

MDSS Manual Laboratory Entry Quick Guidance

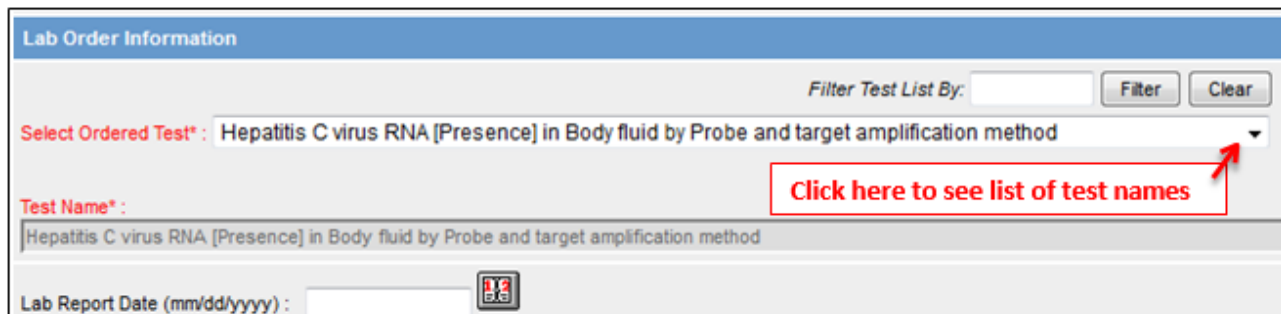
Methods For Manual Entry of Laboratory Data:

We encourage manual entry of all hepatitis C testing results that are not present in the MDSS lab report tab. These results may be obtained in a variety of ways (example: fax, email, verbal report from a medical professional, etc.). Upon receipt of laboratory data:

1. Search for the patient in the MDSS by name and/or DOB
 - a. 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”, then proceed by following the guidelines below (start at step 5)
2. Navigate to the lab reports tab of the corresponding patient



- a. 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
3. Locate the HCV result on the faxed lab
 - a. If the result is a reactive (positive) HCV Ab result, only enter the lab if there is no prior reactive HCV Ab
 - b. If the result is a RNA or genotype result, always enter the result whether positive or negative
 4. To create:
 - a. 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)**
 - i. 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
 - ii. 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
 - iii. 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)

A screenshot of a web form titled 'Lab Order Information'. It features a 'Filter Test List By:' field with 'Filter' and 'Clear' buttons. Below is a 'Select Ordered Test*' dropdown menu with the text 'Hepatitis C virus RNA [Presence] in Body fluid by Probe and target amplification method'. A red box highlights the dropdown arrow with the text 'Click here to see list of test names' and a red arrow pointing to the dropdown arrow. Below the dropdown is a 'Test Name*' field with the same text as the dropdown. At the bottom is a 'Lab Report Date (mm/dd/yyyy):' field with a calendar icon.

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

- a. 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
- b. 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

- c. The MDSS can recognize some values in a text result as valid, but we strongly suggest using coded or numeric results whenever possible
- d. See examples of lab result entry and mapping to the case report form in the next section

7. Click “Add Result”

8. Be sure to click “Save & Finish New Lab” (if not, the lab will not be entered)

9. 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

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:

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

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

Text Result :

Numeric Result :

Diagnostic Section population in CRF:

Hepatitis C		
Antibody to hepatitis C virus [anti-HCV]	POSITIVE <input type="button" value="v"/>	06/23/2022 <input type="button" value="12 5:3"/>
Anti-HCV signal to cut-off ratio	<input type="text"/>	<input type="text"/> <input type="button" value="12 5:3"/>
Supplemental anti-HCV assay [e.g., RIBA]	<input type="text"/> <input type="button" value="v"/>	<input type="text"/> <input type="button" value="12 5:3"/>
HCV RNA [e.g., PCR]	<input type="text"/> <input type="button" value="v"/>	<input type="text"/> <input type="button" value="12 5:3"/>
Quantitative Hepatitis C RT-PCR	<input type="text"/> <input type="button" value="v"/>	<input type="text"/> <input type="button" value="12 5:3"/>
Qualitative Hepatitis C RT-PCR	<input type="text"/> <input type="button" value="v"/>	<input type="text"/> <input type="button" value="12 5:3"/>
Hepatitis C Virus Genotype	<input type="text"/>	<input type="text"/> <input type="button" value="12 5:3"/>

Example 2: Lab result from add new manual Lab Tab

New Result

Filter Test List By: Filter Clear

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: Filter Clear
 Select Result:

Text Result:

Numeric Result: =

Diagnostic Section population in CRF:

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	POSITIVE	06/23/2022
Qualitative Hepatitis C RT-PCR	<input type="text"/>	<input type="text"/>
Hepatitis C Virus Genotype	<input type="text"/>	<input type="text"/>

Example 3: Lab result from add new manual Lab Tab:

New Result

Filter Test List By: Filter Clear

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

Coded Result: Filter Result List By: Filter Clear
 Select Result:

Text Result: positive

Numeric Result:

Diagnostic Section population in CRF:

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	06/23/2022
Hepatitis C Virus Genotype	<input type="text"/>	<input type="text"/>

Example 4 : Lab result from add new manual Lab Tab

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 ▼
Hepatitis C virus genotype [Identifier] in Serum or Plasma by Probe and target amplification method

Filter Result List By:

Coded Result : Select Result: Hepatitis C virus genotype 1 ▼
Hepatitis C virus genotype 1

Text Result :

Numeric Result : ▼ ▼ ▼

Diagnostic Section population in CRF:

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	<input type="text" value="1"/>	<input type="text" value="06/23/2022"/>