Hepatitis of unknown origin

Reporting Protocol 2022

Version 4.0
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Change log

Summary of changes in this reporting protocol

V4.0 (14 October 2022)

1. Deleted variables: PlaceOfResidence, SARS-CoV-2 VaccLastDate, SARS-CoV-2 VaccLastBrand, PeakALT, PeakAST, PeakBillirubin, PeakINR, AdenoCtValueSpecimenDate, ADVSequence, OtherTypingResult, CMVResult, EBVResult, EnterovBloodResult, EnterovThroatResult, HSV1Result, LeptoResult, HHV7Result, RSVResult, INFLResult, RhinoResult, hMPVResult, VaricellaResult, ParovirusResult, HIVResult, LegionellaResult, MycoplasmaResult, ParainfluenzaResult, ASOTResult, BovavirusResult, BrucellaResult, BartonellaResult, BorreliaResult, StoolBacterialPCRResult, StoolBacCultDone, StoolBacCultResult, ThroatBacCultDone, ThroatBacCultResult, ToxResult, JAUNDICEFAM, SARS-CoV-2FAM

V3.0 (2 June 2022)

1. Added variables DateOfDischarge; MetagenomicsLabID; AdenoAssociatedVirusResultPCR; AdenoAssociatedVirusSpecimen; AdenoAssociatedVirusType; AdenoAssociatedVirusCtValue; AdenoAssociatedVirusSpecimenDate

V2.1 (6 May 2022)

1. Added variables Hospitalisation; AdenoUrineResult; AdenoUrineDate; AdenoUnknownSpecimenResult; AdenoUnknownSpecimenDate; AdenoCtValue; AdenoCtValueSpecimenDate; AdenoSeqDone; ADVSequence; OtherTypingResult; RhinoResult; hMPVResult; BrucellaResult; BartonellaResult; BorreliaResult; StoolBacterialPCRResult; AdditionalInfo

2. Added "DISC" (discarded case) to coded value list for variable Classification
3. Added "IgM, IgG, IgMIgG" to coded value list for variable SARS-CoV-2 Serology
4. Added "OTHCOR" to coded value list for variable PrevInfectionDetails
5. Added "SEPSIS" to coded value list for variable Complications
6. Added "ADENO", "ROTA", "ASTRO" to coded value list for variable StoolViralPCRResult

V2.0 (29 April 2022)

1. Note added to case definition
2. Added "Epi-linked" to and removed "Confirmed" from coded value list for variable Classification

3. Variable ClinicalPresentation renamed to PreviousClinicalPresentation
4. Variable ClinicalPresentationOther renamed to PreviousClinicalPresentationOther

5. Variable Adenotype renamed to AdenovType and defined as text
6. Added "Other" to coded value list for variable Complications. Variable configured as repeatable

7. Added "WAITTRANS" (waiting for transplant) to coded value list of variable Transplant and removed from variable Outcome
8. Added variables PlaceOfResidence, PrevInfection, PrevInfectionDetails; PrevInfectionDetailsOther, ComplicationsOther, PeakBillirubin, PeakINR;
9. Variable PeakASP removed

V1.0 (25 April 2022)
Introduction

This reporting protocol is intended for reporting national case-based data for surveillance of hepatitis of unknown origin from all the countries and areas of the WHO European Region, including the 27 countries of the European Union (EU) and the additional three countries of the European Economic Area (EEA), to the European level.

Data are submitted through the case-based record type NOVHEP to the European Surveillance System (TESSy) database hosted at ECDC.

Data can be reported to TESSy either manually, for entry of single cases, or through metadata-standardised csv or xml files for multiple cases (please see technical annex).

Case data should be entered manually into TESSy as soon as possible, and retrospective updates should be submitted through metadata-standardised csv or xml files at least monthly, on the Wednesday (10:00) preceding the publication of the surveillance report (usually last Friday of the month).

This reporting protocol is supplemented by a technical annex, which contains updated generic information for data submission.

