NASTAD

TOOLKIT

Viral Hepatitis Testing

STRATEGIES FOR ASSESSING LABORATORIES

NOVEMBER 2022

This toolkit is intended to assist health department viral hepatitis programs to assess viral hepatitis testing in laboratories operating in their jurisdictions. NASTAD will continue to update the resources available in association with this toolkit as health department peers and other partners develop and implement laboratory assessment and related activities.

Contents

Why should you assess laboratory testing practices?

Assessing the practices of laboratories performing testing for viral hepatitis infection can assist health departments in advancing expansion of viral hepatitis testing, improving engagement and continuity of care to treat and cure viral hepatitis, and strengthening public health surveillance by providing foundational knowledge to inform health communication, education, training, and technical assistance activities. Specific objectives that health departments may wish to accomplish through an assessment of laboratories include:

- Identifying and describing current and potential laboratory capacity for viral hepatitis testing.
- Identifying current laboratory practices relevant to screening for and diagnosis of viral hepatitis infection, including testing strategies essential to efficient and timely engagement in treatment for infection.
- Identifying challenges and factors associated with increasing testing uptake, and implementing testing strategies that promote treatment engagement, including reflex confirmation testing.
- Informing education, training, and capacity building assistance to support increased testing for viral hepatitis, and to improve treatment engagement.
- Evaluating the quality and completeness of reporting infections to public health,
- Strengthening public health surveillance; and
- Responding to requirements of federal viral hepatitis funding.

Additional consideration: health departments should consider focusing laboratory assessment activities consistent with epidemiological impact. You may, for example, choose to solely focus on hepatitis C if you have a low burden of HBV infection and therefore assessing HBV testing practices may be a lower priority.

What domains should be included in an assessment?

There are several domains which may be appropriate for assessment activities. The specific areas of inquiry should be informed by the objectives for assessment. Below are key areas which health departments may consider in developing their approach to assessing laboratories with respect to viral hepatitis testing:

(1) Laboratory capacity, including:

a. **Tests *performed* by the laboratory, including specific assays and test platforms.** Identifying which tests are or are not performed by a laboratory "in-house," can help provide an understanding of current laboratory capacity. In addition, identifying testing platforms used/available within an individual laboratory can help to illuminate opportunities for expansion of testing, including testing for additional infections. Contemporary laboratory test platforms support multiplex testing. Even if a laboratory is not currently performing testing for infection(s) of interest, the test platforms used by the laboratory may enable testing for other infections in the future. For example, a laboratory may routinely perform testing for chlamydia and gonorrhea. Depending on the test platform that the laboratory uses, it may also be possible to use that platform to perform HCV RNA testing. Identifying the specific assays used by a laboratory may also help to clarify interpretation of test results reported to the health department.

b. **Overall volume of testing performed, and positivity for the infection(s) of interest (e.g., HCV).** Examining testing and positivity can help health departments to gain an understanding of laboratory capacity, and the potential to support expanded testing. It can also help with evaluating the completeness of existing reporting to public health. Some jurisdictions may also consider determining volume and percent positivity separately.

(2) Laboratory practices and workflows including:

a. **Tests *referred* to other laboratories.** All laboratories do not perform all tests. In addition, a laboratory may or may not perform all tests in-house for which it accepts orders. Some or all tests ordered, including individual tests that are part of a sequence of tests, may be referred to other laboratories. For example, a laboratory may perform HCV antibody testing in-house, but refer HCV RNA testing to another laboratory. It is common for health systems, comprised of multiple affiliated hospitals and clinics, to consolidate testing, particularly higher complexity molecular testing, in a single laboratory within the health system. It is also not uncommon for laboratories to refer more complex or specialized testing to commercial laboratories. Understanding which tests a laboratory performs in-house, and which tests are referred will contribute to a better understanding of gaps in testing, such as receipt of supplemental testing to confirm diagnosis. Identifying referral testing arrangements may also be helpful to interpreting test results reported to public health.

b. **The sequence (i.e., test algorithm) of tests performed for the infection(s) of interest.** In order to diagnose certain infections, including HCV, multiple tests must be performed in sequence. Ascertaining whether a laboratory offers and/or performs all tests within an algorithm will assist health departments in identifying gaps in testing that may be addressed by changes to procedures or workflows, or through training and education. For example, a laboratory may perform HCV antibody testing, but does not perform or refer specimens for HCV RNA testing to confirm infection. Laboratory personnel may not be aware of the value of supplemental testing to confirm infection and could benefit from education to address this gap. Alternately, the laboratory may not currently have a mechanism to accomplish HCV RNA testing and may benefit from assistance in establishing a partnership with a laboratory that can perform HCV RNA testing.

