

HEPATITIS C CASE CLASSIFICATION AND REPORTING IN MDSS

LHD HCV WEBINAR SERIES

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MARJORIE OSWALD, MPH
VIRAL HEPATITIS EPIDEMIOLOGIST

ADAM HART, MPH
VIRAL HEPATITIS EPIDEMIOLOGIST

OVERVIEW

- Case definitions and reporting requirements
- Reporting hepatitis C cases into MDSS
- Classifying hepatitis C cases
- Deduplicating/merging cases
- MDSS updates/lab reporting

CASE DEFINITIONS AND REPORTING REQUIREMENTS

ACUTE HEPATITIS C CASE DEFINITION, 2020

Clinical Criteria

All hepatitis C virus cases in each classification category should be > 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 >200 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 Hepatitis C virus (HCV) infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)

ACUTE HEPATITIS C CASE DEFINITION, 2020

Laboratory Criteria

Confirmatory laboratory evidence:

- Positive 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) (HCV antigen)

Presumptive laboratory evidence:

- A positive test for antibodies to hepatitis C virus (anti-HCV)

ACUTE HEPATITIS C CASE DEFINITION, 2020

Case Classification

Probable

- A case that meets clinical criteria and has presumptive laboratory evidence, **AND**
- Does not have a hepatitis C virus detection test reported, **AND**
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months,

Confirmed

- A case that meets clinical criteria and has confirmatory laboratory evidence, **OR**
- 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 CASE DEFINITION, 2020

Case Classification

Probable

- A case that does not meet **OR** has no report of clinical criteria, **AND**
- Has presumptive laboratory evidence, **AND**
- Has no documentation of anti-HCV or RNA test conversion within 12 months, **AND**
- Does not have an HCV RNA detection test reported.

Confirmed

- A case that does not meet **OR** has no report of clinical criteria, **AND**
- Has confirmatory laboratory evidence, **AND**
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months.

PERINATAL HEPATITIS C CASE DEFINITION, 2018

Clinical Criteria

Perinatal hepatitis C in pediatric patients may range from asymptomatic to fulminant hepatitis.

Laboratory Criteria For Diagnosis

- HCV RNA positive test results for infants between 2 to 36 months of age; **OR**
- HCV genotype test results for infants between 2 to 36 months of age or greater; **OR**
- HCV antigen test results for infants between 2 to 36 months of age or greater.

Epidemiologic Linkage

Maternal infection with HCV of any duration, if known. Not known to have been exposed to HCV via a mechanism other than perinatal (e.g. not acquired via healthcare).

Case Classification

Confirmed

Infant who has a positive test for HCV RNA nucleic acid amplification test (NAAT), HCV antigen, or detectable HCV genotype at ≥ 2 months and ≤ 36 months of age and is not known to have been exposed to HCV via a mechanism other than perinatal.

REPORTING REQUIREMENTS FOR HEPATITIS C

2022

REPORTABLE DISEASES IN MICHIGAN – BY CONDITION

A Guide for Physicians, Health Care Providers and Laboratories

Report the following conditions to the Michigan Disease Surveillance System (MDSS) or local health department (see reverse) within 24 hours if the agent is identified by clinical or laboratory diagnosis. See footnotes for exceptions.

Report the unusual occurrence, outbreak or epidemic of any disease or condition, including healthcare-associated infections.

Hepatitis C virus (all HCV test results including positive and negative antibody, RNA, and genotype tests) (6)

6) Report pregnancy status, if available.

ENTERING HEPATITIS C CASES INTO MDSS

[Cases](#)[New Case](#)[New Aggregate Cases](#)[Searches](#)[New Search](#)[New Aggregate Search](#)[Disease Specific Search](#)[Search Field Records](#)[Case Definitions](#)[Alert Rules](#)

Investigation Information

Reportable Condition*:

Case Status*:

 State Prison Case

Patient Information

Patient Status* : Patient Status Date* (mm/dd/yyyy) : Case Disposition* : First* : Last* : Middle : Street : City : County : State : Zip : Home Phone (###-###-####): Ext: Other Phone (###-###-####): Ext: Email: Onset Date (mm/dd/yyyy) : Referral Date (mm/dd/yyyy) : Diagnosis Date (mm/dd/yyyy) : Date of Death (mm/dd/yyyy) :

*indicates required items

Cases

New Case

New Aggregate Cases

Searches

New Search

New Aggregate Search

Disease Specific Search

Search Field Records

Case Definitions

Alert Rules

Blank Forms

User Profile

User Directory

Demographics

Race* :


- Caucasian
- Black/African American
- American Indian/Alaska Native
- Native Hawaiian/Pacific Islander
- Asian
- Other Race
- Unknown
- Refused to Answer

Sex* :

Hispanic Ethnicity* :

Arab Ethnicity :

Date of Birth / Age

Date of Birth (mm/dd/yyyy):  Age at Onset (if DOB unknown) : Age Unit :

Parent/Guardian (required if under 18)

First : Last : Middle :

Work / Occupation or School / Grade

Worksites / School :

Occupations / Grade :

Patient Identifiers

MDOC ID :

*indicates required items

Person Providing Referral

First : Last :
Phone (###-###-####): Ext: Email :

Primary Physician

First : Last :
Affiliation :
Phone (###-###-####): Ext: Email :

Street :
City : County : State : Zip :

