

Technical Update: HCV Genotyping now referred to ARUP

Overview

October, 2009

PathGroup Labs will be referring specimens for Hepatitis C virus (HCV) genotyping to ARUP Labs for analysis. HCV viral load will still be performed by PathGroup Labs.

This change is due to changes in the FDA's interpretation of certain guidelines regarding Analyte Specific Reagents, which now prohibit the sale for clinical testing use of certain configurations of reagents. The vendor for PathGroup's HCV Genotyping assay is no longer able to provide the reagents. Pathgroup is exploring other

vendors and other methods of providing this important test.

The ARUP HCV Genotyping assay is performed by reverse-transcription-PCR amplification of the HCV RNA genome, and dideoxy sequencing of the 5'-untranslated region (5'UTR). The assay can genotype and subtype all HCV virus types.

There will be no changes to the test code or CPT code. There will be an additional 1-2 days in the turnaround time due to the need to ship the specimen to ARUP Labs.

Clinical Utility

- Identification of HCV genotypes to determine therapeutic regimens

Methodology: Reverse-transcription PCR and dideoxy (Sanger) sequencing

Test Codes: HCVGT (Hepatitis C Virus Genotyping)

HCVQG (Hepatitis C Virus Quantitation by PCR with Reflex to HCV Genotyping)

CPT Codes: 87902

Specimen Collection, Shipping and Handling: Serum or plasma are acceptable specimen types.

- Blood should be collected in SST® Serum Separation Tubes or in sterile tubes using EDTA (lavender top) as the anticoagulant.
- Store whole blood at 2-25°C for no longer than 6 hours.
- Separate serum or plasma from whole blood within 6 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature. Transfer serum or plasma to a sterile polypropylene tube.
- Store and transport frozen.
- Transportation conditions are the same as the storage conditions.
- Do not allow a specimen to thaw once frozen.

Reference Ranges: There is no reference range for this assay.

Turnaround Time: 5-7 days