Hepatitis C

January 26, 2018

Case Investigation Guidelines

Contents

A. Purpose

The New Jersey Department of Health (NJDOH) recognizes that being a high volume disease, hepatitis C virus (HCV) case report investigations can overburden the limited resources available at the local health departments (LHDs). This guideline aims to provide the process for investigating and classifying cases reported with HCV, with a focus on the identification of instances in which limited resources are most likely to have a positive public health impact. Thus the highest priority is placed on finding acute cases, including those who may have become infected in a healthcare facility. Therefore an emphasis is placed on those individuals infected at 30 years or yonger, or 70 years or older, as they are more likely to have been infected in a healthcare setting. Age groupings (≤30, 31-69, and ≥70 years old) are used to help prioritize cases for disease investigation. Those ≤30 years of age and ≥70 years of age represent about 25% of all cases reported to the NJDOH, Communicable Disease Reporting and Surveillance System (CDRSS).

B. Case Definitions

The Centers for Disease Control and Prevention updated the HCV case definitionin in 2016. NJDOH follows these HCV case definitions.

a. Acute Hepatitis C (2016)

https://wwwn.cdc.gov/nndss/conditions/hepatitis-c-acute/case-definition/2016/

Clinical criteria:
- An illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, or abdominal pain,) **AND**
- Jaundice, **OR**
- Peak elevated serum alanine aminotransferase (ALT) level >200 IU/L during the acute illness

Laboratory criteria for diagnosis:
- A positive test for antibodies to hepatitis C virus (anti-HCV) **OR**
- Hepatitis C virus detection test:
  - Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing), **OR**
  - A positive test indicating presence of hepatitis C viral antigen(s) when available*

*When and if a test for HCV antigen(s) is approved by the FDA and available

Case classification/Status:

Confirmed:
- A case that meets the clinical case definition and has a positive hepatitis C virus detection test (HCV NAT) or HCV antigen **OR**
- A case with a documented negative HCV antibody, HCV antigen or NAT laboratory test result followed within 12 months by a positive result of HCV antigen or NAT (regardless of signs symptoms or LFTs).

Probable:
- A case that meets the clinical case definition and has a positive anti-HCV antibody test, but has no report of a positive HCV NAT or positive HCV antigen test AND

- Does not have a documented negative HCV antibody, HCV antigen or NAT laboratory test result followed within 12 months by a positive result of any of these tests (test conversion) or has no report of test conversion.

Note: A new probable acute case may be re-classified as confirmed acute case if a positive NAT for HCV RNA or a positive HCV antigen(s) test is reported within 12 months. A confirmed acute case may be classified as a confirmed chronic case if a positive HCV RNA NAT or HCV antigen is reported one year or more after acute case onset. A confirmed acute case may not be reported as a probable chronic case (i.e., anti-HCV positive, but with an unknown HCV RNA NAT or antigen status), because of previous HCV RNA NAT reported. Report acute cases by date of diagnosis and chronic cases **by year of diagnosis.**

b. Chronic Hepatitis C (2016)

https://wwwn.cdc.gov/nndss/conditions/hepatitis-c-chronic/case-definition/2016/

Clinical criteria:
- No available evidence of clinical and relevant laboratory information indicative of acute infection. Most hepatitis C virus (HCV)-infected persons are asymptomatic; however, many have chronic liver disease, which can range from mild to severe.

Laboratory Criteria for Diagnosis:
- A positive test for antibodies to hepatitis C virus (anti-HCV) **OR**
- Hepatitis C virus detection test:
    o Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing), **OR**
    o A positive test indicating presence of hepatitis C viral antigen(s)*

*When and if a test for HCV antigen(s) is approved by the FDA and available

Case Classification/Status:

Confirmed:
- A case that does not meet the clinical criteria or has no report of clinical criteria **AND**
- Does not have a documented negative HCV antibody, HCV antigen or NAT laboratory test result followed within 12 months by a positive result of any of these tests (test conversion) or has not report of test conversion **AND**

- Has a positive HCV NAT or HCV antigen test (may have any anti-HCV antibody test result).

Probable:
- A case that does not meet the clinical criteria or has no report of clinical criteria **AND**
- Does not have a documented negative HCV antibody, HCV antigen or NAT laboratory test result followed within 12 months by a positive result of any of these tests (test conversion) or has no report of test conversion **AND**

- Has a positive anti-HCV antibody test, but no report of a positive HCV NAT or positive HCV antigen test.

c. Perinatal Hepatitis C (2017 CSTE Proposed Definition)

http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/2017PS/2017PSFinal/17-ID-08.pdf

Clinical criteria:

- Diagnosis of hepatitis C infection in an infant between 2 months and 36 months of age, or diagnosis of hepatitis C infection in a pregnant woman.

