

The background of the slide is a blurred photograph of a person wearing a white lab coat and yellow gloves. The person is holding a long, thin white swab with a red cap. The background is out of focus, showing what appears to be a laboratory or clinical setting.

The Critical Role of Diagnostics in COVID-19 Management

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SUMMARY OF RECOMMENDATIONS

The COVID-19 pandemic has brought on unprecedented health and economic challenges to policymakers globally. Development of vaccines, understandably, has become the focal point of most countries to decrease the mortality rates and control the spread of disease. However, supplementing vaccine roll-out with effective testing approaches remains essential to control transmission, survey transmission rate, and monitor vaccine efficacy.

With the emergence of new viral strains, testing strategies become increasingly relevant to monitor the spread given the high transmission rate and global prevalence. Through tireless efforts, APAC has gained access to a wide array of screening and other diagnostic tools that can help manage the pandemic and limit its negative impact. Since each of these testing tools meets different objectives, there is a need to tailor the testing approaches to the situation at hand for improved disease control and management of resource constraints.

In this review, we begin to define the role of these testing toolsets individually or in combination to identify hot-spots within the community, re-open economies, resume travel and support vaccine-roll out. We highlight the utility of these tools in practice globally, and we encourage all stakeholders to leverage this 'toolset' to return societies as fast as possible towards economic recovery and growth.

There exists a spectrum of practices that have already been widely adopted in select countries and those that continue to emerge in others. Summarized below are a set of recommendations for integration of robust testing strategies across different scenarios in COVID-19 management.



1. Community Surveillance & hotspot management

- 1.1 Conduct surveillance of patients with symptoms suggestive of COVID-19 infection in primary care centres, nursing homes, and hospitals with a combination of molecular and antigen test
- 1.2 Carry out targeted community surveillance of persons vulnerable to infection, those with a high risk of exposure and high interaction groups such as healthcare workers and delivery personnel with a combination of molecular and antigen test
- 1.3 Conduct population-wide epidemiological surveillance using serological testing to monitor disease prevalence and guide allocation of public health resources and vaccinations
- 1.4 Consider pooled testing to be applied in static and low prevalent population to optimize resource usage. Antigen test can be used in settings where quick turnaround is required
- 1.5 Conduct surveillance using sequencing tools to identify and track novel genomic variants



2. Economic resilience & recovery

- 2.1 Enforce social distancing and universal mask wearing
- 2.2 Employ both forward and backward tracing to identify close contacts of infected cases and "super-spreaders" using a combination of molecular, antigen, and antibody testing
- 2.3 Conduct rostered routine testing of asymptomatic high-risk workers (factories, healthcare) with appropriate legislation to prevent marginalization of employees due to test outcome
- 2.4 Perform pre-event testing for large gatherings of > 100 people, nightlife venues
- 2.5 Conduct regular testing at workplaces and educational institutions. Consider prioritization of critical workplaces where people have a higher exposure risk (e.g. quarantine hotel staff, airport workers) and where there is difficulty in social distancing



3. Travel resumption

- 3.1 Employ risk-based management of border entry based on disease prevalence in country of origin and management capability in receiving country. Entry requirements should consider a combination of testing and quarantine to manage risk dynamically
- 3.2 Consider requirement of a negative pre-departure test within 72 hours (based on common practice) before travel is allowed
- 3.3 Establish testing capacity at the airport/transport hub to reduce turnaround times
- 3.4 Consider combinations of molecular test, antigen test, and repeated tests for scalability while still controlling risk
- 3.5 Ensure cross border cooperation to identify and recognize 'certified laboratories' or test manufacturers using validated test methods for pre-departure testing