Case Notes

CLASSIFYING HEPATITIS C CASES

2020 Hepatitis C Case Classification Table

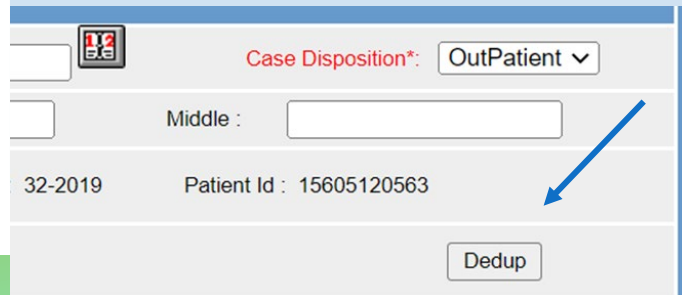
<i>Updated classification rules to be applied in cases reported on 01/01/2020 and thereafter.</i>	One or more of the following: Jaundice, <u>OR</u> Total bilirubin levels ≥ 3.0 mg/dL, <u>OR</u> ALT >200 IU/L, <u>AND</u> the absence of a more likely diagnosis <u>AND</u> age >36 months ¹	
	No <u>OR</u> Unknown	Yes
HCV Antibody Positive ² <u>AND</u> HCV Nucleic Acid Test Unknown <u>OR</u> HCV Antigen Test Unknown	Probable, Chronic	Probable, Acute
HCV Nucleic Acid Test Positive ³ <u>OR</u> HCV Antigen Test Positive	Confirmed, Chronic	Confirmed, Acute ⁴
HCV Nucleic Acid Test Negative	Not a Case	Not a case

¹All HCV cases should be >36 months of age, unless known to have been exposed non-perinatally.
²Any antibody result, regardless of the signal-to-cutoff ratio; includes rapid tests
³Nucleic Acid Tests for HCV include Quantitative HCV RNA tests, Qualitative HCV RNA tests, and HCV Genotype tests
⁴Automatically classify as Confirmed, Acute for a seroconversion if a negative HCV lab test is followed within 12 months by a positive HCV lab test, in the absence of a more likely diagnosis
 * If evidence indicating resolution of infection is received within the calendar year of a case being reported, the case status should be changed to "not a case."

CASE CLASSIFICATION SCENARIOS

Scenario 1

- A new case comes in with positive antibody and RNA lab results
- Person history shows a previous case from 2018 with that was chronic, probable
- What do you do?
 - Merge new case into the old case from 2018



The screenshot shows a user interface for case management. At the top, there is a 'Case Disposition*' dropdown menu set to 'OutPatient'. Below this, there are input fields for 'Middle :'. Further down, the text '32-2019 Patient Id : 15605120563' is displayed. At the bottom, there is a 'Dedup' button, which is highlighted with a blue arrow pointing to it from the right.

Scenario 2

- A new case comes in with positive antibody and RNA lab results and no clinical information
- Person history shows a previous case from 2018 that was acute, confirmed
- What do you do?
 - Keep new case and classify as chronic, confirmed
 - >6 months since acute case was reported

Scenario 3

- A new case comes in with a positive antibody result
 - No clinical information
- Person history shows a previous case from 2020 that was chronic, not a case
- What do you do?
 - Classify the new case as chronic, probable

CASE CLASSIFICATION SCENARIOS

New Negative HCV RNA Lab

- New negative RNA lab comes in for a case already in MDSS
- What do you do?
 - If the case has a referral date of this calendar year= change case status to not a case
 - If the case was from a previous year (already closed out, reported to CDC)
 - Case status does **NOT** change

Reinfections

- Existing case with lab evidence the person previously cleared HCV and are now re-infected
- What do you do?
 - Currently no different actions than a new lab coming in for an existing confirmed/probable case
 - Merge new lab/case to an existing confirmed/probable chronic case
- Reviewing how to handle reinfections, will likely change in the future

Case Created From a Negative Lab

- New case comes in with only a negative RNA or antibody lab result
- What do you do?
 - Close out as not a case
 - Notify MDHHS Viral Hepatitis Unit/Epis

DEDUPLICATING/MERGING CASES

HEPATITIS C DEDUPLICATION GUIDELINES

Why are there duplicate cases?

- Automated patient deduplication in the MDSS does not always catch every possible patient match
- For instance, cases referred with differences in middle names, and inmate number added to names, hyphenated last names, suffixes, etc.

