Mhealthy – Frequently Asked Questions

Available tests for COVID-19 in the market

1. What are the different types of tests available for COVID-19 screening?

There are 3 types of tests for COVID-19 at this time.

1. *RT-PCR test*: This is a confirmatory test that is used for diagnosing COVID-19. The test identifies the presence of the SARS CoV-2 virus (the virus that causes COVID-19 infection) in nasopharyngeal swabs. It has an accuracy of 70-80% in the first 7 days after the onset of symptoms, after which the sensitivity drops below 50%. Hence, this test is most useful in the early phase of infection. However, the limitation in the availability of testing kits and the cost have forced the Indian Council for Medical Research (ICMR) to apply strict guidelines to conduct this test. All the NABL accredited labs are bound to follow these guidelines for conducting the RT-PCR test.

2. Antibody tests: They measure the presence of COVID-19 specific IgM and IgG type antibodies. There are two types of tests, laboratory based, also known as ELISA or CLIA and rapid tests that can be done anywhere, also known as lateral flow immunoassays (like a pregnancy test). These tests are less expensive and the results are available faster.

Antibody tests provide information on whether an individual has been exposed to the virus and has produced antibodies. Typically, antibodies can be detected from the second week after the onset of infection.

Antibody tests are not used for detecting infection. Government uses these tests for seroprevalence. Offices and organizations can use this test to understand the general immunity of their employees. ICMR guidelines allow these tests to be conducted more liberally to manage public health needs.

3. Antigen tests: These are rapid tests that detect the presence of the SARS CoV-2 virus in the sample, such as a nasal swab. The advantage is that they are fast, easy and cheap. Their main disadvantage is that they are not very accurate and have a high chance of a "False Negative" result which means a person with COVID-19 infection may be told that she/he doesn't have the infection. Therefore, these tests are only used in select circumstances and the symptomatic negative cases have to be followed up with an RT-PCR test.

The MHealthy screening solution relies primarily on a proprietary algorithm that uses patient information, information on risk factors for severe Covid disease, antibody tests, andalso on antigen tests to reduce the risk of Covid transmission and severe Covid disease in the workplace.

2. What is MHealthy's solution for COVID-19?

M Healthy COVID Risk Management Solution for corporates is a cost-efficient way to mitigate COVID-19 risk in workplaces by **using multiple approaches and tests to reduce the reliance on the sensitivity and specificity of any single test.**

There are five components in this solution -

1. **Employees register on MHealthy app**

   Self-assessment based on medical history, exposure history, demography and symptoms

2. **Comprehensive Screening at the workplace**

   Screenings tests include Pulse Oximetry, Blood Pressure, Blood Glucose, Temperature, BMI and COVID-19 antibody test. All blood tests are finger-prick based and are completely safe.

3. **Risk profile is generated by using AI/ML based algorithm**

   Low risk employees are cleared for work. At-risk individuals are recommended self-isolation or scheduled for teleconsultation or recommended an antigen test

4. **Telehealth access post results**

   Telemedicine consultation through Ashvin, TechM Telehealth Solution. Doctor can prescribe for an RT-PCR test or necessary care

5. **Screening post recovery before returning to work**

   Employees will be screened before returning to work, as indicated by the algorithm

PART 2 - Questions on MHealthy's Comprehensive Screening/COVID-19 risk screening

Who all should be screened? How often should they be screened? Should they be screened only if they have been exposed to someone with COVID-19 or if they are in the risk group?

Ideally, everyone should be screened on a periodic basis on the HealthCube. Daily screening should be undertaken by employees on the MHealthy app. If someone has been exposed or develops symptoms and wants to be screened, they should approach the facility coordinator to schedule for screening on their premises.

How does the comprehensive screening help identify individuals with COVID-19? Is temperature screening at the entrance not sufficient?

The current risk screening solution is not intended to positively identify those who are infected with COVID-19. Instead, it provides a risk assessment and access to a doctor who can recommend if further testing is required. The risk screening solution is comprehensive and tests not just for temperature but also checks for symptoms, measures oxygen saturation, heart rate and vitals to compute a comprehensive score.

Temperature screening has been widely adopted for public spaces but this is not sufficient (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7014668/). Temperature measurements along with other tests have much better accuracy.

What is the accuracy of the risk scores? Is this comprehensive screening approved by ICMR/CDC etc.?

The device on which the risk screening tests are performed is CE certified and the algorithm has been developed in consultation with leading scientists and doctors. Since the risk screening solution is not diagnostic in nature, it does not require ICMR approval. That said, the purpose of the comprehensive screening is only to lower the risk of Covid. The risk of Covid cannot be fully eliminated.

What data does the algorithm consider to generate the risk score?

