

Viral Hepatitis Testing: Strategies for Assessing Laboratories

Introduction to the Toolkit

26 October 2022

Toolkit Overview

- Rationale
- Domains for assessment
- Targets
- Methodologies
- Application
- Resources



Why Assess Laboratory Practices?

- Practices and capacity foundational to advancing public health goals and objectives
 - Surveillance
 - Screening, diagnosis, treatment
- Context, challenges, and facilitators
- Inform policy, education, training, and capacity building
- Meet federal funding requirements

What domains could be assessed?

- Laboratory capacity
 - Current VH testing
 - Other relevant assays, test platforms
- Laboratory practices and workflows
 - Ordering
 - Referral practices
 - Test sequences
 - Context for testing
- Challenges, facilitators
- Data collection, reporting



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:

How do we identify/connect with laboratories?

- State/local public health laboratories (PHLs)
- Disease surveillance and informatics programs
- Licensing agencies
- Center for Medicare and Medicaid Services (CMS)

What methods could be used to assess labs?

- Analysis of disease surveillance data
- Survey
- Administrative claims data
- Other?

What do we do with the findings?

- Communicate results to laboratories, stakeholders
- Develop/incorporate into education, training
- Strategic use in capacity building

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



Question Bank - Peer Resources!

- HCV RNA reflex testing, barriers
- Testing practices, capacity
- Reporting

Appendix 1: Question Bank

Table 1: Questions on reflex testing and barriers	7
Table 2: Questions on test performed and testing volume	12
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Tips

- The focus should make sense for your jurisdiction
 - Epidemiologic impact
 - Addressing knowledge gaps
 - Select the domains, topics most useful to you and your collaborators
- Collaborate in development, implementation, analysis
- Select a scope and methods that are feasible
 - Consider triangulating data sources
- Commit to sharing findings with stakeholders
- Consider harmonizing with health systems assessment



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Massachusetts Department of Public Health

Assessing Clinical Laboratories: HCV Testing Practices

NASTAD VLC
26 October 2022

Overview: Assessment of Clinical Laboratories

- Collaboration: development, implementation, analysis
- Objective: inform education, training, TA
- Focus: HCV
- Scope: practices supporting/challenges to screening, reflex testing
- Methods:
 - Analysis of surveillance data
 - Identify labs reporting HCV ab+; practicing reflex
 - Survey of clinical laboratories in Massachusetts
 - Obtain detailed information re: HCV testing practices and context
 - Identify issues/challenges to practice change

Analysis of Surveillance Data

HCR RNA Reflexing by Laboratories Reporting Results to MDPH

Parameters:

- Extracted HCV lab results with specimen dates between 7/1/2020 – 6/30/2021
- Using lab results and information on the laboratory testing facility identify which labs conducted HCV antibody testing *and* HCV RNA testing on a sample collected on the same day.
 - If a case had both antibody and RNA results within their event, but the RNA result was not from the same date, this was not considered reflex testing.

Specimen Date	Specimen Number	Specimen Source	Test	Result
06/19/2021		Whole blood sample	Hep C virus RNA: ACnc: Pt: Ser/Plas: Qn: Probe.amp.sig	Negative
06/18/2021		Whole blood sample	Hep C virus Ab: ACnc: Pt: Ser: Ord: EIA	Positive
06/19/2021		Whole blood sample	Hep C virus RNA: ACnc: Pt: Ser/Plas: Qn: Probe.amp.sig	Negative
Specimen Date	Specimen Number	Specimen Source	Test	Result
06/18/2021		Venous Blood	Hep C virus Ab: ACnc: Pt: Ser: Ord:	Positive
06/18/2021		Venous Blood	Hep C virus RNA: ACnc: Pt: Ser/Plas: Qn: Probe.amp.tar detection limit < 50 iu/ml	Negative

Survey of Clinical Laboratories (June 2022)

- Collaboration
 - Leveraged previous survey of laboratory testing strategies
 - SPHL: SME on tool, co-signature, contact information
- Self-administered, online survey
 - Sentinel clinical lab directors, micro directors
 - Domains
 - Current status of HCV testing
 - Test orders accepted
 - Testing performed (in-house and reference lab)
 - Estimated volume of antibody, RNA testing
 - Reflexing status/practices
 - Challenges to implementing reflex testing
- 46 of 57 (81%) laboratories submitted complete response
 - Follow-up: plan for it!

Findings – Some Unexpected

- High variability in screening, reflex testing practice across clinical labs
- Higher throughput, higher capacity labs suboptimal screening, reflexing
- Variability in practices among labs in individual health systems
- Challenges identified:
 - Lab workflows; provider, administration buy-in
 - Complexity in organization of clinical facilities, labs

Lessons Learned

- Approach
 - Surveillance data as starting point, focus
 - Survey data contextualizes surveillance data
 - Precise information re: policies, operations
- Collaboration with SPHL, cross-divisions essential
- Next Steps/in process
 - Follow-up laboratories w/ findings
 - Engage stakeholders, including labs, in developing strategies
 - Integrate with health systems assessment
 - Develop, deliver education, TA



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