To: California Association of Communicable Disease Controllers  
California HIV/Sexually Transmitted Diseases (STD) Controllers Association  
California Conference of Local Health Data Managers and Epidemiologists  
Other Interested Parties

From: Rachel McLean, M.P.H., Chief, Office of Viral Hepatitis Prevention, STD Control Branch, California Department of Public Health (CDPH)

Re: Changes to 2020 Hepatitis C Virus (HCV) Surveillance Case Definitions

Date: January 2, 2020

I am writing to inform you of important changes to the U.S. Centers for Disease Control and Prevention (CDC) surveillance case definitions for acute hepatitis C and chronic hepatitis C, which became effective January 1, 2020. This case definition revision should begin with cases assigned to surveillance year 2020. CDPH will soon modify related forms and guidelines. In the meantime, here is a summary of the key changes.

1) **Age Criteria**
   All reported acute or chronic hepatitis C cases should be older than 36 months of age. Any positive HCV test result in a child 36 months of age or younger should be investigated as a possible Perinatal Hepatitis C case. A **Confirmed** Perinatal Hepatitis C case is defined as an infant who has a positive test for HCV ribonucleic acid (RNA) nucleic acid amplification test, HCV antigen, or detectable HCV genotype from 2 to 36 months of age (inclusive), and who is not known to have been exposed to HCV via a mechanism other than perinatal.

2) **Acute Hepatitis C**
   The 2020 Acute Hepatitis C Case Definition removes the requirement for the presence of a discrete onset of symptoms for acute cases. Use of bilirubin test results (peak elevated total bilirubin levels 3.0 mg/dL or higher) allow for objective measures of jaundice and can be used in absence of symptoms and/or high peak elevated serum alanine aminotransferase (ALT) levels results.

3) **Chronic Hepatitis C, Probable**
   HCV antibody positive cases with evidence of having cleared their infection (i.e., a known negative HCV RNA test result) at the time of initial report should be considered **Not a Case**. (A person with a positive HCV antibody test result and no or unknown HCV RNA results should still be classified as a **Probable** case.)
ACUTE Hepatitis C

<table>
<thead>
<tr>
<th>2016 Case Definition</th>
<th>2020 Case Definition</th>
<th>Notable Changes</th>
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<tbody>
<tr>
<td><strong>Clinical Criteria</strong></td>
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<tr>
<td>An illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), AND (a) jaundice, OR (b) a peak elevated serum alanine aminotransferase (ALT) level &gt;200 IU/L during the period of acute illness.</td>
<td>All HCV cases in each classification category should be &gt; 36 months of age, unless known to have been exposed non-perinatally. One or more of the following: Jaundice, OR Peak elevated total bilirubin levels ≥ 3.0 mg/dL, OR Peak elevated serum alanine aminotransferase (ALT) levels &gt;200 international units per liter [IU/L]. AND The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic HCV infection or other causes, e.g., alcohol exposure, other viral hepatitis, hemochromatosis)</td>
<td>1) Requirement that all cases be more than 36 months of age 2) Peak elevated total bilirubin levels 3.0 mg/dL or higher enough to meet acute hepatitis C case definition (including in lieu of jaundice symptoms or peak ALT levels over 200 IU/L) 3) Specification that another more likely diagnosis (such as evidence of pre-existing advanced liver disease) should be absent.</td>
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**Laboratory Criteria for Diagnosis**
- A positive test for antibodies to hepatitis C virus (anti-HCV)
- Hepatitis C virus detection test:
  - Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative or genotype testing)
  - A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)*

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

**Laboratory Criteria**
- Confirmatory laboratory evidence: Positive HCV 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) (HCV antigen)