The following are some of the parameters taken under consideration to compute the risk score:

- Demographic – Gender, Age
- Medical History
- Exposure History - Contact with COVID-19 confirmed patient, Domestic or International travel in the past 14 days
- Symptoms - Cough, fever, Fatigue, Breathlessness
- Blood Pressure, Blood Glucose, Temperature, Oxygen saturation, BMI and COVID-19 Antibody test results
- Previous screening results

What does each risk score signify? Should we be worried about employees with high-risk scores?

- o L1 indicates that the person has no current risk of COVID-19
- o L2 indicates that the individual may have been exposed to COVID-19 - a 7-14 day quarantine is recommended or a telemedicine consultation is offered.
- o L3 indicates a higher risk of exposure –

  • Telemedicine consultation is initiated

  • The doctor decides if the RT-PCR test is needed

  • 7-14-day quarantine is initiated

Those who receive L3 scores receive medical advice from a physician and will be counseled.

Do any of the tests conducted as a part of comprehensive screening confirm if an individual is positive for COVID-19 ? Does the result generated by the algorithm confirm an active COVID-19 infection?

No, the risk screening tool does not confirm if someone is infected or not. It only advises whether RT-PCR testing is needed.

Does this screening ensure 100% that there will be no transmission of COVID-19 in the workplace? How is this method better over other methods?

MHealthy helps to mitigate COVID-19 risk in workplaces by using a comprehensive assessment process. The risk assessment includes multiple parameters and is more reliable than using only one type of test such as temperature screening. While the risk assessment process helps to reduce the risk of COVID-19, it is not a guarantee that no infections will happen in the workplace. Indeed, there is no testing or screening approach that can guarantee such an outcome. The MHealthy solution will have to be accompanied by workplace safety precautions including mask wearing and distancing.

What samples are required to conduct the tests? How much blood is required to conduct the tests?

The screening protocol includes non-invasive tests for Blood Pressure, Pulse Oximetry and calculation of body mass index. There are two tests that require blood - the Blood Glucose test and COVID-19 antibody test. These tests require only a few drops of blood and are taken by pricking the finger.

How long does it take to do comprehensive screening per individual? When can results be expected?

It takes about 10-15 minutes to do all the tests on each person. The results are generated instantly and a digital health record is shared with each individual through the Mhealthy app.

PART 3 - Questions on COVID-19 antibodies and COVID-19 antibody test rapid antibody kits

What is an antibody?

When there is any infection in the body, the body's immune system responds by producing antibodies to fight off the virus or bacteria. Different infections lead to the formation of different antibodies in the blood. Since COVID-19 is caused by a virus, hence the human body produces antibodies to fight this specific infection.

What does the COVID-19 Antibody Test analyse?

It is assumed that if SARS CoV-2, the virus that causes COVID-19 infects a person, his/her body will produce antibodies to fight the infection. The COVID-19 Antibody Test analyses the blood sample for the presence of antibodies related to COVID-19. If the test gives positive results, it will mean that the person has already had the COVID-19 infection in the recent past (1-3 weeks) and his/her body has developed the antibodies in reaction to the infection. On the other hand, a Negative result will mean that the person has not yet been infected in the recent past. It is important to note that this does not conclusively rule-in or rule-out the COVID-19 infection.

Does this test diagnose an ongoing COVID-19 infection?

No, this test does not diagnose any ongoing COVID-19 infection. This test only helps to analyse whether a person was infected in the recent past and the body developed the antibodies as a response to the infection.

How is the COVID-19 Antibody Test performed? What parameters are analysed in this test?

S. No	Name of the Test	Parametres Tested	Technology		Rapid test
			CLIA	ELISA	
1	COVID-19 Antibody Total	(IgG + IgM)	Yes	---	Detects IgG and IgM
2	COVID-19 Antibody IgG	IgG	----	Yes	
2	COVID-19 Antibody Profile	(IgG and Total)	Yes	Yes	

If I do not have any COVID-19 symptoms, should I get the test?

The COVID-19 antibody test is recommended to anyone who has had a past history of COVID19 like symptoms or is asymptomatic but may have had close contact with

a person who tested positive for COVID-19. The test is also important for a person if he/ her was previously tested positive for COVID-19. However, it is recommended that if you have had any symptoms, to wait for a few days before going for an antibody test (~10-14 days). NOTE: if you belong to the testing population as defined by ICMR, you can get tested regardless of whether you have developed symptoms or not.

In the context of the MHealthy risk screening solution, the antibody test is performed on everyone.

If my COVID-19 antibody test shows 'positive', does it mean that I am protected against future infections?

A positive antibody test means that you have developed an immune response to the COVID19 virus. But there is no conclusive evidence as to how much protection you will have from a future infection or how long the immunity will last. However, evidence from other coronaviruses such as SARS and MERS indicates at least a few months of antibody or T-cell protection in respond to a coronavirus infection.

