

# Manifestations: Clinical

Vital signs are routinely collected as part of the baseline visit to determine eligibility to participate in a trial, to serve as a reference point to select vital signs which may be trended during the trial, and to reveal potential indicators of severity and risk that may not otherwise be obvious. Thus, the Working Group recommends transmitting baseline vital signs as a common data point and encourages researchers to supplement this list with other vital signs as dictated by specific criteria in their individual trials.

The Working Group is not currently recommending frequency for documentation of vital signs. Study sites should provide any core vital sign data that are collected for routine monitoring of participants. For example, vital sign data for ICU patients are typically charted every hour, and these data should be available through the electronic health record.

For outpatient studies, core vital sign data elements should be taken with any in-person assessment. However, the reference time period for vital signs should be a 24-hour clock from midnight to midnight (00:00-23:59) to allow for consistency across studies.

## Date and Time of Vital Signs

Date	_____
	(MM/DD/YYYY)
Time	_____
	(HHMM)

## Vital Sign Timepoints

Baseline (e.g., at admission, at initial encounter if not admission)	<input type="radio"/> Admission <input type="radio"/> Initial Encounter if not admission
Protocol specific timepoints (e.g., Day 1 AM, Day 1 PM, Day 2 AM, at discharge, etc.)	<input type="radio"/> Day 1 <input type="radio"/> Day 2 <input type="radio"/> Discharge
	<input type="radio"/> Unknown

## Vital Signs

Body temperature	_____
	(Celsius)
	<input type="radio"/> Unknown <input type="radio"/> N/A <input type="radio"/> Not Reported
Heart rate	_____
	(beats/min)
	<input type="radio"/> Unknown <input type="radio"/> N/A <input type="radio"/> Not Reported
Systolic blood pressure	_____
	(mmHg)

Unknown  N/A  Not Reported

Diastolic blood pressure

\_\_\_\_\_ (mmHg)

Unknown  N/A  Not Reported

Respiratory rate

\_\_\_\_\_ (breaths/min)

Unknown  N/A  Not Reported

Oxygen saturation

\_\_\_\_\_ (%)

Unknown  N/A  Not Reported

Supplemental oxygen

Yes  No

### Symptoms/Physical Findings

**Additional Guidance: Note that the two lists below are separated into an acute COVID-19/MIS-C symptom list and a Long COVID/PASC list (which includes the acute COVID-19/MIS-C list).**

Which of the following were experienced during current illness and/or confirmed by physical exam?

For each symptom indicate Yes/No/Unknown

#### Acute COVID/MIS-C

	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Abdominal pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bleeding	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chest pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cough	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cyanosis (bluish lips/face)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diarrhea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fatigue	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fever - documented	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Duration in days

\_\_\_\_\_

	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Headache	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Muscle or body aches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nasal congestion or runny nose	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nausea/vomiting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Neck pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
New loss of taste or smell	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Palpitations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Shortness of breath or difficulty breathing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Skin rash	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sore throat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subjective fever/chills/rigors/night sweats	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Swollen glands	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If confirmed by physical exam, cervical lymphadenopathy (at least 1.5 cm in diameter) ?

Yes  No  Unknown

	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Conjunctivitis (Red/pink eye(s))	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oral mucosal change	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If confirmed by physical exam were swollen, red, or cracked lips, strawberry tongue, and/or erythema of the oral/pharyngeal mucosa present?

Yes  No  Unknown

	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Changes in hands and feet (Peripheral extremity changes)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other symptom(s)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Specify

\_\_\_\_\_

**Long COVID/PASC, including above acute COVID/MIS-C symptoms list plus the following:**

	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Allodynia (pain out of proportion to the stimulus)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Altered level of consciousness/confusion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anorexia (decrease in appetite)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anxiety	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cannot move and/or feel one side of body or face	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Depressed mood	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dizziness/lightheadedness/black outs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Exertional fatigue	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Forgetfulness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Irritability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Orthostasis (dizziness/lightheadedness/black outs on sitting up or standing)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If yes, confirmed by changes in heart rate/blood pressure? [Tier 2]  Yes  No  Unknown