Case Definition

Cases of hepatitis of unknown origin should be reported to TESSy if they meet any of the following criteria:

- **Confirmed**: N/A
- **Probable**: A person presenting with an acute hepatitis (non-hepatitis viruses A, B, C, D and E*) with aspartate transaminase (AST) or alanine transaminase (ALT) over 500 IU/L, who is 16 years old or younger, since 1 October 2021.
- **Epi-linked**: A person presenting with an acute hepatitis (non-hepatitis viruses A, B, C, D and E*) of any age who is a close contact of a probable case since 1 October 2021.
- **Discarded**: A subject previously classified as case, that following further investigations did not meet the case definition criteria.

*Cases of hepatitis with known aetiology such those due to specific infectious diseases, drug toxicity, metabolic hereditary, or autoimmune disorders should not be reported under this protocol.

Surveillance Objectives

1. To understand the magnitude and spread of this novel public health threat in the WHO European region to inform a proportionate response
2. To generate hypotheses about disease aetiology in order to guide investigations and initial preventive or control measures
3. To describe the population at highest risk of infection and severe outcomes in order to target preventive or control measures
4. To understand the natural history of disease in order to assess its impact and prepare accordingly

Key variables

Although the current version of the reporting protocol includes a significant number of variables, Member States are strongly encouraged to report data as soon as possible (please see section Data collection schedule), even if incomplete or provisional, so Surveillance Objective 1 can be fulfilled.
case there is the need to discard a case, its classification can be updated so it is removed from analysis.

The variables that are currently considered key include:

- **Age** (mandatory)
- **Classification** (mandatory: Probable, Epi-linked, Discarded)
- **DateOfOnset** (date of onset of first symptoms of disease)
- **DateOfHospitalisation** (date of hospitalisation)
- **AdmittedICUHU** (whether admitted to intensive care unit or high-dependency unit.)
- **Transplant** (whether case received or is waiting for liver transplant)
- **Outcome** (mandatory: recovered, deceased, still on medical treatment)
- Variables related to adenovirus and SARS-CoV-2 testing and results (please see section Laboratory findings)

**How to use this document**

This reporting protocol provides information for data managers in reporting countries in two main sections:

- **Reporting to TESSy** – contains guidelines on how to prepare data for submission to TESSy, deadlines and links to further information.
- **Annex - Hepatitis of unknown origin metadata** – the metadata set for the subject covered by this reporting protocol.

**Finding further information**

Paragraphs denoted by the information icon tell where you can find further information.

Updated links to all the schedules, documentation and training materials mentioned are included in *TESSy Technical Guidelines & Tools* (see the menu 'Technical Guidelines and Tools' when logged in to TESSy), including:

- Metadata sets and history
- Tutorials for data transformation using respectively Excel and Access
- TESSy user documentation
- *CSV* and *XML* transport protocols.

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Reporting to TESSy

This section provides both an overview of the TESSy reporting process and tips on where you can find useful information.

The overall process includes:

1. Familiarising yourself with the data collection deadlines
2. Preparing (exporting and transforming) your data
3. Checking that your data comply with the metadata
4. Checking that your data source profile is up to date
5. Submitting your data to TESSy
6. Finalising and approving your submission.

Data collection schedule

Case data should be entered manually into TESSy as soon as possible, and retrospective updates should be submitted through metadata-standardised csv or xml files at least monthly, on the Wednesday (10:00) preceding the publication of the surveillance report (usually last Friday of the month). Data should be submitted by Wednesday by 10:00, including retrospective updates to cases diagnosed/reported previously).

The following reporting routine is suggested:

1. Report a first timely dataset with the core set of variables (please see section Key variables)
2. Update cases with additional testing results or new case classification, not available at the time of initial report (please see section Submitting your data, "replace" options)

Preparing data

Data relating to new cases should be entered directly in TESSy for individual records ('Manually create a record'). For any retrospective updates by file upload (CSV or XML format), please note that the data need to be in a format that TESSy accepts (see "checking metadata").

Tutorials covering how you can transform your data to the correct TESSy format using Excel or Access are available on the TESSy documents website. Information on the file formats is available in the CSV Transport Protocol and XML Transport Protocol.

Checking metadata

The TESSy metadata define the fields and data formats valid for a given subject. They are updated in agreement with disease and surveillance networks when public health information needs change.

It is especially important to focus on the following areas.

