

# Diagnosis

## SARS-CoV-2 Tested

Has the participant been tested for SARS-CoV-2?  Tested  
 Not Tested  
 Unknown

What was the result?  Positive  
 Negative  
 Unknown

## What tests were performed?

Molecular amplification test (RT PCR, NAAT) - SARS-CoV-2 RNA level Quantitative  Yes  No  Unknown

	Detected	Not Detected	Not detected in pooled specimen	Inconclusive	N/A or Not reported	Unknown
Result	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of test \_\_\_\_\_

Molecular amplification test (RT PCR, NAAT) - SARS-CoV-2 RNA detection Qualitative  Yes  No  Unknown

	Detected	Not Detected	Not detected in pooled specimen	Inconclusive	N/A or Not reported	Unknown
Result	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of test \_\_\_\_\_

SARS-CoV-2 Antigen - SARS-CoV-2 Rapid Antigen  Yes  No  Unknown

	Detected	Not Detected	Not detected in pooled specimen	Inconclusive	N/A or Not reported	Unknown

Result

Date of test \_\_\_\_\_

Serology - SARS CoV-2 IgM  Yes  No  Unknown

Detected Not Detected Not detected in pooled specimen Inconclusive N/A or Not reported Unknown

Result

Date of test \_\_\_\_\_

Serology - SARS CoV-2 IgG or Neutralizing Antibody/Serologic  Yes  No  Unknown

if yes, what is the antibody to?  Spike protein antibody  Nucleocapsid antibody

Detected Not Detected Not detected in pooled specimen Inconclusive N/A or Not reported Unknown

Result

Date of test \_\_\_\_\_

Other  Yes  No  Unknown

Specify other test performed \_\_\_\_\_

Detected Not Detected Not detected in pooled specimen Inconclusive N/A or Not reported Unknown

Result

Date of test \_\_\_\_\_

---

Sample Type Collected (Tier 2)

- Nasal
- Nasopharyngeal
- Saliva
- Endotracheal aspirate
- Bronchoalveolar lavage (BAL) fluid
- Blood
- Stool
- Cord Blood
- Unknown

# Treatment

Highest level of care received during the COVID-19 episode?

- Admitted to the intensive care unit (ICU)  
 Admitted to the hospital  
 Emergency Department assessment  
 Outpatient (in-person and telemedicine)  
 Self-care alone/over-the-counter medications  
 Unknown

Date of current or any previous hospital admission for COVID-19

\_\_\_\_\_

Date of discharge

\_\_\_\_\_

Were any of the following conditions listed as a discharge diagnosis for this COVID-19 related admission?

- Acute COVID  
 MIS-C  
 Kawasaki Disease  
 Long COVID/Post-Acute Sequelae of COVID (PASC)  
 None of the above

Date of current or any previous ICU Admission

\_\_\_\_\_

Date of ICU Discharge

\_\_\_\_\_

Medications of Interest (Acute COVID/MIS-C/Long COVID (PASC) Directed)

What medications did the patient take or receive to treat Acute COVID-19/MIS-C/Long COVID (PASC)

	Yes	No	Unknown	Not Reported
Anti-coagulant - Heparin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Anti-coagulant - Enoxaparin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Anti-coagulant - Warfarin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Anti-coagulant - Direct oral anticoagulant (DOAC)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Anti-coagulant - Antiplatelets/Aspirin therapy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Systemic antibiotic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Specify Antibiotic

\_\_\_\_\_

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Immune modulators/Immunosuppresants - Anakinra	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Immune modulators/Immunosuppresants - Tocilizumab	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Immune modulators/Immunosuppresants - Convalescent plasma	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Immune modulators/Immunosuppresants - SARS-CoV-2 monoclonal antibodies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started \_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped \_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Immune modulators/Immunosuppresants - Intravenous immunoglobulins (IVIG)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started \_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped \_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Immune modulators/Immunosuppresants - Interferon	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started \_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped \_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Immune modulators/Immunosuppresants - Tumor necrosis factor (TNF) inhibitors (i.e. infliximab, etanercept, adalimumab)

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

Immune modulators/Immunosuppresants - NSAID-Ibuprofen

Yes  No  Unknown  Not Reported

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

Anti-viral/Anti-COVID - Remdesivir

Yes  No  Unknown  Not Reported

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

Anti-viral/Anti-COVID - Ribavirin

Yes  No  Unknown  Not Reported

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

Yes  No



Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Diabetic Medications - Insulin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Inhaled Medications - Inhaled steroids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Inhaled Medications - Albuterol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Inhaled Medications - Ipratropium	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

---

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

---

	Yes	No	Unknown	Not Reported
Systemic Steroids - Dexamethasone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

---

	Yes	No	Unknown	Not Reported
Systemic Steroids - Methylprednisolone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

---

	Yes	No	Unknown	Not Reported
Systemic Steroids - Prednisone/Prednisolone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

---

	Yes	No	Unknown	Not Reported
Systemic Steroids - Hydrocortisone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Systemic Steroids - Fludrocortisone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Other medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Specify other

\_\_\_\_\_

Date Medication Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Medication Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

Timing of medications, particularly immune modulators/immunosuppressants, may be important for assessing other relevant data elements, such as lab values. Therefore, as appropriate, the Working Group recommends documenting the time as well as the date when these specific medications are administered.

