TEST CHANGE

Hepatitis Delta Virus by Quantitative PCR

2013881, HDV QNT

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube~~Separator Tube~~ (SST).
Specimen Preparation:	Separate serum from cells. Transport 2~~1~~ mL serum in a sterile container. (Min: 0.5 mL)
Transport Temperature:	Frozen.
Unacceptable Conditions:	
Remarks:	Specimen source required.
Stability:	Ambient: 24 hours; Refrigerated: 1 week; Frozen: 4 months
Methodology:	Quantitative Polymerase Chain Reaction
Performed:	Mon, Thu
Reported:	2-5 days
Note:	The limit of quantification for this test is 2.1 log IU/mL (120 IU/mL). If the test DID NOT DETECT the virus, the result will be reported as "< 2.1 log IU/mL (< 120 IU/mL)." If the test DETECTED the presence of the virus but was not able to accurately quantify the number of copies, the result will be reported as "Not Quantified."
CPT Codes:	87523
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

The quantitative range of this assay is 2.1-6.8 log IU/mL (120 - 5,800,000 IU/mL).

A negative result (less than 2.1 log IU/mL or less than 120 IU/mL) does not rule out the presence of PCR inhibitors in the patient specimen or HDV RNA concentrations below the level of detection of the test. Inhibition may also lead to underestimation of viral quantitation.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

Not Detected