Laboratory criteria for diagnosis:
- Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing) for infants 36 months of age and under.
- HCV Antibody positive and no or unknown HCV RNA NAT (including qualitative, quantitative or genotype testing) for infants between 18 and 36 months of age.

Refer to Perinatal Hepatitis C Investigation for further details
Note: Report perinatal hepatitis C cases by date of diagnosis (for the infant).

C. **Local Health Jurisdiction Standard Investigation Responsibility**

A positive hepatitis C test (HCV antibody; HCV RNA NAT, including genotype) that is reported electronically into CDRSS or directly to the LHD is the primary trigger for investigation of a new case. The LHD's initial goal is to determine if the case is Acute or Chronic hepatitis C. To guide this case classification, the following steps should be taken on all HCV cases reported. (Note: if the case has been previously reported to CDRSS and closed as a confirmed case no further investigation is required. To merge a new case to a confirmed chronic case reference this document http://cdrs-train.doh.state.nj.us/manuals/help/CDRSS_HelpDesk_FAQsv3.pdf).
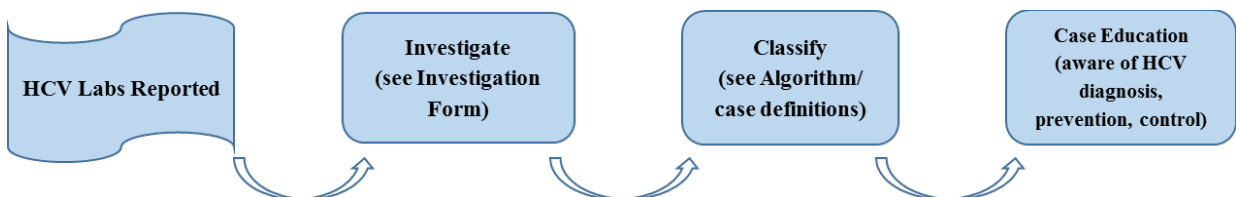
a. **Cases 31 to 69 years of age**
✓ The LHD should make a SINGLE attempt to collect information on the HCV Case Investigation Form (Appendix A) from the provider who ordered the testing. This attempt can be made via phone, fax, email or letter and should be documented in the comments section of CDRSS. Information returned on the form should be entered in CDRSS.
✓ Based on information received the case should be classified appropriately in CDRSS per the HCV Case Classification Algorithm (Appendix B).
   o Contact the referring medical facility for additional information if the case is suspected to be acute (i.e., determined to have either signs and symptoms, or ALT>200 IU/L) as additional information is needed to confirm classification.
   o Cases determined to have a reported positive hepatitis C serology test within 12 months of a documented negative HCV test (i.e., seroconversion) and/or has a health care associated risk factor (hemodialysis, invasive medical procedures, healthcare worker, blood, organ or tissue transplant) will need additional investigation and follow up per the Healthcare Associated Infection (HAI) section.
✓ If no response to the investigation attempt is received and there is no other indication the case might have acute hepatitis C (i.e., determined to have either signs and symptoms or ALT>200 IU/L) the following action can be taken.
   o Close in CDRSS as **Disease – HEPATITIS C, Subgroup - CHRONIC, Case Status – CONFIRMED, Report Status - LHD Closed** or **Case Status PROBABLE** per the HCV Classification Algorithm, **Reason for Status** - **Unable to obtain info from MD**.

b. Cases ≤ 30 or ≥ 70 years of age

✓ The LHD should make TWO attempts to collect information on the HCV Case Investigation Form from the provider who ordered the testing. This attempt can be made via phone, fax, email or letter and should be documented in the comments section of CDRSS. Information returned on the form should be entered in CDRSS.
   o Ideally these two attempts should be at least a week apart and within the first 30 days after the case was reported.
✓ If the attempt to reach the provider is not successful, LHD should make TWO attempts to collect information on the form directly from the patient. These attempts can be done via phone or letter. These attempts should also be documented in CDRSS.
   o Ideally attempts to reach the patient should be done at least a week after provider contact. Each contact to the patient should be at least a week apart and conducted no later than 60 days after the case was initially reported.
✓ If a response is not received from the physician or patient after all attempts, a final letter, template provided (Appendix C) should be sent to the patient asking him/her to contact the health department with the requested information. This letter may not be feasible for those located within institution. In these cases, LHD can skip this step and proceed with case classification per the HCV Case Classification Algorithm. Please see section entitled Correctional Facilities (pg. 11) for dealing with incarcerated individuals at state institutions'.
✓ Based on information received the case should be classified appropriately in CDRSS per the HCV Case Classification Algorithm.
   o Contact the referring medical facility for additional information if the case is suspected to be acute (i.e., determined to have either signs and symptoms, or ALT>200 IU/L) as additional information is needed to confirm classification.
   o Cases determined to have a reported positive HCV serology test within 12 months of a documented negative HCV test (i.e., seroconversion) and/or has a health care associated risk factor (hemodialysis, invasive medical procedures, healthcare worker, blood, organ or tissue transplant) will need additional investigation and follow up per the Healthcare Associated Infection (HAI) section.
✓ If no response to ANY attempt is received within 30 days of sending this final letter, the case should be closed based on existing information in CDRSS per the HCV Case Classification Algorithm, with **Report Status - LHD Closed, Reason for Status - Unable to obtain info from MD**.

