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Early detection of COVID-19 and outbreak mitigation in maritime industries

Robert Hicks, CEO, Offshore Aviation Group
Naomi Matulich-Phillips, Registered Nurse
Simon P. Selwood, PhD, Executive Director, OffshoreDiagnostics

Overview

This white paper includes an overview of maritime industries' challenges related to COVID-19 and describes a solution and a pilot program developed for the United States (U.S.) Navy. We posit that this program offers the best-in-class and most cost-effective solution for early detection of COVID-19 at sites requiring screening and aboard ships where identification of SARS-CoV-2 infection is critical.

Introduction

An outbreak of SARS-CoV-2 within any maritime industry could be devastating, risking negative health outcomes for personnel, disruption of training and operations, possible legal and financial claims and significant time and financial cost of remediation and phased reopening. It is important to ensure we can detect the virus with a high degree of certainty that exceeds industry standards.

A negative COVID-19 test is already required for boarding many vessels and is recommended by the U.S. Centers for Disease Control and Prevention (CDC) in work environments [1]. Employer and institute implementation of testing has also been recommended by the Equal Employment Opportunity Commission (EEOC) [2], is covered under the Americans with Disabilities Act (ADA) [3] and, for many seafarers, may be a necessity under the Jones Act [4].

The challenges of protecting maritime staff and operations from a COVID-19 outbreak

SARS-CoV-2 is highly contagious and can be transmitted through direct contact and via respiratory droplets [5]. In January 2021, an extensive study showed asymptomatic and presymptomatic spread of COVID-19 accounts for 59% of all infections [6]. Nearly half of these infections occur from carriers that never show any significant clinical symptoms. Due to the level of sensitivity required to detect asymptomatic carriers, these can only be identified by molecular testing.

Merchant mariners and cruise industry professionals practice uniquely close living quarters not experienced in many other professions, making protecting staff from and managing COVID-19 outbreaks challenging. The Jones Act, exclusive to the maritime industry, also requires stricter

adherence to health and safety and decreases the burden of proof in litigation, thereby increasing the liability of the employer as shown in the multiple ongoing class action COVID-19 cases [7,8].

Furthermore, SARS-CoV-2 is an RNA virus, which by its nature is highly susceptible to mutation. Nextstrain.org already has thousands of mutations plotted over time, and an article published at Infection Control Today in February 2021 noted that the prominent variants of the virus (United Kingdom (U.K.), Brazil and South Africa strains) represent three different viruses with three different lineages that all evolved the exact same mutation to evade natural immunity and the current vaccines, indicating that we will have to continue adapting our daily routines to manage exposure through practical screening for the foreseeable future.

U.S. Navy case study: a need for molecular testing

Since the COVID-19 outbreak began, many vessels have suffered outbreaks and even superspreader events caused by a presymptomatic or asymptomatic carrier undetected by temperature readings or clinical assessments alone. Some of these occurrences have resulted in varying numbers of crew or passengers enduring hospitalization and even death.

From these events maritime industries have identified two crucial issues to address:

1. A complacency exists when a pandemic goes on past a certain point, allowing a “familiarity” approach to those who work together. Individuals assume that those they are familiar with will continue to be low risk, without any way of knowing if they are COVID-19 negative. This ultimately creates a risk of infection for everyone.
2. An immediate need for better COVID-19 testing pre-boarding and while deployed.

Navy leadership agreed to work with the Offshore Aviation Group (OAG) on a Phase II pilot program to include molecular testing.

Types of tests

There are two types of diagnostic tests available for detection of SARS-CoV-2: nucleic acid amplification tests (NAATs) and antigen tests.

Gold standard NAATs—reverse transcription polymerase chain reaction (RT-PCR) tests—are the most accurate and sensitive, performed by detecting highly replicated viral genetic material. Unfortunately, laboratories capable of this level of analysis at scale are large facilities staffed by qualified scientists, and the test result takes days or weeks to be produced.

Antigen-based tests provide rapid results. Antigens are molecules that are present on the outside of a pathogen. Hence, this type of test often requires a significant viral infection and is best used on patients who are symptomatic. Extensive studies, however, have shown precision of the result to be poor. The most recent report from the CDC shows that the accuracy of antigen testing is maximally 75% in

symptomatic patients and significantly less in asymptomatic and presymptomatic patients—the population most important to diagnose. While experts agree that antigen-based diagnostics are better than taking temperatures alone, **this class of test is not a practical solution for maritime industries**.

Challenges with RT-PCR testing

We've already established that RT-PCR–based testing is the most accurate test type. But standard protocols require that samples be shipped overnight to large, equipped facilities, and results can take up to 10 days to deliver. Individuals must self-quarantine until the result is reported. Another drawback is that the result truly only reflects patients' health at the time the sample was taken days prior.

Maritime industries need results immediately prior to boarding, prior to inter-crew contact and additionally as required once deployed. This necessitates rapid, accurate testing aboard ship.

We set out to find a system that was very accurate and fast to result. In addition, it had to be small and robust enough to deploy on ship, as well as cost-effective, to truly decrease the risk of a COVID-19 outbreak on our vessels.

Our solution

The technology

Thermo Fisher Scientific manufactures a portable, state-of-the art, RT-PCR system called the Accula™ System. This technology has proven to be more accurate than the equipment in high-quality molecular labs [9]. Also, it is robust, inexpensive and can be deployed to multiple locations for near immediate on-site results.