**Presumptive laboratory evidence:** A positive test for antibodies to hepatitis C virus (anti-HCV)

**Epidemiologic Linkage**
No epidemiologic linkage is required for case classification.

**Laboratory Criteria**
- Distinction between presumptive laboratory evidence (indicated by a positive HCV antibody test) and confirmatory laboratory evidence (indicated by a positive HCV RNA or genotype test).
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<tr>
<th>2016 Case Definition</th>
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<td><strong>Probable</strong></td>
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| A case that meets clinical criteria and has a positive anti-HCV antibody test, but has no reports of a positive HCV NAT or positive HCV antigen tests,  
AND | A case that meets clinical criteria and has presumptive laboratory evidence,  
AND | N/A |
| Does not have test conversion within 12 months or has no report of test conversion. | Does not have a hepatitis C virus detection test reported,  
AND |  |
| **Confirmed** | **Confirmed** | **Confirmed** |
| A case that meets clinical criteria and has a positive hepatitis C virus detection test (HCV NAT or HCV antigen),  
OR | A case that meets clinical criteria and has confirmatory laboratory evidence,  
OR | Clarification that HCV RNA test seroconversion should only be considered an acute HCV case in absence of a prior diagnosis of HCV infection. Note: evidence of HCV reinfection or HCV treatment failure would not be considered acute HCV infection for public health surveillance.  
OR |  |
| 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). | A documented negative HCV antibody followed within 12 months by a positive HCV antibody test (anti-HCV test conversion) in the absence of a more likely diagnosis,  
OR |  |
| A documented negative HCV antibody OR negative hepatitis C virus detection test (in someone without a prior diagnosis of HCV infection) followed within 12 months by a positive hepatitis C virus detection test (HCV RNA test conversion) in the absence of a more likely diagnosis |  |  |
## CHRONIC Hepatitis C

<table>
<thead>
<tr>
<th>Clinical Criteria</th>
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<tbody>
<tr>
<td>2016 Case Definition</td>
<td>2020 Case Definition</td>
<td>N/A; Note: the chronic HCV case definition requires the absence of clinical criteria.</td>
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### Clinical Criteria

- No available evidence of clinical and relevant laboratory information indicative of acute infection (refer to the criteria for classification Table VII-B in CSTE position statement 15-ID-03). 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)

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

### Laboratory Criteria

**Confirmatory laboratory evidence:**
Positive HCV 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) (HCV antigen)

**Presumptive laboratory evidence:**
A positive test for antibodies to hepatitis C virus (anti-HCV)

### Epidemiologic Linkage

Distinction between presumptive laboratory evidence (indicated by a positive HCV antibody test) and confirmatory laboratory evidence (indicated by a positive HCV RNA or genotype test).
* When and if a test for HCV antigen(s) is approved by FDA and available.

No epidemiologic linkage is required for case classification.

<table>
<thead>
<tr>
<th>CHRONIC Hepatitis C, Continued</th>
<th>2016 Case Definition</th>
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<tr>
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<td>• A case that does not meet clinical criteria or has no report of clinical criteria, AND</td>
<td>• A case that does not meet OR has no report of clinical criteria, AND</td>
<td>• Has presumptive laboratory evidence, AND</td>
<td>Clarification that a case with presumptive laboratory evidence (a positive HCV antibody test result) is only considered Probable if there is not a known negative HCV RNA result.</td>
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<tr>
<td>• Does not have test conversion within 12 months or has no report of test conversion, AND</td>
<td>• Has no documentation of anti-HCV or RNA test conversion within 12 months, AND</td>
<td>• Does not have an HCV RNA detection test reported.</td>
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<tr>
<td>• Has a positive anti-HCV antibody test, but no report of a positive HCV NAT or positive HCV antigen test.</td>
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<td><strong>Confirmed</strong></td>
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<td>• A case that does not meet clinical criteria or has no report of clinical criteria, AND</td>
<td>• A case that does not meet OR has no report of clinical criteria, AND</td>
<td>• Has confirmatory laboratory evidence, AND</td>
<td>N/A</td>
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<td>• Does not have test conversion within 12 months or has no report of test conversion, AND</td>
<td>• Has no documentation of anti-HCV or HCV RNA test conversion within 12 months.</td>
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<td>• Has a positive HCV NAT or HCV antigen test.</td>
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