c. Schematic of information needed in CDRSS

HCV Labs Reported → Investigate (see Investigation Form) → Classify (see Algorithm/ case definitions) → Case Education (aware of HCV diagnosis, prevention, control)

D. **Public Health Control Measures for Newly Identified Cases**

The role of the LHD in managing HCV largely revolves around providing education to infected persons on how to care for themselves and avoid spreading infection to others. Prevention and education includes information on how HCV is transmitted, how to avoid this transmission, and how patients can protect themselves from other potential sources of liver damage.

Recommended information and support for a new case.

1. Provide basic instruction on transmission of HCV and emphasize the need for ongoing medical evaluation. Treatment is available, and the case-patients should be referred to their health care provider for treatment options.

2. Discuss sexual transmission of HCV. Indicate that HCV may be transmitted during sex, but that the risk is low. All contact with blood during sex should be avoided. Emphasize barrier protection to prevent the spread of HCV, as well to prevent the exposure to and transmission of other pathogens.

3. Discuss household transmission of HCV. Household transmission is rare, but to ensure that it does not happen, the case-patient should not share razors, toothbrushes, nail clippers, or any other item that could be contaminated with blood.

E. **HCV Laboratory Tests**

This guidance document will not delve into detail on laboratory testing. Additional information about individual hepatitis C testing and the clinical algorithm that should be used to test patients can be found at the CDC website, https://www.cdc.gov/hepatitis/hcv/labtesting.htm. Below are a few highlights to consider when classifying cases of hepatitis C in New Jersey.

a. HCV Antibody Test

Prior to January 2018, all qualitative antibody tests were excluded from electronic laboratory reporting in CDRSS. However, all quantitative antibody tests and some qualitative antibody tests (those entered manually by users) were used to create new cases in CDRSS.

As of January 2018, CDRSS will process all antibody tests (qualitative, quantitative or signal to cut off ratio), which will create a new hepatitis C case or append to an existing case. The processing and classification of antibody testing is described in the HCV Case Classification section below.

b. HCV RNA NAT for Qualitative or Quantitative Test

A RNA NAT (qualitative or quantitative) test is a confirmatory test for hepatitis C. However, if reported as "not detected" and is the only HCV test reported for the case or it follows the report of a positive antibody test, the case is closed as **Disease – HEPATITIS C, Subgroup - PENDING, Case Status - NOT A CASE, Report Status - LHD Closed, Reason for Status - Does not meet case definition**. If another case exists for the person, merge the cases but do not change the primary case classification.

c. Genotype Test

A positive genotype test is considered a confirmatory test for hepatitis C. However sometimes this test is reported in CDRSS electronically but the value field has a comment saying "specimen has insufficient HCV RNA virus to obtain genotyping". These reports should not be considered when classifying a case using the HCV algorithm. To further illustrate this, two examples are provided below.

- Example 1 – A CDRSS record is created with a genotype laboratory test value populated as "specimen has insufficient HCV RNA virus to obtain genotyping" as the only HCV serology test performed on the patient. If this is the only case that exists for this person, this case can be closed as **Disease – HEPATITIS C, subgroup - PENDING, Case Status - NOT A CASE, Report Status - LHD Closed.** If another case exists for the person, merge the cases but do not change the primary case classification.
- Example 2 - A CDRSS record is created in which genotype testing with an "insufficient…." result is added to a case in which a HCV Antibody test was also performed. When evaluating for case assignment, only the antibody test and not the genotype test should be used. This case would be closed as **Disease – HEPATITIS C, Subgroup - CHRONIC, Case Status – PROBABLE, Report Status - LHD Closed.**

Note: Reference materials for Interpreting and Communicating HCV Test Results

https://www.cdc.gov/hepatitis/resources/professionals/pdfs/counselingandtestingpc.pdf

http://www.hepatitisc.uw.edu/go/screening-diagnosis/diagnostic-testing/core-concept/all

