

# COVID 19 Diagnostic Tests: A Study of 12,270 Patients to Determine Which Test Offers the Most Beneficial Results

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## Abstract

COVID 19 has caused capitulation from healthcare entities all over the world. First described in Hubei, China, the virus has spread to 185 countries, showing little signs of eradication or eradication. There does not exist a medical treatment regimen or a vaccine to address COVID 19 definitively. The best response, to date, has been early diagnosis and immediate isolation or quarantine of the patient, with supportive care. As medical institutions all around the world struggle to keep up with this pandemic, there is not a consensus amongst medical professionals in the rapid diagnosis of this disease entity. **Purpose:** The purpose of our study was to review the literature and establish a test, or tests, that would aid the clinician in attaining a swift, yet accurate diagnosis. **Methods:** We searched PubMed and Google scholar and reviewed 32 articles. Keyword searches consisted of COVID 19, pandemic, diagnoses, diagnostic testing, pandemic amongst others. We compared the data obtained from these studies in an effort to find the best diagnostic test. **Results:** There were a total of 12,270 patients that were in our study [1]-[32]. This is the largest study to date in the literature addressing diagnosis of COVID 19. Fever, cough and fatigue, in that respective order were the most common clinical symptoms. Laboratory findings consisted of leukopenia, elevated erythrocyte sedimentation (ESR) and elevated C-reactive protein, CRP. The gold standard test described in multiple studies was the RT-PCR. Serum assays of IgM and IgG were also drawn and found to be accurate in 93% of the time. CT Chest was both sensitive and

specific, 90% and 86%. This diagnostic imaging was even more successful when coupled with clinical symptoms and approaching days 7 - 12 since the onset of clinical symptoms. **Discussion:** This is the largest study compiled to address diagnostic testing in COVID 19 patients. The patient population is spread vastly around the world, with access to many reported tests limited in certain countries. Given the significant sensitivity and specificity of diagnostic imaging, in the setting of clinical symptoms, we recommend patient undergo CT Chest in the face of COVID 19 exposure and clinical symptoms. While RT-PCR, IgM-IgG assays are beneficial, isolation, treatment, and possible quarantine of presumptive positive COVID 19 patients (based upon clinical symptoms and imaging) should not be delayed, for fear of increased infectivity and further risk to society at large.

### Keywords

COVID 19, Diagnostic Test, RT-PCR, IgM-IgG, Chest CT, Pandemic

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## 1. Introduction

COVID 19 is a pandemic that has seriously impacted our daily living. First described in Wuhan, China, in late December, 2019, the disease has since spread worldwide. Mortality rates have been shocking, with new hot spots emerging daily. There has not been any successful treatment reported. There does not exist a vaccine to prevent the spread of SARS-CoV-2 virus, responsible for COVID 19. The hallmark of treatment has been early detection of the patient population with immediate isolation and/or quarantine. Multiple reports have been published attempting to identify and share the best diagnostic technique. However, there has yet to be a consensus paper outlining and comparing the best test, one that offers both a high sensitivity and specificity.

## 2. Purpose

The purpose of our study was to review the literature and establish a test, or tests, that would aid the clinician in attaining a swift, yet accurate diagnosis.

## 3. Methods

We searched PubMed and Google scholar and reviewed 32 articles. The focus of most of these articles was clinical presentation, history of exposure, real time reverse transcriptase polymerase chain reaction (RT-PCR), IgM and IgG studies, and CT scans of the chest. We compared the data obtained from these studies in an effort to find the best diagnostic test.