	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Joint pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hallucinations (seeing or hearing things others do not see or hear) [should not be completed for children < 15 years old]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hypersomnia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Insomnia (difficulty sleeping)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Malaise (including post-exertional malaise)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Muscle weakness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Paresthesia (numbness or tingling somewhere in the body)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Persistent cough	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If yes, productive?  Yes  No  Unknown

	Yes - Experienced	Yes - Experienced and Confirmed by Physical Exam	No	Unknown
Problems with balance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Problems with gait/falls	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Toe rashes (red/purple sores or blisters on the feet, including the toes)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble concentrating or difficulty thinking ("brain fog")	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Weight loss	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Failure of expected weight gain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Failure of expected linear growth	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other symptom(s)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Specify \_\_\_\_\_

### Infant-Specific Symptoms/Physical Findings (Tier 2)

In addition to the above, which of the following were experienced by the infant during illness?

For each symptom indicate Yes/No/Unknown

Dehydration  Yes  No  Unknown

Date Symptoms Presented \_\_\_\_\_

(MM/DD/YYYY)

Date Symptoms Resolved \_\_\_\_\_

(MM/DD/YYYY)

Ongoing

Full or bulging fontanelle  Yes  No  Unknown

Date Symptoms Presented \_\_\_\_\_

(MM/DD/YYYY)

Date Symptoms Resolved \_\_\_\_\_

(MM/DD/YYYY)

Ongoing

Fussiness  Yes  No  Unknown

Date Symptoms Presented \_\_\_\_\_

(MM/DD/YYYY)

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Date Symptoms Resolved

\_\_\_\_\_

(MM/DD/YYYY)

Ongoing

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Increased work of breathing/shallow breathing

Yes  No  Unknown

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Date Symptoms Presented

\_\_\_\_\_

(MM/DD/YYYY)

---

Date Symptoms Resolved

\_\_\_\_\_

(MM/DD/YYYY)

Ongoing

---

Lethargy

Yes  No  Unknown

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Date Symptoms Presented

\_\_\_\_\_

(MM/DD/YYYY)

---

Date Symptoms Resolved

\_\_\_\_\_

(MM/DD/YYYY)

Ongoing

---

Poor feeding

Yes  No  Unknown

---

Date Symptoms Presented

\_\_\_\_\_

(MM/DD/YYYY)

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Date Symptoms Resolved

\_\_\_\_\_

(MM/DD/YYYY)

Ongoing

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### Complications/Conditions

Did the patient develop any of the following complications/conditions since the diagnosis of COVID (organized by organ system):

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Fibromyalgia/amplified pain syndrome

Yes  No  Unknown

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Date of Onset/Diagnosis (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Date of Resolution (Tier 2)

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

Ongoing

---

Post viral fatigue syndrome

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

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Seizure

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

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Date of Resolution (Tier 2)

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

Ongoing

---

Stroke: intracerebral hemorrhage

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

---

Stroke: ischemic cerebrovascular accident

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

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Date of Resolution (Tier 2)

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

Ongoing

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Diabetic Ketoacidosis (DKA)  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

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Date of Resolution (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

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Ongoing

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New onset diabetes  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

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Date of Resolution (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

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Ongoing

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Pancreatitis  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

---

Date of Resolution (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

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Ongoing

---

Acute respiratory distress syndrome (ARDS)  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

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Date of Resolution (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

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Ongoing

---

Bronchiolitis  Yes  No  Unknown

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Date of Onset/Diagnosis (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)



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Date of Resolution (Tier 2)

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

Ongoing

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Deterioration of prior chronic pulmonary diseases

Yes  No  Unknown

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Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

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Lung fibrosis

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

---

Pneumonia

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

---

Pulmonary embolism

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

---

Cardiac arrhythmias  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

---

Ongoing

---

Cardiac failure

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

---

Ongoing

---

Cardiomyopathy

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

---

Ongoing

---

Coronary artery abnormalities

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

---

Ongoing

---

Myocarditis/pericarditis/ pericardial effusion

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

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---

Date of Resolution (Tier 2)

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

Ongoing

---

Myositis

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

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Shock

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

---

Arthritis

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

---

Physical disability/muscular weakness

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

Ongoing

---

Acute kidney injury  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

---

Ongoing

---

Acute liver dysfunction

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

---

Ongoing

---

End stage renal disease (ESRD)

