



Testing for COVID-19 onboard

Gard receives many questions about the use of COVID-19 antigen tests onboard ships. But how accurate are these tests - and are ship operators recommended to roll out antigen test kits across their fleets? In this article, Dr. Ingrid H. Johansen outlines some basic principles for ship operators to consider prior to implementing the use of antigen tests as part of their onboard prevention and outbreak management strategies.

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11 March 2021 marks the one-year anniversary since the WHO declared COVID-19 a global pandemic. On the date of the declaration, the WHO reported 118,319 confirmed cases of COVID-19 globally. One year later, this number has risen to above 117,000,000 and includes more than 2,600,000 deaths. It is the scenario the public health community has feared for decades. A novel virus has emerged and is spreading rapidly around the world, causing a significant threat to international health and the economy.

On the positive side, in recent months several effective COVID-19 vaccines have been approved and bring renewed hope for the pandemic to finally come to an end. However, it has also become clear that the production and distribution of vaccines are complex processes that will take time. The roll-out of vaccination programs varies enormously from country to country and it may take years before most of the global population has been vaccinated. In the meantime, basic public health measures remain the foundation of the world's response. For public health authorities this means testing, contact tracing, isolation, supported quarantine and quality care. For individuals it means avoiding crowds, physical distancing, hand hygiene, and masks. For the shipping industry, it means continuing restrictions on travel and port operations resulting in sustained challenges relating to crew changes, repatriation of sick crew and concerns for the wellbeing of seafarers.

Investing in testing

Testing is part of the first line of defence against COVID-19, enabling early identification and isolation of cases to slow transmission, and provision of targeted care to those affected. To date, testing during the pandemic has mostly relied on the use of polymerase chain reaction (PCR) tests. This test method remains the 'gold standard' for detecting the virus that causes COVID-19 and for diagnosing an active COVID-19 infection. PCR-tests are generally very accurate but analysing the tests can take time. Hence, to complement PCR-testing, many countries have started clinical validation of the performance of antigen tests' and some have integrated the use of antigen tests in their national testing strategies.

Antigen tests offer multiple operational benefits compared to PCR-tests. They can provide results in minutes, are relatively inexpensive, and are also supplied as complete test kits for near-patient use, which means that the analysis with visual readout of the result can also be performed onboard ships. It is worth noting, however, that an antigen test is not the same as an antibody test. Where an antigen test is designed to look for active virus in the body, a test that looks for antibodies to the virus can only help identify persons that have been infected with COVID-19 at some point in the past. An antibody test is *not* suitable for diagnosing active infection.

Gard receives many questions about the use of antigen tests onboard ships. But how accurate are these antigen tests - and are ship operators recommended to roll out antigen test kits across their entire fleets? In our two previous insights from 2020, "An introduction to testing for COVID-19" and "COVID-19 tests may give false sense of security", Dr. Ingrid H. Johansen at the Norwegian Centre for Maritime and Diving Medicine explains the complexity of testing for COVID-19 in general terms. In this third article, she discusses some of the issues to be aware of in order to safely use antigen tests onboard ships. Sharing interesting and useful insight on the performance of antigen tests, Dr. Johansen outlines some basic principles for ship

operators to consider prior to implementing the use of antigen tests as part of their onboard prevention and outbreak management strategies.

Performance of antigen tests

Like the PCR-tests, antigen tests are designed to detect the virus that causes COVID-19. However, while antigen tests are easier to use and offer rapid results compared to PCR-tests, there is also a trade-off between speed and accuracy. At the time of writing, most of the available and approved antigen tests show lower sensitivity compared to the standard PCR-test, while their specificity is generally reported as high. But what does this mean in practice?

The accuracy of a medical test is determined by measuring two things: sensitivity and specificity. A sensitive test will identify people with the disease. Sensitivity measures the share of people with the disease who will have a positive test result. A specific test will show negative results in people without the disease. Specificity measures correct negatives. Going back to the antigen tests:

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Lower sensitivity than PCR-tests"

means that the ability of the antigen tests to detect the virus that causes Covid-19 is poorer than the PCR-tests. Antigen tests need higher levels of virus in the body than PCR-tests in order to show a correct positive result and the time window when you are likely to get a positive result is therefore shorter than for PCR-tests. This means that at a given time you may have a negative antigen result, while the more sensitive PCR-test may return a positive result.

• "High specificity"

means that, when an antigen test is used according to the manufacturer's instructions, a false positive test is unlikely to occur. However, false positive results will occur, and this risk is higher when the tests are used in populations where the baseline risk of infection is low.

As explained in more detail in previous Gard Insights, all tests, test procedures and analyses carry some uncertainty. The timing of the test is crucial in order to obtain an accurate test result.

Basic principles for use of antigen tests onboard ships

1. Select the right antigen test kit

Ship operators that decide to use antigen tests onboard their ships should look for a test that complies with the minimum performance requirements set by the WHO at \geq 80% sensitivity and \geq 97% specificity. The higher the sensitivity and specificity, the better! The test should be easy to use and manufacturer's instructions for sample collection, safe handling, proper waste management, and use must be followed precisely. The test should also be approved by the relevant governmental bodies. If the test is purchased in Europe, look for tests that are CE-IVD marked and verified. An overview of antigen tests granted emergency use authorization (EUA) can be found on the following webpages:

• WHO:

Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV-2

• US FDA:

Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2

In terms of port calls and crew changes, ship operators should be aware that each country and port authority may have their own procedures for testing and accepted brands of tests.