- **Field formats**
  Many fields require that data are formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.

- **Coded values**
  Some fields only permit the use of specific values (coded values). For example, M, F, UNK, or Other are the coded values for Gender and any other value in a Gender field will be rejected.

- **Repeatable fields**
  For variables where multiple items of the coded value list apply, the field should be repeated as needed to include only one item per field. If not applicable, use N/A.
The metadata file contains all the definitions and rules you need to comply with to format your data correctly. The file can be downloaded as an Excel file from the TESSy documents website. By filtering the fields in the file by subject, you can see the fields required for your subject and the rules applying to these fields.

The *Tessy User Guide* provides instructions on how you work with the metadata file.

### Checking your data source profile

Before submitting your data, please review the profile for your data source(s) in TESSy (go to **Data Sources**), and update the information, if necessary.

Complete and up-to-date data source information for each subject facilitates surveillance data interpretation - each surveillance system has different features that need to be considered when comparing data at international level.

If your data source information is outdated and you do not have access rights to update it, please ask your National Focal Point for Surveillance or National Coordinator to do so.

In-depth information on the data source variables is available in the TESSy user documentation.

### Submitting your data

Data are submitted through the TESSy web interface (go to **Upload**).

The *Tessy User Guide* provides instructions on how to submit files to TESSy, and the TESSy user documentation provides in-depth descriptions of all the upload methods.

The screenshot below shows the different options available for NOVHEP data submissions, including manual submissions (individual records), zero reporting and CSV/XML uploads.
Finalising your submission

The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process.

The result of your upload – i.e. rejected or validated – is displayed immediately after the conclusion of the check in the Validation details webpage. Please review the result carefully:

- If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that you need to correct.
- If your file has been validated, there might be warnings and remarks relating to possible data quality issues or to potential overwriting of existing records that you should consider.

When you file has been validated and you are satisfied that all corrections have been made, please ensure prompt approval – unapproved uploads can block the approval of other uploads.

The TESSy user documentation provides information on reviewing validation results and adjusting reporting periods to avoid overwriting existing records.

General training and guidance on reporting is available on the TESSy website.
TESSy HelpDesk

Email: TESSy@ecdc.europa.eu

Telephone number: +46-(0)8-5860 1601

Availability: 9:00 – 16:00 Stockholm time, Monday to Friday (except ECDC holidays)
Annex - Hepatitis of unknown origin metadata

Revisions of metadata set

The most recent metadata set is available from the TESSy website under the "Technical Guidelines & Tools" tab (as shown below).

When you open a metadata set, the tab ‘Changes’ lists historical changes.

Current record type versions

Table 1 shows the record type versions to be used when reporting hepatitis of unknown origin surveillance data to TESSy.

Table 1: Current record type version for hepatitis of unknown origin

<table>
<thead>
<tr>
<th>Record Type</th>
<th>Type of data</th>
<th>Record type version</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOVHEP</td>
<td>Case-based</td>
<td>4</td>
</tr>
<tr>
<td>NOVHEP</td>
<td>Case-based</td>
<td>3</td>
</tr>
<tr>
<td>NOVHEP</td>
<td>Case-based</td>
<td>2 - deactivated</td>
</tr>
<tr>
<td>NOVHEP</td>
<td>Case-based</td>
<td>1 - deactivated</td>
</tr>
</tbody>
</table>

Changes to hepatitis of unknown origin surveillance metadata

**Record type NOVHEP Version 4 – 14 October 2022**

Inactivated variables (from NOVHEP v3): PlaceOfResidence, SARSCoV2VaccLastDate, SARSCoV2VaccLastBrand, PeakALT, PeakAST, PeakBilirubin, PeakINR, AdenoCtValueSpecimenDate, ADVSequence, OtherTypingResult, CMVResult, EBVResult, EnterovBloodResult, EnterovThroatResult, HSV1Result, LeptoResult, HHV7Result, RSVResult, INFResult, RhinoResult, hMPVResult, VaricellaResult, ParvovirusResult, HIVResult, LegionellaResult, MycoplasmaResult, ParainfluenzaResult, ASOTResult, BovavirusResult, BrucellaResult, BartonellaResult, BorreliaResult, StoolBacterialPCRResult, StoolBacCultDone, StoolBacCultResult, ThroatBacCultResult, ToxResult, JAUNDICEFAM, SARSCoV2FAM

