

Notification Date: August 10, 2021 Effective Date: August 19, 2021

Hepatitis E Virus RNA Detection and Quantification by Real-Time RT-PCR, Serum

Test ID: HEVQU

Explanation:

This test, previously suspended due to reagent supply issues, will resume with a new performing platform. The following changes will apply due to this transition:

Previous Specimen Volume Requirement	New Specimen Volume Requirement
1.2 mL (minimum 0.6 mL)	1.8 mL (minimum 0.8 mL)
Previous Limit of Detection (LoD)	New Lower Limit of Detection (LoD) *
11 IU/mL	58 IU/mL
Previous Lower Limit of Quantification (LLoQ)	New Lower Limit of Quantification (LLoQ)
100 IU/mL	500 IU/mL

^{*} Results for specimens with HEV RNA detected at levels above the LoD, but below the LLoQ, will be reported as "<500 IU/mL". The upper limit of quantification (ULoQ) of the new assay remains unchanged at 5,000,000 IU/mL (or 6.70 log₁₀ IU/mL).

Questions

Contact James Conn, Laboratory Technologist Resource Coordinator at 800-533-1710.