**General Instructions:**

* Please complete the form for all children who are enrolled as controls in the case-control evaluation to examine the potential causes of pediatric hepatitis of unknown etiology.
* Yellow fields do not need to be submitted to CDC.
* Greyed out fields do not require information.
* ControlID: Please assign using the caseID followed by a dash and two numbers (ie. ‘-01-04’). For example, if the caseID = ‘GA0001’ the control ID would be GA0001-01 for the first enrolled control and so on for each additional control enrolled (up to a maximum of 4 controls per case).
* Some sections may be best completed by a clinician (e.g. Clinical Info)
* Vaccination information should be captured from the state Immunization Information System as the primary source.
* Any relevant information that does not fit in a designated section can be noted in the “Notes” section.
* All dates should be in the format MM/DD/YYYY.

**Reminder about adenovirus testing:**

CDC is requesting residual/available respiratory, stool, and blood (including whole blood, plasma or serum) specimens be sent to CDC for testing and (if adenovirus positive) typing.

Please refer to the specimen protocol for additional instructions on testing/shipping of specimens.

**Submission Instructions:**

CDC requests submission of completed forms on a rolling basis. Please upload completed forms to the ShareFile folder via one of the following:

1. Scanned/electronic copy of the completed form
2. CSV export from REDCap database (if using CDC REDCap data structure in state/local REDCap instance)

For questions related to form completion or submission instructions, email ncirddvdgast@cdc.gov

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| **Date form completed:** \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_ |
| **DEMOGRAPHICS***Yellow fields do not need to be submitted to CDC* |
| **Patient’s name (Last, First, M.I.)** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **DOB:** \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_ |
| **Age:** □ Days □ Months □ Years | **Sex assigned at birth:** □ Male □ Female □ Refused □ Don’t know  |
| **Street Address:**   |   |
| City: County: State: Zip: \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Phone (Cell/Home):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Phone (Cell/Home):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Ethnicity:** □ Hispanic or Latino  □ Not Hispanic or Latino  □ Unknown |  **Race** □ American Indian/Alaska Native □ Native Hawaiian/Pacific Islander**(check all that apply)** □ Asian □ White □ Black/African American □ Other (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |

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| **SIGNS/SYMPTOM HISTORY** |
| Did the patient have any of the following signs/symptoms in the past 2 weeks? |
| Category of signs/symptoms | Check all that apply: |
| First Respiratory sign/symptom Onset:\_\_\_\_/\_\_\_\_\_/\_\_\_\_  □ Unknown  | □ Cough □ Congestion □ Rhinorrhea □ Sore throat □ Wheezing □ Shortness of breath□ Conjunctivitis (pink eye) |
| First GI sign/symptom Onset: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ □ Unknown | □ Diarrhea □ Nausea □ Vomiting □ Abdominal Pain  |
| Date of systemic sign/symptom Onset: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ □ Unknown | □ Fatigue □ Fever (Max) \_\_\_\_\_\_\_\_ °F □ Decreased appetite □ Other, specify: |

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| **CLINICAL INFORMATION***Yellow fields do not need to be submitted to CDC.**For date of initial evaluations, please note the date that the child first sought medical care for this illness.* |
| **Patient Height:** \_\_\_\_\_\_\_\_\_\_□ ft/in □ cm □ Unknown | **Patient Weight:** \_\_\_\_\_\_\_\_\_\_\_ **□** Ibs □ Kg □ Unknown  |
| **Reason patient was receiving medical care:**  | □ Tonsillectomy□ Ear tubes (Tympanostomy) □ Illness of infectious etiology, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ Other surgical procedure, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Chronic illness, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Injury, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ □ Other, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Date of evaluation:** \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_□ Unknown  |
| **Where was the patient first identified?** | □ Primary care provider□ Urgent care□ Emergency department | □ Hospital □ Unknown□ Other, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Name of facility: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Was the patient hospitalized for this illness?** □ Yes □ No □ Unknown |
| *If patient was hospitalized:* **Hospital:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Medical Record #:** \_\_\_\_\_\_\_\_\_**Admission Date (Initial Hospital):**\_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_ □ Unknown admission date **Was the patient transferred from another hospital?** □ Yes □ No □ Unknown*If yes*, which hospital? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Transfer Date: \_\_\_/\_\_\_/\_\_\_\_\_\_ □ Unknown Final patient outcome: □ Survived, discharge home  □ Survived, discharged other location  □ Died *If yes,* was an autopsy performed? □ Yes □ No □ Unknown □ Unknown **Date of discharge / death:** \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_ □ Unknown date of discharge/death |
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| *If patient was hospitalized:* **ICD-10 discharge codes:** Primary code: Other codes (list up to 10):