4. Supporting vaccine roll-out

- 4.1 Consider vaccine prioritization by identifying individuals with pre-existing immunity
- 4.2 Maintain national registries of vaccine recipients to track long term safety and efficacy
- 4.3 Investigate vaccine response and durability in vulnerable populations, using antibody levels as a surrogate measure of protection
- 4.4 Monitor asymptomatic cases via routine testing of a subset of high-risk vaccine recipients
- 4.5 Regularly quantify antibody levels in the vaccinated population, to determine threshold of protection against COVID-19 and validate initiatives such as immunity/vaccine passports
- 4.6 Use quantitative antibody assay traceable to international reference material so that antibody level among different methods is standardized and comparable
- 4.7 Develop policies around the recognition of test results and test types to assess immunity to ensure results are acceptable across countries

1. INTRODUCTION

By the end of 2020, over 11.5 million people in the Asia-Pacific (APAC) region had contracted COVID-19, with an average mortality rate of 1.5%¹. The pandemic and the stringent restrictions that followed have severely impacted the region's economies, some of which experienced a GDP contraction of up to 6%². Lately, new variants with potentially greater infectivity have been identified in South Africa, Europe, and Asia^{3,4}, and such mutations are expected to evolve with increasing spread⁵. Testing strategies play a pivotal role in gaining an understanding of the rate of transmission, and in the identification of hotspots with existing or new viral strains for early isolation and response.

As of January 2021, different vaccines have been approved for use, while others are at different stages of clinical trials. Government agencies and vaccine suppliers face ongoing challenges over vaccinating the whole population against a backdrop of limited supply. The long-term efficacy and safety of vaccines (six months after use) are mostly unknowns. It thus becomes critical to monitor for population-scale side effects and effective immunity following vaccine roll-out. Furthermore, assessment of vaccine efficacy in response to emerging new strains needs to be routinely monitored. Finally, the extent to which vaccines will limit disease transmission is still unknown, underlining the continued need for testing to stop transmission.

Thus, alongside therapeutic and preventive measures to tackle COVID-19, a robust testing strategy is crucial for optimal public health outcomes (e.g., case numbers, disease prevalence, vaccine efficacy) and economic outcomes (e.g., economic recovery, reopening of businesses), aspects of which include the early identification of hotspots with asymptomatic cases, rapid isolation to contain the spread of the disease, and the appropriate allocation of resources for preparedness to manage future outbreaks.

Implementing asymptomatic screening on a national scale is essential but comes with challenges:

- Limited resources and capabilities to lift testing capacity (supply of diagnostic kits, trained staff)
- Inaccessible testing centres and an over-reliance on a limited number of institutionalized centres like hospitals, that are also perceived as 'high risk' venues by patients
- Long waiting times for sample submission and collection making the process cumbersome for the public
- A lack of centralized coverage for diagnosis and corresponding treatment costs deterring low-income sections of the population from undergoing testing

This review highlights use-cases of testing strategies and technologies already being used to confront various pandemic scenarios and challenges. Drawing on global and regional use-cases of testing, this paper evaluates the new imperatives in testing to contain COVID-19 spread and reduce the risk of case resurgence and allow the re-opening of economies.

2. TESTING APPROACHES FOR COVID-19 MANAGEMENT

There are three main approaches to COVID-19 testing for both symptomatic and asymptomatic individuals (Figure 1). At the close of 2020, molecular test remains the gold standard diagnostic test, given its highest sensitivity to low viral loads. Antigen testing detects high viral loads and is useful to assess infectivity of an individual typically within the first week from the formation of a detectable viral load^{6,7}. Emerging global guidance suggests that antigen testing can be used to rapidly identify infectious individuals⁸. Since the viral load curve is similar between symptomatic and asymptomatic patients, antigen testing can be utilized to identify infectious patients in both populations within the first 10 days of infectiousness⁹. Frequent antigen testing (every 1-3 days in high exposure areas) can be leveraged to deliver comparable or higher sensitivity to molecular tests¹⁰. Antigen testing further presents advantages due to the rapid turn-around times¹¹ and lower skill-set requirements to conduct the test¹².