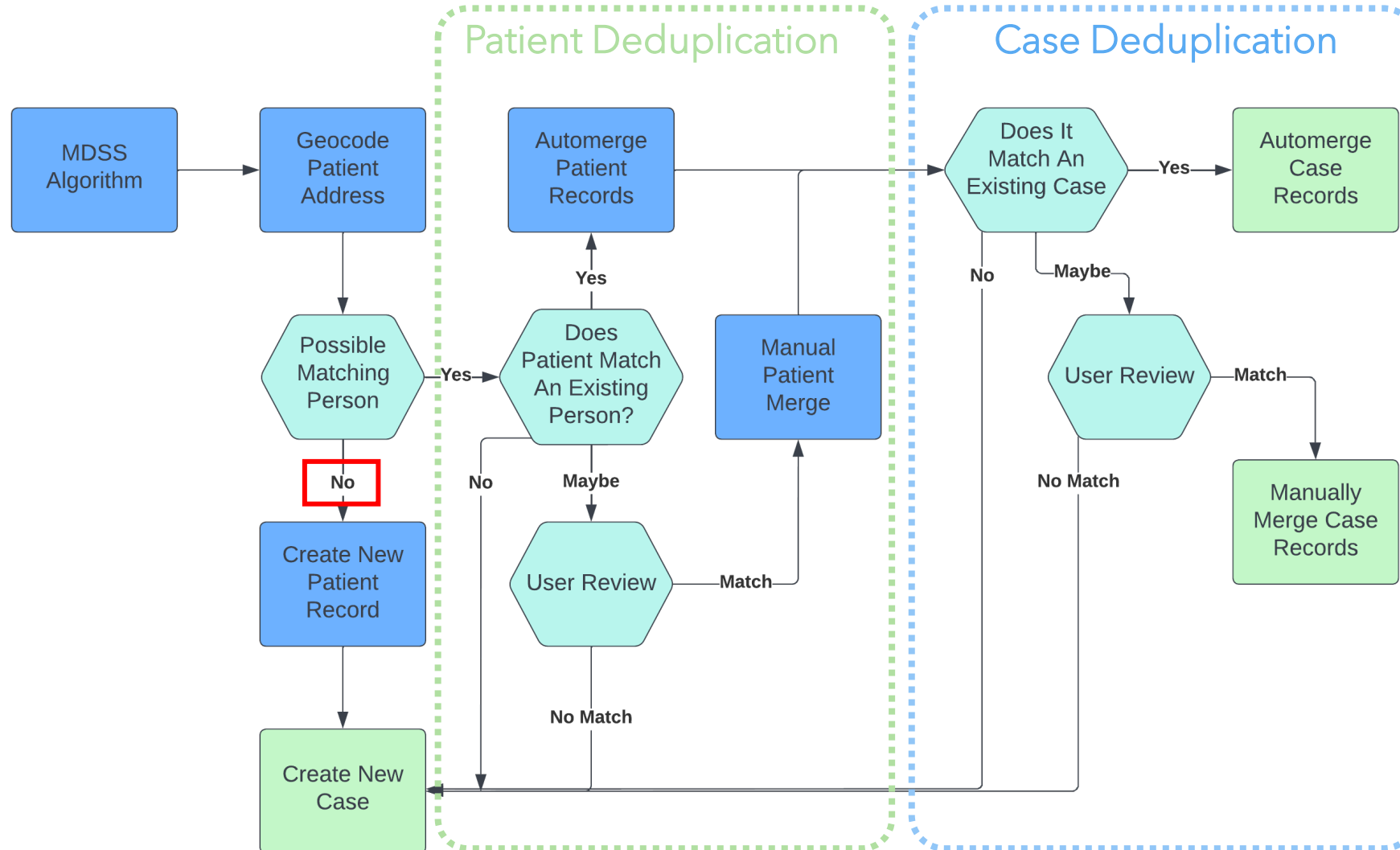
Dedup vs Supercede

- Use the dedupe button to deduplicate new cases when an appropriately classified case already exists for the patient
 - This should be the primary option
- Use a "Not a Case, Superseded" designation only to prevent loss of LHD-entered data in a duplicate case

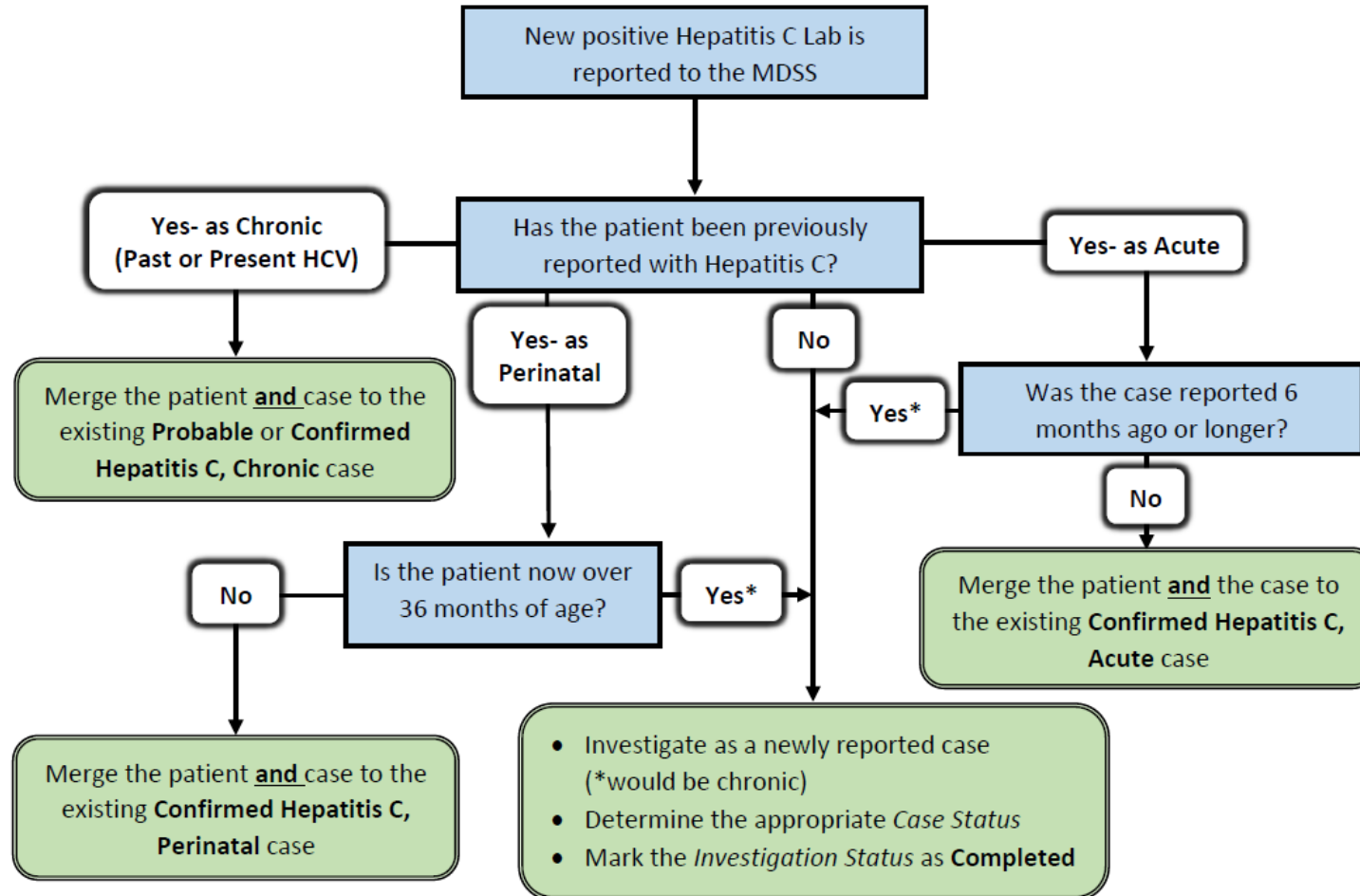
Considerations

- Confidence in match to previous case
- Status/Classification of previous case
- Timing of case reporting
- Data contained in new and old cases

