

NEW TEST ANNOUNCEMENT**MML JACKSONVILLE****NOTIFICATION DATE:** May 19, 2010**EFFECTIVE DATE** June 10, 2010**HEPATITIS C ANTIBODY SCREEN WITH REFLEX TO HCV RNA BY
PCR, SERUM
#800294**

EXPLANATION: Mayo Medical Laboratories is pleased to announce that our Jacksonville Laboratory will be adding Hepatitis C Antibody Screen with Reflex to HCV RNA by PCR, Serum to their test menu. The testing and reporting is equivalent to Rochester test, Hepatitis C Antibody Screen with Reflex to HCV RNA by PCR, Serum (Test code #15060).

REFLEX TESTS:

Unit Code	Reporting Name	Available Separately	Always Performed
800226	HCV RNA Detect/Quant, S	Yes	No

USEFUL FOR: Detection and diagnosis of chronic HCV infection

METHODOLOGY: 800294: Chemiluminescence Immunoassay
800226 Real-Time Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

REFERENCE VALUES: Negative

SPECIMEN REQUIREMENTS: Draw blood in a serum gel tube(s). (**Heparinized specimen or serum drawn in a plain, red-top tube is not acceptable.**) Aseptically spin down within 1 hour of draw, immediately refrigerate specimen, freeze specimen within 12 hours of draw, and send 2 mL of serum frozen in a screw-capped, round-bottom, plastic vial. Forward promptly.

CAUTIONS:

- This test profile is not useful for detection or diagnosis of acute hepatitis C, 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.
- A single negative HCV RNA test result together and a reactive HCV antibody screen result with an S/CO ratio of $>$ or $=8.0$ do 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 of <10 years of age
 - Grossly icteric (total bilirubin level of >20 mg/dL)

- Grossly lipemic (triolein level of >3,000 mg/dL)
- Grossly hemolyzed (hemoglobin level of >500 mg/dL)
- Presence of particulate matter
- Cadaveric specimens

MML LIST FEE: \$ 131.80

CPT CODE: 86803/Hepatitis C antibody screen
87522/Hepatitis C, quantification (if appropriate)

ANALYTIC TIME: 1 day

DAY(S) SET-UP: Monday through Saturday

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager
Greg Renkly Mayo Medical Laboratories' Technologist Support
Telephone: 800-533-1710