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

---

Ongoing

---

Bleeding events

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

---

Ongoing

---

Deep vein thrombosis

Yes  No  Unknown

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If there is a venous thrombosis, where is it located?  
(Tier 2)

- Intracranial  
 Extracranial  
 Both  
 Unknown or not reported

---

Date of Onset/Diagnosis (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Date of Resolution (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Ongoing

---

Appendicitis

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Date of Resolution (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Ongoing

---

Gastroesophageal reflux disease (GERD)

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Date of Resolution (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Ongoing

---

Gastrointestinal hemorrhage

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Date of Resolution (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Ongoing

---

Gastrointestinal perforation

Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Date of Resolution (Tier 2)

\_\_\_\_\_

(MM/DD/YYYY)

---

Ongoing

---

Peritonitis  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

---

Date of Resolution (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing

---

Bacteremia  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

---

Date of Resolution (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing

---

Pulmonary aspergillosis  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

---

Date of Resolution (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing

---

Toxic shock syndrome (TSS)  Yes  No  Unknown

---

Date of Onset/Diagnosis (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

---

Date of Resolution (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

---

Ongoing

---

Other (specify)  Yes  No  Unknown

---

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

---

Date of Onset/Diagnosis (Tier 2)

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

---

Date of Resolution (Tier 2)

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

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Ongoing

# Manifestations: Laboratory

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Labs at Diagnosis (work up of condition)

Additional Guidance: The Tier 1 lab values include, but are not limited to, those parameters necessary for the diagnosis of MIS-C (including markers of inflammation) and other conditions associated with acute and long COVID/PASC. Inclusion in Tier 1 does not suggest that all of these labs are recommended to be performed in all pediatric patients/studies, but rather that the test values or Not Done should be reported when performed.

Similar to vital signs, the Working Group is not currently recommending frequency for documentation of specific clinical labs. Study sites are encouraged to provide any lab data that are collected for routine monitoring of participants in addition to the value at diagnosis (i.e., work up of condition), which will vary between outpatient and inpatient settings. However, the reference time period for labs should be a 24-hour clock from midnight to midnight (00:00-23:59) to allow for consistency across studies.

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Lab tests performed?  Yes  No  Unknown

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Date of Lab Sample Collection

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

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Time of lab sample collection

\_\_\_\_\_  
(HHMM)

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Date of Lab Sample Collection

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

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Time of lab sample collection

\_\_\_\_\_  
(HHMM)

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Date of Lab Sample Collection

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

---

Time of lab sample collection

\_\_\_\_\_  
(HHMM)

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Date of Lab Sample Collection

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

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Time of lab sample collection

\_\_\_\_\_  
(HHMM)



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Date of Lab Sample Collection

\_\_\_\_\_

(MM/DD/YYYY)

Time of lab sample collection

\_\_\_\_\_

(HHMM)

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Date of Lab Sample Collection

\_\_\_\_\_

(MM/DD/YYYY)

Time of lab sample collection

\_\_\_\_\_

(HHMM)

**For each of the below, report test value at diagnosis (i.e., work up of condition) or trial entry with units or "Not Done"**

**Any lab tests performed? (Tier 1)**

	Yes	No	Unknown	Not Performed
White blood cell count (WBC)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

\_\_\_\_\_

([unit type])

	Yes	No	Unknown	Not Performed
Absolute lymphocyte count (ALC)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

	Yes	No	Unknown	Not Performed
Absolute neutrophil count (ANC)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

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

Result

C-reactive protein (CRP)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Erythrocyte sedimentation rate (ESR)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Procalcitonin	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Ferritin	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
LDH	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Albumin	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Glucose	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Sodium	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			

Creatinine	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Blood urea nitrogen (BUN)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Aspartate aminotransferase (AST)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Alanine transaminase (ALT)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
D-dimer	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Fibrinogen	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Troponin (TNI)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
BNP/NT-Pro-BNP	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Lactate	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			

**Tier 2 Labs**

	Yes	No	Unknown	Not Performed
Absolute eosinophil count	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

	Yes	No	Unknown	Not Performed
Absolute monocyte count	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

	Yes	No	Unknown	Not Performed
Absolute basophil count	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

