



Office of the Chief Scientist

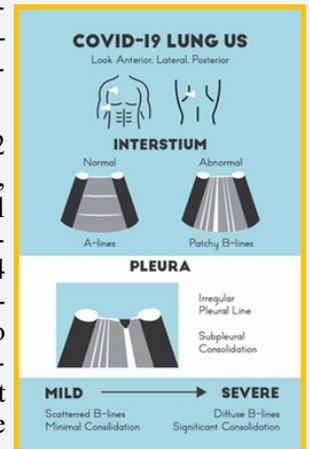
Research Highlights

July 2020

Predictive modeling including point-of care lung ultrasound (P-LUS) for emergency triage of patients with acute respiratory symptoms related to COVID-19.

The ongoing COVID-19 pandemic by SARS-CoV-2 virus has affected over 2.6 million patients worldwide and caused 180k+ deaths since the first case was detected in China in November 2019. Approximately 80% of the patients infected present with fever or mild upper respiratory symptoms, while the other 20% patients (primarily of older age or with pre-existing conditions) show more severe respiratory compromise requiring a hospital admission (15% of all cases) or even ICU admission (5%). Progressive respiratory failure and hypoxemia can occur rapidly, in the course of <72h hours. The predictive value of several clinical risk factors and laboratory biomarkers is being investigated. The case-fatality rate of COVID-19 patients vary greatly, ranging from <5% to 50% if they need ICU and mechanical ventilation.

The daily number of COVID-19 patients (defined as infected or presumably infected by SARS-CoV-2) presenting to the Brooke Army Medical Center Emergency Department (ED), Fort Sam Houston, Texas, have increased, and the clinical deterioration requiring hospital admission or even mechanical ventilation is quick and difficult to predict. This pandemic has disrupted the allocation of hospital personnel and resources to non-COVID-19 patients. This Defense Health Agency (DHA) funded 6.4 study proposes point-of-care-LUS (P-LUS) as a solution. P-LUS is a portable, noninvasive, rapid diagnostic technique capable of detecting low- and high-risk COVID-19 patients, with the potential to improve hospital resource allocation efficiency, patient outcomes (via early detection of deterioration), and reduce hospital personnel and equipment exposure. The Butterfly iQ is a portable, low-cost and low-maintenance P-LUS device capable of far-forward use to facilitate timely and effective triage of patients with acute respiratory symptoms.



Comparison of Two Next Generation Diagnostic SARS-CoV-2 Testing Platforms with Integrated Sample Processing and Evaluation of Multiple Specimen Types

The COVID-19 pandemic has created significant challenges in meeting the demand for diagnostic testing. Due to the necessity for immediately available COVID-19 tests, the FDA has allowed emergency use authorization (EUA). However, EUA does not have the same stringent requirements as the longer 510(k) process. EUA can be obtained by testing the kit on contrived samples only, rather than on COVID-19 patient specimens, and the FDA has issued alerts on potential false positive/negative results on some EUA approved COVID-19 tests. This highlights the need for an independent assessment of the COVID-19 tests to determine the most accurate, rapid tests to use for the DoD. Further, as most COVID-19 tests require nasopharyngeal (NP) swab samples in viral transport media (VTM), this has created a supply issue. Thus, COVID-19 tests which can use other sample sources for detection (e.g. saliva, oropharyngeal swab, nasal swab wash), as well as other forms of transport media, could alleviate these reagent supply challenges.

The Center for Advanced Molecular Detection, 59th Medical Wing, JBSA-Lackland, Texas, was awarded a 6.4 project by DHA to compare two fully-automated real-time PCR based systems for sensitivity, specificity and accuracy: The BioFire® Respiratory 2.1 Panel (RP 2.1), which detects for 21 different respiratory viruses including COVID-19, and the Cepheid Xpert® Xpress COVID-19 test. Sample sources including NP swabs, oropharyngeal swabs, nasal wash and saliva will be assessed, along with a comparison of saline to VTM, to determine which platform provides the optimal results for all sample types, and if saline can be used as an optional transport media.



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