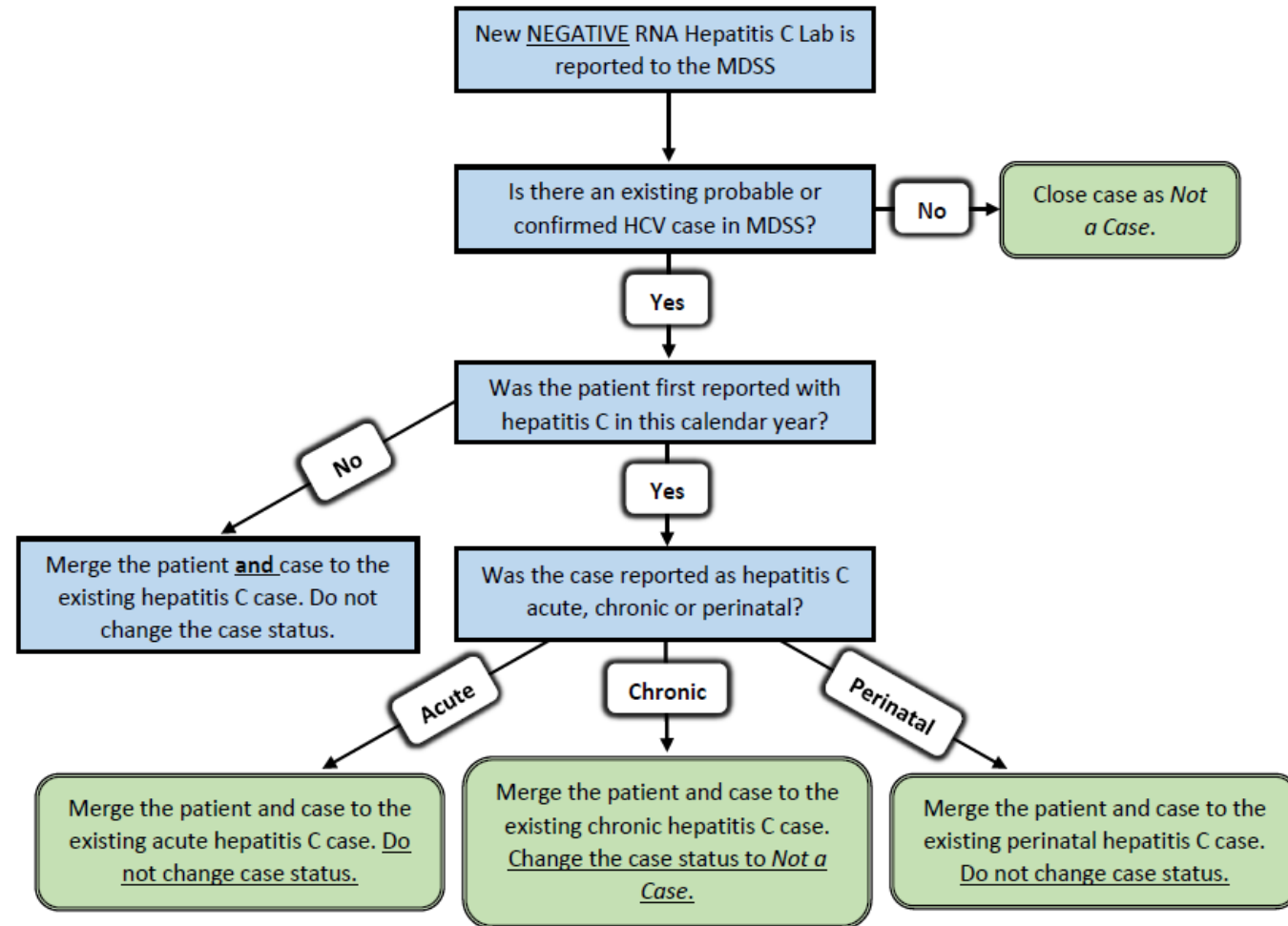
MDSS AUTOMATED DEDUPLICATION WORKFLOW



DEDUPLICATING POSITIVE HEPATITIS C REPORTS



DEDUPLICATING NEGATIVE HEPATITIS C REPORTS



SAMPLE DEDUPLICATION

Patient Deduplication						
Please select the records to merge with the data entered.						
Merge	Score	First Name	Middle Name	Last Name	Date of Birth	Gender
	Case Status	Investigation Status	Disease	Referral Date	Investigator	Jurisdiction
<input checked="" type="radio"/>	100.0%	JOHN		DOE JR	01/01/1990	MALE
<input type="radio"/>	100%	JOHN	X	DOE JR.	01/01/1990	MALE
	Probable	New	Hepatitis C, Chronic	07/11/2022	[REDACTED]	Statewide
<input type="radio"/>	84.54%	[REDACTED]				MALE
<input type="radio"/>	81.18%	[REDACTED]				MALE
	Confirmed	Completed	Novel Coronavirus COVID-19	12/28/2021	[REDACTED]	Kent County
<input type="radio"/>	72.65%	[REDACTED]				MALE
	Confirmed	Completed	Novel Coronavirus COVID-19	10/21/2021	[REDACTED]	St Clair County
<input type="radio"/>	72.65%	[REDACTED]				MALE
	Confirmed	Completed	Tuberculosis	05/25/2005	[REDACTED]	Kent County
	Not a Case	Superceded	Tuberculosis	06/08/2005	[REDACTED]	Kent County
<input type="radio"/>	72.46%	[REDACTED]				UNKNOWN
	Suspect	New	Novel Coronavirus COVID-19	03/30/2022	[REDACTED]	Macomb County