c. **The circumstances under which certain tests or testing sequences are performed.** Various tests or testing sequences may be ordered and/or performed by a laboratory depending on factors which may include: (1) circumstances of the patient (e.g., pregnancy, other "risk" for infection), (2) the clinic or department in which a patient encounter occurred (e.g., testing performed in an emergency department or part of an outbreak), or (3) facility-specific policies/procedures (e.g., as part of intake for treatment, panel testing). For example, HBV is often included in obstetric panels, and HCV as part of these panels is becoming more common. In another example, laboratories may provide reflex to HCV RNA as a standard of practice for health care workers as part of exposure panels. At the same time, however, reflex to HCV RNA for patients may be available only if ordered by a provider. Understanding the specific circumstances under which tests and testing sequences are performed will assist the health department to understand gaps in testing, and to identify strategies to address them.

d. **Tests which may be ordered through a laboratory.** All laboratories do not offer all tests. Identifying the laboratories which offer testing for the infection(s) of interest will assist health departments to focus future communication, training, and technical assistance. Assessing the specific test orders accepted by the laboratory may be useful to understanding gaps in testing. For example, some laboratories may permit ordering of "stand alone" HCV antibody tests and reflex to HCV RNA for HCV antibody positive results may not be offered or may only be available if specifically ordered by a provider, or other circumstances.

(3) Other areas of potential interest for future considerations as funding allows may include:

a. **Challenges and facilitators.** Laboratories weigh several factors in making decisions about what tests and testing strategies they offer. A range of policy, administrative, operational, and resource issues are among these. Assessing challenges and facilitators that laboratories have experienced or might anticipate relative to expanding testing for infections of interest, or in changing practices such as implementing reflex testing will assist in evaluating the feasibility of desired changes, and to identify the type of support that a health department may be able to provide. It may be instructive to obtain the perspective of laboratories that have successfully implemented a particular test and/or testing strategy to identify strategies which may help other laboratories overcome similar challenges.

b. **Data collected and reported by laboratories.** Public health surveillance relies significantly on laboratory reporting, which is often incomplete in terms of critical patient information such as race and ethnicity and pregnancy status. Assessment may provide an opportunity to identify data collected in the laboratory information system, but not currently reported to public health, or to explore possibilities for improved data collection and reporting, including opportunities for leveraging data available in EHRs from submitting clinical facilities/providers. Assessment of laboratories also provides an opportunity to identify laboratories who may not be reporting, or reporting inconsistently, to public health authorities, consistent with jurisdictional statute and regulation.

How do you identify the targets for assessment of laboratory practices?

One or more sources which identify individual laboratories, and which ideally provide current contact information is essential. However, collaboration with key, credible stakeholders throughout your assessment is equally important not only to identify and provide contact information, but to facilitate access and engagement of the laboratories.

There are multiple sources of data and information which could be used to identify the "universe" of laboratories that would be appropriate targets for assessment. Some of these are described below.

(1) State/local public health laboratories (PHLs): State and local PHLs maintain active and ongoing communication with and provide training and technical assistance to clinical laboratories that serve as sentinel laboratories. Your PHL may provide contact information and may also be able to facilitate laboratory engagement in assessment activities (e.g. by co-signing a solicitation, or reaching out on your behalf). Your PHL can also provide assistance in developing the assessment methods and tools. Here is a listing of Association of Public Health Laboratories (APHL) member labs: https://www.aphl.org/membership/Pages/memberlabs.aspx. APHL conducts a periodic survey of state and local public health laboratories to ascertain current capacity and practices regarding laboratory HIV and HCV testing, Survey domains and questions may aid health departments in developing methods for assessment of clinical laboratories. The report of the most recent survey is available at: https://www.aphl.org/aboutAPHL/publications/Documents/ID-2022March-HIV-and-HCV-Survey-Report.pdf. PHLs are well-connected with commercial laboratories, including regional and national commercial laboratories, and therefore may be able to connect you with appropriate contacts in commercial laboratories in your jurisdiction, or make introductions.

(2) Disease surveillance programs: Disease surveillance and/or informatics programs work routinely with laboratories reporting to the health department. Disease surveillance programs can help you to identify high volume reporting laboratories to focus assessment efforts, and they can likely provide contact information and may be able to make introductions.

(3) Licensing boards/agencies: Licensing of clinical laboratories is regulated by states, and in many jurisdictions falls within the purview of the state health department. You may be able obtain a list of licensed laboratories and contact information. Licensing boards/agencies may also be willing to assist with some communication to laboratories.

(4) Center for Medicare and Medicaid Services (CMS): CMS provides a listing of Clinical Laboratory Improvement Amendments (CLIA) laboratories and other facilities that are certified by the Department of Health and Human Services under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. Â§263a to perform laboratory testing. Reports can be generated by state and include facility name, address, and type of certificate: https://qcor.cms.gov/main.jsp

What methodologies can be used to assess laboratory practices?

