Case ID: _____

Version 1.1 rev. 5/2/22

MEDICAL RECORD ABSTRACTION FORM: PEDIATRIC HEPATITIS OF UNKNOWN ETIOLOGY

DEPARTAMENTO DE SALUD

General Instructions:

Please complete the form for all children who meet the case definition: hepatitis of unknown etiology (with or without adenovirus testing) among children <10 years with aspartate aminotransferase (AST) or alanine aminotransferase (ALT) (>500 U/L) since October 1, 2021.

- Greyed out fields to not require information.
- Several sections may be best completed by a clinician: Clinical Info, Diagnosis & Treatment, Radiologic Findings, Summary of Clinical Assessment.
- Vaccination information should be captured from the Puerto Rico Department of Health (PRDOH) Immunization Information System as the primary source.
- Any relevant information that does not fit in a designated section can be noted in the "Summary of Clinical Assessment" section.
- All dates should be in the format MM/DD/YYYY.

Reminder about adenovirus testing:

- PRDOH is recommending adenovirus PCR testing on all specimen types including respiratory, stool, and blood (including whole blood, plasma or serum) specimens.
- PRDOH requests all positives to be submitted for typing. Please, reach out to the contacts below to coordinate the shipment or delivery to PRDOH of the positive specimens.

Submission Instructions:

- PRDOH is requesting the submission of completed forms on a rolling basis. Please sent the encrypted completed forms thought email at: crodriguez@salud.pr.gov and cc the regional epidemiologist.
- PRDOH is currently working on a Spanish version of this form.

Melissa Bello Pagán	Metro Region	mbello@salud.pr.gov
Jazmin Román Sierra	Caguas Region	jroman@salud.pr.gov
Edna Ponce Peréz	Fajardo Region	eponce@salud.pr.gov
Juan B. Mendez	Arecibo Region	jmendez@salud.pr.gov
Carla Duggal	Bayamón Region	carla.duggal@salud.pr.gov
Maria Ramos Zapata	Ponce Region	maramos@salud.pr.gov
Diego Samot Bidot	Mayaguez/Aguadilla Region	diego.samot@salud.pr.gov

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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 □ Unkn

Street Address:

Current gender identity: □ Male □ Female □ Transgender □ None of these □ Unkn

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

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
First Hepatitis sign/symptom Onset: _____/_____/_____ □ Unknown	□ Dark-colored urine □ Pale stool □ Jaundice or scleral icterus
Date of systemic sign/symptom Onset: _____/_____/_____ □ Unknown	□ Fatigue □ Fever (Max) _____ °F □ Decreased appetite □ Other _____

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

Date of initial evaluation (for this illness): _____/_____/_____ □ Unknown

Where was the patient first identified?
□ Primary care provider □ Hospital
□ Urgent care □ Unknown
□ Emergency department □ Other, specify
□ Hepatologist/subspecialty appointment _____

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 □ Unknown

Date of discharge / death: _____/_____/_____ □ Unknown date of discharge/death

DIAGNOSES & TREATMENT

Yellow fields do not need to be submitted to CDC.

Was the patient diagnosed with any of the following measures of severity of hepatitis/liver disease:

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Hepatomegaly (enlarged liver)	□ Yes □ No □ Unknown
Splenomegaly (enlarged spleen)	□ Yes □ No □ Unknown
Ascites	□ Yes □ No □ Unknown
Acute liver failure (rapid loss of liver function)	□ Yes □ No □ Unknown
Hepatic encephalopathy (loss of brain function due to liver failure)	□ Yes □ No □ Unknown
Hemophagocytic lymphohistiocytosis (buildup of white blood cells in organs)	□ Yes □ No □ Unknown

Was the patient diagnosed with pneumonia at time of clinical presentation/hospitalization? □ Yes □ No □ Unknown