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

Result

	Yes	No	Unknown	Not Performed
Total bilirubin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

	Yes	No	Unknown	Not Performed
Prothrombin time (PT)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

	Yes	No	Unknown	Not Performed
International normalized ratio (INR)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

	Yes	No	Unknown	Not Performed
Activated partial thromboplastin time (aPTT)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result

IL-6	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Complement	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Hemoglobin A1C	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
pH	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
pCO2	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
paCO2	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Calcium	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Cerebrospinal fluid (CSF) WBC	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
CSF red blood cell count (RBC)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			

CSF Protein	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
-------------	------------------------------	-----------------------------	----------------------------------	--

Result  
\_\_\_\_\_

CSF Glucose	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
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Result  
\_\_\_\_\_

Other, Specify	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
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Specify other  
\_\_\_\_\_Result  
\_\_\_\_\_**Most Abnormal Labs (Tier 2)**

Any labs repeated during admission that were more abnormal than initial values?

 Yes  No  Unknown

White blood cell count (WBC)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
------------------------------	------------------------------	-----------------------------	----------------------------------	--

Result  
\_\_\_\_\_

Absolute lymphocyte count (ALC)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
---------------------------------	------------------------------	-----------------------------	----------------------------------	--

Result  
\_\_\_\_\_

Absolute neutrophil count (ANC)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
---------------------------------	------------------------------	-----------------------------	----------------------------------	--

Result  
\_\_\_\_\_

Platelets	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
-----------	------------------------------	-----------------------------	----------------------------------	--

Result  
\_\_\_\_\_

C-reactive protein (CRP)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Erythrocyte sedimentation rate (ESR)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Procalcitonin	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Ferritin	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
LDH	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Albumin	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Glucose	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Sodium	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			

Creatinine	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Blood urea nitrogen (BUN)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Aspartate aminotransferase (AST)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Alanine transaminase (ALT)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
D-dimer	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Fibrinogen	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Troponin (TNI)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
BNP/NT-Pro-BNP	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			
Lactate	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result	_____			



Tier 2				
	Yes	No	Unknown	Not Performed
Absolute eosinophil count	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Result _____				
Absolute monocyte count	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Result _____				
Absolute basophil count	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Result _____				
Hemoglobin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Result _____				
Total bilirubin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Result _____				
Prothrombin time (PT)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Result _____				
International normalized ratio (INR)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Result _____				
Activated partial thromboplastin time (aPTT)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Result _____				

IL-6	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result				
Complement	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result				
Hemoglobin A1C	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result				
pH	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result				
pCO2	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result				
paCO2	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result				
Calcium	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result				
Cerebrospinal fluid (CSF) WBC	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result				
CSF red blood cell count (RBC)	Yes <input type="radio"/>	No <input type="radio"/>	Unknown <input type="radio"/>	Not Performed <input type="radio"/>
Result				

	Yes	No	Unknown	Not Performed
CSF Protein	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result \_\_\_\_\_

	Yes	No	Unknown	Not Performed
CSF Glucose	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Result \_\_\_\_\_

	Yes	No	Unknown	Not Performed
Other, Specify	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

Result \_\_\_\_\_

**Other Viral/Bacterial/Fungal Test Positive (Tier 2)**

Any other viral testing positive?  Yes  No

**List other viral tests that were positive**

Specify other positive viral test \_\_\_\_\_

Specify other positive viral test \_\_\_\_\_

Specify other positive viral test \_\_\_\_\_

Specify other positive viral test \_\_\_\_\_

Specify other positive viral test \_\_\_\_\_

Specify other positive viral test \_\_\_\_\_

**Blood Cultures**

Positive blood cultures?

Yes  No

Organism

\_\_\_\_\_

Date

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

Organism

\_\_\_\_\_

Date

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

Organism

\_\_\_\_\_

Date

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

Organism

\_\_\_\_\_

Date

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

Organism

\_\_\_\_\_

Date

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

Organism

\_\_\_\_\_

Date

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

# Manifestations: Cardiopulmonary Diagnostic Assessments

Additional Guidance: Similar to vital signs and clinical labs, the Working Group is not currently recommending frequency for documentation of specific cardiopulmonary assessments. Study sites are encouraged to provide any cardiopulmonary assessment data that are collected for monitoring of participants, in addition to the data reporting abnormality.

