REFLEX CONFIRMATORY TESTING FOR HEPATITIS C VIRUS INFECTION

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy on reflex confirmatory testing for hepatitis C virus (HCV) infection.

2. SUMMARY OF MAJOR CHANGES: This updated VHA directive includes the following changes:
   a. Removal of references to HCV Recombinant Immunoblot Assay (RIBA), as this test is no longer available in the United States, including use of RIBA in the recommended algorithm for confirmatory testing in Attachment A;
   b. Attachment A is rescinded;
   c. Attachment B on standardized HCV reporting terminology is rescinded, including the previous directive’s requirement that the lab test interpretation field include a link to a table in Attachment B; and
   d. Renaming of the Responsible Program Office from the Public Health Strategic Healthcare Group to HIV, Hepatitis and Related Conditions Programs (HHRC).


4. RESPONSIBLE OFFICE: The Director, HIV, Hepatitis, and Related Conditions Programs (HHRC) is responsible for the content of this directive. Questions may be addressed to Office of Specialty Care Services in the Office of the Deputy Under Secretary for Health for Policy and Services (10P), or directly to HHRC at VAHHRC@va.gov.


6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of March 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Acting Under Secretary for Health

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REFLEX CONFIRMATORY TESTING FOR HEPATITIS C VIRUS INFECTION

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy on reflex confirmatory testing for hepatitis C virus (HCV) infection. **AUTHORITY:** 38 USC 7301(b).

2. BACKGROUND

a. Laboratory testing for HCV infection is recommended for those individuals who are at increased risk for HCV infection, particularly those born between 1945-1965 ("birth cohort testing"). Specific guidance on offering testing for HCV infection is outlined in the Clinical Preventive Services Guidance Statement on Screening for Hepatitis from the VHA National Center for Health Promotion and Disease Prevention, available at [http://vaww.prevention.va.gov/Screening_for_Hepatitis_C.asp](http://vaww.prevention.va.gov/Screening_for_Hepatitis_C.asp). **NOTE:** This is an internal VA Web site not available to the public.

b. Laboratory testing for HCV includes serologic testing for the presence of anti-HCV antibodies to determine whether an individual has ever been infected with HCV, and subsequent confirmatory assays for HCV ribonucleic acid (RNA) in the blood (HCV viremia) to determine whether an individual has chronic infection. Confirmatory testing, (testing an assay for detection of HCV RNA for a patient with a positive HCV serologic test result, in order to determine whether the patient has chronic hepatitis C), of individuals with a positive HCV serologic test result is necessary to identify those individuals who have chronic HCV. The United States Centers for Disease Control and Prevention (CDC) recommend such testing in patients with a positive serologic test result (subpar 5d and e) available at [https://www.cdc.gov/hepatitis/HCV/GuidelinesC.htm](https://www.cdc.gov/hepatitis/HCV/GuidelinesC.htm).

c. VHA Directive 2009-063, Reflex Confirmatory Testing for Chronic Hepatitis C Virus Infection, dated November 25, 2009, mandated reflex confirmatory testing for the first time within VHA to ensure that all patients with positive serologic test results for HCV are evaluated for the presence of chronic HCV infection. This requires automatic performance of confirmatory testing for a patient with a positive HCV serologic test result without the need for an additional order by a clinician or collection of an additional specimen from a patient.

3. POLICY

Among individuals who do not have a prior positive HCV RNA result, it is VHA policy that reflex confirmatory testing using RNA testing be performed on all specimens that are reactive by initial serologic testing for HCV antibodies. This directive does not apply to individuals with a previous positive HCV RNA result.

4. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health, or designee, is
b. **Deputy Under Secretary of Health for Operations and Management.** The Deputy Under Secretary of Health for Operations and Management (10N), or designee, is responsible for:

   (1) Communicating the contents of this directive to each of the Directors of the Veterans Integrated Services Networks (VISN).

   (2) Ensuring that each VISN Director has the resources required to support the fulfillment of the terms of this directive in all of the VA health facilities within that VISN.

   (3) Confirming that each VISN has and utilizes on an ongoing basis a means for ensuring the terms of this directive are fulfilled in all the VA health facilities of the VISN.

   (4) Communicating information from VA medical facilities to 10P11 and HHRC.

c. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services (10P), or designee, is responsible for providing policy to ensure national administrative and clinical oversight of HHRC programs. The policy will be used to support the Deputy Under Secretary for Health for Operations and Management’s operational oversight to ensure all facilities with laboratory capabilities are in compliance with specific guidance on offering testing for HCV infection as outlined in the Clinical Preventive Services Guidance Statement on Screening for Hepatitis from the VHA National Center for Health Promotion and Disease Prevention (see paragraph 2.a.) and the CDC (see paragraph 2.b).

d. **HIV, Hepatitis and Related Conditions Programs (HHRC) within the Office of Specialty Care Services.** HHRC is responsible for providing scientific and technical guidance related to the timely and accurate diagnosis of chronic HCV infection via serologic and confirmatory testing, in collaboration with VHA National Pathology and Laboratory Medicine Service.

e. **Veterans Integrated Service Network (VISN) Director.** The VISN Director, or designee, is responsible for ensuring VA medical facility Directors adhere to this directive.

f. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

   (1) Ensuring that reflex confirmatory HCV testing is implemented as a locally performed test, a fee basis test, or as a test performed by another Department of Veterans Affairs (VA) facility with established HCV RNA testing capability;

   (2) Ensuring equal access to reflex confirmatory HCV testing at all points of care at the local health care system where lab testing is provided;

  g. **Director, Pathology and Laboratory Medicine Service (P&LMS).** The
Director, P&LMS at each facility is responsible for selecting appropriate methodologies for implementation of reflex confirmatory HCV testing, and ensuring reflex confirmatory testing is being performed to current Centers for Disease Control and Prevention (CDC) guidelines.

5. REFERENCES


   b. VHA Directive 1088, Communicating Test Results to Providers and Patients.

   c. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures.