Did patient receive a liver transplant?	□ Yes □ No □ Unkn	If yes, which hospital? _____	**Date of 1st Transplant:** _____/_____/_____ □ Date Unknown
Did patient receive a second transplant?	□ Yes □ No □ Unkn	If yes, which hospital? _____	**Date of 2nd Transplant:** _____/_____/_____ □ Date Unknown

Was the patient treated with:
…cidofovir? □ Yes □ No □ Unknown
…brincidofovir? □ Yes □ No □ Unknown
…steroids? □ Yes □ No □ Unknown *If treated with steroids,* please specify: _____

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

CDC recommends adenovirus testing on all respiratory, stool, and blood specimens. Any specimen that is positive for adenovirus should be sent for typing. Please see the specimen protocol for additional instructions.
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)**	***If positive,* is specimen available for typing?**
Stool	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		□ 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
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
Blood qPCR	_____ (copies/mL) Date _____/_____/_____ □ Whole blood □ Plasma □ Serum _____ (copies/mL) Date _____/_____/_____ □ Whole blood □ Plasma □ Serum _____ (copies/mL) Date _____/_____/_____ □ Whole blood □ Plasma □ Serum _____ (copies/mL) Date _____/_____/_____ □ Whole blood □ Plasma □ Serum _____ (copies/mL) Date _____/_____/_____ □ Whole blood □ Plasma □ Serum		

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Adenovirus typing results	☐ Not Sent (not typed) ☐ Type 41 ☐ Other type, specify_____ ☐ Pending

HEPATITIS VIRUS TESTING

If specimen collection date is not available, use date of laboratory result

Diagnostic Test	Tested/Result	Date Specimen Collected (mm/dd/yyyy)
Hepatitis A		
IgM anti-HAV	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
IgG anti-HAV	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
Total anti-HAV	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
HAV RNA[2]	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
Hepatitis B		
HBsAg	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
IgM anti-HBc	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
Total anti-HBc	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
HBeAg	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
HBV DNA[2]	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
Hepatitis C		
anti-HCV	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
HCV RNA[2]	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
Hepatitis D		
anti-HDV	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
HDV RNA[2]	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
Hepatitis E		
IgM anti-HEV	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
IgG anti-HEV	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	
HEV RNA[2]	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn	

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)

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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

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Pathogen	Tested/Result	Test Method	Date (mm/dd/yyyy)
Cytomegalovirus	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Epstein-Barr virus	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Human herpesvirus 6	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Human herpesvirus 7	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Varicella-zoster virus	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Enterovirus	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Human immunodeficiency virus	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Parvovirus B19	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Herpes simplex virus-1	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Herpes simplex virus-2	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Measles	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		
Leptospirosis	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn		

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

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)				
INR (International Normalized Ratio)				
Alkaline phosphatase (ALP, U/L)				
Prothrombin time (PT)				
Fibrinogen				
C-reactive protein (CRP, mg/dL)				
Erythrocyte Sedimentation Rate (ESR, mm/hr)				
White blood cell (WBC) count (Cells x 10^9/L)				
Total Lymphocyte Count (Cells x 10^3/µL)				
Absolute Neutrophil Count (Cells/mm^3)				
Hematocrit (HCT, %)				
Platelets (Plt, Cells x 10^9/L)				
Sodium (Na, mEq/L)				
Chloride (Cl, mmol/L)				
Potassium (K, mEq/L)				
Carbon dioxide (C02, mmol/L)				
Calcium (mg/dL)				

Glucose (mg/dL)				
Creatinine (mg/dL)				
Blood urea nitrogen (BUN, mg/dL)				
Albumin (g/dL)				
Uric acid (UA, mg/dL)				
Antinuclear antibody (ANA)				
Smooth muscle antibody (ASMA)				
Liver kidney microsomal antibody (LKM)				
Immunoglobulin (IgG)				

TOXICOLOGY

Provide highest value (and date) and put information on any additional tests in the "Summary of Clinical Assessment" section.

