Quarterly HOTLINE: Effective August 20, 2018

New Test **3000572** **Hepatitis C Virus (HCV) by Quantitative NAAT** **HEPC QNT**

Additional Technical Information

Methodology: Quantitative Transcription Mediated Amplification
Performed: Sun-Sat
Reported: 1-3 days

Specimen Required: Collect: Lavender (EDTA), Pink (K_2EDTA), Yellow (ACD), Plasma Preparation Tube (PPT), or Serum Separator Tube (SST).
Specimen Preparation: Separate from cells within 6 hours of collection. Transfer 2 mL serum or plasma to an ARUP Standard Transport Tube. (Min: 1.2 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Heparinized specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 5 days; Frozen: 2 months

Reference Interval: Not Detected

Interpretive Data:
Normal range for this assay is "Not Detected".
The quantitative range of this assay is 10 - 100,000,000 IU/mL (1.0 – 8.0 log IU/mL).

Lower limit of quantitation (LLoQ):
10 IU/mL (1.0 log IU/mL)
LLoQ values do not apply to diluted specimens.
A result of "Not Detected" does not rule out the presence of inhibitors in the patient specimen or hepatitis C virus RNA concentrations below the level of detection of the test. Care should be taken when interpreting any single viral load determination.

This test should not be used for blood donor screening, associated re-entry protocols, or for screening Human Cell, Tissues and Cellular Tissue-Based Products (HCT/P).

Note: The limit of quantification for this RNA assay is 10 IU/mL (1.0 log IU/mL). If the assay DID NOT DETECT the virus, the test result will be reported as "Not Detected" If the assay DETECTED the presence of the virus but was not able to accurately quantify the number of copies, the test result will be reported as "< 10 Detected".

Specimens received with less than minimum volume for testing will automatically be run with a dilution according to the guidelines below:
-Specimens with 240-700 µL will be diluted 1:3 resulting in a quantitative range of 30 - 300,000,000 IU/mL (1.48-8.48 log IU/mL) .

This test is intended for use as an aid in the management of HCV-infected patients undergoing anti-viral therapy in conjunction with clinical and laboratory markers of infection. This test is also used in assessing HCV RNA levels at baseline, during treatment, at the end of treatment, and at the end of follow up of treatment to determine sustained or non-sustained viral response.

CPT Code(s): 87522

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.