

Notification Date: October 4, 2021 Effective Date: November 2, 2021

Hepatitis C Virus (HCV) Antibody with Reflex to HCV RNA, PCR, Symptomatic, Serum

Test ID: HCVDX; performed at Mayo Clinic Laboratories Florida.

Useful for:

Diagnosis of recent or chronic hepatitis C virus (HCV) infection in symptomatic patients.

This test is **not offered** as a screening or confirmatory test for HCV for blood, human cells, or tissue donors.

This test profile is **not useful for** detection or diagnosis of acute HCV since HCV antibodies may not be detectable until after 2 months following exposure and HCV RNA testing is not performed on specimens with negative anti-HCV screening test results.

Reflex Tests:

Test ID	Reporting Name	Available Separately	Always Performed
HCVQN	HCV RNA Detect/Quant, S	Yes	No

Methods:

Chemiluminescence Immunoassay (CIA)

Reference Values:

Negative

See Viral Hepatitis Serologic Profiles in Special Instructions.

Specimen Requirements:

Supplies: Aliquot Tube, 5 mL (T465)

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 2 mL

Collection Instructions:

- Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
- 2. Aliquot serum into plastic vial.

Minimum Volume: 1 mL

Specimen Stability Information:

Specimen Type	Temperature	Time
Serum SST	Frozen (preferred)	28 days
	Refrigerated	5 days

Cautions:

A single negative hepatitis C virus (HCV) RNA test result together with a reactive HCV antibody screen result with a signal-to-cutoff ratio of 8.0 or greater does not rule out the possibility of chronic HCV infection. Repeat testing for HCV RNA in 1 to 2 months is recommended in patient at risk for chronic hepatitis C.

Infants born to HCV-infected mothers may have false-reactive HCV antibody test results due to transplacental passage of maternal HCV IgG antibodies. HCV antibody testing is not recommended until at least 18 months of age in these infants.

Performance characteristics have not been established for the following types of serum specimen:

- -Individuals under 10 years of age
- -Grossly icteric (total bilirubin level of >20 mg/dL)
- -Grossly lipemic (triolein level of >3000 mg/dL)
- -Grossly hemolyzed (hemoglobin level of >500 mg/dL)
- -Presence of particulate matter
- -Cadaveric specimens

CPT Code:

86803

87522 (if appropriate)

Day(s) Performed: Monday through Saturday Report Available: 1 to 3 days

Questions

Contact Bonnie Meyers, Laboratory Technologist Resource Coordinator at 800-533-1710.