2. Use antigen tests in addition to other measures, not instead of

Antigen testing can be used to build a more solid base for decisions on how to handle suspected cases on board and for choosing the right interventions. However, testing does not substitute for other protection measures and the following are still regarded as best practices to prevent outbreaks of COVID-19 on board ships:

- Embarking crew should be subject to 14 days' pre-boarding quarantine, ideally as close to the port of embarkation as possible, with safe transport onto the ship upon completion.
- As far as practicable, ship-shore interaction should be limited.
- If the virus has been brought onboard, measures to prevent further spread of the virus onboard should include isolation of ill crew members, frequent hand wash, respiratory hygiene shipboard self-distancing, and generally enhanced hygienic standards.

Ship operators are therefore advised to pay particular attention to the following IMO recommendations:

• MSC.1/Circ.1636:

Recommended Framework of protocols for ensuring safe ship crew changes and travel during the coronavirus (COVID-19) pandemic

• Circular Letter No.4204/Add.16:

COVID-19 related guidelines for ensuring a safe shipboard interface between ship and shore-based personnel

• Circular Letter No.4204/Add.27: Protocols to mitigate the risks of COVID-19 cases on board ships

3. Use antigen tests only when COVID-19 is suspected

A potential dilemma with positive tests is that you must act on the result. As mentioned above, all tests come with an inbuilt uncertainty and a risk of falsely showing a positive result. The risk of false positive antigen test results is higher when the baseline risk of infection is low.

So far, we have learned that COVID-19 infections come with a broad range of symptoms that resemble other common diseases, such as common cold, influenza, malaria, etc. It has also been established that a person with COVID-19 may be infectious 48 hours before experiencing any symptoms, and some can be infected without ever falling ill. However, the person must have been exposed to the virus, i.e. have been in close contact with an infected person, during the last 14 days in order to be infected. Hence, broad screening across entire fleets by use of antigen tests may cause more harm than good. Some might be falsely reassured by a negative test result and change their behaviour. Others may have to be isolated on basis of a false positive result, even if they are not infected. There might also be cases where other diseases with symptoms similar to those of COVID-19 will be mistaken for COVID-19, causing unnecessary delays in the treatment of and care for other medical conditions.

4. Never trust a single negative test

The detection of virus in the body depends on how long the person has been infected, the amount of virus in the body, the quality of the test, and the quality of testing. As explained, antigen tests need higher levels of virus in the body to be positive compared to PCR-tests. They are most likely to be positive during the first 5 days from the onset of symptoms but may give a positive result 1-2 days before onset of symptoms. Hence, performing a test too early after a person has been infected, or too long after onset of symptoms, increases the possibility of a false negative result.

A single negative test is therefore no guarantee that the person is not infected. Repeated negative tests increase the likelihood that the person is not infected. Several governmental agencies now advocate that recurring testing with antigen tests every 2-3 days can be used to confirm a true negative test result with a higher degree of certainty. In these repeated test regimes, the last test has to be taken at least 7 days after last possible exposure to the virus to confirm that the person is not infected.

Conclusion: The role of antigen tests onboard

Despite all the potential challenges and dilemmas related to testing for COVID-19, antigen tests might have a role to play in outbreak prevention and management strategies for cruise ships, vessels sailing deep sea, and vessels that are stationary at sea for weeks at a time. However, the tests should primarily be used to verify suspected COVID-19 illness in persons with symptoms, or to screen asymptomatic persons who have been in close contact with someone known to be infected with COVID-19. In the latter case, persons should be quarantined independent of the test result. In case of a positive test result, the person should be isolated.

Interpreting test results for COVID-19 can be complicated and should be carried out in collaboration with qualified health personnel.

Gard's comment

In Gard we believe that the use of antigen tests can serve as an extra layer of protective measures, both to reduce the risk of the coronavirus being brought onboard by embarking crews or visitors, and to manage a potential outbreak onboard. However, as Dr. Johansen has explained in this and previous insights, testing for COVID-19 is a complex issue and no test is fail-safe.

Prior to rolling out antigen test kits across fleets, we recommend ship operators to liaise with qualified health personnel and discuss how antigen tests can best be used as part of each ship's overall COVID-19 prevention and control strategy. It is important to set the criteria for selecting a particular antigen test kit and also agree on the scenarios and settings during which it is appropriate to use antigen tests. Personnel involved in taking the tests must be well trained, also in interpreting the test results. And, last but not least, it must be clearly defined how to act on the test results in each of the agreed scenarios. Although not developed specifically for a shipboard setting, the US CDC's "Antigen Test Algorithm" could be used as guidance on how to act on antigen test results.

There will be dilemmas and concerns associated with onboard testing. We are therefore grateful to Dr. Johansen for providing the above guidance and basic principles and hope it provides useful input to our Members' and clients' future planning efforts. Ship operators must also bear in mind that each country imposes their own COVID-19 restrictions on vessels and crew, which means that some port authorities may accept negative antigen tests as evidence that there is no infection onboard, others may not. We therefore strongly recommend that ship operators and masters, well in advance of arriving at any port, seek guidance from local port authorities and ships' agents on restrictions and other preventive measures currently in effect.

The following guidances are also relevant:

WHO: SARS-CoV-2 antigen-detecting rapid diagnostic tests - an implementation guide

ECDC: Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK $\,$

CDC: Interim Guidance for Antigen Testing for SARS-CoV-2