Antibody/serological tests, on the other hand, are most sensitive 2-4 weeks after exposure¹³ and, as antibodies may persist for months thereafter, the test is useful to aid diagnosis of patients who present late after symptom onset, and to perform epidemiological surveillance. Antibody tests may indicate the presence of protective immunity against SARS-CoV-2, although this awaits further evidence. Proactive screening for antibodies can also be used to identify plasma donors for convalescent plasma therapy, which is being actively researched for therapeutic use in India, and U.S.A^{14,15}.













Types of testing	MOLECULAR TEST	ANTIGEN TEST	ANTIBODY TEST
Sample input	Nasopharyngeal/nasal/throat/saliva swab	Nasopharyngeal/nasal/throat swab	Finger stick/blood draw
Purpose	Detection of viral SARS-CoV-2 RNA	Detection of viral SARS-CoV-2 proteins	Detection of immune response to SARS-CoV-2 antigens (e.g., nucleocapsid or spike protein)
Strengths	 High sensitivity even for low viral loads  Regarded as gold standard to diagnose SARS-CoV-2 infection	 Identification of infectious individuals  Quick turnaround time and low cost	 Diagnosis of patients with past infections  Measurement of surrogate/native immunity
Challenges	 Scalability challenges due to high cost and resource intensive process  Relatively long turnaround time	 Only detects active infections with high viral loads  Possible requirement of further testing to confirm infection	 Not suited to detect active infection but to identify individuals with immune response  Lack of robust understanding on correlation between antibody levels and level of protection garnered

Figure 1: Testing approaches for COVID-19

3. USE-CASES OF TESTING AND RECOMMENDATIONS IN COVID-19 MANAGEMENT

The various assays – molecular test, antigen test, and antibody test, individually and in combination, can be tailored for use in varied situations and meet different objectives, contributing to improved health and economic outcomes. The following subsections further elaborate on each of these aspects and offer recommendations on appropriate measures that policymakers can consider in setting their national testing strategies.

3.1 Community surveillance and hotspot management

Molecular and antigen tests can be combined to conduct mass community testing to identify asymptomatic clusters and facilitate early isolation.

Targeted community testing of vulnerable and high interaction population segments

Once the asymptomatic transmission of the virus came to light, Singapore, for example, developed a testing program targeting three communities: persons vulnerable to infection; persons with a high risk of exposure, such as migrant workers in marine and construction sectors and frontline health workers; and persons with a high frequency of interaction with other people, such as drivers, food & beverage vendors, and delivery personnel. A rostered routine testing of the community groups is being carried out every 14 days using molecular and serological testing, especially of dormitory workers to identify hotspots within the community¹⁶. Antigen test is further being piloted for use at the 7-day interval for early detection¹⁷, followed by a confirmatory molecular test for anyone who tested positive.

On a similar note, South Korea is adopting antigen test for early detection of asymptomatic cases amongst vulnerable community groups such as nursing homes and elder-care hospitals¹⁸.

Pooled testing to decrease turnaround times of large-scale screening measures

The pooled sampling method, typically used to screen blood samples before blood transfusion, was used by China during its first wave of COVID-19, testing more than nine million people within just five days. This same approach was subsequently adopted by Israel, the US, Thailand, and Germany¹⁹. Pooled sample testing is best suited to static populations (e.g., workers residing in dormitories already under a localized lockdown) and for lower health risk groups such as school children. Pooled sample testing provides speed and scale - pooling of 4-5 samples using a single kit reduces the number of test kits and test processing needed and hence turnaround time. The pooled sampling method requires molecular testing.

Syndromic & sentinel surveillance for epidemiological modelling of COVID-19 prevalence

Early warning syndromic and sentinel systems rely on event-based surveillance of local acute respiratory infection (ARI) and influenza-like illness (ILI) outbreaks to estimate the prevalence of COVID-19. New Zealand's COVID-19 epidemiological modelling²⁰ required expanded general practitioner (GP) ILI consultation monitoring to detect increases in ILI activity based on a random sampling of ~380 GP practices (~ 10% of total number of GPs in the nation). The New Zealand government also established an active sentinel SARI (severe acute respiratory illness) surveillance system to reveal excess illness in the population. Active surveillance data needs to be used for epidemiological modelling to monitor an ongoing outbreak and predict potential hotspots²¹. Information

on disease prevalence in a region would determine the positive predictive values (PPV) and negative predictive values (NPV) of testing strategies. For instance:

- Low prevalence: High NPV but low PPV requiring confirmatory molecular test of positive cases to reduce the risk of false positives
- High prevalence: High PPV but low NPV requiring confirmatory molecular test of negative cases to reduce the risk of false negatives. Increased frequency of antigen tests can usefully supplement molecular tests.

