

NEW TEST ANNOUNCEMENT

MML NEW ENGLAND

NOTIFICATION DATE: June 8, 2010 **EFFECTIVE DATE:** July 8, 2010

HEPATITIS C ANTIBODY SCREEN WITH REFLEX TO HCV RNA BY PCR, SERUM #200142

NOTE: The testing and reporting is equivalent to Rochester test #15060, HCV Ab Scrn w/Reflex to HCV PCR, S

USEFUL FOR: Detection and diagnosis of chronic HCV infection.

METHODOLOGY: Chemiluminescence Immunoassay

REFERENCE VALUES: Negative

TESTING ALGORITHM: If hepatitis C virus (HCV) antibody screen by chemiluminescence immunoassay is reactive, then #600008, HCV RNA Detect/Quant, Serum will be performed at an additional charge.

SPECIMEN REQUIREMENTS: Draw blood in 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, refrigerate specimen immediately, 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.
- The combination of a single negative HCV RNA test result and a reactive HCV antibody screen result with a 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:
 - o Individuals of <10 years of age
 - o Grossly icteric (total bilirubin level of >20 mg/dL)
 - o Grossly lipemic (triolein level of >3,000 mg/dL)
 - o Grossly hemolyzed (hemoglobin level of >500 mg/dL)
 - o Presence of particulate matter
 - o Cadaveric specimens

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 Friday