Overview

Useful For

Detection of acute hepatitis C virus (HCV) infection before the appearance of HCV antibodies in serum (ie, <2 months from exposure) in women who are pregnant

Detection and confirmation of chronic HCV infection in women who are pregnant

Quantification of HCV RNA in serum of women who are pregnant for monitoring disease progression of chronic HCV infection (HCV antibody-positive)

Testing Algorithm

The following algorithms are available in Special Instructions:

-Chronic Hepatitis C Treatment and Monitoring Algorithm: Direct Antiviral Antigen (DAA) Combination

-Hepatitis C: Testing Algorithm for Screening and Diagnosis

Special Instructions

- Hepatitis C: Testing Algorithm for Screening and Diagnosis
- Chronic Hepatitis C Treatment and Monitoring Algorithm: Direct Antiviral Agent (DAA) Combination

Highlights

This test is a reflex test for hepatitis C virus (HCV) antibody screen-reactive serum specimens to confirm the presence of HCV in pregnant individuals.

This test is suitable for diagnosis of acute HCV in women who are pregnant and are either high-risk or immunosuppressed and who may be negative for HCV antibodies.

This test can be used to establish a baseline HCV viral load and monitor disease progression of chronic hepatitis C in women who are pregnant.

Method Name

Real-Time Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

NY State Available

Yes

Specimen

Specimen Type

Serum SST

Ordering Guidance

For detection and quantification of hepatitis C (HCV) RNA in serum for the diagnosis and monitoring progress of acute or chronic hepatitis C in women who are pregnant.

Shipping Instructions

1. Freeze serum immediately, and ship specimen frozen on dry ice only.

2. If shipment will be delayed for more 24 hours, freeze serum at -20 to -80 degrees C (up to 84 days) until shipment on dry ice.

Specimen Required

Supplies: Aliquot Tube, 5 mL (T465)

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 1.5 mL

Collection Instructions:

1. 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.

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

Specimen Minimum Volume

0.8 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	84 days	
	Refrigerated	6 days	

Clinical & Interpretive

Clinical Information

Of all individuals infected with hepatitis C virus (HCV), about 75% of them will develop chronic hepatitis C, with ongoing viral replication in the liver and detectable HCV RNA in serum or plasma, eventually resulting in cirrhosis. The remaining 25% of the individuals infected recover from the infection without evidence of viral replication or presence of detectable HCV RNA in serum or plasma. Chronic HCV infection can be cured at variable success rates with either combined interferon-alpha and ribavirin therapy or interferon-free combination of direct-acting antiviral (DAA) agents.

The antiviral response rates correlate with pretreatment serum or plasma HCV RNA levels (viral load) and the HCV genotype found in the individuals infected. The optimal duration of combined interferon and ribavirin therapy can be determined from the patient's pretreatment viral load and HCV genotype. Clinical trial studies indicated that a decrease in HCV RNA levels of more than 2 log IU/mL at 4 weeks or 12 weeks of therapy is predictive of an increased chance of achieving a sustained virologic response (defined as undetectable HCV RNA levels in serum 6 months after completing antiviral therapy). Despite receiving longer duration of antiviral therapy (48 weeks versus 24 weeks), patients with chronic infection due to HCV genotypes 1 and 4 generally have less favorable sustained virologic response rates (40%-50%) than those infected with genotypes 2 and 3 (>80%). Due to the necessary prolonged duration (typically 24 to 48 weeks duration) and low cure rates of such antiviral therapy, interferon-based therapy has been supplanted with potent interferon-free DAA combination therapy now.

Cure rates, as defined by sustained virologic response, of over 90% are observed among patients who are HCV-infected and treated with interferon-free DAA combinations that are of shorter treatment duration(eg, 8 or 12 weeks) than those of interferon-based therapy. Current guidelines for antiviral therapy of chronic hepatitis C recommend quantitative testing for HCV RNA in serum or plasma before initiating antiviral therapy, at 4 weeks of therapy, and at 12 weeks after completion of therapy. HCV RNA level of below 25 IU/mL in serum or plasma at 12 weeks after ending therapy is the therapeutic goal and indicates an SVR is achieved. Quantitative HCV RNA testing can be considered at the end of therapy and at 24 weeks or later after completion of antiviral therapy.

The following algorithms are available in Special Instructions:

-Chronic Hepatitis C Treatment and Monitoring Algorithm: Direct Antiviral Antigen (DAA) Combination

-Hepatitis C: Testing Algorithm for Screening and Diagnosis

Reference Values

Undetected

Interpretation

This assay has a result range of 15 to 100,000,000 IU/mL (1.18 log to 8.00 log IU/mL) for quantification of hepatitis C virus (HCV) RNA in serum.

An "Undetected" result indicates that the HCV is absent in the patient's serum specimen.

