HCV – Part 2

CDEpi Office Hours

March 11, 2021

Overview
HCV Part 1 – March 4, 2020 (recorded)

- Overview of Hepatitis C
- 2020 case definition
- Laboratory testing and serology
- Treatment overview

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Overview
HCV Part 2, March 11, 2020

- Evaluating lab results in MIDIS
- Case investigations
- Frequently asked questions
- Tips and resources

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Quick Refresher: Hepatitis C testing, laboratory algorithm and case definition

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HCV related laboratory tests

- Hepatitis C Antibody (HCV Ab)
  - Detects the presence of antibodies to the HCV
  - It cannot distinguish whether someone has an active or previous infection
- Hepatitis C RNA Qualitative
  - Used to confirm active infection in a HCV antibody positive person
  - Usually performed through PCR testing
- Hepatitis C RNA Quantitative (Viral Load)
  - Used to confirm active infection in a HCV antibody positive person
  - Used to monitor therapy
  - Usually performed through PCR testing
- HCV Genotype
  - Used to predict response to therapy, determine length of treatment
- HCV Resistance Testing
  - Used to predict response to therapy, ***not intended to diagnose chronic infection***

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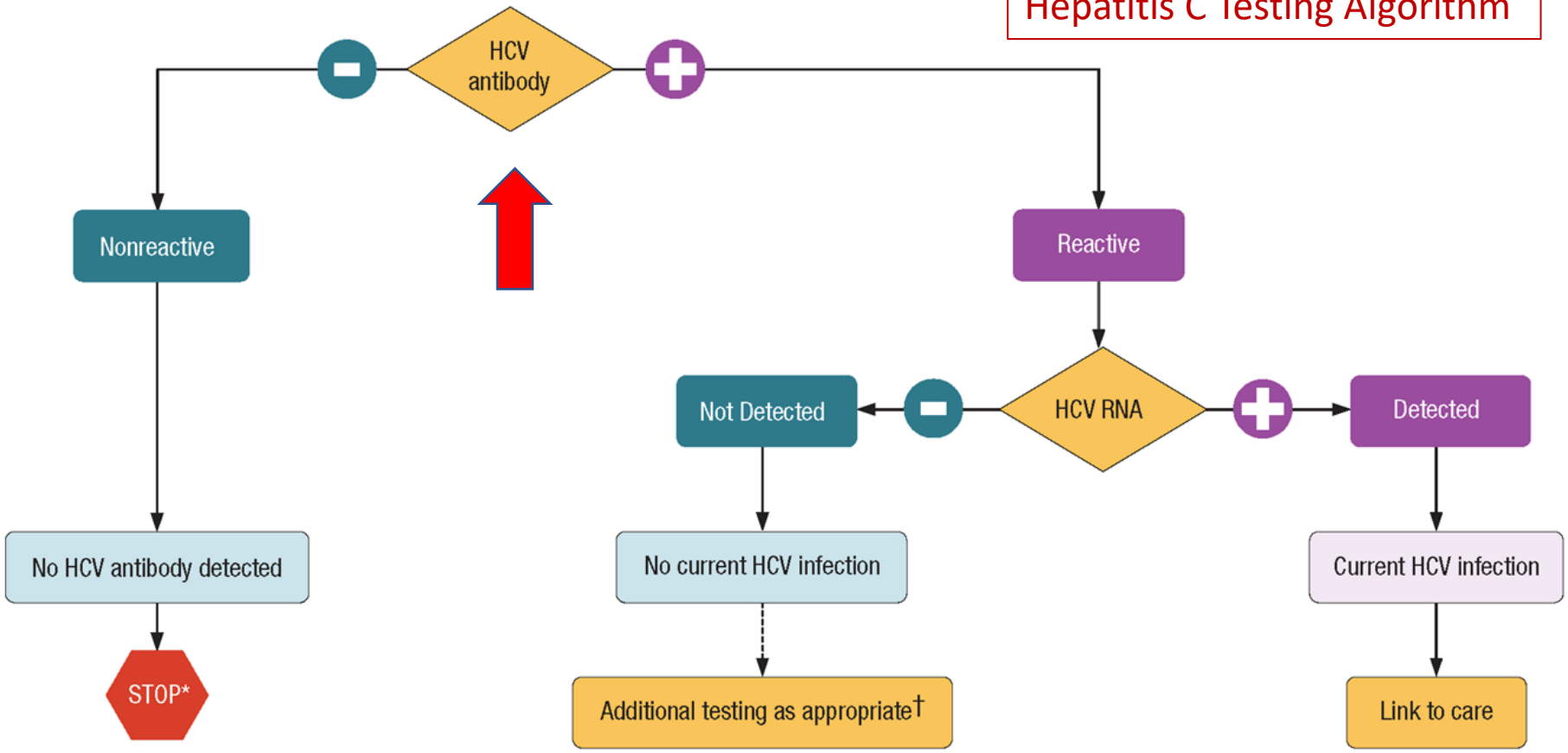
Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Hepatitis C Testing Algorithm



