

# COVID-19 Laboratory Testing Guide

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## What is COVID-19?

COVID-19 (coronavirus disease 2019) is the disease resulting from infection with a newly emerged coronavirus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2).<sup>1</sup> Coronaviruses are a family of RNA viruses usually found in animals. Mutations in the virus can result in human infection and subsequent spread.<sup>2</sup>

SARS-CoV-2 is closely related to the SARS virus identified in 2003 (SARS-CoV) and (to a lesser degree) the MERS-CoV virus from 2012. All three can produce a severe respiratory syndrome and associated mortality.<sup>2-4</sup> While both SARS-CoV and the MERS-CoV viruses seem to have a higher comparative rate of mortality (especially MERS-CoV), the newly emerged SARS-CoV-2 appears much more infectious, with significant human-to-human transmission.<sup>5-7</sup> Asymptomatic individuals may transmit the virus, challenging infection control.<sup>8,9</sup> Its rapid spread has produced a true global pandemic.

## Diagnosis of COVID-19:

Diagnosis cannot be made solely on signs or symptoms as these overlap with other respiratory illness, so confirmation of the presence of the virus is essential. Table 1 describes the range and percent of symptoms seen in confirmed COVID-19 infections.

Sign or symptom	% of patients
Fever	83–99
Cough	59–82
Fatigue	44–70
Anorexia	40–84
Sputum production	28–33
Shortness of breath	31–40
Myalgia (muscle aches)	11–35

**Table 1.** Range and percent of symptoms seen in confirmed COVID-19 infections.<sup>13</sup>

In some populations, a loss of taste or smell is also a widely reported symptom.<sup>10</sup> Molecular testing specific for the SARS-CoV-2 RNA is used to confirm presence of the virus, and serology testing can identify antibodies to the virus.<sup>11,12</sup> In addition, antibody testing is a promising approach to assess prevalence of infection and potentially identify immunity. It remains to be confirmed whether antibodies to SARS-CoV-2 offer protection (immunity) from subsequent exposure.

## Conclusion:

Testing is critical to differentiate COVID-19 from other respiratory diseases such as influenza or RSV (respiratory syncytial virus). Widespread testing will both inform a COVID-19 diagnosis and aid a greater understanding of disease prevalence, especially in infections that are asymptomatic.

# Clinical classification and transmission of COVID-19<sup>14-27</sup>

## Clinical classification



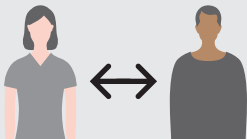
Incubation period  
median 5 days,  
range 1–27 days

Patients with  
mild symptoms  
in week 1...

...may progress  
in week 2

**Progression  
may be rapid  
and sudden.**

## Human-to-human transmission



Possible transmission  
during asymptomatic  
phase 4–6 days before  
the onset of symptoms.

Possible transmission after  
remission of the symptoms

Possible  
transmission

**Highest risk of transmission  
during symptomatic phase**

Possible  
transmission

## Disease spectrum



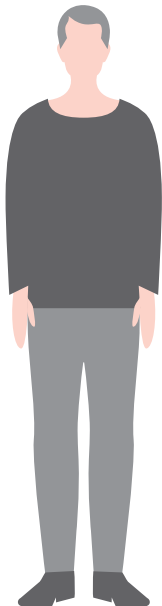
Asymptomatic	Symptomatic			Remission
No symptoms* <b>1.2–17.6%</b>	Mild to Moderate <b>80%</b>	Severe <b>10–15%</b>	<b>Critical</b> <b>2–5%</b>	
Infectious virus can be shed, viral loads may be comparable to symptomatic patients	No signs (mild) or some signs (moderate) of pneumonia on imaging	<ul style="list-style-type: none"> <li>Respiratory distress of <math>\geq 30</math> breath per minute</li> <li>Oxygen saturation <math>\leq 93\%</math> at rest</li> <li><math>\text{PaO}_2/\text{FiO}_2 \leq 300</math> mmHg</li> <li>Lung lesion progression <math>&gt;50\%</math> in 24–48h</li> </ul>	<ul style="list-style-type: none"> <li>Respiratory failure requiring mechanical ventilation</li> <li>Shock</li> <li>Any organ failure requiring ICU care</li> <li>Case/fatality rate current estimation 0.3 to 4%</li> </ul>	

\*Recent SARS-CoV-2 testing studies demonstrate a wide variety of asymptomatic patients between 1% and >80% partially due to different stages of outbreak, testing availability and population studied

# Course of patients at risk and/or infected by COVID-19<sup>14-27</sup>



## Identification of high risk patients



- Age >65 years
- Any age with severe obesity BMI >40
- Pre-existing pulmonary disease (chronic lung disease or moderate to severe asthma, COPD, lung cancer, pulmonary hypertension, emphysema (smoking, A1AT deficiency))
- Chronic kidney disease
- Diabetes
- History of:
  - hypertension (treated and untreated)
  - cardiovascular disease
  - liver disease
  - transplants or other immunosuppression (ex. cancer treatment)
- Patients with HIV or other immunocompromised conditions
- Patients with endocrine pathologies
- Use of biologic drugs



## Population triage<sup>2,3,4</sup>

### Epidemiologic surveillance

#### Laboratory testing:

- RT-PCR
- Anti-SARS-CoV-2 antibodies



## Recovery

#### Laboratory testing:

- Anti-SARS-CoV-2 antibodies (IgG, Total)