There is not a single method that health departments should use to assess laboratory practices in viral hepatitis testing. Rather, health departments should strive to select the method(s) most feasible within their capacity and resources, and which optimize available data sources. Some of the possible types of data and sources are described below. These methods could be used alone or in combination. For example, a review of the surveillance data may show a proportion of laboratories appear to be reflexing from HCV antibody to RNA testing. You may want to confirm that finding through a survey of laboratories and ask about justifications and barriers for those laboratories that are not performing reflex testing.

(1) Disease surveillance data. Disease surveillance data, specifically laboratory reports of the infection of interest, can provide information on relative volume of positive tests (and possibly negative test results depending on regulations) performed. Analysis of laboratory reports can help health departments to focus their assessment efforts on the highest volume laboratories. Used in conjunction with other data, such as clinic volume, these data may help to further narrow down assessment activities, e.g., high volume clinical facilities with a relatively lower volume of viral hepatitis testing.

(2) Survey of laboratories. Conducting a survey of laboratories allows health departments to gather relatively granular data on the topics most pertinent to meeting the objectives of the assessment. Surveys can be self-administered or administered through interview. They can be conducted "online" through a survey application (e.g., REDCap, SurveyMonkey®), or "on paper" (e.g., through fillable PDF, or handwritten). In developing a survey tool, health departments should consider collaborating with their PHL to develop a tool and approach that will be appropriately focused and is technically accurate. The PHL may also offer assistance with recruitment, such as promoting a survey through a regular newsletter to laboratory directors. Collaboration with the health department HIV and/or STI programs may also be helpful as these programs may have similar interests in surveying laboratories or have experience with such surveys. You may be able to combine survey efforts (e.g. a combined survey of HIV and viral hepatitis testing practices) and share the burden for fielding the survey and conducting follow-up to maximize response. Surveys are often time intensive in terms of initial recruitment and follow-up needed to obtain responses. Collaborating with your PHL or other health department programs may improve feasibility of a survey and improve response rates. An important consideration is the audience. For example, if it is sent to lab directors, they may have answers to or be able to collect answers to a wide variety of questions, but they may have less time so survey length is important. Alternatively, if a survey is sent to disease surveillance/informatics programs; they may not be able to answer all the questions.

Some resources: https://www.alchemer.com/resources/blog/enhance-survey-response-rate/

https://www.cdc.gov/healthyyouth/evaluation/pdf/brief21.pdf

You may consider sending the survey to multiple contacts in a laboratory to improve response rates. As with all survey efforts, it is likely that you will need to send multiple, periodic reminders to prompt survey completion, and/or work with other contacts in a facility to prompt response. Collaboration with your PHL, your surveillance program, and your HIV, STD, or other health department programs can help to optimize participation of laboratories in assessment activities. Collaboration in this way can help to identify appropriate contacts, maximize engagement of laboratories, and enhance credibility of assessment activities. Collaboration can also be helpful in sharing the workload for assessment activities.

Sample questions are available in Appendix 1.

(3) Administrative claims data. Laboratory facilities performing testing are identified in administrative claims data (i.e., data on claims for payment submitted by laboratories and health care providers to health insurers). Health departments may be able to access data, or submit an analytic query, through their state Medicaid program (for patients enrolled in Medicaid). Some states have All Payers Claims Data sets which could provide the volume of tests, by type of test (using CPT codes) performed patients enrolled in commercial insurance plans. Resources for CPT codes can be found via the AMA (requires subscription) and HepFree NYC.

The funding announcement, CDC-RFA-PS21-2103, provides health departments with the option to focus assessment activities on laboratories reporting 80% or greater of HCV antibody tests and tests for HBV or, alternatively, to survey all CLIA-certified laboratories in the jurisdiction. Health departments should adopt the approach to assessment which is feasible and which best aligns with epidemiological impact.

Several national, commercial laboratories routinely perform HCV RNA testing by reflex. CDC has indicated that health departments are not required to conduct in-depth assessment regarding HCV RNA reflex testing practices of these laboratories. Depending on the scope of a health department's assessment (e.g. if combining assessment of testing for other infections), it may be appropriate to include commercial laboratories in your assessment. If testing practices of commercial laboratories are to be assessed, it is recommended that health departments engage through local laboratories operating in your jurisdiction.