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

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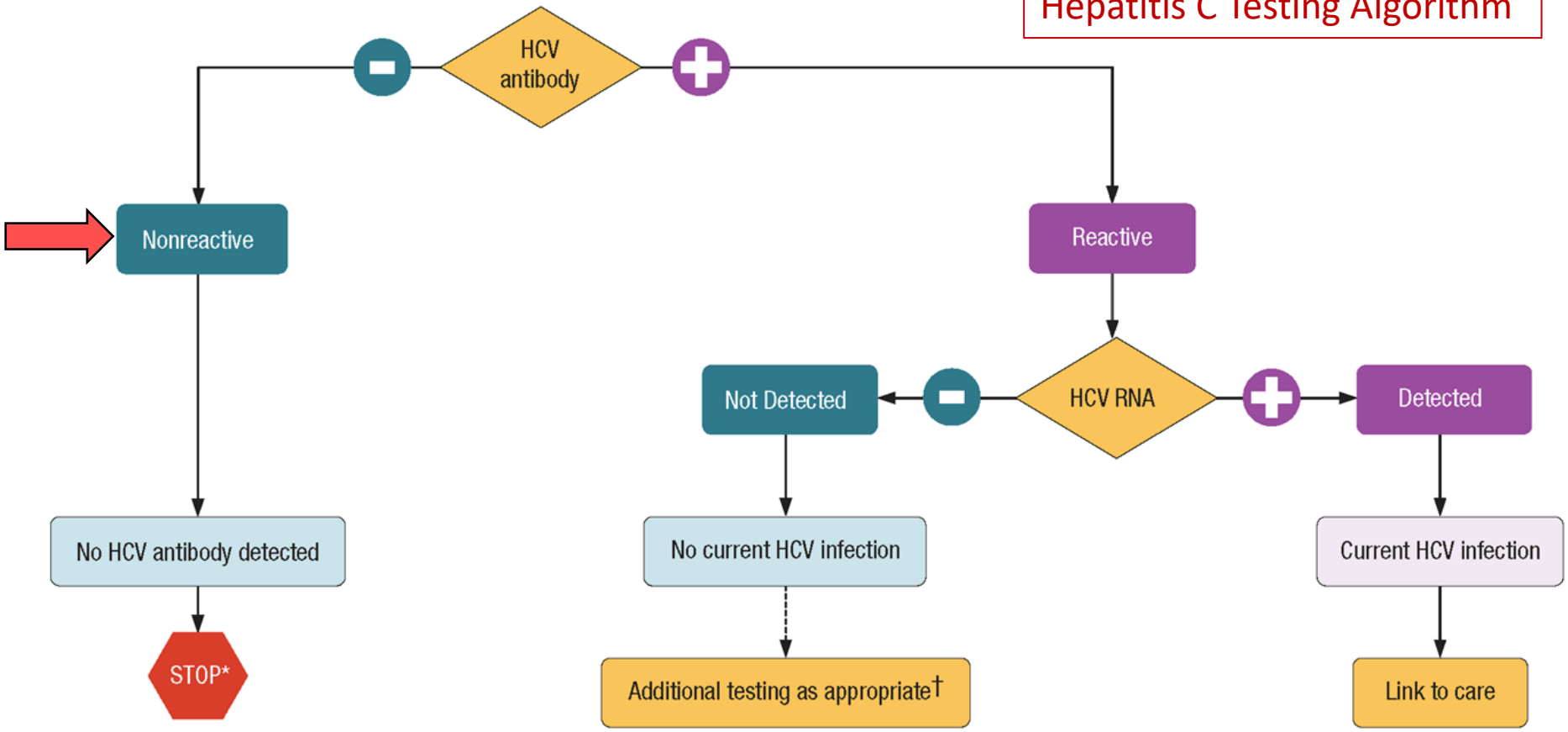