F. Hepatitis C Case Classification

NJDOH has developed an HCV Case Classification Algorithm (Appendix B) to assist LHDs with assigning the case status for hepatitis C cases in CDRSS.

a. HCV Antibody as Only Test

Included at the top of this algorithm is how NJDOH plans to manage newly implemented antibody testing. Cases reported into CDRSS via electronic laboratory reporting, in which a HCV antibody test (qualitative or quantitative) is the only test listed for that person will be created as **PROBABLE/E-CLOSED** case. If another test result (i.e., HCV NAT, genotype testing, antigen*) is added to a case with a previous antibody test result, the case will be changed to **RUI/Pending** for LHD investigation. In addition, NJDOH will conduct routine analysis on all **PROBABLE/E-CLOSED** cases to look for elevated liver enzymes, or for cases which might be associated with a health care facilities (e.g., dialysis laboratory). Cases for which either of these are found will be changed to **Report Status - Pending** and the LHD will be asked to further investigate using the protocols defined above.

b. Manual Entry of HCV Antibody

If single positive HCV antibody tests are manually entered into CDRSS, these will be entered and saved as **RUI/Pending** for LHD investigation. Please refer to the Case Classification Algorthim to ensure appropriate follow-up and case classification.

*When and if a test for HCV antigen(s) is approved by the FDA and available

c. Case final classification after Standard Investigation

After investigation is completed and case status has been assigned based on the HCV Case Classification Algorithm (Appendix B) the following are the *only* assignments which should be used to classify a closed case in CDRSS.

Table1. Possible HCV case classification assignments after investigation has been completed

Disease Subgroup	Case Status	Symptoms (headache, fever, nausea etc.) or ALT>200	HCV RNA NAT / Genotype	Positive HCV Antibody only
Chronic	**Confirmed**	No	Positive	No
Chronic	**Probable**	No	Unknown/Not reported	Yes
Acute	**Confirmed**	Yes	Positive	No
Acute	**Probable**	Yes	Unkown/Not reported	Yes
Perinatal	**Confirmed**	No	Positive	No
Pending	**Not a Case**	No	Negative	No

G. Perinatal Hepatitis C Investigation

Approximately 6 of every 100 infants born to HCV-infected mothers become infected with the virus. Transmission occurs at the time of birth, and no prophylaxis is available to prevent it. The risk is increased by the presence of maternal HCV viremia at delivery and is 2–3 times greater if the woman is coinfected with HIV. For purposes of perinatal HCV surveillance, infant and maternal status should be ascertained.

Infants 36 months of age and under should only be assessed for perinatal HCV infection and not according to the 2015 Surveillance Case Definition of Hepatitis C. The laboratory and epidemiologic criteria described in the 2015 case definitions for acute and chronic hepatitis C should only apply to individuals 36 months of age or more. However, if there is evidence that the case was exposed to HCV via a mechanism other than perinatal (e.g. was acquired via healthcare), and is under 36 months of age, it can and should be classified under the 2015 position statement.

✓ When possible, in order to verify source of infection the LHD should investigate all infants with HCV positive test to determine if the mother was confirmed to have acute and/or chronic HCV.

✓ The following actions should be taken for children between 2 months and 36 months of age. Reference the Hepatitis C Perinatal Case Classification Algorithm (Appendix D) and steps below for investigation, as well as CDRSS case classification.
  o In CDRSS, classify the case to **Disease - HEPATTIS C, Subgroup - PERINATAL, Case Status – Confirmed, Report Status - LHD Closed** if a positive HCV RNA NAT, Genotype or Antigen* positive confirmatory lab results are reported.
  o In CDRSS, classify the case to **Disease - HEPATTIS C, Subgroup - PERINATAL, Case Status - Report Under Investigation (RUI)** if only a positive hepatitis C Antibody test is reported. Case Status should remain as (RUI) until the actions below are completed.

- LHD should contact the healthcare provider and recommend HCV RNA NAT, including genotype or HCV Antigen* test prior to 36 months of age. LHD should ask the provider to notify them with results, both negative and positive.
  - HCV RNA NAT, Genotype or Antigen* confirmatory testing is recommended for children with a positive HCV antibody test, prior to 36 months of age.
    - If a confirmatory test is positive the case is classified in CDRSS **Disease - HEPATITIS C, Subgroup - PERINATAL, Case Status – Confirmed, Report Status - LHD Closed**.
    - If the confirmatory test is negative or not detected the case is assigned in CDRSS as **Disease - HEPATTIS C, Subgroup - PERINATAL, Case Status - Not a Case, Report Status - LHD Closed**.
  *When and if a test for HCV antigen(s) is approved by the FDA and available

- ✓ If the infant is less than 2 months of age with positive HCV Antibody test, the recommendation is that a confirmatory test be repeated between 2 months and 36 months of age.
- ✓ For cases, older than 36 months of age the standard HCV investigation procedure should be followed.