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  **Were there additional codes beyond those listed above:** □ Yes □ No □ Unknown |

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| **UNDERLYING HEALTH CONDITIONS** |
| **Did the patient have any of the following underlying health conditions?** □ Yes □ No □ Unknown |
| *If yes, check all that apply:*□ Asthma (or Reactive Airway Disease)□ Congenital Heart Disease□ Diabetes Mellitus (Type 1 or 2) □ Leukemia/Lymphoma□ Sickle cell anemia  □ Seizure/Seizure disorder  | □ Other cancer, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Developmental disorder, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Premature Birth (Gestational age at birth: \_\_\_\_\_\_\_\_\_\_\_ weeks)□ History of any transplant, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Other condition, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **ADENOVIRUS TESTING***Provide information on any repeat testing or multiple sample types in the ‘Other sample, specify’ fields and write-in the specimen type.* |
| **Diagnostic Test** | **Tested/Result** | **Specimen Collection Date (mm/dd/yyyy)** | **Is specimen available for shipping to CDC?** |
| Stool | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn***If tested, specify type:***□ Multipanel PCR □ Other PCR □ Antigen |  | □ Yes □ No □ Unkn |
| Respiratory or throat | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn***If tested, specify type:***□ Multipanel PCR □ Other PCR □ Antigen |  | □ Yes □ No □ Unkn |
| Whole blood  | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  | □ Yes □ No □ Unkn |
| Plasma | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  | □ Yes □ No □ Unkn |
| Serum | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  | □ Yes □ No □ Unkn |
| Other sample, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  | □ Yes □ No □ Unkn |
| Other sample, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  | □ Yes □ No □ Unkn |
| Other sample, specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  | □ Yes □ No □ Unkn |
| **Diagnostic test** | **Value and units** | **Specimen Collection Date (mm/dd/yyyy)** | **Specimen type** |
| Blood qPCR | \_\_\_\_\_\_\_\_\_ □ copies/mL □ IU/mL |  | □ Whole blood □ Plasma □ Serum  |
| \_\_\_\_\_\_\_\_\_ □ copies/mL □ IU/mL |  | □ Whole blood □ Plasma □ Serum  |
| \_\_\_\_\_\_\_\_\_ □ copies/mL □ IU/mL |  | □ Whole blood □ Plasma □ Serum  |
| \_\_\_\_\_\_\_\_\_ □ copies/mL □ IU/mL |  | □ Whole blood □ Plasma □ Serum  |
| \_\_\_\_\_\_\_\_\_ □ copies/mL □ IU/mL |  | □ Whole blood □ Plasma □ Serum  |
| Adenovirus typing results | ☐ Not Sent (not typed) ☐ Type 41 ☐ Could not be typed ☐ Other type, specify\_\_\_\_\_\_\_\_\_ ☐ Pending  |