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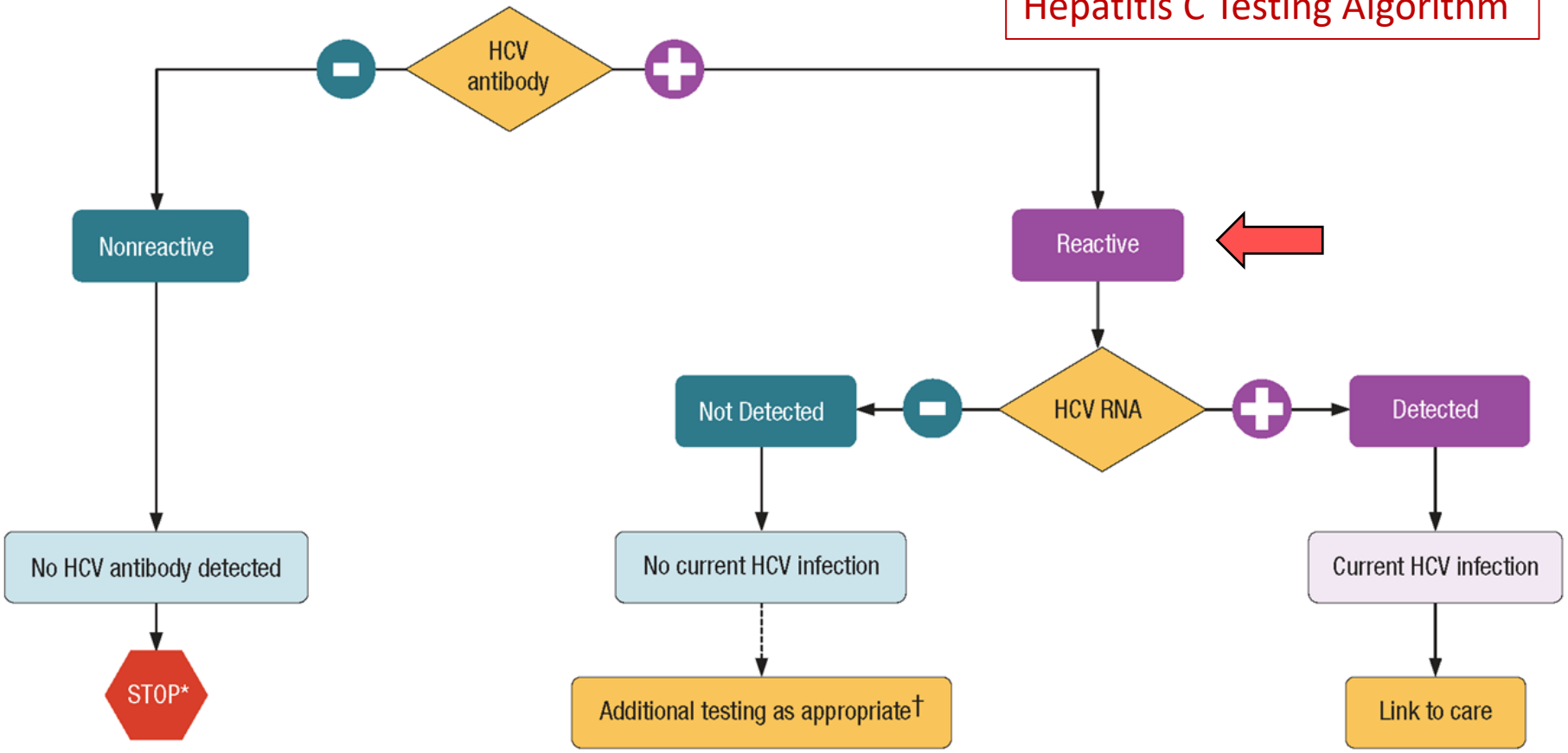