**Record type NOVHEP Version 3 – 2 June 2022**

New variables: DateOfDischarge, MetagenomicsLabID, AdenoAssociatedVirusResultPCR, AdenoAssociatedVirusSpecimen, AdenoAssociatedVirusType, AdenoAssociatedVirusCtValue, AdenoAssociatedVirusSpecimenDate

**Record type NOVHEP Version 2 – 29 April 2022**
New variables: PlaceofResidence; PrevInfection; PrevInfectionDetails; PrevInfectionDetailsOther; ComplicationsOther; DateOfPrevSARS-CoV2; SARS-CoV2VaccLastDate; SARS-CoV2VaccLastBrand; AdenoStoolDate; AdenoRespDate; AdenoWholeBloodDate; AdenoSerumDate; AdenoOtherDate; SARS-CoV2PCRDate; Hospitalisation; AdenoUrineResult; AdenoUrineDate; AdenoUnknownSpecimenResult; AdenoUnknownSpecimenDate; AdenoCtValue; AdenoCtValueSpecimenDate; AdenotypeSpecimen; AdenoSeqDone; ADVSequence; OtherTypingResult; RhinoResult; hMPVResult; BrucellaResult; BartonellaResult; BorreliaResult; StoolBacterialPCRResult; AdditionalInfo

Changes in coded value lists: Please refer to Error! Reference source not found.

INACTIVATED variables (from NOVHEP v1):
ClinicalPresentation - renamed to PreviousClinicalPresentation
ClinicalPresentationOther - renamed to PreviousClinicalPresentationOther
Adenotype - renamed to AdenovType
PeakASP - removed

Record type NOVHEP Version 1 – 22 April 2022
NOVHEP metadata

The NOVHEP metadata, record type version 3, is used for reporting case-based data on hepatitis of unknown origin.

In the descriptions of the variables, the following conventions are used:

**VariableName**
Literal name of a variable. This never contains spaces. Case is only used to improve readability.

**Coding**
Code as accepted by the system.

**Description of code**
Description of the meaning of a possible values for a specific variable.

Example: The gender of a case is described in the variable **Gender**, that can have the possible values **M** for ‘Male’, **F** for ‘Female’, **O** for ‘Other’ and **Unk** for ‘Unknown’.

Common TESSy Variables

**RecordID (mandatory)**
Unique case identifier (used in the country)

Coding: Text (max 80 characters)

Please note that ID must be unique if they are derived from the same national reporting system; records with the same ID will be overwritten.

**RecordType (mandatory)**
Structure and format of the data (case based reporting or aggregate reporting).

Coding: NOVHEP

**RecordTypeVersion**
Indicates the version of the Record type used in the reported batch. If no RecordTypeVersion is provided in the batch, it is set automatically with current version of the Record type. RecordTypeVersion is required when no metadata set is provided at upload or when a RecordTypeVersion, other than the current one, needs to be used.

Coding: NUM

**Subject (mandatory)**
Subject of the data reported.

Coding: NOVHEP = Novel hepatitis

**DataSource (mandatory)**
The data source (surveillance system) that the record originates from.

Coding: To be assigned by each country to an existing data source, or to a newly created one.

The data source specifies the surveillance system from which the data originates and is generated and revised/updated by the national focal point in each Member State. The descriptions of the surveillance systems submitted to TESSy (section Data Sources) will be used to assist with data interpretation. Make sure that the subject "NOVHEP" is associated with this data source.
**ReportingCountry (mandatory)**
The country reporting the case(s).
Coding: International organization for standardization (ISO) 3166-1-alpha-2, (two-letter code)
(See the coded values list)

This variable identifies the country reporting the case.