SAMPLE DEDUPLICATION

Patient Record Merge		
Source	New Data	Existing
Patient Record ID		19852103088
Created Date	07/11/2022	07/11/2022
Last Modified Date	07/11/2022	07/11/2022
First Name	<input type="radio"/> JOHN	<input checked="" type="radio"/> JOHN
Middle Name	<input type="radio"/>	<input checked="" type="radio"/> X
Last Name	<input type="radio"/> DOE JR	<input checked="" type="radio"/> DOE JR.
Date of Birth	<input type="radio"/> 01/01/1990	<input checked="" type="radio"/> 01/01/1990
Gender	<input type="radio"/> MALE	<input checked="" type="radio"/> MALE
Race	<input type="radio"/> UNKNOWN	<input checked="" type="radio"/> UNKNOWN
Ethnicity	<input type="radio"/> UNKNOWN	<input checked="" type="radio"/> UNKNOWN
Arab Ethnicity	<input type="radio"/> UNKNOWN	<input checked="" type="radio"/> UNKNOWN
Home Phone	<input type="radio"/>	<input checked="" type="radio"/>
Other Phone	<input type="radio"/>	<input checked="" type="radio"/>
Parent/Guardian First Name	<input type="radio"/>	<input checked="" type="radio"/>
Parent/Guardian Middle Name	<input type="radio"/>	<input checked="" type="radio"/>
Parent/Guardian Last Name	<input type="radio"/>	<input checked="" type="radio"/>
Patient Status	<input checked="" type="radio"/> ALIVE	<input type="radio"/> ALIVE
Patient MDOC ID	<input type="radio"/>	<input checked="" type="radio"/>
Patient Addresses		
Addresses	<input checked="" type="checkbox"/> MAKE CURRENT ADDRESS 555 MAIN ST	555 MAIN ST ANONYMOUS, MI
Patient Case Information		
Case Status		Probable
Investigation Status		New
Disease		Hepatitis C, Chronic
Referral Date		07/11/2022
Investigator		HARTWICK, EDWARD F
Jurisdiction		Statewide
<input type="button" value="Continue"/> <input type="button" value="Back"/> <input type="button" value="Defer"/> <input type="button" value="No Merge"/> <input type="button" value="Help"/>		

SAMPLE DEDUPLICATION

Patient Record Merge Confirmation	
Patient Record #19852103088 will be replaced with the merged Patient Record. A new patient record will be created with the following merged patient data.	
Merged Record Details	
Status	ALIVE
First Name	JOHN
Middle Name	X
Last Name	DOE JR.
Date of Birth	01/01/1990
Gender	MALE
Race	UNKNOWN
Ethnicity	UNKNOWN
Arab Ethnicity	UNKNOWN
Home Phone	
Other Phone	
Parent/Guardian First Name	
Parent/Guardian Middle Name	
Parent/Guardian Last Name	
MDOC ID	
Address(es)	555 MAIN ST ANONYMOUS, MI
<input type="button" value="Complete Merge"/> <input type="button" value="Back"/> <input type="button" value="Defer"/> <input type="button" value="No Merge"/> <input type="button" value="Help"/>	

SAMPLE DEDUPLICATION

Case Deduplication for JOHN X DOE JR.

Select an existing JOHN X DOE JR. case as a match or choose to create a new case from the entered data.

Investigation Status	Case Status	Disease	Referral Date	Onset Date	Investigator	Jurisdiction	
New		Hepatitis C, Chronic	07/11/2022		TBD	TBD	<input type="button" value="Create"/>
New	Probable	Hepatitis C, Chronic	07/11/2022		HARTWICK, EDWARD F	Statewide	<input type="button" value="Matches Existing"/>

Case Record Merge

Case	New Data	Existing
Investigation Status	New	New
Case Status		Probable
Condition	Hepatitis C, Chronic	Hepatitis C, Chronic
Referral Date	07/11/2022	07/11/2022
Onset Date		
Investigator	TBD	EDWARD F,HARTWICK
Jurisdiction	TBD	Statewide
Case Details	<input type="button" value="View PDF"/>	<input type="button" value="View PDF"/>
Case to Keep	<input type="radio"/>	<input checked="" type="radio"/>