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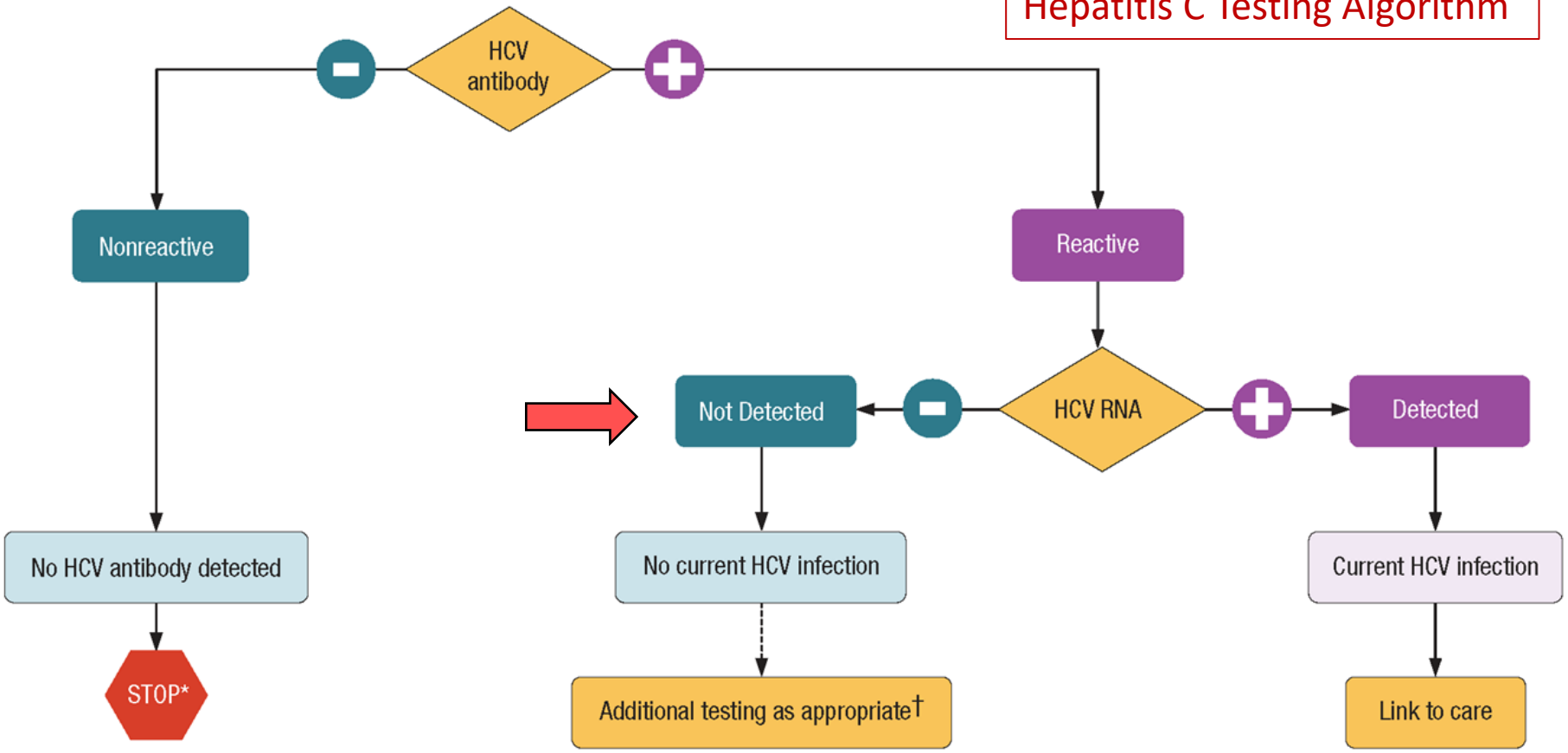

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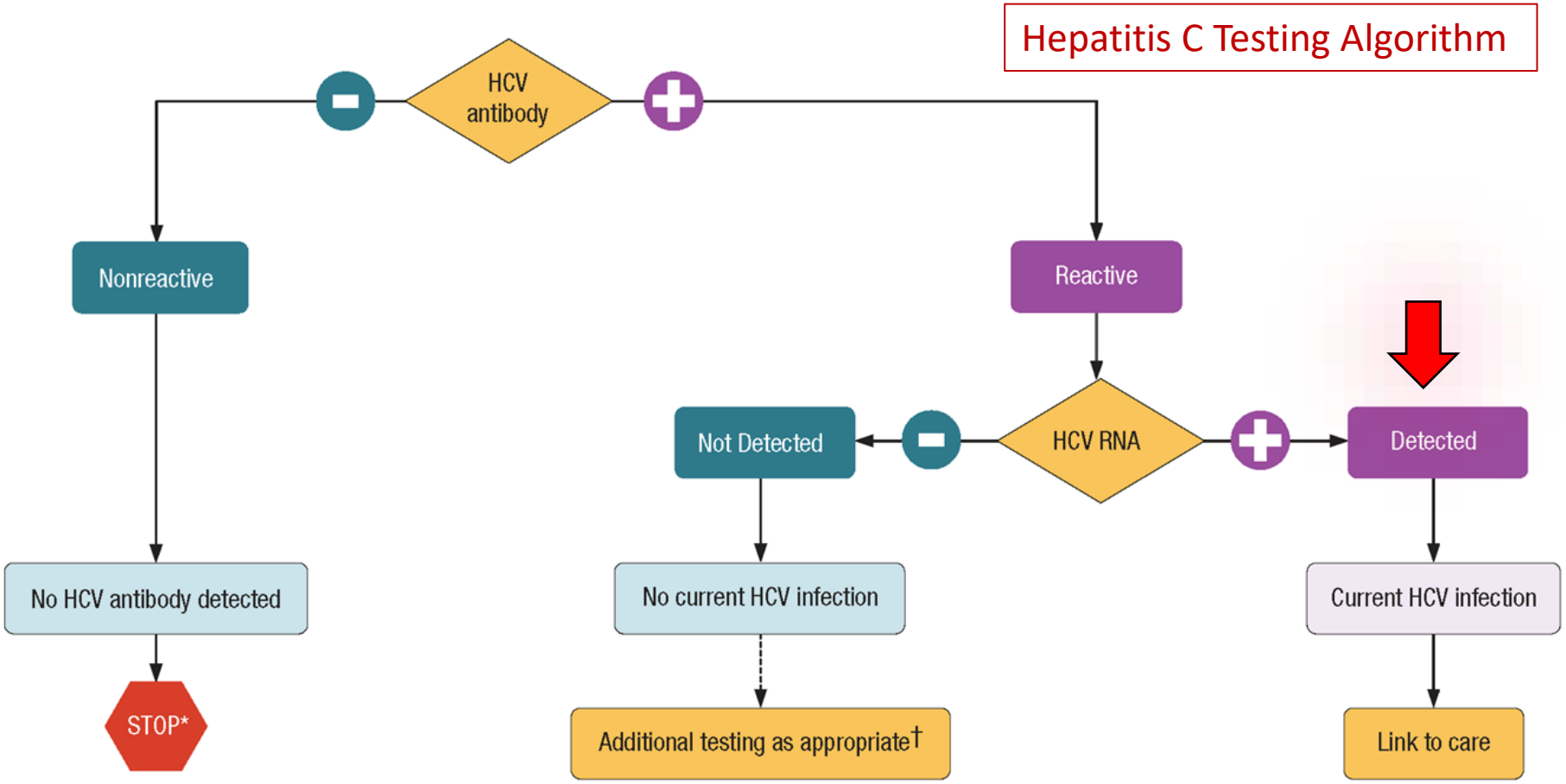