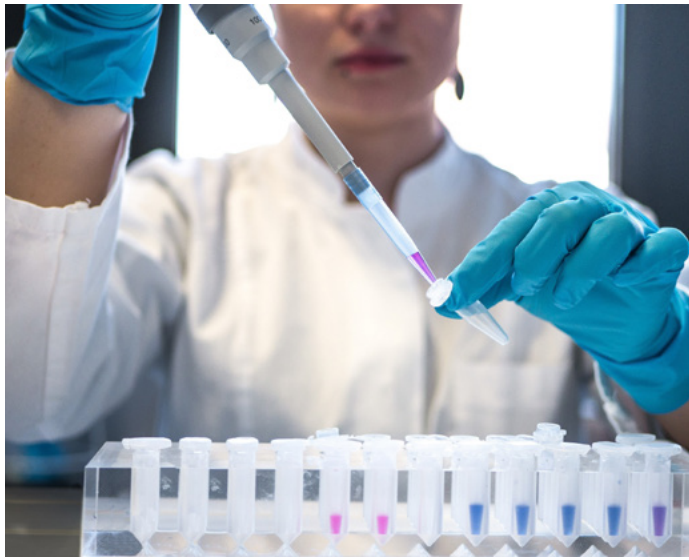
What should we do with the findings of the assessment?

What you learn from the assessment should, ideally, help to inform communication, education, training, and capacity building assistance needed to support laboratories to make practice changes to achieve identified objectives. You may find, for example, that a barrier to implementation of reflex testing in a laboratory relates to clinician interest or understanding of the value of ordering reflex testing, suggesting a need to provide clinician education. Alternately, you may learn through your assessment that reflex testing is routine only for healthcare exposures, suggesting capacity that can be leveraged to expand reflex testing given appropriate training and operational changes to the laboratory and clinical workflows.

You should plan to share the findings of the assessment with key stakeholders including elimination planning partners, community advisory groups and coalitions, and related health department programs. It is also good practice to share findings of an assessment with the laboratories that contributed to the effort. Communication to the laboratories should ideally be accompanied by relevant information about application of findings to capacity building assistance, and/or education regarding recommended laboratory practices. Consider collaborating with the health department PHL, HIV and/or STI programs, and/or health department communications department to develop appropriate information and recommendations, as well as on developing the approach and content of education, training, and capacity building assistance.

What resources and examples are available to help us develop and implement our assessment?

Each health department will need to decide what objectives they want to achieve in conducting an assessment of laboratories, and what methods are most feasible and desirable in achieving these objectives. To support health departments, NASTAD will compile and maintain a repository of tools and resources, including surveys and assessments developed and used by health department peers. To access the repository please refer to Appendix 1.



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and the following persons that facilitated the review whose contributions and support made this publication possible:

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Appendix 1: Question Bank

Table 1: Questions on test performed and testing volume

Jurisdiction	Questions on tests performed	Questions on testing volume
California	Please use the table below to specify which hepatitis C virus (HCV) tests your laboratory conducted, either directly or through a reference laboratory, and total testing volume in 2021. Please enter zero (0) if you have offered this but did not do any in 2021. Tests: Hepatitis C virus (HCV) antibody, Hepatitis C virus (HCV) ribonucleic acid (RNA), Hepatitis C virus (HCV) genotype, Other, please specify Values: Number of tests conducted in-house in 2021, Number of tests conducted by a reference laboratory in 2021, N/A - Our laboratory does not perform this test	
Connecticut	Does your laboratory test for HCV antibody? · Yes · No, we send HCV testing to the reference lab specified below	
Idaho	Does your laboratory provide viral hepatitis testing (hepatitis A, B, or C)? Does your laboratory conduct the following Hepatitis A (HAV) testing? (Check all that apply) · Anti-HAV, IgM · Anti-HAV, Total · Other, please specify Does your laboratory conduct the following Hepatitis B (HBV) tests? (Check all that apply) · HBsAg · Anti-HBc, Total · Anti-HBc, IgM · HBeAg · Anti-HBs · HBV DNA, PCR (qualitative) · HBV DNA, PCR (quantitative) · HBV genotype · Other, please specify Does your laboratory conduct the following Hepatitis C (HCV) tests? (Check all that apply) · Anti-HCV (screening EIA) · HCV RNA, PCR (qualitative) · HCV RNA, PCR (quantitative) · HCV genotype · Other, please specify	

Table 1: Questions on test performed and testing volume

Jurisdiction	Questions on tests performed	Questions on testing volume
Massachusetts	Is HCV testing of any type (e.g., antibody, RNA, genotyping) currently available through your laboratory facility either because you perform testing in-house, and/or refer specimens for testing? • Yes • No Which of the following test orders are accepted by your laboratory? (Check all that apply) • HCV antibody only • HCV RNA only • HCV antibody with reflex to HCV RNA • Other: Does your laboratory perform HCV antibody testing? • Yes • No • Don't know Does your laboratory perform HCV RNA testing? • Yes • No • Don't know	Approximately how many HCV antibody tests did you perform in CY 2021? Approximately how many HCV RNA tests did you perform in CY 2021?