A result of "<15 IU/mL (<1.18 log IU/mL)" indicates that HCV RNA is detected, but the HCV RNA level present cannot be quantified accurately below this lower limit of quantification of this assay. When clinically indicated, follow-up testing with this assay is recommended in 1 to 2 months. To assess response-guided therapy eligibility, an "Undetected" result is required, and a result of "<15 IU/mL mL (<1.18 log IU/mL)" should not be considered equivalent to an "Undetected" result.

A quantitative result expressed in IU/mL and log IU/mL indicates the degree of active HCV viral replication in the patient. Monitoring HCV RNA levels over time is important to assess disease progression and/or monitoring a patient's response to anti-HCV therapy.

A result of ">100,000,000 IU/mL (>8.00 log IU/mL)" indicates the presence of active HCV viral replication, and the HCV RNA level present cannot be quantified accurately above this upper limit of quantification of this assay.

An "Inconclusive" result reported with a comment indicates that testing failed, likely due to presence of inhibitory substances in the submitted serum specimen. A new specimen should be collected for retesting.

Cautions

Except for patients who are immunocompromised or patients with suspected acute hepatitis, laboratory evaluation of hepatitis C virus (HCV) infection status should begin with HCV serologic testing, including testing for the presence of HCV antibodies (see Hepatitis C: Testing Algorithm for Screening and Diagnosis in Special Instructions). A diagnosis of chronic HCV infection should not be based solely on the presence of detectable or quantifiable HCV RNA in a single serum specimen.

An "Undetected" HCV RNA test result with a "Reactive" HCV antibody screen result may be due to 1) a false-reactive

HCV antibody screen result; 2) resolved or past HCV infection; or 3) transient low viremia (ie, episodic viral replication) of active HCV infection. To distinguish between the first 2 conditions, another HCV antibody test (eg, HCCAD / Hepatitis C Virus Antibody Screen for Cadaveric or Hemolyzed Specimens, Serum) can be requested. To distinguish between the latter 2 conditions, patients should be retested for HCV RNA in 1 to 2 months, as clinically indicated.

Clinical Reference

1. Centers for Disease Control and Prevention (CDC): Testing for HCV infection: an update of guidance for clinicians and laboratorians. MMWR Morb Mortal Wkly Rep. 2013 May 10;62(18):362-365

2. American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA): HCV guidance: Recommendations for testing, managing, and treating hepatitis C. AASLD, IDSA; Accessed January 28, 2021. Available at www.hcvguidelines.org/contents

3. Society for Maternal-Fetal Medicine (SMFM), Hughes BL, Page CM, Kuller JA: Hepatitis C in pregnancy: screening, treatment, and management. Am J Obstet Gynecol. 2017 Nov;217(5):B2-B12

4. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: Pregnancy and HIV, viral hepatitis STD and TB prevention: HCV challenges. CDC; Reviewed May 22, 2019. Accessed January 28, 2021. Available at www.cdc.gov/nchhstp/pregnancy/challenges/hcv.html

5. Schillie S, Wester C, Osborne M, Wesolowski L, Ryerson AB: CDC recommendations for hepatitis C screening among adults-United States, 2020. MMWR Morb Mortal Wkly Rep. 2020 Apr 10;69(2):1-17

Performance

Method Description

The cobas hepatitis C virus (HCV) assay is an FDA-approved, in vitro nucleic acid amplification test for the quantification of HCV RNA in human serum using the cobas 6800 System or cobas 8800 System for fully automated viral nucleic acid extraction (generic silica-based capture technique) and automated amplification and detection of the viral nucleic acid sequence. This polymerase chain reaction (PCR) assay amplifies sequences within the highly conserved 5' noncoding region of the HCV genome and generates amplification products that are detected and quantified in real-time with 2 sequence-specific TaqMan probes. A non-HCV armored RNA quantitation standard (RNA QS) is introduced into each specimen during sample preparation to serve as internal control for nucleic acid extraction and PCR amplification/detection processes. Fluorescent reporter dye-labeled TaqMan probes hybridized to the complementary HCV target sequences and RNA QS sequence undergo hydrolysis during PCR amplification step to generate fluorescent signal detected in 2 different dye channels. Concentration of the HCV RNA in a patient's serum sample is determined by a ratio of the intensity of the fluorescent dye from the cleaved HCV target sequence probes and that from the RNA QS target probe detected throughout the PCR process.(Package insert: cobas HCV-Quantitative nucleic acid test for use on the cobas 6800/8800 Systems. Roche Molecular Systems, Inc; Doc rev. 1.0, 10/2015)

PDF Report

No

Specimen Retention Time

2 months

Performing Laboratory Location

Rochester

Fees & Codes

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

87522

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HCVRP	HCV RNA Detect/Quant Prenatal, S	11011-4

Result ID	Reporting Name	LOINC®
609749	HCV RNA Detect/Quant Prenatal, S	11011-4