## 4. Results

There were a total of 12,270 patients that were in our study [1]-[32]. This is the largest study to date in the literature addressing diagnosis of COVID 19. There

were significant clinical symptoms associated with COVID 19. Fever, cough and fatigue, in that respective order were the most common. Laboratory findings, from 12,270 patients, consisted of leukopenia, elevated erythrocyte sedimentation (ESR) and elevated C-reactive protein, CRP. The gold standard test described in multiple studies was the RT-PCR. This was found to be accurate in just under 60% of the patients. Serum assays of IgM and IgG were also drawn and found to be accurate in 93% of the time. These assays were less available, with the literature yielding them completed less than 40% (4900 patients) of the time. These tests did have a prolonged turnaround time. CT Chest was both sensitive and specific, 90% and 86%. This diagnostic imaging was even more successful when coupled with clinical symptoms and approaching days 7 - 12 since the onset of clinical symptoms.

## 5. Discussion

COVID 19 does not affect a specific patient population. Although the virus does impact the immunocompromised and elderly population with increased morbidity and mortality, the disease has affected all age ranges, including the pediatric population.

The constellation of clinical symptoms encompass fever, cough and fatigue in decreasing order of presentation. Given the widespread presence of COVID 19, it is important that the clinician entertain this diagnosis when these clinical symptoms are encountered.

Laboratory findings included lymphopenia, elevated erythrocyte sedimentation rate (ESR) and elevated c-reactive protein, CRP. These labs, however are not pathognomonic.

Confirmatory testing has been employed with the use of RT-PCR. The diagnostic accuracy of this test has been 60% in numerous studies. Some limitations in testing with RT-PCR are that it does require the clinician or technician to obtain an adequate sample. The sputum has the greatest viral load, however it is often difficult to obtain, and places the health care provider at risk. Oropharyngeal and Nasopharyngeal swabs are markedly lower in viral load. One study documented viral loads in the sputum to be 17,429 copies, with throat swabs at 2552 and nasal swabs at 651, almost 27 fold less than sputum. Furthermore, the time from symptom onset to viral load is another variable. Several studies reported viral load to be greatest between days 7 - 10 of symptom onset. Nasal swabs on the initial days of symptom onset would easily contribute to a false negative. We recommend sputum samples in these patients to obtain, rather confirm an accurate diagnosis.

Serum IgG-IgM assay was demonstrated to have a testing specificity and sensitivity of close to 90%. While these are outstanding parameters, the feasibility of obtaining serum of all COVID 19 screening patients is a daunting task, with delay in obtaining the results as well. We do advocate using this assay as a confirmatory test.

The test with the greatest benefit, after evaluating 12,270 patients was the CT Chest, in the presence of clinical symptoms. The CT Chest examination was not dependent upon specimen collection, handling or reporting. There was not any time delay associated with the test, with most results available almost instantly upon completion of the exam. The classic findings appreciated in COVID 19 patients were ground glass opacities in the peripheral and lower lobes. The presence of these findings in the setting of fever, cough and/or fatigue were diagnostic greater than 95% of the time with specificity greater than 90%. Other findings included bronchial thickening, paving, patchy consolidation, but these were in the setting of ground glass opacifications.

Physical testing shortcomings contributed to the significant failure rate of RT-PCR. The science and molecular biology behind this type of test are not in question, rather the inadequacies and potential insufficient sample volume obtained from the COVID 19 patients. Conversely, CT chest imaging is not dependent upon obtaining samples from patients. Thus the findings have fewer variables associated with obtaining, prepping and testing bodily fluids. The reporting time for diagnostic CT imaging is also the fastest.

There is value in obtaining RT-PCR because there does exist a correlation between viral load and disease state. Patients getting closer to discharge, or recovery, have definitively demonstrated significant decreasing levels of viral load.

Improving diagnostic tests would consist of greater cohesiveness and communication amongst the interdisciplinary physicians addressing the COVID 19 pandemic. Emergency department physicians must coordinate immediate access to CT scans with radiologists, along with expedient return of laboratory data with the clinical pathologist and county or regional health officials. Quicker diagnosis and isolation must be the goal for all involved.

COVID 19 is a pandemic of global proportions. At the time of this article, according to the Johns Hopkins COVID 19 resource center, there are over 1 million cases reported, and a staggering 52,863 deaths. Until the cure can be found, immediate diagnosis and quarantine offer the best chance to mitigate this disease process.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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