Genomic surveillance of COVID-19 variants

In recent months more new variants have been reported globally, leading to the need for countries to step up on genomic surveillance efforts to help assist with public health decisions.

The World Health Organisation (WHO), on 28th December 2020, highlighted the importance of increasing global sequencing capacity to facilitate testing and tracking of new variants. Channels for sharing genomic information are already in place and should be leveraged – such information can be shared promptly via WHO or global non-profit viral genome databases such as GISAID²².

In Japan, mutant strains originating from the UK and South Africa have been detected in imported cases and a further novel strain was detected in travellers returning from Brazil²³. This was made possible through the availability of sequencing capacity.

In summary, the following testing approaches to community surveillance are recommended for consideration by policymakers:

Recommended testing approaches: Community surveillance for early identification and control of case numbers

1. Conduct surveillance of patients with symptoms suggestive of COVID-19 infection in primary care centres, nursing homes, and hospitals with a combination of molecular and antigen test
2. Carry out targeted community surveillance of persons vulnerable to infection, those with a high risk of exposure and high interaction groups such as healthcare workers and delivery personnel with a combination of molecular and antigen test
3. Conduct population-wide epidemiological surveillance using serological testing to monitor disease prevalence and guide allocation of public health resources and vaccinations
4. Consider pooled testing to be applied in static and low prevalent population to optimize resource usage. Antigen test can be used in settings where quick turnaround is required
5. Conduct surveillance using sequencing tools to identify and track novel genomic variants

3.2 Economic resilience & recovery

Testing is a prerequisite for the early and safe reopening of any economy. Routine testing and contact tracing in workplaces and schools have proven effective across multiple countries in APAC.

Comprehensive contact tracing to prioritize at-risk populations

Vietnam adopted a systematic method of contact tracing by categorizing cases based on tracing degrees of contact from F0 (the infected individual) through F1 (persons having had close contact with F0), F2 (persons who have had close contact with F1), all the way up to F5²⁴. This categorization was then used as a decision-making tool to determine testing strategy (mandatory or symptomatic case basis) and quarantine measures (institutional vs. home isolation).

Technology has been used as a solution to conduct contact tracing at scale. China has co-opted existing apps like WeChat & Alipay for registration and contact tracing, overcoming the problem of achieving high download rates with opt-in apps like Singapore's Trace Together²⁵. Combining contact tracing with extensive testing, China was able to avoid a potential second wave in a high-density city like Shanghai following the detection of local community cases²⁶.

The spread of COVID-19 has been suggested to follow the 80:20 rule where 80% of local transmission can be tied back to 20% of positive cases²⁷. To identify the 'super-spreaders', Singapore uses the backward tracing approach, which entails charting out the activities of the individual two weeks prior to the detection so as to identify potential sources of transmission.

Reopening workplaces & educational institutions

Acting quickly to minimize business disruption, China and Singapore were among the first countries to reopen workplaces with testing as an integral part of their effort.

- Mass testing of workers in China occurred post-lockdown. Molecular testing and antibody screening allowed for safe reopening of workplaces without the need for staggered work weeks²⁸. Over 95% of industrial enterprises resumed work in March 2020 once the first wave was contained²⁹
- Singapore extended testing to students residing on-campus in tertiary institutions to identify asymptomatic cases within this community group
- The use of antigen test is being piloted as qualification criteria for entry into mass events and conferences in Singapore and Denmark to minimize the risk of super-spreading events^{30,31}
- Antigen test has been adopted for population scale testing in Slovakia to allow early re-opening of the economy. In tandem with other restrictions, the three rounds of testing are expected to have contributed to an overall reduction in disease prevalence by 59%³².