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HCV Case Definition - 2020

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Surveillance Case Definition (2016) – *Acute Hepatitis C*

Clinical Criteria

One or more of the following:

- 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**
- Jaundice **OR**
- Peak elevated serum alanine aminotransferase (ALT) level >200 IU/mL during the period of acute illness

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Surveillance Case Definition (2016) – *Acute Hepatitis C*

Only 20% to 30% develop symptoms

Clinical Criteria

One or more of the following:

- ~~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**~~
- Jaundice **OR**
- Peak elevated serum alanine aminotransferase (ALT) level >200 IU/mL during the period of acute illness **OR**
- **NEW - Peak elevated total bilirubin levels ≥ 3.0 mg/dL**

AND

NEW - The absence of a more likely diagnosis (i.e., acute or advanced liver disease due to other causes such as alcohol exposure, other viral hepatitis, hemochromatosis, pre-existing chronic HCV infection, etc.)

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Surveillance Case Definition (2020) – *Acute Hepatitis C*

Clinical Criteria

One or more of the following:

- Jaundice **OR**
- Peak elevated total bilirubin levels ≥ 3.0 mg/dL **OR**
- Peak elevated serum alanine aminotransferase (ALT) level >200 IU/mL during the period of acute illness

AND

- The absence of a more likely diagnosis (i.e., acute or advanced liver disease due to other causes such as alcohol exposure, other viral hepatitis, hemochromatosis, pre-existing chronic HCV infection, etc.)

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Quick Reference for Case Status

Acute Hepatitis C

- Clinical criteria* and positive antibody *only* = **Probable**
- Clinical criteria* AND positive RNA test = **Confirmed**
- Documented test conversion = **Confirmed**

AND

*Absence of a more likely diagnosis

Chronic Hepatitis C

No test conversion or clinical criteria

- Positive antibody and no RNA = **Probable**
- Positive antibody and positive RNA = **Confirmed**
- Positive RNA only = **Confirmed**

REMEMBER:

Positive antibody and negative RNA is **not a case**

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HCV Screening Recommendations - 2020

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CDC Recommendations for HCV Screening - 2020

Prior, focus of routine screening was on adults born between 1945 and 1965

Universal hepatitis C screening:

- Hepatitis C screening at least once in a lifetime for **all adults** aged 18 years and older*
- Hepatitis C screening for **all pregnant women during each pregnancy***

* except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%

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CDC Recommendations for HCV Screening - 2020

One-time hepatitis C testing regardless of age or setting among people with recognized conditions or exposures:

- People with HIV
- People whoever injected drugs/shared needles
- People with select medication conditions (e.g., hemodialysis)
- People with prior transfusion or organ transplant recipients
- Healthcare personnel with needlestick injuries or mucosal exposure to HCV+ blood
- Children born to mothers with HCV infection

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Evaluating HCV lab results in MIDIS

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Acute HCV

Probable acute HCV

MIDIS case status = "*probable*"

