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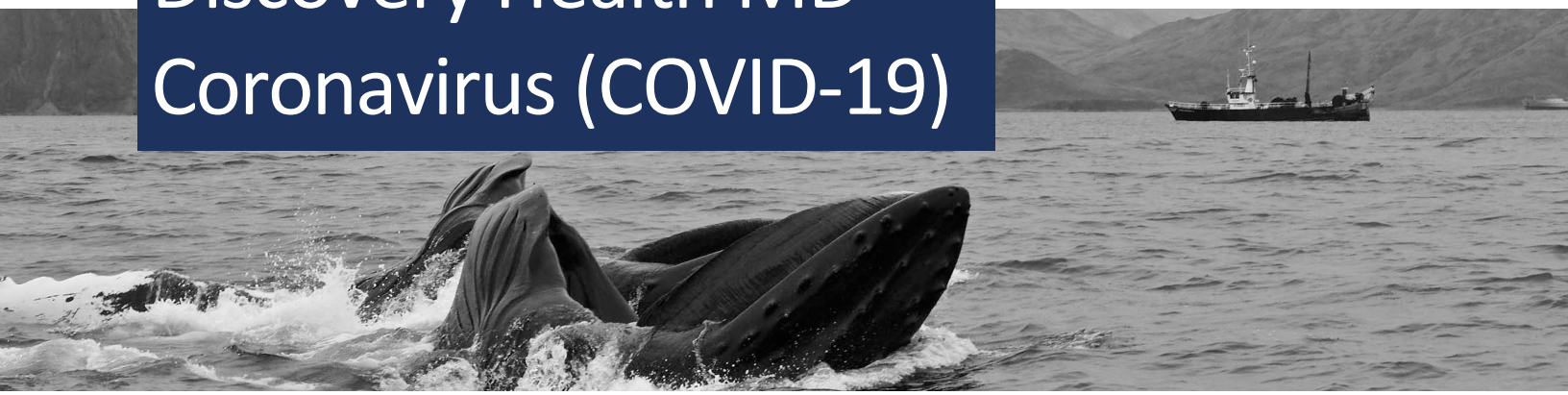
Discovery Health MD Coronavirus (COVID-19)



COVID-19 TESTING UPDATE – *We Are Not Quite There Yet*

By now, you have all been bombarded with offers for COVID-19 testing from medical suppliers.

What's going on?

The Food and Drug Administration (FDA) has a process for approving new laboratory tests. During the pandemic, an Emergency Use Authorization (EUA) pathway was created to fast track approval for COVID-19 tests. On March 16, the FDA allowed commercial manufacturers to begin distributing tests under certain circumstances prior to granting an EUA[1]. They specifically allowed serological tests to identify antibodies to SARS-CoV-2 (COVID-19) to be distributed with some required disclaimers.

What does this mean?

Testing currently being performed in hospitals and medical facilities uses a technology called RT-PCR. This detects a piece of the virus' genetic material. Taking a sample may involve placing a swab deep into the nose, and the tests may take 1-5 days for a result. These samples must be processed in a laboratory.

The serology tests being advertised measure antibodies to the COVID-19 virus. When our bodies are exposed to an infection, we make antibodies, and this test is designed to detect those antibodies. Different types of antibodies are created at different stages of an infection. IgM antibodies generally appear early in an infection, and IgG antibodies later. These serology tests are designed to measure one of them, or both.

What is so attractive about these serologic tests is that they can be performed with a fingerstick drop of blood, do not require processing in a laboratory, and can give results within minutes. These are desirable qualities in any COVID-19 test.

However, these tests are not useful for diagnosis of COVID-19 or screening of asymptomatic people. They are specifically not designed for these purposes. These tests were designed to study whether people are developing immunity to COVID-19. Eventually they may be useful to determine who is safe to go back to work, who already has immunity, but that is going to take some time.

In the meantime, serologic tests should not be used to diagnose sick people or to screen asymptomatic people. Please do not consider using these tests for those purposes.

What's next?

There are multiple rapid molecular tests that have been granted an EUA under the FDA that are coming on to the market. These tests look for genetic material or proteins from viruses and can be performed without being processed in a laboratory, giving results within minutes. Some hospital systems are starting to use these tests.

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References: (1) ***https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help***

One drawback of these tests is that they often may not be very sensitive, meaning that they can give a false negative result if someone truly has the disease. Since these tests are so new, we are still learning their accuracy.

Eventually, these tests will become more widely available and the hope is that they will have an important role in the screening of asymptomatic crew and the rapid diagnosis of COVID-19 onboard, but we are not there yet.

What can we do in the meantime?

Once validated, rapid, accurate, point of care testing is widely available, it will become an important part of screening programs. We are advising companies to consider how they are going to integrate testing into their existing programs. By now, companies should be pre-screening all arriving crew for fever, symptoms, travel or exposure history. These screening processes should continue, and testing will not replace them.

The next step will be designing screening programs with people trained to collect and process samples, and an understanding of how a test result will be interpreted in a clinical context.

For now, continue to advocate for access to rapid, accurate and validated point of care testing. Explain the importance of prioritizing testing within the commercial maritime industry to keep this critical driver of the economy moving. We need tests that are appropriate for screening large numbers of asymptomatic people and for accurately diagnosing people with symptoms.

This is a remarkably fast changing landscape in the evolution of this pandemic. There will be a large volume of information and mis-information circulating in the next few weeks. It is important to work together to make sure we are doing everything possible to protect our mariners, shore-based employees, and communities that we call upon.

Much of the commercial marine industry has done an exemplary job implementing extreme procedures designed to prevent the virus from being introduced on board. Until such time as reasonable test kits with proven performance characteristics become available for use by the marine industry and others, continue implementing measures previously recommended. These include but are not be limited to: education, awareness of symptoms, pre-screening, social distancing, limiting access on board to essential persons only, and practicing high levels of hygiene.

Remain focused on the task at hand, advocate for point of care test kits, and most of all be safe!