Was a test for acetaminophen drug levels conducted?	□ Yes □ No □ Unkn	If yes, drug level (mcg/mL):_____	Date: _____/_____/_____

RADIOLOGIC FINDINGS

This section is best completed by a clinician. If there are multiple ultrasounds/CTs, list the date of first test and enter dates/ findings of additional tests in the key findings field for that test (i.e. CT, ultrasound, etc.)

Were any of the following conducted:

Imaging Study	Conducted	Date (mm/dd/yyyy)	Key Findings
Abdominal ultrasound	□ Yes □ No □ Unkn		
Abdominal CT scan	□ Yes □ No □ Unkn		
Abdominal MRI	□ Yes □ No □ Unkn		
Other, specify_____	□ Yes □ No □ Unkn		

PATHOLOGIC FINDINGS

Did the patient have liver tissue analyzed by pathology? □ Yes □ No □ Unknown *(If no, skip to next section)*

Liver biopsy

Specimen collected □ Yes □ No (If no, skip to native liver explant section) □ Unkn **Specimen collection date:**

If yes… What were the findings (check all that apply)

□ Acute/active hepatitis
□ Autoimmune hepatitis
□ Bile duct injury/inflammation
□ Chronic hepatitis
□ Fibrosis
□ Hemophagocytosis
□ Interface hepatitis
□ Microvesicular steatosis
□ Macrovesicular steatosis
□ Portal inflammation/hepatitis
□ Smudge cells
□ Viral/intranuclear inclusions

…Was there hepatocellular necrosis? □ Yes □ No □ Unknown

select type (check all that apply):
□ Single Cell □ Confluent
□ Piecemeal □ Diffuse/Massive

Other findings, specify:

…What were the results for Adenovirus immunohistochemistry/immunostaining? □ Pos □ Neg □ Not done □ Unknown

…Was other immunohistochemistry performed? □ Yes □ No □ Unknown

If other immunohistochemistry performed, what were the results:

Pathogen	Tested/Result
HSV1	□ Not tested □ Pos □ Neg □ Indeterm □ Pending □ Unkn

HSV2	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn
CMV	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn
VZV	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn
Measles	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn
Other pathogen(s), specify:	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn

Native liver explant (post liver transplant)

Specimen collected □ Yes □ No □ Unknown **Specimen collection date:**

If yes… What were the findings (check all that apply)

□ Acute/active hepatitis	□ Fibrosis	□ Macrovesicular steatosis
□ Autoimmune hepatitis	□ Hemophagocytosis	□ Portal inflammation/hepatitis
□ Bile duct injury/inflammation	□ Interface hepatitis	□ Smudge cells
□ Chronic hepatitis	□ Microvesicular steatosis	□ Viral/intranuclear inclusions

…Was there hepatocellular necrosis? □ Yes □ No □ Unknown

select type (check all that apply):
□ Single Cell □ Confluent
□ Piecemeal □ Diffuse/Massive

Other findings, specify:

…What were the results for Adenovirus immunohistochemistry/immunostaining? □ Pos □ Neg □ Not done □ Unknown

…Was other immunohistochemistry performed? □ Yes □ No □ Unknown

If other immunohistochemistry performed, what were the results:

Pathogen	**Tested/Result**					
HSV1	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn
HSV2	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn
CMV	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn
VZV	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn
Measles	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn
Other pathogen(s), specify:	□ Not tested	□ Pos	□ Neg	□ Indeterm	□ Pending	□ Unkn

SUMMARY OF CLINICAL ASSESSMENT

Use this section to add any additional relevant information and indicate the likely cause of the patient's hepatitis based on the clinician's judgement/assessment

Based on the diagnostic workup, is there a most likely cause of this patient's hepatitis?

□ Hepatitis D	□ Adenovirus	□ Medication toxicity, if yes specify_____
□ Hepatitis E	□ Herpes simplex virus	□ Other viral infection, specify_____
□ Autoimmune hepatitis	□ EBV	□ Other, specify _____
□ Wilson's disease	□ CMV	□ Remains unknown
	□ VZV	

Any other clinically relevant information?

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DEPARTAMENTO DE SALUD

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*					

**past year only*