Oregon

Does your laboratory perform any of the following tests?

Hepatitis A Virus (HAV) Testing
Anti-HAV, IgM
Anti-HAV, Total
Other, please specify

Hepatitis B Virus (HBV) Testing
HBsAg
Anti-HBc, total
Anti-HBc, IgM
Anti-HBs
HBV DNA, PCR (qualitative)
HBV DNA, PCR (quantitative)
HBV genotype
Other, please specify

Hepatitis C Virus (HCV) Testing
Anti-HCV(screening EIA)
HCV RNA, PCR (qualitative)
HCV RNA, PCR (quantitative)
HCV genotype
Other, please specify

Hepatitis D Virus (HDV) Testing
Anti-HDV
Other, please specify

Hepatitis E Virus (HEV) Testing
Anti-HEV, IgM
Anti-HEV, IgG
Other, please specify

Options:

- Yes
- No, sent to reference laboratory
- Total number positive in calendar year 2021 (include tests done by your lab and reference lab)
- No, we do not offer this test

Jurisdiction	Questions on tests performed	Questions on testing volume

Table 1: Questions on test performed and testing volume

South Carolina	Please indicate what Hepatitis B testing services your lab offers and the total yearly testing volume for each service (check all that apply): • Hepatitis B surface antigen (HBsAg) assay, Testing volume: • Hepatitis B surface antibody (anti-HBs), Testing volume: • Total Hepatitis B core antibody (anti-HBc), Testing volume: • IgM antibody to Hepatitis B core antigen (IgM anti-HBc), Testing volume: • Hepatitis B DNA test, Testing volume: • None of the above Please indicate what Hepatitis C testing services your lab offers and the total yearly testing volume for each service (check all that apply): • Hepatitis C antibody assay, Testing volume: • Hepatitis C antibody reflex to RNA PCR, Testing volume: • Hepatitis C RNA test (Quantitative), Testing volume: • Hepatitis C RNA test (Qualitative), Testing volume: • Hepatitis C genotype test, Testing volume: • Resistance testing NS5A, Testing volume: • None of the above

Tennessee	Do you currently test for the following? (check all that apply) · Hepatitis B Surface Antigen (HBsAg) · IgM antibody to Hepatitis B Core Antigen (IgM anti-HBc) · Hepatitis B "e" Antigen (HBeAg) · Nucleic Acid Amplification Testing for Hepatitis B DNA § Quantitative § Qualitative § Genotype · Hepatitis C Antibody (anti-HCV) · Nucleic Acid Amplification Testing for Hepatitis C RNA § Quantitative § Qualitative § Genotype	

Jurisdiction	Questions on tests performed	Questions on testing volume
Utah	Does your laboratory perform any of the following HCV tests (select all that apply)? · Anti- HCV (EIA or CIA) · Anti-HCV (Supplemental RIBA) · HCV RNA, PCR (qualitative) · HCV RNA, PCR (quantitative) · HCV Genotype · Other, please specify Does your laboratory perform tests grouped as hepatitis panels? If Yes: · What types of panels are tested (select all that apply) · Acute hepatitis · Liver panel · Other, please specify Are there HCV tests you would like to perform but currently do not have the capacity? If so, specify which tests (select all that apply) · Anti- HCV- screening immunoassay · Anti-HCV- supplemental immunoassay (RIBA) · HCV RNA PCR- qualitative · HCV RNA PCR- quantitative · HCV genotyping · ALT · AST · Bilirubin · Other, please specify	

Table 1: Questions on test performed and testing volume

Jurisdiction	Questions on tests performed	Questions on testing volume
Washington	Does your lab test for HCV in-house? • Yes • No Which HCV test(s) does your lab perform in-house? • HCV antibody – Qualitative • HCV antibody - Signal-to-cutoff ratio • HCV antigen • HCV RNA – Qualitative • HCV RNA – Quantitative (viral load) • HCV genotype Standalone HCV antibody testing only tests for HCV antibodies, with no reflex to HCV RNA (viral load) testing. Does your lab conduct standalone HCV antibody testing? • Yes • No How many positive HCV antibody tests were automatically reflexed to RNA between January 1, 2021 – December 31, 2021?	How many standalone HCV antibody tests did your lab perform in-house between January 1, 2021 – December 31, 2021? Please indicate how many HCV tests with a positive (reactive or detected) result were performed onsite with a collection date between January 1, 2021 and December 31, 2021. If you did not perform any tests with a positive result, please enter 0 *Note: If there is a significant gap between the reported number of tests performed and results received by DOH, more specific information will be requested.* • HCV antibody – qualitative • HCV antibody – signal-to-cutoff ratio • HCV antigen • HCV RNA – qualitative • HCV RNA – quantitative • HCV genotype For each type of test shown in the table below, please indicate how many of each test was performed on-site with a collection date between January 1, 2021 and December 31, 2021 If you did not perform any, please enter “0”. • HCV antibody – qualitative • HCV antibody – signal-to-cutoff ratio • HCV antigen • HCV RNA – qualitative • HCV RNA – quantitative • HCV genotype