Overall, recommended below are complementary testing approaches that countries can consider in overcoming challenges to reopening the economy:

Recommended testing approaches: Economic resilience and recovery

1. Enforce social distancing and universal mask wearing
2. Employ both forward and backward tracing to identify close contacts of infected cases and "super-spreaders" using a combination of molecular, antigen, and antibody testing
3. Conduct rostered routine testing of asymptomatic high-risk workers (factories, healthcare) with appropriate legislation to prevent marginalization of employees due to test outcome
4. Perform pre-event testing for large gatherings of > 100 people, nightlife venues
5. Conduct regular testing at workplaces and educational institutions. Consider prioritization of critical workplaces where people have a higher exposure risk (e.g. quarantine hotel staff, airport workers) and where there is difficulty in social distancing

3.3 Travel resumption

Testing can hasten the safe reopening of national borders with shorter quarantine requirements. Several APAC countries have been experimenting with testing solutions that ease constraints on cross-border business activity.

Airport screening and border controls

Various APAC countries are experimenting with new testing protocols to accelerate upon-arrival testing.

- A dedicated COVID-19 airport testing facility at Singapore's Changi Airport will begin testing in early 2021, mitigating the need to transport samples from the airport to the laboratory, thereby reducing test turnaround times by 40%³³. With post arrival testing already in place as of January 2021, Singapore has unilaterally opened borders to short-term visitors from countries such as Australia, Vietnam, New Zealand etc. presenting a negative molecular test result when tested upon arrival³⁴
- Similarly, a molecular test centre at Japan's Narita airport provides outbound travellers with virus-free certifications³⁵
- In China, a combination of molecular and IgM antibody testing is mandatory for arrivals to reduce likelihood of false negatives³⁶
- In addition to traveller screening, border control workers are required to undergo fortnightly testing in APAC countries including in New Zealand³⁷ and Singapore³⁸, given their high frequency of public interaction and volume of cargo handling.

Flexible quarantine and additional test protocols

A 14-day quarantine period for international arrivals is required across most of APAC. However, the nature of quarantine enforcement varies across countries. Selected countries allow self-isolation at home while others mandate stay at managed facilities. Nonetheless, molecular testing is a requirement in most countries for release from quarantine irrespective of the number of days in quarantine. There is further opportunity to combine molecular and antigen test on staggered days to reduce quarantine periods that undoubtedly deter travellers³⁹.

Below are recommended measures that countries can consider for safe resumption of travel:

Recommended testing approaches: Travel resumption
<ol style="list-style-type: none"> 1. Employ risk-based management of border entry based on disease prevalence in country of origin and management capability in receiving country. Entry requirements should consider a combination of testing and quarantine to manage risk dynamically 2. Consider requirement of a negative pre-departure test within 72 hours (based on common practice) before travel is allowed 3. Establish testing capacity at the airport/transport hub to reduce turnaround times 4. Consider combinations of molecular test, antigen test, and repeated tests for scalability while still controlling risk 5. Ensure cross border cooperation to identify and recognize 'certified laboratories' or test manufacturers using validated test methods for pre-departure testing

3.4 Supporting vaccine roll-out

The duration and level of protection provided by COVID-19 vaccines remains uncertain, as is the effectiveness of vaccines in immune-compromised and elderly patients with poor response to vaccinations. Therefore, alongside vaccine deployment, there is a need for complementary testing to prioritize and monitor the effect of the vaccine in real world usage over time.

Vaccine prioritization

COVID-19 vaccine supply is expected to meet 30 - 40% of global demand in 2021⁴⁰. There is a clear need to prioritize who receives a vaccine first. Individuals who have recovered from COVID-19 are expected to possess native immunity to the virus for a period of time, and this already immune population could be a significant driver of where to 'save' scarce vaccine supplies in countries which have suffered a high incidence of COVID-19 through 2020/2021.

