TEST CHANGE

Hepatitis C Virus (HCV) by Quantitative NAAT

3000572, HEPC QNT

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pink (K2EDTA), ~~yellow (ACD),~~ plasma preparation tube (PPT), or serum separator tube (SST).
Specimen Preparation:	Separate from cells within 24~~6~~ hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube (ARUP supply #15824). Available online through eSupply using ARUP Connect(TM) or contact ARUP Client Services at 800-522-2787. (Minimum volume~~. (Min~~: 1.3~~2~~ mL)
Transport Temperature:	Frozen~~.~~
Unacceptable Conditions:	Heparinized specimens~~.~~
Remarks:	
Stability:	After separation from cells: Room temperature~~Ambient~~: 24 hours (Critical: s~~S~~hip FROZEN); Refrigerated: 6~~5~~ days; Frozen: 3~~2~~ months
Methodology:	Quantitative Polymerase Chain Reaction (PCR~~Transcription-Mediated Amplification (TMA~~)
Performed:	Sun-Sat
Reported:	1-3 days
Note:	The limit of quantification for this RNA assay is 15~~10~~ IU/mL (1.18~~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 test will be reported as "Not Quantified, Detected." ~~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 uL 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 antiviral 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 nonsustained viral response.~~

CPT Codes:	87522
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

~~Normal range for this assay is "Not Detected."~~
The quantitative range of this test~~assay~~ is 15~~10~~ -100,000,000 IU/mL (1.18~~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 is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection.

This test is also intended for use as an aid in the management of patients with an HCV infection undergoing antiviral therapy. The assay can be used to measure 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 nonsustained viral response. The results must be interpreted within the context of all relevant clinical and laboratory findings.

This test should not be used for blood donor screening, associated reentry protocols, or for screening human cells, tissues and cellular tissue-based products (HCT/P).

Reference Interval:

Not Detected

HOTLINE NOTE: There is a numeric map change associated with this test. Refer to the Hotline Test Mix for interface build information.