Table 2: Questions on reflex testing and barriers

Jurisdiction*	Questions on Reflex Testing	Questions on barriers to reflex testing
California	When does your laboratory conduct reflex HCV RNA testing on a specimen that has tested positive/reactive for HCV antibody (anti-HCV), either in house or through a reference laboratory? · All HCV antibody positive/reactive specimens undergo reflex HCV RNA testing · Only upon provider request do HCV antibody positive/reactive specimens undergo HCV RNA reflex testing · No HCV antibody positive/reactive specimens undergo HCV RNA reflex testing · If performed by an outside laboratory, provide the laboratory name: · Other, please specify:	If your laboratory does not conduct HCV RNA reflex testing **for all HCV antibody positive/reactive specimens**, what barriers would need to be resolved to do so? Please check all that apply. · Barriers related to COVID-19 · Changes to laboratory information system · Competing priorities/limited staffing · Concerns about insurance reimbursement · Cost of purchasing new laboratory equipment or supplies · HCV RNA test in use not FDA approved for diagnosis · No capacity to conduct in-house HCV RNA testing · Requirement to collect two samples of blood · Risk of cross contamination when using single specimen sample · Need standing order · Not applicable · Other, please specify:
Connecticut	If the HCV antibody test is positive, does your laboratory reflex to HCV RNA testing? · Yes · No	

Table 2: Questions on reflex testing and barriers

Jurisdiction*	Questions on Reflex Testing	Questions on barriers to reflex testing
Hawaii	When does your laboratory conduct (or send out to another lab) reflex confirmatory testing (PCR for HCV RNA) on a positive HCV antibody (anti-HCV) specimen that was collected at the same time? · All specimens that are positive on HCV antibody screening test undergo HCV RNA reflex testing. · Only when requested by a provider do specimens that are positive on HCV antibody screening test undergo HCV RNA reflex testing. · No specimens that are positive on HCV antibody screening test undergo HCV RNA reflex testing. · Other, please specify Does your laboratory routinely perform neutralization for each positive HBV surface antigen (HBsAg) specimen that should receive HBsAg neutralization testing? *Reflex/additional confirmatory (i.e. neutralization) testing is needed on specimens that have a signal-to-cutoff value within a specified range, which is determined by the Instructions for Use of the test assay.* · Yes, neutralization is conducted by our laboratory. · Yes, neutralization is sent to a reference laboratory. · No neutralization is conducted, either by our laboratory or a reference laboratory. · Other, please specify	If your laboratory does not conduct (or send out) HCV RNA reflex testing **for all specimens** that are positive on HCV antibody screening test, what are barriers that would need to be resolved to start doing so? · Laboratory testing policy · Payer or insurance issues · Lack of IT support for changes in laboratory information system · Lack of laboratory equipment or supplies · Other, please specify
Idaho	For specimens that test positive for HCV antibodies, please indicate if RNA reflex testing is performed on the specimen collected at the same time. · All specimens that are positive on HCV antibody screening test have RNA reflex testing performed at the same time · Specimens that are positive on HCV antibody screening test undergo HCV RNA testing only when requested by a physician · No HCV RNA reflex test is performed · Other, please specify	If you do not conduct HCV RNA reflex testing, what types of barriers would need to be resolved for your laboratory to conduct reflex testing? (Check all that apply) · Laboratory testing policy · Payer or insurance issues · Lack of IT support for changes in laboratory information system · Lack of laboratory equipment or supplies · Other resources needed