**DateUsedForStatistics (mandatory)**
The date used for statistics is date of reporting to national health authority.
Coding: yyyy-mm-dd

**Status**
Status of reporting NEW/UPDATE or DELETE (inactivate). Default if left out: NEW/UPDATE. If set to DELETE, the record with the given recordId will be deleted from the TESSy database (or better stated, invalidated.) If set to NEW/UPDATE or left empty, the record is newly entered into the database.
Coding: [Statuses]:
DELETE = Delete a previously reported record
NEW/UPDATE = Report a new or update a previously reported record (default)

**Demographic variables**

**Age (mandatory)**
Age of patient in years as reported in the national system at the time of disease onset.
Coding: NUM

**AgeMonths**
Age of patient in months as reported in the national system for cases < 2 years of age at the time of disease onset.
Coding: NUM

**Gender**
Gender of the reported case.
Coding: Sex:
F = Female
M = Male
O = Other (e.g. transsexual)
Unk = Unknown
Case classification

Classification (mandatory)
Case classification according to agreed case definition.
Coding: ClassificationNOVHEP
    PROB = Probable
    EPILINK = Epi-linked case
    DISC = Discarded case

Clinical findings and outcomes

PreviousClinicalPresentation (repeatable)
Clinical symptoms and signs in the four weeks preceding the onset of hepatitis.
Coding: PrecedingSymptomsNOVHEP:
    CONJ = Conjunctivitis
    DIARR = Diarrhoea
    FEVER = History of fever / chills
    HEAD = Headache
    NONE = None
    O = Other, please specify
    RESP = Respiratory symptoms
    RASH = Rash
    SORETHR = Sore throat
    UNK = Unknown
    VOMIT = Nausea / vomiting

PreviousClinicalPresentationOther
Other clinical symptoms and signs in the four weeks preceding the onset of hepatitis.
Coding: TEXT

PrevInfection
Patient had a confirmed acute infectious disease in the four weeks preceding the onset of hepatitis.
Coding: YesNoUnk:
    N = No
    Unk = Unknown
    Y = Yes
If yes, please specify in PrevInfectionDetails.
**PrevInfectionDetails (repeatable)**

Specify pathogen responsible for previous known acute infectious disease in the four weeks preceding the onset of hepatitis.

**Coding:**

- ADENO = Adenovirus
- ASTRO = Astrovirus
- BOCA = Bocavirus
- CAMP = Campylobacter
- CMV = CMV
- COX = Coxsackie
- EBV = EBV
- ESCCOL = E. coli
- ENV = Enterovirus
- HSV1 = HSV1
- HHV6 = HHV6
- HHV7 = HHV7
- METAP = Metapneumovirus
- INFL = Influenza
- LEGI = Legionella
- LEPT = Leptospira
- NOROV = Norovirus
- O = Other, please specify
- OTHER = Other coronavirus (non SARS-CoV-2)
- PARAINFL = Parainfluenza
- PARV = Parvovirus
- ROTA = Rotavirus
- RSV = RSV
- SALM = Salmonella
- SAPO = Sapovirus
- SHIG = Shigella
- YERS = Yersinia
- UNK = Unknown

**PrevInfectionDetailsOther**

If other previous known acute infectious disease in the four weeks preceding the onset of hepatitis not included in PrevInfectionDetails, please specify.

**Coding:**

- TEXT

**ClinicalSymptoms (repeatable)**

Clinical symptoms and signs since onset of hepatitis.
Coding: ClinicalSymptomsNOVHEP:
ANO = Anorexia / poor feeding
CONJ = Conjunctivitis
DARKU = Dark urine
DIARR = Diarrhoea
FEVER = Fever
HEAD = Headache
HEPATOME = Hepatomegaly
IRR = Irritability / confusion
JAUNDICE = Jaundiced
O = Other, please specify
PAINABDO = Pain – abdominal
RESP = Respiratory symptoms
RASH = Rash
SORETHR = Sore throat
STOBLO = Bloody stool
STOPAL = Pale stool
UNK = Unknown
VOMIT = Nausea / vomiting
WEAK = General weakness

ClinicalSymptomsOther
Other reported clinical symptoms anytime during illness, not found in the list of possible values.
Coding: TEXT

Complications (repeatable)
Complications at any time.
Coding: ALF = Acute Liver Failure
BMF = Bone Marrow Failure
RF = Renal Failure
HAEM = Haemorrhage
HEPENCEPH = Hepatic encephalopathy
COMA = coma
SEPSIS = Sepsis/Multi-organ failure
O = other

ComplicationsOther
Other reported complications, not found in the list of possible values. Please separate using a semi-colon (;) if multiple.