MDSS UPDATES / LAB REPORTING

MDSS UPDATES AND LAB REPORTING

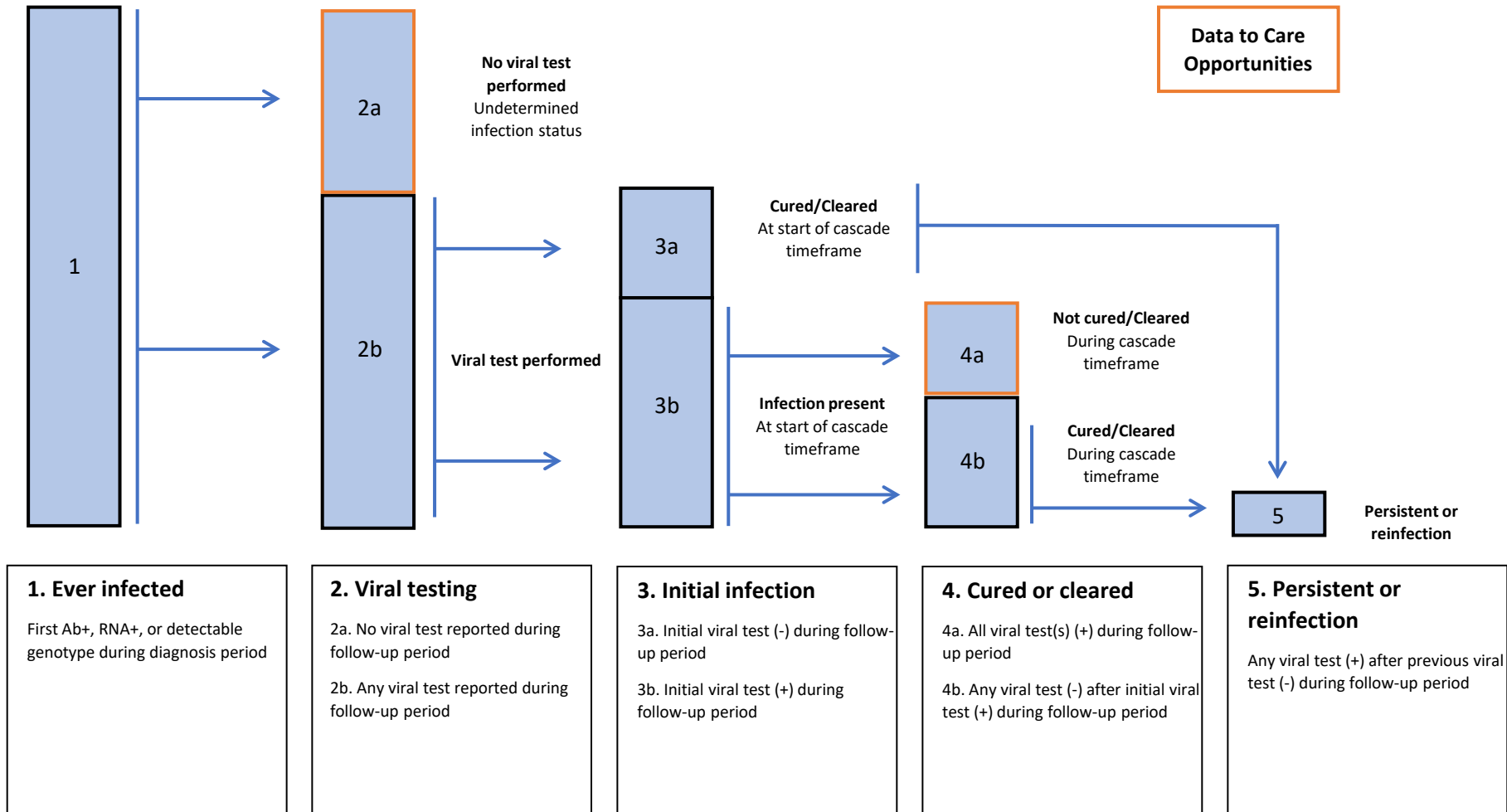
Changes to Diagnostics Section

- The diagnostics section of the case detail form is now static (un-editable) for manual entry of lab report data
- Lab reports must now be entered via “Create New Lab” button in the Lab Reports tab

Rationale For Change

- Relates to objectives for an ongoing CDC initiative to create viral hepatitis clearance cascades
 - Uniformity and consistency of hepatitis C lab reporting is vital
- Allows for expedited identification of persons with no documentation of cure or clearance of infection, and more focus on linkage to care

SAMPLE CLEARANCE CASCADE



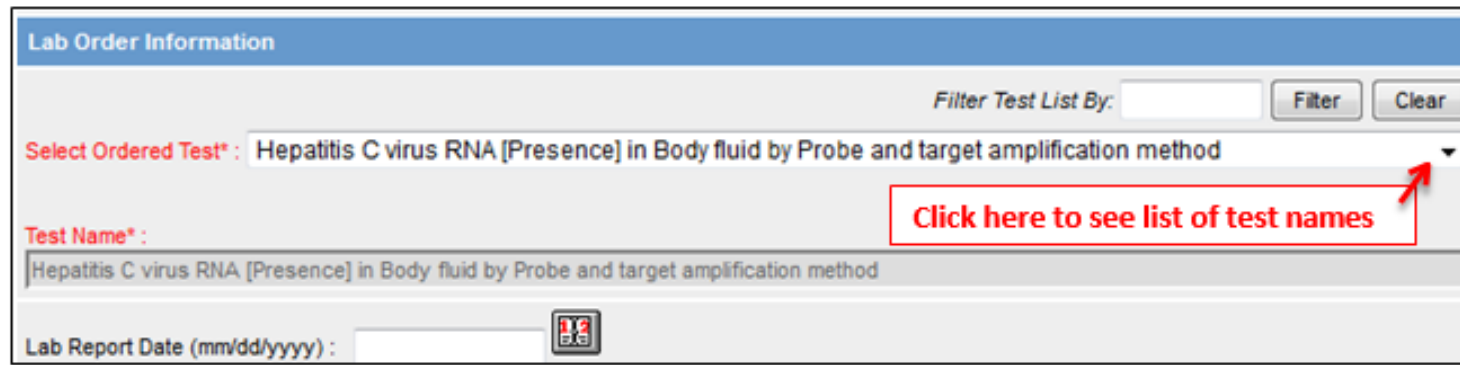
MANUAL ENTRY OF LAB REPORTS

- Search for the patient in the MDSS by name and/or DOB
 - If the person does not exist within the MDSS, proceed to create a new case with the appropriate classification, enter demographic information, click "Enter Lab Data" and "Create New Lab Report"
- Navigate to the lab reports tab of the corresponding patient
 - If the case is in completed status, you will need to change to completed-follow up to enter lab data and then back to completed after finishing



MANUAL ENTRY OF LAB REPORTS

- To create:
 - Click “create new lab report” and select the appropriate test from the “Select Ordered Test” drop down (Always select an option from this drop-down menu)
 - If “Other” is selected, this result will not populate the case report form and may result in inability to close the case under the correct classification
 - The drop-down list is populated with common test names for the condition that is currently being entered or edited. Test and result names that are specific to the condition being reported are listed first followed by generic tests
 - Always use the most detailed result provided. (In order from least detail to most detail: HCV Ab, HCV RNA [Presence], HCV RNA [Units/volume], HCV Genotype)



The screenshot shows a web form titled "Lab Order Information". At the top right, there is a "Filter Test List By:" field with "Filter" and "Clear" buttons. Below this is a dropdown menu labeled "Select Ordered Test*" with the selected text "Hepatitis C virus RNA [Presence] in Body fluid by Probe and target amplification method". A red box with a red arrow points to the dropdown arrow. Below the dropdown is a "Test Name*" field containing the same text. At the bottom left, there is a "Lab Report Date (mm/dd/yyyy):" field with a calendar icon.