H. Healthcare-Associated Infection (HAI)

There are multiple reports of the transmission of viral hepatitis in healthcare settings owing to poor injection practices and other breaches in infection control. One of the goals of HCV surveillance is to identify these preventable exposures so that gaps can be identified and prevention measures put in place to prevent future disease transmission. Information received as part of a routine HCV investigation which reveals a health care associated risk factors may indicate the possibility of a HAI and warrants further investigation. A few special circumstances are highlighted below.

a. Dialysis

Patients requiring hemodialysis are at high risk for infection because the process of hemodialysis requires vascular access for prolonged periods. In an environment where multiple patients receive dialysis concurrently, repeated opportunities exist for person-to-person transmission of infectious agents, directly or indirectly via contaminated devices, equipment and supplies, environmental surfaces, or hands of personnel. Furthermore, hemodialysis patients are immunosuppressed, which increases their susceptibility to infection, and they require frequent hospitalizations and surgery, which increases their opportunities for exposure to health care associated infections. To reduce transmission of infectious agents, dialysis center in New Jersey routinely test patients undergoing chronic dialysis and have been proactive about reporting seroconversion and working with public health officials to determine where breeches may have occurred.

> *Investigation implications:* If a HCV case investigation reveals the patient is a current or past recipient of dialysis, this should be documented in the CDRSS record. LHD should contact NJDOH to determine if a more in-depth investigation is required.

b. Injection Safety/Drug Diversion

Injected medicines are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Unsafe injection practices put patients and healthcare providers at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures and settings.

Investigation implications: If a HCV case investigation reveals the patient has had significant medical procedures with no traditional HCV risk factors, this should be documented in the CDRSS record. LHD should contact NJDOH to determine if a more in-depth investigation is required.

I. Correctional Facilities

Per regulation (NJAC 8:57), state institutions are required to report communicable diseases directly to NJDOH. Some of these facilities have been trained to use CDRSS. NJDOH will continue to work with these facilities to create a process for case surveillance and CDRSS reporting. The LHD should make the **Report Status – LHD Review**. Correctional facilities have procedures in place to notify LHDs when a prisoner is released into their jurisdiction with a communicable disease. Once a prisoner is released and has been relocated into the LHD's jurisdiction, the LHD now has an obligation to conduct additional investigations, if necessary.

The LHD is responsible for investigating all non state correctional facility cases.

Appendices

Appendix A: Hepatitis C Case Investigation Form

NJ DEPARTMENT OF HEALTH COMMUNICABLE DISEASE SERVICES
HEPATITIS C CASE INVESTIGATION FORM

CDRSS #:

PATIENT INFORMATION

Name _Last_	_First_	_Middle_

Ethnicity
☐ Hispanic   ☐ Non-Hispanic   ☐ Other/Unknown

Address   _Street_

Race
☐ White   ☐ Black   ☐ Asian
☐ American Indian or Alaskan Native
☐ Native Hawaiian/Hawaiian / Pacific Islander
☐ Other/Unknown

Apt.   _City_   **County**

State   _Zip_   **Phone #** _ - -_

Email

If child <36 months, is the mother HCV+?
☐ Yes   ☐ No   ☐ Unknown

Sex
☐ Male   ☐ Female   ☐ Other / Unknown

DOB   **Age**

DIAGNOSIS

Has patient been diagnosed with hepatitis C at any time in the past? ☐ Yes   ☐ No   ☐ Unknown

If "Yes" - Dates of PREVIOUS diagnosis and illness onset:

↳ _Diagnosis:_   ↳ _Onset:_

If "No" – Date of illness onset for **NEW** diagnosis:

↳ Patient informed of **NEW** diagnosis?   ☐ Yes   ☐ No   ☐ Unknown
↳ Disease information provided?   ☐ Yes   ☐ No   ☐ Unknown
↳ Did this include information about prevention and control?
☐ Yes   ☐ No   ☐ Unknown   ☐ N/A

CLINICAL SYMPTOMS

Did the patient have any symptoms?
☐ Yes   ☐ No   ☐ Unknown

If "Yes", provide onset date and symptoms that apply →

☐ Fever   ☐ Malaise
☐ Anorexia   ☐ Nausea
☐ Diarrhea   ☐ Jaundice
☐ Abdominal Pain

Date of earliest symptom onset:

☐ Other Symptom:

LABORATORY INFORMATION

Reason for current hep C testing:
☐ Symptoms   ☐ Routine testing   ☐ Reported Risk Factors
☐ Prenatal Screening   ☐ Other:

In the past 12 months, did patient have a negative Hep C test result?
☐ Yes   ☐ No   ☐ Unknown

Most recent lab tests: ☐ No Tests Performed

Test	Anti-HCV	HCV RNA PCR	HCV Genotype	ALT (SGPT)	AST (SGOT)	Bilirubin
Result						
Date						

RISK FACTORS

Patient ever have contact with person known to have hep C? _(indicate type of contact)_	☐ Sex Partner ☐ Other: ☐ Household Member (non-sexual)		☐ Yes ☐ No ☐ Unknown	
Lifetime number of sexual partners? _(indicate number)_	# male:	# female:	☐ Yes ☐ No ☐ Unknown	
Patient ever incarcerated for more than 24 hours?	Type of facility:		☐ Yes ☐ No ☐ Unknown	
Patient ever receive a blood transfusion?	☐ Yes (before 1992) ☐ Yes (after 1992)		☐ No ☐ Unknown	
Patient ever accidentally punctured with a needle or other object soiled with blood?			☐ Yes ☐ No ☐ Unknown	
Was patient ever treated for a sexually transmitted disease?			☐ Yes ☐ No ☐ Unknown	
Patient ever had a tattoo?			☐ Yes ☐ No ☐ Unknown	
Patient ever had a body piercing?			☐ Yes ☐ No ☐ Unknown	
Patient ever exposed to someone else's blood? _(medical, dental, public safety blood worker)_			☐ Yes ☐ No ☐ Unknown	
Patient ever undergone hemodialysis?			☐ Yes ☐ No ☐ Unknown	
Patient ever injected drugs not prescribed by a doctor?			☐ Yes ☐ No ☐ Unknown	
Patient had dental work or oral surgery within the last 6 months?			☐ Yes ☐ No ☐ Unknown	
Patient currently a resident of a long-term care facility?			☐ Yes ☐ No ☐ Unknown	

General comments or other risk factors:

Please return the completed form to:

Is there anything in patient's history that warrants further public health investigation?
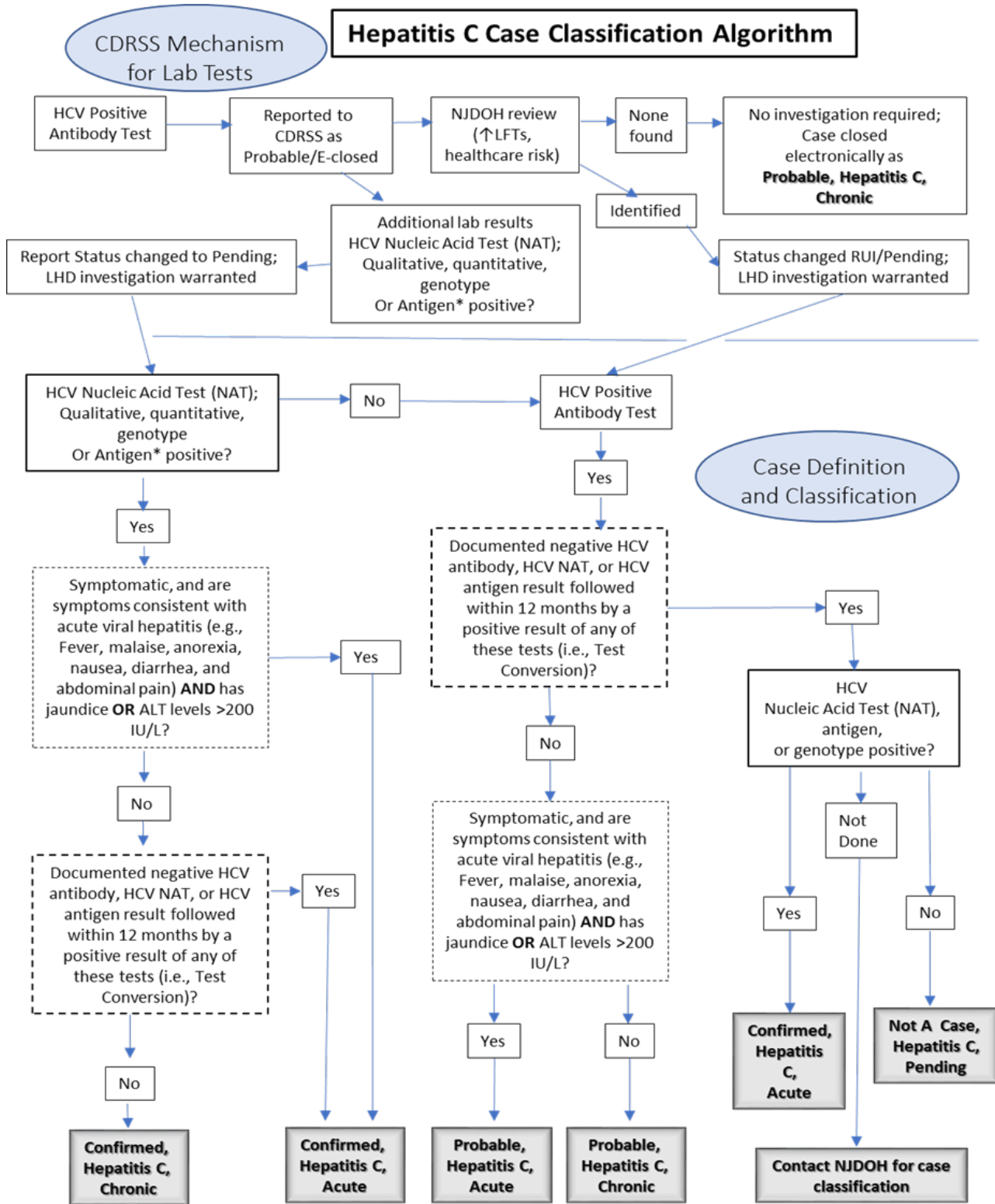☐ Yes   ☐ No   ☐ Unknown
Please explain:

Name of _Clinical Contact_: **Email:**   **Date Sent (to LHD):**

CDS-17
OCT 17

Appendix B: HCV Case Classification Algorithm

Hepatitis C Case Classification Algorithm

CDRSS Mechanism for Lab Tests

HCV Positive Antibody Test → Reported to CDRSS as Probable/E-closed → NJDOH review (↑LFTs, healthcare risk) → None found → No investigation required; Case closed electronically as **Probable, Hepatitis C, Chronic**

NJDOH review → Identified → Status changed RUI/Pending; LHD investigation warranted

Reported to CDRSS as Probable/E-closed → Additional lab results HCV Nucleic Acid Test (NAT); Qualitative, quantitative, genotype Or Antigen* positive? → Report Status changed to Pending; LHD investigation warranted

Case Definition and Classification

HCV Nucleic Acid Test (NAT); Qualitative, quantitative, genotype Or Antigen* positive? → No → HCV Positive Antibody Test

HCV Nucleic Acid Test (NAT); Qualitative, quantitative, genotype Or Antigen* positive? → Yes → Symptomatic, and are symptoms consistent with acute viral hepatitis (e.g., Fever, malaise, anorexia, nausea, diarrhea, and abdominal pain) **AND** has jaundice **OR** ALT levels >200 IU/L?

Symptomatic... → Yes → **Confirmed, Hepatitis C, Acute**

Symptomatic... → No → Documented negative HCV antibody, HCV NAT, or HCV antigen result followed within 12 months by a positive result of any of these tests (i.e., Test Conversion)?

Documented negative... → Yes → **Confirmed, Hepatitis C, Acute**

Documented negative... → No → **Confirmed, Hepatitis C, Chronic**

HCV Positive Antibody Test → Yes → Documented negative HCV antibody, HCV NAT, or HCV antigen result followed within 12 months by a positive result of any of these tests (i.e., Test Conversion)?

Documented negative... → Yes → HCV Nucleic Acid Test (NAT), antigen, or genotype positive?

Documented negative... → No → Symptomatic, and are symptoms consistent with acute viral hepatitis (e.g., Fever, malaise, anorexia, nausea, diarrhea, and abdominal pain) **AND** has jaundice **OR** ALT levels >200 IU/L?

Symptomatic... → Yes → **Probable, Hepatitis C, Acute**

Symptomatic... → No → **Probable, Hepatitis C, Chronic**

HCV Nucleic Acid Test (NAT), antigen, or genotype positive? → Not Done → Yes → **Contact NJDOH for case classification**

HCV Nucleic Acid Test (NAT), antigen, or genotype positive? → Yes → **Confirmed, Hepatitis C, Acute**

HCV Nucleic Acid Test (NAT), antigen, or genotype positive? → No → **Not A Case, Hepatitis C, Pending**