Coding: TEXT DateOfOnset
Date of onset of first symptoms of disease.
Hospitalisation
Whether the case was admitted to hospital.
Coding: YesNoUnk:
N = No
Unk = Unknown
Y = Yes

DateOfHospitalisation
Date of Hospitalisation. If multiple hospitalisations, please indicate the first related to hepatitis.
Coding: yyyy-mm-dd

DateOfDischarge
Date of discharge from hospital. If multiple hospitalisations, please use the end date of the most recent hospitalisation related to hepatitis.
Coding: yyyy-mm-dd

AdmittedICUHDU
Whether admitted to intensive care unit or high-dependency unit.
Coding: YesNoUnk:
N = No
Unk = Unknown
Y = Yes

AdmittedTransUnit
Whether case was admitted to transplant unit.
Coding: YesNoUnk:
N = No
Unk = Unknown
Y = Yes

Transplant
Whether case received liver transplant.
Coding:
N = No
Unk = Unknown
WAITTRANS = Waiting for transplant
Y = Yes
HistologyBiop
Liver histology results either from biopsy, removed organ or post mortem – please indicate including any immunohistochemistry for adenovirus or other infectious agents.
Coding: TEXT
Ideally, results should be reported in English.

Outcome (mandatory)
Information on the outcome of the case.
Coding: OutcomeNOVHEP:
ALIVE = Alive, recovered, cured
DIEDHEP = Died due to severe acute hepatitis
DIEDOTHER = Death not related to severe acute hepatitis
DIEDUNK = Cause of death unknown
STILLTREATMENT = Still on medical treatment (not recovered)
UNK = Unknown outcome

DateOfDeath
Date of death (exact date only).
Coding: yyyy-mm-dd

Precondition (mandatory) (repeatable)
Patient’s underlying condition or conditions.
Coding: PreconditionsNOVHEP:
ASPL = Asplenia
ASTH = Asthma
AUTOIMMUNE = Autoimmune disease
CANC = Cancer, malignancy
CARDIACDIS = Cardiac disorder, excluding hypertension
DIAB = Diabetes
ENDO = Endocrine disease
GASTRO = Gastrointestinal tract disease
GENET = Genetic disorder
HIV = HIV/other immune deficiency
HYPERT = Hypertension
KIDNEY = Kidney-related condition, renal disease
IMMUN = immunosuppressed
LIVER = Liver-related condition, liver disease
LUNG = Chronic lung disease, excluding asthma
METAB = Metabolic disorder
NEUROMUS = Neuromuscular disorder, chronic neurological
NONE = None
O = Other precondition, please specify
OBES = Obesity
PREG = Pregnant
TB = Tuberculosis
UNK = Unknown precondition

PreconditionOther
Details of underlying conditions, if precondition is coded as ‘other’, but is known. Please separate using a semi-colon (;) if multiple.
Coding: TEXT
Previous SARS-CoV-2 infection or vaccination

PrevSARSCoV2
Patient had a confirmed infection with SARS-CoV-2.
Coding: Unk = Unknown
        Y = Yes

DateOfPrevSARSCoV2
Date of previous SARS-CoV-2 infection.
Coding: yyyy-mm-dd (preferred)
        yyyy-Www
        UNK = Unknown
If no exact date available, please provide an estimate.

SARSCoV2VaccStatus
Indicates if the case is vaccinated against SARS-CoV-2 and number of vaccine doses received.
Coding: VaccStatusCOVID:
        1DOSE = 1 dose
        2DOSE = 2 doses
        3DOSE = 3 doses
        4DOSE = 4 doses
        DOSEUNK = Vaccinated with unknown number of doses
        NOTVACC = 0 doses - unvaccinated
        UNK = Unknown vaccination status

SARSCoV2Serology
Serology result for past SARS-CoV-2 infection during this episode of illness.
Coding: SARSCoV2Serology:
        N = Negative
        NT = Not tested
        P = Positive unspecified
        IgM = IgM detected
        IgG = IgG detected
        IgMIgG = IgM and IgG detected
        IN = Indeterminate / equivocal
        UNK = Tested, but result unknown
        DK = Don't know if tested

Laboratory findings
**AdenoStoolResult**

Result of adenovirus test on stool specimen.