Test Results

Hepatitis C virus Ab [Presence] in Serum or Plasma by Immunoassay: REACTIVE

Reference Range: (Nonreactive) - (Final)

- The patient meets the clinical criteria
- No report of an RNA test
- No test conversion within 12 months

Acute HCV

Confirmed acute HCV

MIDIS case status = "*confirmed*"

Test Results	
Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by amplification method: 729000 IU/ML Reference Range: (UNDETECTED) - (Final)	Probe and target

- The patient meets the clinical criteria

Chronic HCV

Probable HCV

MIDIS case status = "*probable*"

No longer use "suspect" as a case status

Test Results

Hepatitis C virus Ab Signal/Cutoff in Serum or Plasma by Immunoassay:
24.00 1
Reference Range: (<1.00) - (Final)

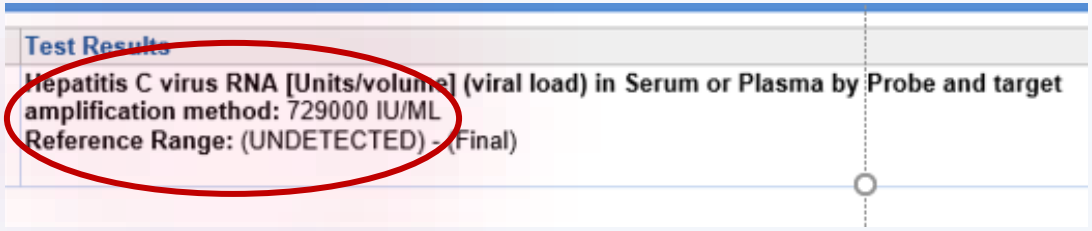
Hepatitis C virus Ab [Presence] in Serum or Plasma by Immunoassay:
Reactive (qualifier value)
Reference Range: (NON-REACTIVE) - (Final)

- The patient does not meet the clinical criteria
- No test conversion

Chronic HCV

Confirmed HCV

MIDIS case status = "*confirmed*"



- The patient does not meet the clinical criteria
- No test conversion

(may or may not have an antibody test)

Chronic HCV

There is no active infection

MIDIS case status = “not a case”

Mark as reviewed. Do not need to start an investigation

Test Results

Hepatitis C virus Ab [Presence] in Serum or Plasma by Immunoassay:
Anti HCV Reactive: The CDC recommends confirmatory testing - (Final)
Hepatitis C virus Ab [Presence] in Serum or Plasma by Immunoassay:
Reactive
Reference Range: (Nonreactive) - (Final)

Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe and target amplification method:
<15 NOT DETECTED - (Final)
Reference Range: (NOT DETECTED) - (Final)

Hepatitis C virus RNA [log units/volume] (viral load) in Serum or Plasma by Probe and target amplification method:
<1.18 NOT DETECTED - (Final)
Reference Range: (NOT DETECTED) - (Final)

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Frequently Asked Questions

Q: Why do I see detectable RNA that is followed by RNA not detected?

A: For confirmed chronic cases, this indicates that the infection is resolved and there is not current infection

Date Collected	Test Results
08/22/2013	**Hepatitis C virus (HCV), Quantitative by PCR:** HCV RNA Viral Load - 6.7 Log iu/ml positive =4998290.00000 iu/ml
11/01/2018	**Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe and target amplification method:** 3370000.0000 IU/mL - (Final)
01/15/2019	**Hepatitis C virus Ab Signal/Cutoff in Serum or Plasma by Immunoassay:** >11.0 s/co ratio **Reference Range:** (0.0-0.9) - (Final)
01/15/2019	**Hepatitis C virus genotype [Identifier] in Serum or Plasma by Probe and target amplification method:** Hepatitis C virus subtype 1a
05/28/2019	**Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe and target amplification method:** Not detected

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MIDIS Demonstration

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Step 1 – Documents requiring review

Step 2 – See if it's a new or old case

- Existing investigation found
- Very early MIDIS ID – email or call

Step 3 – Existing Case

- Attach lab to the investigation

Step 4 – New Case

- Confirm diagnosis and determine the case status
- Open the investigation
- Investigate and follow-up
- Complete and close the investigation

  **Check for required data elements

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MIDIS Demonstration

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Frequently Asked Questions

Q: Can there be a negative HCV antibody test result and detectable RNA?

A: This may happen if it is an acute case. Early in the disease, there may be too few antibodies to detect.

Q: The provider ordered an RNA test that came back undetected. There was no antibody test. Three months later, the next test was an antibody test that came back positive.

Is this a new infection?

A: It is not possible to tell if this is a new infection with these two test results. The provider would need to order a second confirmatory test.

Wait to start the investigation and contact the provider to see if an RNA test has been or will be ordered.