*When and if a test for HCV antigen(s) is approved by the FDA and available

Appendix C: HCV Letter

{Local Health Department Letter}

Date

Patient Name

Patient Address

Dear Mr./Ms. X,

The _____Health Department has made several attempts to contact you regarding a positive laboratory result that was received. New Jersey Administrative Code (NJAC 8:57) requires physicians, laboratories and institutions (e.g., prisons, long term care, rehabilitation) to report certain communicable diseases to state and local health departments for follow up and investigation. Please contact our office at the phone number below so we may discuss this matter with you. If you are not aware of recent positive laboratory result, you may want to contact your health care provider prior to contacting our office.
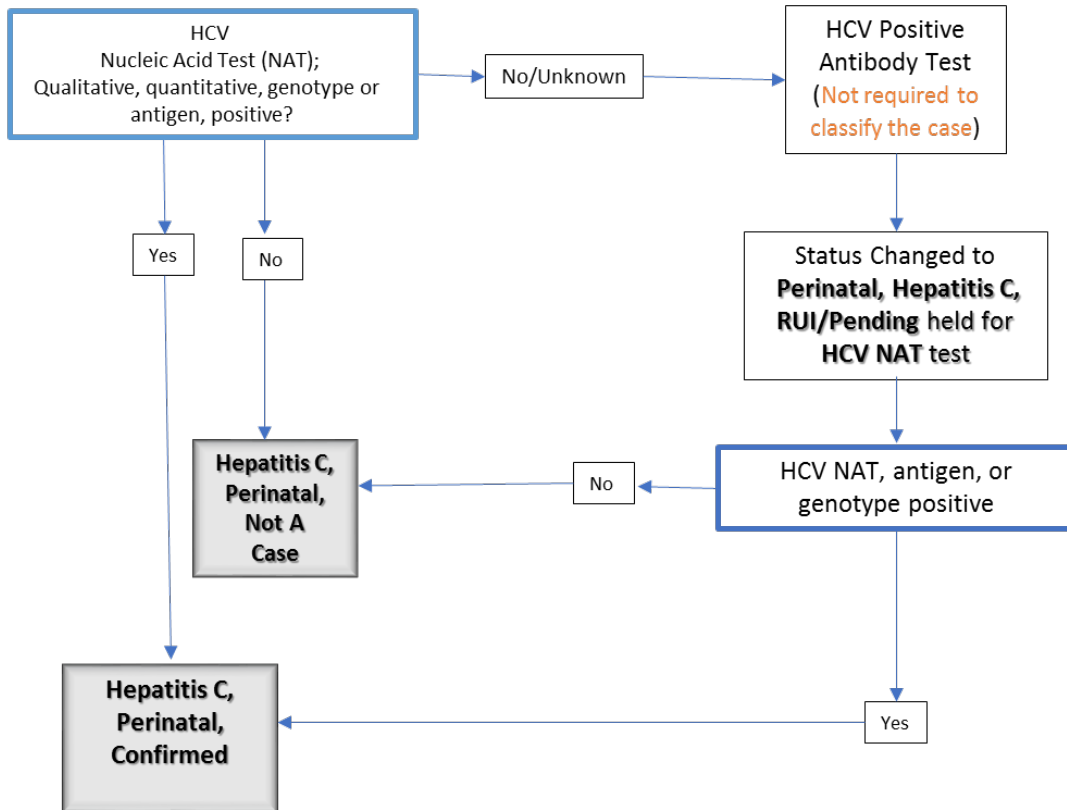

Thank you,

_____Health Department

Phone:

Fax:

Email:

Appendix D: Perinatal Hepatitis C Case Classification Algorithm

Hepatitis C Perinatal Case Classification Algorithm
For infants between 2 months and 36 months of age

HCV
Nucleic Acid Test (NAT);
Qualitative, quantitative, genotype or antigen, positive?

No/Unknown

HCV Positive
Antibody Test
(Not required to classify the case)

Yes | No

Status Changed to
Perinatal, Hepatitis C, RUI/Pending held for **HCV NAT** test

Hepatitis C, Perinatal, Not A Case

No

HCV NAT, antigen, or genotype positive

Hepatitis C, Perinatal, Confirmed

Yes

❖ If the infant is less than 2 months of age with positive HCV test, the recommendation is that a confirmatory test be repeated between 2 months and 36 months of age.

❖ For cases, older than 36 months of age the standard Hep C investigation procedure should be followed.

Appendix E: Interpretation of Laboratory Test Names used for Case Classification in CDRSS

CDRSS Test Name	Test Type
Hepatitis C Virus Antibody (Anti-HCV)	Antibody test
Hepatitis C Virus Antibody Signal to Cut Off Ratio (S/CO)	Antibody test
Hepatitis C Virus Genotype	Nucleic Acid Test (NAT)
Hepatitis C Virus RNA (PCR – Qualitative)	Nucleic Acid Test (NAT)
Hepatitis C Virus RNA (PCR – Quantitative)	Nucleic Acid Test (NAT)
Alanine Aminotransferase (ALT) *Serum glutamic pyruvic transaminase (SGPT)*	Liver function
Alkaline Phosphatase (Alk Phos)	Liver function
Aspartate Aminotransferase (AST) *Serum glutamic-oxaloacetic transaminase (SGOT)*	Liver function
Bilirubin Total – Bili (total)	Liver function