**Coding:**  
LaboratoryResultNOVHEP:  
N = Negative  
NT = Not tested  
P = Positive  
IN = Indeterminate / equivocal  
UNK = Tested, but result unknown  
DK = Don’t know if tested

**AdenoStoolDate**

Date of adenovirus test on stool specimen. In case of multiple specimens, indicate first date (if all negative) or date of first positive result.

**Coding:**  
yyyy-mm-dd  
UNK= Unknown

**AdenoUrineResult**

Result of adenovirus test on urine specimen.

**Coding:**  
LaboratoryResultNOVHEP:  
N = Negative  
NT = Not tested  
P = Positive  
IN = Indeterminate / equivocal  
UNK = Tested, but result unknown  
DK = Don’t know if tested

**AdenoUrineDate**

Date of adenovirus test on urine specimen. In case of multiple specimens, indicate first date (if all negative) or date of first positive result.

**Coding:**  
yyyy-mm-dd  
UNK= Unknown

**AdenoRespResult**

Result of adenovirus test on respiratory specimen.

**Coding:**  
LaboratoryResultNOVHEP:  
N = Negative  
NT = Not tested  
P = Positive  
IN = Indeterminate / equivocal
UNK = Tested, but result unknown
DK = Don't know if tested

**AdenoRespDate**
Date of adenovirus test on respiratory specimen. In case of multiple specimens, indicate first date (if all negative) or first date of positive result.
Coding: yyyy-mm-dd
UNK= Unknown

**AdenoWholeBloodResult**
Result of adenovirus test on whole blood specimen.
Coding: LaboratoryResultNOVHEP:
N = Negative
NT = Not tested
P = Positive
IN = Indeterminate / equivocal
UNK = Tested, but result unknown
DK = Don't know if tested

**AdenoWholeBloodDate**
Date of adenovirus test on whole blood specimen. In case of multiple specimens, indicate first date (if all negative) or first date of positive result.
Coding: yyyy-mm-dd
UNK= Unknown

**AdenoSerumResult**
Result of adenovirus test on serum specimen.
Coding: LaboratoryResultNOVHEP:
N = Negative
NT = Not tested
P = Positive
IN = Indeterminate / equivocal
UNK = Tested, but result unknown
DK = Don't know if tested

**AdenoSerumDate**
Date of adenovirus test on serum specimen. In case of multiple specimens, indicate first date (if all negative) or first date of positive result.
Coding: yyyy-mm-dd (preferred)
UNK= Unknown
**AdenoOtherResult**

Result of adenovirus test on other specimen (not stool, respiratory, blood, plasma).

Coding: LaboratoryResultNOVHEP:
- N = Negative
- NT = Not tested
- P = Positive
- IN = Indeterminate / equivocal
- UNK = Tested, but result unknown
- DK = Don't know if tested

**AdenoOtherDate**

Date of adenovirus test on another specimen (not stool, respiratory, blood, plasma). In case of multiple specimens, indicate first date (if all negative) or first date of positive result.

Coding: yyyy-mm-dd
- UNK= Unknown

**AdenoUnknownSpecimenResult**

Result of adenovirus test where type of specimen is unknown.

Coding: LaboratoryResultNOVHEP:
- N = Negative
- NT = Not tested
- P = Positive
- IN = Indeterminate / equivocal
- UNK = Tested, but result unknown
- DK = Don't know if tested

**AdenoUnknownSpecimenDate**

Date of adenovirus test where type of specimen is unknown. In case of multiple specimens, indicate first date (if all negative) or first date of positive result.

Coding: yyyy-mm-dd
- UNK= Unknown

**AdenoCtValue**

Ct (cycle threshold) value of adenovirus in blood or serum. If multiple results, indicate the lowest value.