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Frequently Asked Questions

Q: Can a patient have a normal liver enzyme (e.g., ALT) level and still have chronic hepatitis C?

A: Yes. It is common for patients with chronic hepatitis C to have liver enzyme levels that go up and down, with periodic returns to normal or near normal levels.

Q: How can I tell if a patient has an investigation in another jurisdiction?

A: There are a couple of hints that may indicate an existing case:

- *Low MIDIS ID – 12841*
- *The patient has addresses in other counties*

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Sally Sunday | Female | 02/20/1955 (66 Years) **Patient ID:**

Summary | Events | Demographics

Expand All

Patient Demographics

Go to: Patient Summary | Administrative | Name | Address | Phone & Email | Identification | Race | Ethnicity | Sex & Birth | Mortality | General Patient

Patient Summary

Address (Home)
15 7th Street
Pleasantville, Montana 59601
Lewis and Clark County

Home
406-555-6666

No ID Info Available

Race
White
Ethnicity
Not Hispanic or Latino

Administrative

General Comments:

Name

	As of	Type	Last	First	Middle	Suffix
Details	03/08/2021	Legal	Sunday	Sally		

Address

	As of	Type	Address	City	State	Zip
Details	03/08/2021	House/Home	15 7th Street	Pleasantville	Montana	59601
Details	02/18/2021	House/Home	1515 12th Street	Billings	Montana	59101

If you believe there may be an old investigation, call or email Helen McCaffrey (444-4734 or hmccaffrey@mt.gov) and we can check. **This will save you the effort of creating an investigation and allow you to see previous labs.**

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Frequently Asked Questions

Q: What is the criteria to distinguish a new HCV case from an existing case

A: Evidence for re-infection may include a case of confirmed chronic HCV infection that has at least two sequential negative HCV viral detection tests reported, indicative of treatment initiation and sustained virologic response, followed by a positive HCV viral detection test.

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Frequently Asked Questions

Q: I put in an investigation for chronic HCV but have gotten more information and need to change it to an acute HCV. How do I change conditions?

A: Please call or email Helen McCaffrey (444-4734 or hmccaffrey@mt.gov)

Q: How do I merge investigations?

A: Please call or email Helen McCaffrey (444-4734 or hmccaffrey@mt.gov)

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Tips!

- Start the investigation as soon as possible – generally the case status will be "*probable*" until more information is received
- Don't wait for RNA levels to come back to start an investigation
  - You may have to call the provider
- Click "Create Notifications" button as soon as you can (within 7 days)
- Some laboratory positives come from facilities or organizations where the patient is not receiving care for Hepatitis C
  - Ideal Option
  - Blood donation
  - Life insurance screenings

  In these cases, contact the patient directly to implement control measures. Find out if they will seek follow up care for confirmation of chronic disease and/or treatment
- Don't call out of state jurisdictions directly as per MT ARM 37.314. Contact CDEpi for such follow-up

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Resources

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Will be put on secret website!

MIDIS ID: _____

Hepatitis C Case Determination Tool

Date: _____ Patient name: _____ DOB: _____

Provider name and phone #: _____

Lab Test Results Checklist			
Disease	**Lab Test**	**Results positive or negative**	**Results quantitative**
Hepatitis C	anti-HCV (HCV Ab)		
	HCV RNA		
Liver Enzymes	ALT		
Bilirubin levels	Peak elevated level		

Healthcare Provider Question Checklist

Reason for Testing

1. **Screening:**
   - **Routine screen for present concern:** **yes/no** i.e. starting on a liver toxic medication, cancer treatment, known chronic case to the physician, baseline screening, etc.

     or
   - **At risk:** **yes/no** i.e. IDU, MSM, born out of the United States, STD, co-morbidity such as HIV, recent exposure, contact to a case, etc.
2. **Symptoms:**
   - Jaundice: **yes/no**
   - Peak Elevated total bilirubin levels ≥ 3.0 mg/dL: **yes/no**
   - ALT > 200 IU/L for Hep C: **yes/no**
3. **Was there a previous negative HCV Ab, Ag or RNA test in past 12 months? Yes/no.**
4. **Other likely diagnosis?** (e.g., liver disease due to alcohol exposure, other viral hepatitis, drug over use, etc.)? **yes/no. If yes, please specify:** _____

Other Information

- Recent vaccination with hepatitis B vaccine: **yes/no**
- Race and ethnicity: _____
- Hospitalization? **Yes/no. If yes, please specify:** _____

DRAFT

MIDIS ID: _____

If this is a probable or confirmed acute case, please gather the information needed for the Hepatitis extende tab in MIDIS