### Intensive Intervention (Treatment/Device)

	Yes	No	Unknown	Not Reported
Invasive mechanical ventilation (e.g., endotracheal intubation, mechanical ventilation via tracheostomy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Invasive Treatment Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Invasive Treatment Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
New tracheostomy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Invasive Treatment Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Invasive Treatment Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Noninvasive mechanical ventilation (e.g., CPAP, BiPAP, NIPPV)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Invasive Treatment Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Invasive Treatment Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Extracorporeal membrane oxygenation (ECMO)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Invasive Treatment Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

Date Invasive Treatment Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Vasoactive medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Invasive Treatment Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?  Yes  No

---

Date Invasive Treatment Stopped

---

(MM/DD/YYYY)

---

	Yes	No	Unknown	Not Reported
Arterial catheter placement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Date Invasive Treatment Started

---

(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Invasive Treatment Stopped

---

(MM/DD/YYYY)

---

	Yes	No	Unknown	Not Reported
Cardiopulmonary resuscitation with/without return of spontaneous circulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Date Invasive Treatment Started

---

(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Invasive Treatment Stopped

---

(MM/DD/YYYY)

---

	Yes	No	Unknown	Not Reported
Central venous catheter placement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Date Invasive Treatment Started

---

(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Invasive Treatment Stopped

---

(MM/DD/YYYY)

---

	Yes	No	Unknown	Not Reported
Low flow oxygen therapy (e.g. nasal cannula, simple mask, face tent)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Date Invasive Treatment Started

---

(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Invasive Treatment Stopped \_\_\_\_\_  
(MM/DD/YYYY)

---

High flow oxygen therapy	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Reported <input type="radio"/>
--------------------------	------------------------------	-----------------------------	----------------------------------	---------------------------------------

---

Date Invasive Treatment Started \_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Invasive Treatment Stopped \_\_\_\_\_  
(MM/DD/YYYY)

---

Invasive management of thrombosis (e.g., surgical thrombectomy, endovascular thrombectomy, catheter-directed thrombolysis)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Reported <input type="radio"/>
--	------------------------------	-----------------------------	----------------------------------	---------------------------------------

---

Date Invasive Treatment Started \_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Invasive Treatment Stopped \_\_\_\_\_  
(MM/DD/YYYY)

---

Renal replacement therapy (RRT)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Reported <input type="radio"/>
---------------------------------	------------------------------	-----------------------------	----------------------------------	---------------------------------------

---

Date Invasive Treatment Started \_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing?  Yes  No

---

Date Invasive Treatment Stopped \_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Pacemaker placement	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Invasive Treatment Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

 Yes  No

Date Invasive Treatment Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Left ventricular assist device (LVAD)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date Invasive Treatment Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

 Yes  No

Date Invasive Treatment Stopped

\_\_\_\_\_  
(MM/DD/YYYY)

	Yes	No	Unknown	Not Reported
Other intensive intervention	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Specify other

\_\_\_\_\_

Date Invasive Treatment Started

\_\_\_\_\_  
(MM/DD/YYYY)

Ongoing?

 Yes  No

Date Invasive Treatment Stopped

\_\_\_\_\_  
(MM/DD/YYYY)**Do Not Resuscitate/Limitation of Support**

Was there a "Do Not Resuscitate" order or any other limitation of support?

 Yes  No  Unknown

# Outcomes

## Patient Survival

Did the patient die?  Yes  
 No  
 Unknown

Was the death COVID-19 related (including MIS-C)?  Yes  
 No  
 Unknown  
 N/A or not reported

Date of Death \_\_\_\_\_

If hospitalized for suspected or diagnosed COVID-19 and survived, to where was the participant discharged?  Home  
 Rehabilitation Facility/Nursing Facility  
 Other  
 Unknown  
 N/A or not reported

Specify other \_\_\_\_\_

What was the COVID-19 severity at time of maximum severity of illness?  Asymptomatic/presymptomatic infection  
 Mild illness  
 Moderate illness  
 Severe illness  
 Critical illness  
 Unknown  
 N/A or not reported

NIH Severity Definitions:

- Asymptomatic or Presymptomatic Infection: Individuals who test positive for SARS-CoV-2 using a virologic test (i.e., a nucleic acid amplification test [NAAT] or an antigen test) but who have no symptoms that are consistent with COVID-19.

- Mild Illness: Individuals who have any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have shortness of breath, dyspnea, or abnormal chest imaging.

- Moderate Illness: Individuals who show evidence of lower respiratory disease during clinical assessment or imaging and who have an oxygen saturation (SpO<sub>2</sub>)  $\geq$ 94% on room air at sea level.

- Severe Illness: Individuals who have SpO<sub>2</sub>  $<$  94% on room air at sea level, a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO<sub>2</sub>/FiO<sub>2</sub>)  $<$  300 mm Hg, or lung infiltrates  $>$ 50%.

- Critical Illness: Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

- In pediatric patients, radiographic abnormalities are common and, for the most part, should not be the only criteria used to determine the severity of illness. The normal values for respiratory rate also vary with age in children; thus, hypoxia should be the primary criterion used to define severe COVID-19, especially in younger children.