020
2. Financial express – opinion on why-extending-lockdown-could-be-catastrophic, May 1, 2020
3. Reopening India: Implications for economic activity and workers, Mckinsey, May 2020
4. the Economist –The 90 economy that lockdowns will leave behind, April 30, 2020
5. COIVID.India. org cases as of May 27, 2020
6. Economic times - 40-day-lockdown-to-inflict-320bn-loss-on-indian-economy-report
7. Coronavirus: India's biggest concerns are COVID-19 patients with no symptoms, the Mint Apr 22, 2020
8. GOI guidelines, 2020; WHO interim guidance, 2020
9. BCG report as of 20-mar-2020
10. Amanat et al. 2020 [5] Haveri et al. 2020 [6] Woelfel et al. 2020 [7] Kissler et al. 2020 [8] Li et al. 2020
11. Liang et al, 2020; Duan et al., 2020
12. How to best implement Coronavirus testing in the US, Apr 2020, BCG Report
13. Center for Disease Dynamics, Economics and Policy, Dr Ramanan Laxminarayan, Outlook India new cases to peak in Early July
14. Economic times –MSMEs see-potential-return-of-lock down-in-the-future-as-a-major-challenge-unido-survey, May 2020
15. Study led by researchers from the Helmholtz Centre for Infection Research.
16. Developing a National Strategy for Serology Testing in the United States, John Hopkins, Apr 2020
17. https://foreignpolicy.com/2020/05/02/herd-immunity-india-coronavirus-pandemic/
18. https://theprint.in/opinion/indias-lockdown-2-can-cost-as-many-lives-as-it-saves/402269/
19. https://arstechnica.com/science/2020/04/lockdowns-flatten-the-economic-curve-too/
20. COVID -19 India Impact Survey, IFC Apr 2020 report; 4. Forum; EY –FICCI report
21. Hindu- coronavirus infections are the highest in Asia, Apr 28
22. BCG testing our way out of COVID
23. Developing a National Strategy for Serology Testing in the United States, John Hopkins, Apr 2020;
24. Coronavirus: India's biggest concerns are COVID-19 patients with no symptoms, the Mint Apr 22, 2020
25. Reuters survey of 500 economists and WEO, YPO survey
26. IMA business confidence & performance survey; 4. Forum; EY –FICCI report
27. WSJ – To get back to work companies seek coronavirus tests for workers, May 2020
28. News18.com Center likely to extend lockdown in 11 cities , May 26 2020
29. PIB India – Stay at home, Stay Safe (BCG Model, May 22)
30. Government to offer antibody tests to health and social care staff and patients in England, UK Govt, May 21, 2020

Established in 1927, FICCI is the largest and oldest apex business organisation in India. Its history is closely interwoven with India's struggle for independence, its industrialization, and its emergence as one of the most rapidly growing global economies.

A non-government, not-for-profit organisation, FICCI is the voice of India's business and industry. From influencing policy to encouraging debate, engaging with policy makers and civil society, FICCI articulates the views and concerns of industry. It serves its members from the Indian private and public corporate sectors and multinational companies, drawing its strength from diverse regional chambers of commerce and industry across states, reaching out to over 2,50,000 companies.

FICCI provides a platform for networking and consensus building within and across sectors and is the first port of call for Indian industry, policy makers and the international business community.

FICCI Medical Device Team

Shobha Mishra Ghosh
Assistant Secretary General
FICCI

Harsh Vardhan
Senior Assistant Director
FICCI

Kapil Chadha
Research Associate
FICCI

Email: mdf@ficci.com