Coding: NUM

**AdenotypeDone**
Whether adenovirus typing was done.
Coding: YesNoUnk:
  N = No
  Unk = Unknown
  Y = Yes

AdenotypeSpecimen
Type of specimen on which adenovirus typing was done.
Coding: SpecimenNOVHEP:
  BLOOD = Blood
  SERUM = Serum
  RESP = Respiratory
  STOOL = Stool
  O = Other
  URINE = URINE
  Unk = Unknown

AdenovType
Result of adenovirus typing.
Coding: TEXT

AdenoSeqDone
Whether adenovirus sequencing was done.
Coding: YesNoUnk:
  N = No
  Unk = Unknown
  Y = Yes

MetagenomicsLabID
In case there were metagenomics results submitted to Epipulse, please provide Lab ID in this field (unique in the country, including a prefix for country of origin)
Coding: TEXT

AdenoAssociatedVirusResultPCR
Result of PCR test for adeno-associated virus
Coding: LaboratoryResultNOVHEP:
N = Negative
NT = Not tested
P = Positive
IN = Indeterminate / equivocal
UNK = Tested, but result unknown
DK = Don't know if tested

**AdenoAssociatedVirusSpecimen**
Type of specimen on which adeno-associated virus typing was done.
Coding: SpecimenNOVHEP:
  BLOOD = Blood
  SERUM = Serum
  RESP = Respiratory
  STOOL = Stool
  O = Other
  URINE = URINE
  Unk = Unknown

**AdenoAssociatedVirusType**
Adeno-associated virus type or types identified
Coding: TEXT

**AdenoAssociatedVirusCtValue**
Ct (cycle threshold) value of adeno-associated virus. If multiple results, indicate the lowest value.
Coding: NUM

**AdenoAssociatedVirusSpecimenDate**
Date of adeno-associated virus sample. on which the lowest Ct (cycle threshold) value was measured.
Coding: yyyy-mm-dd (preferred)
UNK= Unknown

**SARSCoV2PCR**
Result of PCR for SARS-CoV-2 (after onset of hepatitis).
Coding: LaboratoryResultNOVHEP:
  N = Negative
  NT = Not tested
  P = Positive
  IN = Indeterminate / equivocal
  UNK = Tested, but result unknown
  DK = Don't know if tested
**SARSCoV2PCRDate**
Date of SARS-CoV-2 PCR test (after onset of hepatitis). In case of multiple specimens, indicate first date (if all negative) or first date of positive result.

Coding: yyyy-mm-dd (preferred)
UNK = Unknown

**HHV6Result**
Whether HHV6 test was done during this episode of illness and what the result was.

Coding: LaboratoryResultNOVHEP:
N = Negative
NT = Not tested
P = Positive
IN = Indeterminate / equivocal
UNK = Tested, but result unknown
DK = Don't know if tested

**StoolViralPCRResult**
Whether viral stool PCR was done during this episode of illness and what the result was.

Coding: StoolViralPCRNOVHEP:
N = Negative
NT = Not tested
ADENO = Adenovirus detected
SAPO = Sapovirus detected
NORO = Norovirus detected
ENTERO = Enterovirus detected
ROTA = Rotavirus detected
ASTRO = Astrovirus detected
O = Other
UNK = Tested, but result unknown

**StoolVirCultDone**
Whether viral stool culture was done during this episode of illness.

Coding: YesNoUnk:
N = No
Unk = Unknown
Y = Yes

**StoolVirCultResult**
Result of viral stool culture during this episode of illness.
Coding: TEXT

**AdditionalInfo**
Any other relevant laboratory or clinical information not included in any other variable.
Coding: TEXT

**Epidemiological links and travel history**

**EpiLink**
Epidemiological link to other case.
Coding: YesNoUnk:
N = No
Unk = Unknown
Y = Yes

**EpiLinkCaseID**
Unique case identifier (RecordID used in the country) of other case to which there is an epidemiological link.
Coding: TEXT

**Travel**
Whether the case has travelled to another country or region in the 30 days prior to symptom onset.
Coding: YesNoUnk:
N = No
Unk = Unknown
Y = Yes
Regular domestic travels (such as daily commutes) should not be considered for this purpose.

**TravelLocation**
Location of travel in the 30 days prior to symptom onset.
Coding: TEXT