MANUAL ENTRY OF LAB REPORTS

- Complete the provider/lab/specimen information to the best of your ability
- Lab report date: the date the result was produced (if this is missing, use the date that information was acquired)
 - Whenever possible, complete the specimen collection date
- Click "New Result" and enter the result as completely as possible
 - Always use the coded result or numeric result section when possible
 - If entering a numeric result, the first drop down is the numeric symbol (=, >, <), the second drop down is most commonly used for a decimal (see below), while the third drop down denotes the units
- Click "Add Result"

The screenshot shows a "New Result" form with the following fields and options:

- Reported Test Name:** Filter Test List By: [] Filter Clear. Select Test: Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe with amplification.
- Coded Result:** Filter Result List By: [] Filter Clear. Select Result: []
- Text Result:** []
- Numeric Result:** [x] Numeric Result: [=] [555555] [.] [5] [iu/mL]
- Comments:** []
- Relevant Clinical Information:** []

MANUAL ENTRY OF LAB REPORTS

- Be sure to click "Save & Finish New Lab"
 - The lab will not be saved if you skip this step
- If entered correctly using coded selections from the drop-down menu/numeric result section the lab data should be present in the case report form

The screenshot shows a web-based lab report entry form. At the top, there is a blue header bar with the word "Results" on the left and a "New Result" button on the right. Below the header, the "Reported Test Name" is "Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe with amplification", with "Edit" and "Delete" buttons to its right. The form contains several input fields: "Numeric Result" with the value "= 555555 . 5 iu/mL", "Reference Range", "Comments", and "Relevant Clinical Information". At the bottom of the form, there are three buttons: "Save & Finish New Lab" (highlighted with a red box), "Cancel", and "Help".

Results		New Result
Reported Test Name : Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe with amplification		Edit Delete
Numeric Result :	= 555555 . 5 iu/mL	
Reference Range :		
Comments :		
Relevant Clinical Information :		
Save & Finish New Lab		Cancel Help

Example 1: HCV Ab lab result added with coded result







New Result

Reported Test Name : *Filter Test List By:*
 Select Test: Hepatitis C virus Ab [Presence] in Body fluid
 Hepatitis C virus Ab [Presence] in Body fluid

Coded Result : *Filter Result List By:*
 Select Result: POSITIVE
 POSITIVE

Text Result :

Numeric Result :

Hepatitis C		
Antibody to hepatitis C virus [anti-HCV]	POSITIVE ▾	06/23/2022 
Anti-HCV signal to cut-off ratio	<input type="text"/>	<input type="text"/> 
Supplemental anti-HCV assay [e.g., RIBA]	<input type="text"/> ▾	<input type="text"/> 
HCV RNA [e.g., PCR]	<input type="text"/> ▾	<input type="text"/> 
Quantitative Hepatitis C RT-PCR	<input type="text"/> ▾	<input type="text"/> 
Qualitative Hepatitis C RT-PCR	<input type="text"/> ▾	<input type="text"/> 
Hepatitis C Virus Genotype	<input type="text"/>	<input type="text"/> 

Example 2: HCV RNA lab result added with numeric result

New Result

Filter Test List By:

Reported Test Name : Select Test: Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe with amplification

Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe with amplification

Coded Result : Filter Result List By:

Select Result:

Text Result :

Numeric Result :

Hepatitis C		
Antibody to hepatitis C virus [anti-HCV]	<input type="button" value="v"/>	<input type="text"/> <input type="button" value="1 2 e.g"/>
Anti-HCV signal to cut-off ratio	<input type="text"/>	<input type="text"/> <input type="button" value="1 2 e.g"/>
Supplemental anti-HCV assay [e.g., RIBA]	<input type="button" value="v"/>	<input type="text"/> <input type="button" value="1 2 e.g"/>
HCV RNA [e.g., PCR]	<input type="button" value="v"/>	<input type="text"/> <input type="button" value="1 2 e.g"/>
Quantitative Hepatitis C RT-PCR	POSITIVE <input type="button" value="v"/>	06/23/2022 <input type="button" value="1 2 e.g"/>
Qualitative Hepatitis C RT-PCR	<input type="button" value="v"/>	<input type="text"/> <input type="button" value="1 2 e.g"/>
Hepatitis C Virus Genotype	<input type="text"/>	<input type="text"/> <input type="button" value="1 2 e.g"/>

Example 3: HCV RNA lab result added with text result

New Result








Filter Test List By:

Reported Test Name : Select Test: **Hepatitis C virus RNA [Presence] in Body fluid by Probe and target amplification method** ▼

Coded Result : Filter Result List By:
 Select Result:

Text Result :

Numeric Result :

Hepatitis C		
Antibody to hepatitis C virus [anti-HCV]	<input type="text"/>	<input type="text"/> 
Anti-HCV signal to cut-off ratio	<input type="text"/>	<input type="text"/> 
Supplemental anti-HCV assay [e.g., RIBA]	<input type="text"/>	<input type="text"/> 
HCV RNA [e.g., PCR]	<input type="text"/>	<input type="text"/> 
Quantitative Hepatitis C RT-PCR	<input type="text"/>	<input type="text"/> 
Qualitative Hepatitis C RT-PCR	POSITIVE ▼	<input type="text" value="06/23/2022"/> 
Hepatitis C Virus Genotype	<input type="text"/>	<input type="text"/> 

Example 4: HCV Genotype lab result added with coded result

New Result








Filter Test List By:

Reported Test Name : Select Test: Hepatitis C virus genotype [Identifier] in Serum or Plasma by Probe and target amplification method

Coded Result : Filter Result List By:
 Select Result: Hepatitis C virus genotype 1

Text Result :

Numeric Result :

Hepatitis C		
Antibody to hepatitis C virus [anti-HCV]	<input type="text"/>	<input type="text"/> 
Anti-HCV signal to cut-off ratio	<input type="text"/>	<input type="text"/> 
Supplemental anti-HCV assay [e.g., RIBA]	<input type="text"/>	<input type="text"/> 
HCV RNA [e.g., PCR]	<input type="text"/>	<input type="text"/> 
Quantitative Hepatitis C RT-PCR	<input type="text"/>	<input type="text"/> 
Qualitative Hepatitis C RT-PCR	<input type="text"/>	<input type="text"/> 
Hepatitis C Virus Genotype	1	06/23/2022 

TROUBLESHOOTING

- If you are unable to close a case because the diagnostics section is not complete:
 - Check to be sure the lab results are completed using the correct coded names and results
 - If the issue is with an ELR, click to edit the lab and make necessary changes
- Periodically there may be issues with system interpretation of electronic messaging from labs
 - If labs and results are recorded correctly but not mapping to the correct field of the case report form, report the issue to your regional epidemiologist

GUIDANCE NOW AVAILABLE!

