Attachment A: PEDIATRIC HEPATITIS OF UNKNOWN ETIOLOGY MEDICAL RECORD ABSTRACTION FORM: CONTROLS

Control ID: _____

MATCHED CASE ID:_____

Form Approved: OMB No. # 0920-0879
Exp. Date 08/31/2026

Version 19 Aug 2022

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

PEDIATRIC HEPATITIS OF UNKNOWN ETIOLOGY MEDICAL CHART ABSTRACTION FORM: CONTROLS

Version: 19 Aug 2022 *CONTROL ID:_____*

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 (check all that apply) ◻ American Indian/Alaska Native ◻ Native Hawaiian/Pacific Islander ◻ Asian ◻ White ◻ Black/African American ◻ Other (_____)

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) _____ ℉ ◻ Decreased appetite ◻ Other, specify:

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: _____** ◻ lbs ◻ 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

If patient was hospitalized: **ICD-10 discharge codes:**

Primary code:	Other codes (list up to 10):				

Were there additional codes beyond those listed above: ◻ Yes ◻ No ◻ Unknown

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 _____

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		

GASTROINTESTINAL TESTING

PEDIATRIC HEPATITIS OF UNKNOWN ETIOLOGY MEDICAL CHART ABSTRACTION FORM

Version: 19 Aug 2022 *CONTROL ID:*_____

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: _____	

RESPIRATORY TESTING

Greyed out fields do not require information

Was a respiratory specimen collected for testing?	◻ Yes ◻ No ◻ Unknown If 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:	

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:	

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 <u>previously</u> 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

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 10^9/L)				
Total Lymphocyte Count (Cells x 10^3/µL)				
Absolute Neutrophil Count (Cells x 10^3/µL)				
Hemoglobin (HGB, g/dL)				
Platelets (Plt, Cells x 10^9/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)				

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*

NOTES

Use this section to document any other relevant info or notes