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| **GASTROINTESTINAL TESTING***Greyed out fields do not require information. If multiple stool samples were collected/tested, mark pathogens detected on any specimen and provide details in the “Summary of Clinical Assessment” section.* |
| Was a stool specimen collected for testing? | □ Yes □ No, skip to next section □ Unknown | Date of first specimen collection \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ |
| **Gastrointestinal panel testing** |
| **Test Performed** | **Test Type** | **Pathogens Detected (check all that apply)** |
| □ Yes □ No □ Unknown | □ Luminex xTAG□ Biofire / FilmArray□ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Unknown | □ No pathogens detected □ *Campylobacter*□ *Clostridium difficile*□ *Plesiomonas shigelloides*□ *Salmonella*□ *Yersinia enterocolitica* | □ *Vibrio* □ *Vibrio cholerae* □ Enteroaggregative E. coli (EAEC)□ Enteropathogenic E. coli (EPEC) □ Enterotoxigenic E. coli (ETEC) *lt/st*□ Shiga-like toxin-producing *E. coli* (STEC)□ *E. coli* O157□ *Shigella*/Enteroinvasive E. coli (EIEC) | □ *Cryptosporidium* □ *Cyclospora cayetanensis*□ *Entamoeba histolytica*□ *Giardia lamblia*□Astrovirus□ Norovirus GI/GII□ Rotavirus A□Sapovirus (I, II, IV and V) |
| **Non-panel tests** |
| **Pathogen** | **Tested/Result** | **Test Type** | **Details** |
| Bacterial culture | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  | If positive, pathogen: |
| Norovirus | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: | □ GI □GII □ Not specified |
| Sapovirus | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: | □ I □ II □ III □ IV □ Not specified |
| Astrovirus | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: | □ Type: □ Not specified |
| Rotavirus | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ EIA □ Other: \_\_\_\_\_\_\_\_\_ | □ Genotype: □ Not specified |
| Ova & Parasite | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  | If positive, pathogen isolated: \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| C. difficile | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | Name of test: \_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

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| **RESPIRATORY TESTING***Greyed out fields do not require information* |
| Was a respiratory specimen collected for testing?  | □ Yes □ No □ UnknownIf yes, specify specimen type \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date of specimen collection \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ |
| **Respiratory panel testing** |
| **Test Performed** | **Test Type** | **Pathogens Detected (check all that apply)** |
| □ Yes □ No □ Unknown | □ Luminex NxTAG RPP□ Luminex NxTAG RPP + SARS-CoV-2□ Luminex VERIGENE RP Flex□ Biofire / FilmArray RPP□ Biofire / FilmArray PN□ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_□ Unknown | □ No pathogens detected□ Coronavirus HKU1□ Coronavirus NL63□ Coronavirus 229E□ Coronavirus OC43□SARS-CoV-2 | □ Human Metapneumovirus□ Human Rhinovirus/Enterovirus□ Influenza A □ Influenza A/H1□ Influenza A/H3□ Influenza A/H1-2009□ Influenza B□Respiratory Syncytial Virus | □ Parainfluenza Virus 1□ Parainfluenza Virus 2□ Parainfluenza Virus 3□ Parainfluenza Virus 4□ *Bordetella parapertussis**□ Bordetella pertussis**□ Chlamydia pneumoniae**□ Mycoplasma pneumoniae**□* Other : |
| **Other respiratory specimen tests conducted** |
| **Pathogen** | **Tested/Result** | **Details** | **Date (mm/dd/yyyy)** |
| SARS-CoV-2 PCR | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  |  |
| SARS-CoV-2 Antigen | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  |  |
| SARS-CoV-2, Serology (anti-nucleocapsid)  | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  |  |
| SARS-CoV-2, Serology (anti-spike) | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  |  |
| SARS-CoV-2, Other specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  |  |
| Other test (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | If positive, pathogen isolated:  |  |
| Other test (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | If positive, pathogen isolated:  |  |

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| **OTHER VIRAL TESTING** |
| **Pathogen / Test Type** | **Tested/Result** | **Test/Specimen Type** | **Date (mm/dd/yyyy)** |
| Cytomegalovirus- PCR | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ Whole blood PCR □ Plasma PCR |  |
| Epstein-Barr virus (EBV)- PCR | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ Whole blood PCR □ Plasma PCR  |  |
| EBV- Viral Capsid Antigen IgG | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  |  |
| EBV- Viral Capsid Antigen IgM | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  |  |
| EBV- Nuclear Antigen (EBNA) IgG | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  |  |
| EBV- Early antigen (EA) IgG | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn |  |  |
| Human herpesvirus 6 | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn  | □ PCR □ Other: |  |
| Human herpesvirus 7 | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: |  |
| Varicella-zoster virus | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: |  |
| Enterovirus | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: |  |
| Human immunodeficiency virus | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: |  |
| Parvovirus B19 | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: |  |
| Herpes simplex virus-1 | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: |  |
| Herpes simplex virus-2 | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: |  |
| Measles | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: |  |
| Leptospirosis | □ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn | □ PCR □ Other: |  |