The Accula SARS-CoV-2 test, available for use in CLIA-Waived environments under an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), produces results in 30 minutes.

With the Accula System, we have the ability to rapidly deploy best-of-breed testing solutions to maritime industries at large.

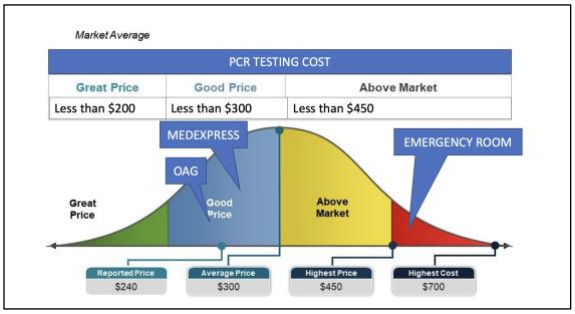
Cost

A comparison of the out-of-pocket expenses for standard RT-PCR testing is as follows:

MedExpress (results in 3–5 days)

$129.00 (office visit)

$100.00 (RT-PCR test)



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$40.00 (shipping to LabCorp)

Total Cost: $269.00

Offshore Diagnostics
(results in 30 minutes)

Total Cost: $250.00

Our RT-PCR–based screening procedure provides the same accuracy as LabCorp without a doctor's office referral, the cost of overnight shipping, and third-party lab fees. Most importantly, our process reduces the time between testing and conclusive results to 30 minutes.

Benefits

- **Physician referral or patient evaluation—**our physicians order testing and are brought into the loop if a patient test result is positive and requires reporting to the health department. This saves time, money and exposure.
- **No overnight shipping**—our labs are set up at the point of embarkation. The plan provides on-site point-of-care and does not require shipping overnight, which provides a cost savings of roughly $20 per test.
- **Reduced risk of government fines**—in the United States, the Department of Transportation (DOT) assigns the enforcement of federal regulations to two of its branches, the Pipeline and Hazardous Materials Association (PHMSA) and the Federal Aviation Administration (FAA). Both of these organizations are authorized to inspect facilities involved in the transportation of all dangerous goods, including infectious and biological substances, and will issue fines and penalties for violations if regulations are overlooked.
- **No exposure at a clinic or waiting for test results**—GateKeeper™ assessments are conducted at shipping terminals while testing takes place. This reduces infection exposure between sample acquisition and result and prohibits an asymptomatic employee from spreading the disease.
- **Use of nasal vs. nasopharyngeal (NP) swab**—the nasal swab specimen is utilized to optimize sensitivity and enable widespread, effective point-of-care testing. Early in the COVID-19 pandemic, NP swabs were were thought to provide the most robust detection of patient infection. However, according to the Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19 from March 18, 2021, nasal swabs have comparable performance to NP swabs for the detection of SARS-CoV-2 RNA and are amenable to patient self-collection, which provides flexibility and reduces strain on trained health care staff.

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Summary of pilot program developed for U.S. Navy

We set out to demonstrate to all interested parties an efficient and accurate way to conduct COVID-19 testing in a maritime setting. Supported by the U.S. Navy, our goal for the pilot program was to ensure that the virus did not impact operations on the vessel M/V Saint Ex. We pre-screened Navy personnel on-site in a convenient, secure setting immediately before being allowed to board and again 48 hours after deployment (and additionally as needed) with the Accula System. As part of the pilot program, the crew of the vessel also received quarantine procedures and guidelines for living quarters on the ship, should they be required.

All participants completed an online questionnaire and consent form before they arrival at the Offshore Diagnostics lab for the boarding pre-screen. Personnel were not permitted to enter the docking area until they received a negative Accula test result. Person-to-person contact was avoided, and health care practioners wore appropriate personal protective equipment and adhered to strict protocols to limit the possibility of all exposures, sample contamination, or subject-to-subject contact prior to receiving results.

Nasal swab samples were collected by registered nurses through an open car window and remote temperatures taken. The individuals remained in their car until the test result was provided and further instructions given to either proceed to the vessel or be referred to a doctor for treatment and quarantine.

All crew members were free of symptoms and tested negative using the Accula System at the boarding pre-screen. Due to inclement weather, departure was delayed, and the M/V Saint Ex crew remained on the ship without departing for an additional 48 hours. Before departure, the crew was re-screened for symptoms and using the Accula System and remained symptom-free and negative for SARS-CoV-2 RNA.

Screening was conducted on the vessel at approximately 48 hours after departure to ensure that anyone who may have recently come in contact with an infected individual, had an undetected level of infection prior to departure, or was missed was retested while aboard ship. All participants remained symptom-free and negative for SARS-CoV-2.

Summary

In summary, maritime industries cannot afford to risk negative health outcomes for personnel, disruption of training and operations, possible legal and financial claims and significant time and financial cost of remediation and phased reopening in the event of an outbreak.

We have created a best-in-class testing model that will scale to fit the needs, safety, and security of our crew and partners. We are making a significant investment in capabilities for COVID-19 and future testing requirements.

We believe that by protecting seagoers, rapid, RT-PCR testing with the Accula System will become the industry standard.

References

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