However, there is still a lack of robust understanding of the long-term stability of immunity levels in recovered individuals, which is necessary information to determine safe de-prioritization for vaccination⁴¹. Serological testing of native immunity in individuals with a quantitative understanding of required antibody threshold levels may help guide vaccine administration to those most at risk.

Monitoring vaccine efficacy

Given the uncertainty over the long-term efficacy of vaccines, serological testing to monitor vaccine efficacy post roll-out is essential. This involves the monitoring of neutralizing antibodies generated over time. To investigate vaccine response, it is necessary to use a quantitative antibody test, and preferably an anti-spike/RBD antibody assay, given most front-runner vaccines only consist of the spike protein. "Test-negative" case-control design is also useful for vaccine evaluation, which includes conducting molecular or antigen tests on infected and control population segments⁴². Such screening methods can further support the roll-out of vaccine 'passports' for safe entry to mass events, conferences, out-patient clinics and for travel.

However, a clear understanding of the correlation between neutralizing antibodies and immune protection is essential to understanding prolonged vaccine efficacy⁴³. Furthermore, validation of vaccine passports requires further standardization of policies on test result interpretation and test types to assess sustained immunity. The expertise of existing working groups such as the Asian Harmonization Working Group could potentially be utilized for this purpose⁴⁴.

Described below are testing measures that countries can implement to support vaccine roll-out:

Recommended testing approaches: Pre- and post- vaccine rollout
<ol style="list-style-type: none"> 1. Consider vaccine prioritization by identifying individuals with pre-existing immunity 2. Maintain national registries of vaccine recipients to track long term safety and efficacy 3. Investigate vaccine response and durability in vulnerable populations, using antibody levels as a surrogate measure of protection 4. Monitor asymptomatic cases via routine testing of a subset of high-risk vaccine recipients 5. Regularly quantify antibody levels in the vaccinated population, to determine threshold of protection against COVID-19 and validate initiatives such as immunity/vaccine passports 6. Use quantitative antibody assay traceable to international reference material so that antibody level among different methods is standardized and comparable 7. Develop policies around the recognition of test results and test types to assess immunity to ensure results are acceptable across countries

4. CONCLUSION AND FUTURE PANDEMIC PREPAREDNESS

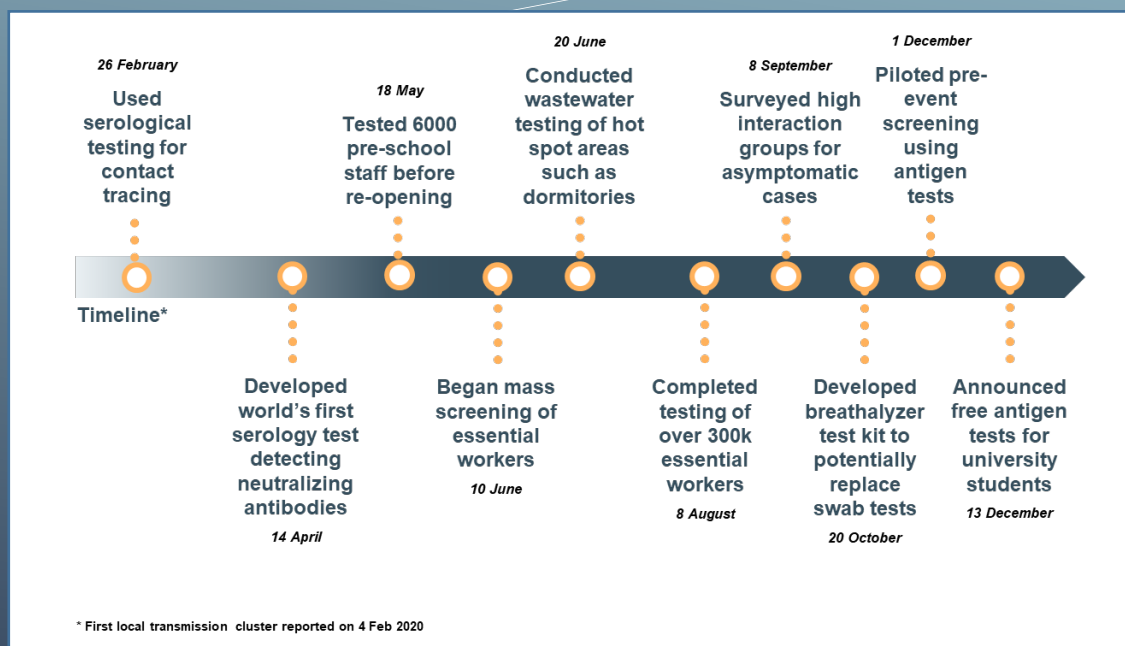
The healthcare and economic challenges posed by COVID-19 throughout the world are unique in the last century. Through the extraordinary commitment of health officials, providers, HCPs and their partners in industry throughout the last year, the APAC region already has access to a wide array of screening and other diagnostic tools and techniques that can help manage the pandemic and limit its negative effects on society. This review has shown the utility of these new tools in practice in the region, and we encourage all stakeholders to fully leverage this ‘toolset’ to return societies as fast as possible towards economic growth and reopening.