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| **PATIENT HISTORY OF COVID-19***List the most recent positive test. Any additional positive tests can be noted in the “Summary of clinical assessment” section.* |
| Has this patient previously tested positive for SARS-CoV-2? (before current illness) |
| **Positive test** | **Test Type** | **Date (most recent, mm/dd/yyyy)** |
| □ Yes □ No □ Unknown | □ PCR □ Antigen □ Serology □ Unknown | □ Date Unknown |

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| **LABORATORY MARKERS***Greyed out fields do not require information* |
| **Test Name** | **Initial Value**  | **Date (mm/dd/yyyy)** | **Highest Value**  | **Date (mm/dd/yyyy)** |
| Alanine aminotransferase (ALT, U/L) |  |  |  |  |
| Aspartate aminotransferase (AST, U/L) |  |  |  |  |
| Total bilirubin (mg/dL) |  |  |  |  |
| Conjugated bilirubin (mg/dL) |  |  |  |  |
| Unconjugated bilirubin (mg/dL) |  |  |  |  |
| INR (International Normalized Ratio) |  |  |  |  |
| Alkaline phosphatase (ALP, U/L) |  |  |  |  |
| Ammonia (µg/dL) |  |  |  |  |
| Prothrombin time (PT) |  |  |  |  |
| White blood cell (WBC) count (Cells x 109/L) |  |  |  |  |
|  Total Lymphocyte Count (Cells x 103/µL) |  |  |  |  |
|  Absolute Neutrophil Count (Cells x 103/µL) |  |  |  |  |
| Hemoglobin (HGB, g/dL) |  |  |  |  |
| Platelets (Plt, Cells x 109/L) |  |  |  |  |
| Sodium (Na, mEq/L) |  |  |  |  |
| Chloride (Cl, mmol/L) |  |  |  |  |
| Potassium (K, mEq/L) |  |  |  |  |
| Carbon dioxide (C02, mmol/L) |  |  |  |  |
| Blood urea nitrogen (BUN, mg/dL) |  |  |  |  |
| Creatinine (mg/dL) |  |  |  |  |
| Glucose (mg/dL) |  |  |  |  |
| Calcium (mg/dL) |  |  |  |  |
| Albumin (g/dL) |  |  |  |  |
| Uric acid (UA, mg/dL) |  |  |  |  |
| Fibrinogen |  |  |  |  |
| C-reactive protein (CRP, mg/dL) |  |  |  |  |
| Erythrocyte Sedimentation Rate (ESR, mm/hr) |  |  |  |  |
| Antinuclear antibody (ANA) |  |  |  |  |
| Smooth muscle antibody (ASMA) |  |  |  |  |
| Liver kidney microsomal antibody (LKM) |  |  |  |  |
| Immunoglobulin (IgG) |  |  |  |  |

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| **VACCINATION INFORMATION** *Information on vaccinations received should be captured from the state Immunization Information System as the primary source.* *For SARS-CoV-2 vaccination, please indicate the vaccine manufacturer for each dose.**Greyed out fields do not require information.* |
| **Vaccination** | **Date Dose 1 (mm/dd/yyyy)** | **Date Dose 2 (mm/dd/yyyy)** | **Date Dose 3 (mm/dd/yyyy)** | **Date Dose 4 (mm/dd/yyyy)** | **Date Dose 5 (mm/dd/yyyy)** |
| Hepatitis B |  |  |  |  |  |
| Rotavirus |  |  |  |  |  |
| DTaP/Tdap |  |  |  |  |  |
| Hib |  |  |  |  |  |
| PCV13 |  |  |  |  |  |
| IPV |  |  |  |  |  |
| MMR |  |  |  |  |  |
| Varicella |  |  |  |  |  |
| Hepatitis A |  |  |  |  |  |
| SARS-CoV-2*(add vaccine manufacturer below date)* | Manufacturer: | Manufacturer: | Manufacturer: |  |  |
| Influenza\* |  |  |  |  |  |
| Additional vaccines / doses (list vaccine & date) |  |  |  |  |  |

*\*past year only*

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| **NOTES***Use this section to document any other relevant info or notes* |
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