(MICHIGAN.GOV/HEPATITIS > HEPATITIS C > REPORTING)

MDSS Manual Laboratory Entry Quick Guidance

Methods For Manual Entry of Laboratory Data:
We encourage manual entry of all hepatitis C testing results that are not present in the MDSS. Results may be obtained in a variety of ways (example: fax, email, verbal report from a receipt of laboratory data).

- Search for the patient in the MDSS by name and/or DOB
 - If the person does not exist within the MDSS, proceed to create a new classification, enter demographic information, click "Enter Lab Data" and proceed by following the guidelines below (start at step 5)
- Navigate to the lab reports tab of the corresponding patient

Case Reporting | Address History | Demographics | Referrer | **Lab Reports** | Notes | Map

- If the case is in completed status, you will need to change to completed then back to completed after finishing
- Locate the HCV result on the faxed lab
 - If the result is a reactive (positive) HCV Ab result, only enter the lab if that
 - If the result is a RNA or genotype result, always enter the result whether
 - To create:
 - Click "create new lab report" and select the appropriate test from the " (Always select an option from this drop down menu)
 - If "Other" is selected, this result will not populate the case report inability to close the case under the correct classification
 - The drop down list is populated with common test names for that being entered or edited. Test and result names that are specific are listed first followed by generic tests
 - Always use the most detailed result provided. (In order from least HCV RNA [Presence], HCV RNA [Units/volume], HCV Genotype

Lab Order Information

Select Ordered Test*: Hepatitis C virus RNA [Presence] in Body fluid by Probe and target amplification

Test Name*: Hepatitis C virus RNA [Presence] in Body fluid by Probe and target amplification method [Click here to see](#)

Lab Report Date (mm/dd/yyyy):

- Complete the provider/lab/specimen information to the best of your ability given been provided (depending on the circumstance, some of this may be omitted)
 - Lab report date: the date the result was produced (if this is missing, use acquired)
 - Whenever possible, complete the specimen collection date
- Click "New Result" and enter the result as completely as possible

Michigan Department of Health and Human Services – Viral Hepatitis Unit - [mdhhs](#) - Updated: June 29, 2022

- Always use the coded result or numeric result section when possible. The MDSS mapping process does not analyze free text fields for auto-population of the case report form, and this may result in inability to close the case under the correct classification
- If entering a numeric result, the first drop down is the numeric symbol (=), most commonly used for a decimal (see below), while the third drop down

New Result

Filter Test List By: Filter Clear

Select Test: Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe with

Reported Test Name: Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe with amplification

Filter Result List By: Filter Clear

Select Result:

Coded Result:

Text Result:

Numeric Result: [=] 555555 [.] 5 [u]/mL

Comments:

Relevant Clinical Information:

- The MDSS can recognize some values in a text result as valid, but we strongly encourage numeric results whenever possible
- See examples of lab result entry and mapping to the case report form in the

- Click "Add Result"
- Be sure to click "Save & Finish New Lab" (if not, the lab will not be entered)

Results

Reported Test Name: Hepatitis C virus RNA [Units/volume] (viral load) in Serum or Plasma by Probe with amplification

Numeric Result: = 555555 . 5 u/mL

Reference Range:

Comments:

Relevant Clinical Information:

[Save & Finish New Lab](#) Cancel Help

- If entered correctly using coded selections from the drop down menu/numeric result be present in the case report form

Sample Lab Result Entry and Mapping to the Case Report Form:

Visual Sample	Ordered Test Dropdown on Lab Order Tab	Hepatitis C Diagnostic Tests Section
Example 1	Hepatitis C virus Ab [Presence] in Body fluid	Antibody to hepatitis C virus [anti-HCV]
Example 2	Hepatitis C virus RNA [Presence] in Body fluid by Probe and target amplification method	HCV RNA Qualitative Hepatitis C RT-PCR
Example 3	Hepatitis C virus Ag [Units/volume] in Serum by Immunoassay	HCV RNA Quantitative Hepatitis C RT-PCR
Example 4	Hepatitis C virus genotype [Identifier] in Serum or Plasma by Probe and target amplification method	Hepatitis C Virus Genotype
	Other	Not mapped

Example 1: Lab result from add new manual Lab Tab

New Result

Filter Test List By: Filter Clear

Select Test: Hepatitis C virus Ab [Presence] in Body fluid

Reported Test Name: Hepatitis C virus Ab [Presence] in Body fluid

Filter Result List By: Filter Clear

Select Result: POSITIVE

Coded Result: POSITIVE

Text Result:

Numeric Result:

Diagnostic Section population in CRF:

Hepatitis C

Antibody to hepatitis C virus [anti-HCV]	POSITIVE	08/23/2022
Anti-HCV signal to cut-off ratio		
Supplemental anti-HCV assay (e.g., RIBA)		
HCV RNA (e.g., PCR)		
Quantitative Hepatitis C RT-PCR		
Qualitative Hepatitis C RT-PCR		
Hepatitis C Virus Genotype		

THANK YOU!

Marjorie Oswald, MPH
Viral Hepatitis Epidemiologist
MDHHS
OswaldM@michigan.gov

Adam Hart, MPH
Viral Hepatitis Epidemiologist
MDHHS
HartA6@michigan.gov

Viral Hepatitis Unit
MDHHS
MDHHS-Hepatitis@michigan.gov
www.michigan.gov/hepatitis