For 2 Weeks to 6 Months Prior to Onset of Clinical Signs	Yes/No
Was the patient a contact to an HCV case?	
Sexual Exposures in the Prior 6 Months	**Yes/No**
What is the sexual preference of the patient?	
How many male sex partners?	
How many female sex partners?	
Was the patient ever treated for an STD?	
For 2 Weeks to 6 Months Prior to Onset of Clinical Signs	**Yes/No**
Did the patient undergo hemodialysis	
Have an accidental stick/puncture with a needle or other object contaminated with blood?	
Receive blood or blood products (transfusion)	
Receive any IV infusions and/or injections in the outpatient setting	
Have other exposure to another person's blood	
Was patient employed as a public safety worker having direct contact with human blood	
In the Time Period Prior to Onset	**Yes/No**
Did the patient receive a tattoo	
Inject drugs not prescribed by a doctor	
Use street drugs but not inject	
Have any part of their body pierced (other than ear)?	

DRAFT

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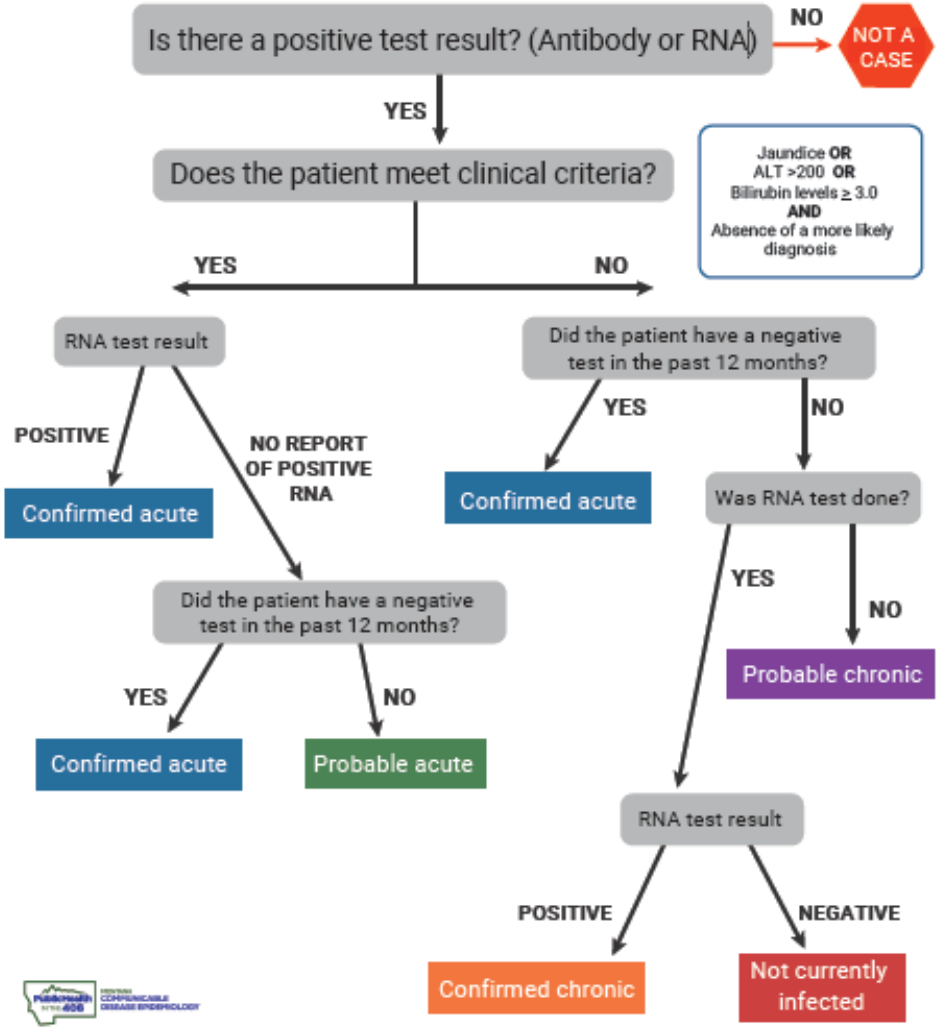
Applying case definition for Hepatitis C



created December, 2019

Resources:

- The ABCs of Hepatitis-CDC 2020
  - https://www.cdc.gov/hepatitis/resources/professionals/pdfs/abctable.pdf
- Hepatitis C Professional Resources Website-CDC
  - https://www.cdc.gov/hepatitis/hcv/profresourcesc.htm
- Montana Healthcare Programs website and questions may be directed to the Medicaid Pharmacist at 406-444-5951 or Pharmacy Program Officer at 406-444-2738. https://medicaidprovider.mt.gov/Portals/68/docs/forms/HepCPAForm01102020.pdf

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Thank you!!

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