#### Confirm immunization (under investigation)



## Diagnosis and Determination of Disease Status

### Disease detection:

- Molecular testing (RT-PCR)

### Immune Response:

- Anti-SARS-CoV-2 antibodies (IgG, Total)

### Imaging:

- Chest CT
- Ultrasound
- X-ray



## Monitoring

#### Laboratory testing:

- Arterial blood gas
- Complete blood count
- Acute phase proteins, inflammation & coagulation
- Liver, kidney, cardiac function biomarkers
- Additional testing related to comorbidities

#### Imaging:

- Chest CT (ground glass opacification)
- Ultrasound



# The essential role of laboratory diagnostics in SARS-CoV-2 infection<sup>14-27</sup>



## Essential lab testing

<b>Daily labs</b>	CBC with differential (trend total lymphocyte count) Comprehensive metabolic panel: <ul style="list-style-type: none"> <li>• Electrolytes: Na, K, Total CO<sub>2</sub>, Chloride</li> <li>• Total protein and Albumin</li> <li>• Creatinine</li> <li>• Bilirubin, ALT, AST</li> </ul> CPK (total creatine kinase) Lactate
<b>Risk stratification</b>	D-dimer, Ferritin, CRP, ESR, LDH, Cardiac troponin
<b>Viral serologies</b>	HBV, HCV, HIV Ab/Ag

## Frequent laboratory abnormalities in patients with COVID-19<sup>†</sup>

 Decreased	 Increased
Blood lymphocyte count (35–75%)	Neutrophil count
Albumin (50–98%)	Erythrocyte sedimentation rate (ESR; up to 85%)
Hemoglobin (41–50%)	C-reactive protein (CRP; 75–93%)
	Lactate dehydrogenase (LDH; 27–92%)
	Alanine aminotransferase (ALT)
	Aspartate aminotransferase (AST)
	Total bilirubin
	Cardiac troponin
	Procalcitonin (6–25%)
	Prothrombin time (PT)
	D-dimer (36–43%)








<sup>†</sup>Approximate percentage of patients

Additional essential lab testing	Test	Potential clinical significance
<b>Arterial blood gas</b>	pH, PaCO <sub>2</sub> , PaO <sub>2</sub> , and aHCO <sub>3</sub>	For ventilator adjustments
<b>Hematology</b>	Lymphopenia with atypical lymphocytes Leukocytosis, Neutrophilia, low eosinophils Thrombocytopenia: Platelet count	Decreased immunological response to the virus Bacterial (super) infection Consumption (disseminated) coagulopathy
<b>Hemostasis</b>	Prothrombin time, D-Dimer	Activation of blood coagulation and/or disseminated coagulopathy PT and D-dimer are significant predictors of disease severity
<b>Inflammation/Infection</b>	CRP, Ferritin, IL6, TNF $\alpha$ , SAA Procalcitonin	Severe viral infection/viremia Bacterial (super) infection
<b>Cardiac</b>	High-sensitivity troponin, CK-MB, BNP/NT-proBNP	Increased levels may be associated with higher mortality <sup>‡</sup>
<b>Liver</b>	Albumin, ALT, AST, Bilirubin	Impairment of liver function, Liver injury
<b>Renal</b>	Creatinine, Cystatin C	Kidney injury

<sup>‡</sup>This information represents a potential novel clinical utility. Data have not been reviewed by FDA or any other regulatory agency

# Impact of Comorbidities on COVID-19 Patients

Patients with comorbidities (like diabetes mellitus, hypertension, cardiovascular, chronic lung and chronic kidney disease) are particularly susceptible to COVID-19 infection and are likely to have more severe illness<sup>14-26</sup>

	Comorbidities	Additional testing	Impact of COVID-19
	<b>Cardiovascular disease</b>	Troponin, Natriuretic peptides, CKMB	Precipitates cardiac complications like: acute heart failure, myocardial infarction, myocardial injury, cardiac arrest.
	<b>Chronic kidney disease</b>	Blood: Creatinine, Cystatin C, eGFR Urine: Albumin	Challenges for patients on dialysis, in particular, in-center hemodialysis; uremic patients are particularly vulnerable to infection and may exhibit greater variations in clinical symptoms and infectivity.
	<b>Heart/liver/kidney transplant</b>	Immunosuppressant Drugs: Mycophenolate, Cyclosporine, Tacrolimus, Sirolimus, Everolimus	Patients may be more vulnerable due to immunocompromised status.
	<b>Viral co-infection</b>	Hepatitis B serologies (anti-HBs, anti-HBc, and HBsAg) Hepatitis C serology (anti-HCV), unless positive in past HIV 1/2/O, CD4 count	Viral serologies assist in interpretation of ALT elevations, present in ~25% of COVID-19 patients. HIV patients may get severe side effects when taking Tocilizumab (drug being used for COVID-19 pneumonia). <sup>§</sup> Hepatitis patients are at higher risk for liver complications.
	<b>Diabetes</b>	Blood glucose	Patients with diabetes who are infected with COVID-19 may see their glycemic control deteriorate during the illness.
	<b>Chronic lung disease</b>	LDH	Patients may be more vulnerable due to lung function insufficiency.
	<b>Chronic liver disease</b>	Albumin, AST, ALT, Total Protein, Bilirubin, PT INR	Patients may be more vulnerable due to liver function insufficiency.

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Siemens Healthineers' SARS-CoV-2 molecular and serology tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories. The molecular test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. The serology test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. The serology test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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