Regional Medical Laboratory
4142 South Mingo Road
Tulsa, OK. 74146-3632

MEMORANDUM

To: All Regional Medical Laboratory (RML) clients

From: Cindi Starkey, MD, PhD, Chief of Molecular Diagnostics
Sonja Matthews, MT (ASCP), SC, Director of Clinical Operations
Patty Loykasek, HTL (ASCP), QIHC, BS, Molecular Test Development Specialist

Date: April 30, 2014

Subject: **HCV GENOTYPE BY PCR**

RML is pleased to announce we are now offering HCV genotype testing by PCR in-house. We will be utilizing the Abbott RealTi*m*e HCV Genotype II assay. This test will replace the HCV genotype line probe assay (LiPA). The use of reverse transcription-polymerase chain reaction (RT-PCR) will reduce the turnaround time, will provide a more objective interpretation, and will allow for digital archiving. In addition, the required viral load for RT-PCR is 500 IU/mL, and the LiPA assay requires 615 IU/mL. The accuracy of the RT-PCR result is double checked using an Abbott proprietary algorithm based on mathematical principles (maxRatio).

The RT-PCR assay will discriminate between HCV genotypes 1a, 1b, 2, 4, and 5. Genotype 6 will be a send-out test until this genotype is added to the IVD Abbott RealTi*m*e assay. In the US, approximately 75% of patients with HCV have genotype 1, 20-25% have genotypes 2 or 3, with small numbers of genotypes 4, 5, or 6. Of the genotype 1 patients, approximately 70% will be subtype 1a, and the remaining 30% will be subtype 1b.

Test Name: Hepatitis C Genotype, PCR
Order Mnemonic: HCV GENO
Test number: 5594650
Methodology: real time PCR (RT-PCR)
Specimen Required: EDTA plasma frozen within 2 hrs of collection
CPT code: 87902

If you have questions, please contact Cindi Starkey, MD, PhD, Chief of Molecular Diagnostics, Sonja Matthews MT (ASCP), SC, Director of Clinical Operations or Patty Loykasek, HTL (ASCP), QIHC, BS, Molecular Test Development Specialist at 918-744-2553 or 800-722-8077.