Table 2: Questions on reflex testing and barriers

Jurisdiction*	Questions on Reflex Testing	Questions on barriers to reflex testing
Massachusetts	If an HCV antibody test result is reactive are specimens reflexed to test for HCV RNA? · Yes, in all circumstances · Yes, in some circumstances · No Under which circumstances is HCV RNA reflex testing performed? · If providers order reflex to RNA along with HCV antibody testing · Reflex testing is a standard of care for certain clinics or departments · Reflex testing is standard with certain test panels · Other: In which clinics or departments is HCV RNA reflex testing a standard of care? (Check all that apply) · Emergency department · Inpatient · Outpatient clinics · Main hospital or clinic · Satellite location · Other: With which test panels is HCV RNA reflex testing standard? If an HCV antibody test result is reactive, reflex to HCV RNA testing is performed using (Check one) · The same specimen used for antibody testing · A 2nd specimen collected at the same time as the specimen used for antibody testing · A 2nd specimen collected after the initial specimen used for antibody testing · Other: When approximately did your facility implement HCV RNA reflex testing? In CY 2021, approximately what percentage of HCV antibody reactive specimens were reflexed to HCV RNA testing? Have you considered implementing HCV RNA reflex testing for your facility? · Yes, there are plans underway to implement reflex testing · Yes, but there are no immediate plans to implement reflex testing · No · Don't know · Other	What challenges have you experienced, or would you anticipate with regard to implementing HCV RNA reflex testing for your facility? (Check all that apply) · Recognition/buy-in regarding the value of reflex testing among administration · Recognition/buy-in regarding the value of reflex testing among ordering providers · Recognition/buy-in regarding the value of reflex testing among laboratory staff · Availability of reflex testing at current reference lab · Integration of reflex testing into existing laboratory workflows · Availability of/access to appropriate testing platforms · Sufficient laboratory staffing to implement · Sufficient time to train laboratory staff · Education/training for ordering providers · Modifying laboratory test ordering system(s) · Modifying laboratory information system · Adequacy of health insurer payment for reflex testing · Cost of acquiring testing equipment · Cost of reagents · Other costs · Other:

Table 2: Questions on reflex testing and barriers

Jurisdiction*	Questions on Reflex Testing	Questions on barriers to reflex testing
Oregon	For specimens with anti-HCV screening-test positive results, please indicate on what basis reflex testing is performed (PCR for HCV RNA) on a specimen collected at the same time (either by your laboratory or by sending the specimen out to another laboratory). · All specimens that are positive on the HCV antibody screening test have reflex testing performed by PCR · Specimens that are positive on the screening test undergo HCV RNA testing only when requested by a physician · No reflex testing or HCV RNA test is performed · Other, please specify:	If you do not conduct hepatitis C reflex testing, what types of barriers would need to be resolved for your lab to conduct reflex testing? Please check all that apply: · Laboratory testing policy · Payer or insurance issues · Lack of IT support for changes in laboratory information system · Lack of laboratory equipment or supplies · Other resources needed
South Carolina	Does the lab perform HBsAg confirmation reflex testing? · Yes, the reflex testing is performed in-house · Yes, the reflex testing is outsourced to another lab. Please list lab conducting HBV reflex testing: · No, the lab does not offer reflex testing Does the lab perform HCV RNA confirmation reflex testing? · Yes, the reflex testing is performed in-house · Yes, the reflex testing is outsourced to another lab. Please list lab conducting HCV reflex testing: · No, the lab does not offer reflex testing	If no, what are the barriers to providing this service?
Tennessee	If Hepatitis C Antibody (anti-HCV) is positive, do you automatically process qualitative or quantitative Nucleic Acid Amplification Testing for Hepatitis C RNA on the same sample (reflex testing)? (Yes/No)	What (if any) challenges have you encountered as it relates to either hepatitis B virus or hepatitis C virus testing or reporting?
Utah	For specimens with anti-HCV screening-test positive results, please indicate on what basis reflex testing is performed: · No reflex testing or HCV RNA test is performed · All specimens that are positive on an HCV antibody screening test have reflex testing performed by PCR · Specimens that are positive on an HCV antibody screening test undergo HCV RNA testing only when requested by the ordering provider · Other, please specify	If you do not conduct HCV reflex testing, which types of barriers would need to be resolved for your laboratory to do so? Select all that apply: · Laboratory testing policy · Payer/insurance issues · IT support for changes in laboratory information system · Laboratory equipment/supplies · Other, please specify

Table 2: Questions on reflex testing and barriers

Jurisdiction*	Questions on Reflex Testing	Questions on barriers to reflex testing
Washington	Reflex testing means that if a hepatitis C antibody test is positive, the laboratory immediately performs a confirmatory HCV RNA test on the same specimen. Does your lab conduct HCV RNA reflex testing? • Yes • No Is reflex performed in-house? • Yes • No (Name of reference lab used): When does reflex testing occur? • Automatically • At provider request • Other: If your lab does not conduct or send out HCV RNA reflex testing, are you interested in doing so? • Yes • No • Unsure • N/A	If your lab does not conduct or send out HCV RNA reflex testing, what resources would you require to do so? • Change in lab testing policy (Specify): • More guidance needed on reflex testing protocols/procedures (Specify): • Payer or insurance solutions (Specify): • IT support • Additional testing equipment • Additional staffing • Increased demand/volume of tests • No additional resources needed Please describe any additional challenges or factors preventing your lab from making HCV reflex testing a routine procedure:

Table 3: Questions on surveillance reporting

Jurisdiction	Questions on reporting	Questions on barriers to reporting
California	How does your laboratory report positive viral hepatitis test results to your local health department? Please select all that apply. • Report by electronic laboratory reporting (HL7 Standard ELR) • To the California Department of Public Health, California Reportable Diseases Information Exchange (CalREDIE) • To the County of San Diego Department of Public Health, Web Confidential Morbidity Report (WebCMR) • To the Los Angeles County Department of Public Health, Integrated Reporting, Investigation, and Surveillance (IRIS) System • To the San Francisco Department of Public Health (SFDPH), Virtual Epidemiologic Network (MAVEN) system • Non-HL7 electronic formats (i.e., SFDPH via secure file transfer protocol ("flat file" transfer)) • By Fax/mail • Results reported by reference laboratory that conducts test • Not reported • Not sure	If your laboratory does not report all positive laboratory test results to public health via ELR HL7 standard message format, what barriers prevent your laboratory from doing so? Please check all that apply *(CA Code of Regulations Title 17 Section 2505 requires that all laboratory test results be reportable in HL7 standard message format.)* • Barriers related to the COVID-19 pandemic • Competing priorities/limited staffing • Cost of purchasing new information technology equipment or systems • Limited technological capacity of laboratory information system • Limited expertise in laboratory information technology • Low volume of tests conducted for reportable diseases • Other, please specify
Hawaii	Does your laboratory routinely report to DOH all results from reflex HCV RNA confirmatory tests conducted by your lab (or sent to another lab)? Test results include positive, negative, invalid, indeterminate, or other. • Yes • No • Other, please specify Please share additional info on testing or reporting practices for reflex HCV RNA testing for positive HCV antibody (anti-HCV) specimens through your laboratory. Does your laboratory routinely report to DOH all results from neutralization tests (for specimens that should receive HBsAg neutralization testing) conducted by your lab (or sent to another lab)? • Yes • No • Other, please specify Please share any additional info on reflex neutralization testing for positive HbsAg specimens that should receive HBsAg neutralization testing through your laboratory.	

Table 3: Questions on surveillance reporting

Jurisdiction	Questions on reporting	Questions on barriers to reporting
Idaho	How do you report positive markers of viral hepatitis? (Check all that apply) · Report to Local Public Health Authority by electronic lab reporting (ELR) · Report to Local Public Health Authority by fax or email · Results reported by reference laboratory that performs the tests · Comments	What barriers, obstacles, or issues arise for reporting positive markers for viral hepatitis?
Oregon	How do you report positive markers of viral hepatitis to public health? Please Check all that apply. · Report to OHA or Local Public Health Authority by electronic lab reporting (ELR) · Report to OHA or Local Public Health Authority by phone or fax · Results Reported By reference laboratory that performs test · Not reported · I don't know	If you do not report these results to public health, what are the obstacles or issues that prevent your laboratory from doing this?
Tennessee	Do you report the following laboratory results to the Tennessee Department of Health? (Check all that apply) · Positive Hepatitis B Surface Antigen (HBsAg) · Positive IgM antibody to Hepatitis B Core Antigen (IgM anti-HBc) · Positive Hepatitis B "e" Antigen (HBeAg) · Positive Nucleic Acid Amplification Testing for Hepatitis B DNA (Quantitative, Qualitative, or Genotype) · Positive Hepatitis C Antibody (anti-HCV) · Positive Nucleic Acid Amplification Testing for Hepatitis C RNA · Negative Nucleic Acid Amplification Testing for Hepatitis C RNA If any of the above are positive, · Pregnancy Status · Alanine Aminotransferase (ALT) Results · Bilirubin Results	What (if any) challenges have you encountered as it relates to either hepatitis B virus or hepatitis C virus testing or reporting?

Table 3: Questions on surveillance reporting

Jurisdiction	Questions on reporting	Questions on barriers to reporting
Washington	Please complete the following table indicating the frequency and method of HCV screening and confirmatory test reporting from your laboratory to DOH: • How often do you send results? (Daily, Weekly, Monthly, etc) • How? (for example, ELR, mail, or fax) Options • HCV antibody – Qualitative • HCV antibody – Signal-to-cutoff ratio • HCV antigen • HCV RNA – Qualitative • HCV RNA – Quantitative (viral load) • HCV genotype Does your lab report indeterminate results for any of the following tests? • HCV antibody – Qualitative • HCV antibody – Signal-to-cutoff ratio • HCV antigen • HCV RNA – Qualitative • HCV RNA – Quantitative (viral load) Does your lab report negative results for any of the following tests? • HCV antibody – Qualitative • HCV antibody – Signal-to-cutoff ratio • HCV antigen • HCV RNA – Qualitative HCV RNA – Quantitative (viral load)	