Does the antibody test correlate with the symptoms or severity of the disease?

There is no established correlation yet of antibody levels and symptoms but those with mild symptoms have been known to develop lower counts of antibodies than those who become very ill.

Please note that the rapid antibody test which is offered as part of the MHealthy risk screening solution is a qualitative test. It does not provide any antibody count.

Is social distancing needed if I have developed antibodies against COVID-19 infection?

It is not conclusively proven till now that having antibodies implies that a person has become immune to subsequent infection from the COVID-19 virus. Therefore, it is advised that even if you have a positive result for having antibodies, you must continue with social distancing, hand washing, wearing a mask etc.

Is this test approved by ICMR?

The COVID-19 rapid antibody kit used as a part of Mhealthy solution is approved by ICMR.

What is the accuracy and sensitivity of the antibody test used for screening?

COVID-19 antibody test has a sensitivity of 98% and a specificity of 96%

PART 4- Questions on the screening device and its components

What does the screening ecosystem comprise of?

The uniqueness of the ecosystem balances the complexity of the operations of medical devices. Procedures are intelligently simplified, standard operating methods help in minimising the possibility of human errors and at the same time making the whole experience easy for anyone to join, take benefit and also contribute to the ecosystem. The Screening Device ecosystem consists of following four integral parts.

• The Hub-A portable battery-operated instrument that can screen multiple health parameters through the performance of diagnostic tests on an individual

• EZ Dx-A mobile device application to control the operations of the Hub, visualize the results and communicate the results to a secure web-based data repository

• Mhealthy Data Doc-Data visualization and analysis tool on a dedicated secure portal for remote monitoring and electronic records review

• Mhealthy Assures On-Ground implementation package including training, support and quality overview

What are certifications of this device? Is this device clinically validated?

The devices used for screening are CE certified, and CDSCO cleared.

PART 5 Questions on Teleconsultation

How can I book an appointment?

For all Level 3 cases (Risk Category "Telemedicine" or "RT-PCR Advised), appointments can be booked by Self or can be booked by Assisted Care team. Once an appointment is booked, SMS is received to your registered mobile.

- If audio consultation is booked, you will receive an audio call from the doctor.
- If video consultation is booked, you need to log in to the Ashvin portal to accept the Video call from the doctor.

Do I need the Internet for teleconsultation?

The Internet is not required for Audio Consultations. You will need the ability to connect to the internet, in case of video consultation. Application is best viewed in Chrome browser. Better you can use Mobile Chrome browser or Laptop browser.

Can I cancel the appointment?

Yes, you can cancel the appointment. Log in to Ashvin portal, You can cancel the appointment available in Assisted Care tab in Dashboard. Select the Cancel button against the appointment record you want to Cancel.

How do I access prescription after Consultation?

You can access the prescription from Ashvin portal after the consultation is completed with the doctor. Log in to Ashvin portal, view completed appointments under Past Appointments section, select the Cancel button against the appointment record you want to Cancel.

Will I have consultation with the same doctor every time?

For further appointments reach to Assisted care team by writing to us at mhealthy@techmahindra.com

In case of any issues, where do I contact?

In case of any issues, write to us at mhealthy@techmahindra.com

Who has access to my medical reports?

Doctors doing consultation have access to medical reports, you can also have access to medical reports.

What can I do if I miss the call from the doctor?

You need to wait, the Doctor shall call back. Alternatively, you can also reach the Assisted care team.

Are the audio/video calls done during a consultation recorded?

Not recorded at this point in time.

What do I need to prepare in advance before the start of consultation?

Be available during the appointment time and be ready with all your health complaints / records. In case you are using a laptop, ensure that you have an inbuilt camera and microphone.

I don't need teleconsultation service for my employees, we have an inhouse doctors' team.

PART 6: Questions on Dashboards and Employer Reports

How does the dashboard benefit the employer?

The dashboard provides overview of the risk levels of different individuals at each facility and also includes weekly screening analytics that can give insights into the number of people screened, number of people who are in self-isolation and can help track the individuals that need to be screened prior to coming back to work.

PART 7: Questions on delivery and implementation

What is the delivery model - is this a direct purchase of a product or is this a service?

The solution is presented as a service package to the customer as-

The package includes on-site screening, software and data services for employer for reviewing analytics of screening, teleconsultation and digital health records for employees
   a) Solution integration with Employee database
   b) On-site deployment of services by Mhealthy team
   c) Screening of customer employees and report sent via Mobile app
   d) Teleconsultation on the basis of level of threat diagnosed
   e) Doctor's recommendations are stored as e-prescription on the app
   f) Access to complete user dashboard to derive data driven decision making

Is there a minimum order quantity required ?

 The number of screens per site/facility should be more than 500 per month.