## Cardiovascular Diagnostic Assessment Abnormalities

Did the patient have any cardiovascular diagnostic assessments performed (beyond physical exam) ?  Yes  No  Unknown

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
ECG (Tier 2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Cardiovascular Diagnostic Assessment Date \_\_\_\_\_

Was there  Abnormal function  
 Pericardial effusion  
 Coronary artery abnormalities

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
ECHO (Tier 2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Cardiovascular Diagnostic Assessment Date \_\_\_\_\_

Was there  Abnormal function  
 Pericardial effusion  
 Coronary artery abnormalities

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
Cardiac MRI (Tier 2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Cardiovascular Diagnostic Assessment Date \_\_\_\_\_

Was there  Abnormal function  
 Pericardial effusion  
 Coronary artery abnormalities

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
Other test	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Specify test

Cardiovascular Diagnostic Assessment Date

Was there

- Abnormal function  
 Pericardial effusion  
 Coronary artery abnormalities

### Pulmonary Diagnostic Assessment Abnormalities

Did the patient have any pulmonary diagnostic testing (beyond physical exam and radiographic imaging)

Yes  
 No  
 Unknown

Additional Guidance: Please note that while the 6-Minute Walk Test (6-MWT) is currently grouped with the Pulmonary Diagnostic Assessments, it is also used as a Cardiovascular Diagnostic Assessment. Please refer to the footnote for 6-MWT assessment in MIS-C patients.

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
6-Minute Walk Test (Tier 2) [only ages 6+]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Pulmonary Diagnostic Assessment Date

(MM/DD/YYYY)

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
Pulmonary Function Test (Tier 2) [only ages 6+]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Pulmonary Diagnostic Assessment Date

(MM/DD/YYYY)

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
Co-oximetry (Tier 2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Pulmonary Diagnostic Assessment Date

(MM/DD/YYYY)

---

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
2-Minute Walk Test (Tier 2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Pulmonary Diagnostic Assessment Date

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

---

	Yes - abnormalities detected	Yes normal	No - not performed	Unknown
Other tests (specify test) performed (Tier 2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

---

Specify other

\_\_\_\_\_

Pulmonary Diagnostic Assessment Date

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

# Manifestations: Imaging

## Radiographic Imaging Abnormalities

**Additional Guidance: Similar to vital signs and clinical labs, the Working Group is not currently recommending frequency for documentation of specific radiographic imaging. Study sites are encouraged to provide any radiographic imaging data that are collected for monitoring of participants, in addition to the data reporting abnormality.**

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
Did the patient have a chest x-ray performed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of Chest X-Ray

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

Time of Chest X-Ray

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

## Tier 2

Did the patient have any other radiographic imaging performed?  Yes  No  Unknown

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
CT Brain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of CT Brain

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

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
CT Chest	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of CT Chest

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



	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
CT Abdomen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of CT Abdomen

(MM/DD/YYYY)

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
Lung Ultrasound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of Lung Ultrasound

(MM/DD/YYYY)

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
Vascular Ultrasound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of Vascular Ultrasound

(MM/DD/YYYY)

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
Abdominal Ultrasound	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of Abdominal Ultrasound

(MM/DD/YYYY)

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
Neonatal Ultrasound Brain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(Only performed on infants with open anterior fontanelle)

Date of Neonatal Ultrasound (brain)

(MM/DD/YYYY)

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
MRI Brain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of MRI Brain

(MM/DD/YYYY)

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
MRI Spine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of MRI Spine \_\_\_\_\_  
(MM/DD/YYYY)

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
MRI Abdomen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Date of MRI Abdomen \_\_\_\_\_  
(MM/DD/YYYY)

	Yes - abnormalities detected	Yes - normal	No - not performed	Unknown
Other radiographic imaging (specify test) performed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

1. Specify test \_\_\_\_\_

1. Date of Other Radiographic Imaging (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

2. Specify test 2 \_\_\_\_\_

2. Date of Other Radiographic Imaging (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)

3. Specify test 3 \_\_\_\_\_

3. Date of Other Radiographic Imaging (Tier 2) \_\_\_\_\_  
(MM/DD/YYYY)