A combination approach of diagnostics based on context/nuance of the specific situation is deemed important for consideration in the management of COVID-19. Another element for consideration would be leveraging standardised, interoperable digital platforms supplemented with privacy regulations to establish proof of testing and/or vaccination. The recent guidelines on proof of vaccination for medical purposes by the European Commission highlights the need to have such an initiative in place⁴⁵.

Future outbreaks, though inevitable, can be contained early with appropriate preparedness measures in place. This includes collaborations at regional and global levels to ensure harmonization of public policies for testing strategies and response. Such measures can be further supplemented with open public communication of up-to-date information on testing strategies and guidelines to align all the stakeholders involved. Considering the challenges encountered in this pandemic, countries are already taking steps to conduct epidemiological surveillance to look out for high-risk viral strains that might be the cause of the next outbreak or surge. It is further essential that such surveillance data is shared at a regional level to closely monitor any developments and initiate response to minimize both health and economic impact.

Case Study: Evolution of testing approaches in Singapore

As the pandemic progressed, Singapore adopted various testing strategies at different stages to minimize transmission whilst ensuring early re-opening of workplaces and educational institutions



5. GLOSSARY

Antigen test: Method of COVID-19 detection relies on detection of SARS-COV2 viral proteins in nasal swabs or other respiratory secretions using a lateral flow immunoassay

Backward contact tracing: Process of determining the source of infection by mapping the activities of the individual (tested positive) in the past two weeks

Forward contact tracing: Process of identifying closed contacts once an individual is tested positive so as to prevent further spread

Influenza-like illness (ILI): Referred to patients who have flu like symptoms such as fever, cough or sore throat

Negative predictive value (NPV): Probability that individuals with a negative test result truly do not have the disease

Positive predictive value (PPV): Probability that individuals with a positive test result truly have the disease

Molecular testing: Method of COVID-19 detection involving the detection of nucleic acid from SARS-CoV-2 in respiratory specimens collected using nasal, nasopharyngeal, throat or saliva swabs

Receptor Binding Domain (RBD): Domain located on the spike protein of coronavirus playing a role in viral-attachment, fusion, and entry into the host cell

Severe Acute Respiratory Infection (SARI): Referred to patients who have flu like symptoms such as fever, cough or sore throat and requires hospitalization

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About APACMed

We provide a unifying voice for the medical devices and in-vitro diagnostics industry in Asia Pacific. The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in-vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific. Our mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.

Promoting innovation and shaping policy that advances healthcare access for patients

ACCESS: Improve access to high quality healthcare for patients.

INNOVATION: Support innovative new technologies and start-ups that improve the quality of care and healthcare outcomes.

HARMONISATION: Aligned with international best practices promoting speed to access via common regulatory standards.

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