ClearPoint DIAGNOSTIC LABORATORIES

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LAB ALERT – TEST ENHANCEMENT

NOTIFICATION DATE: 10/22/2013
EFFECTIVE DATE: 10/25/2013

Change in Reportable Range for HCV Viral Load Assay (HCVQT, HCVQTR)

SUMMARY OF CHANGE: Our current HCV viral load assay has a linear range of 43 - 69,000,000 IU/mL. Our new version of this assay will have a wider reportable range of 15 - 100,000,000 IU/mL.

CLINICAL UTILITY: Current guidelines for the management and treatment of hepatitis C virus (HCV) recommend quantitative testing for HCV RNA before the start of antiviral therapy, during therapy (response guided therapy), and generally 12 to 24 weeks following the end of treatment. The goal of treatment is to obtain extended rapid virologic response (eRVR, defined as HCV RNA undetectable at 4 and 12 weeks) or early virologic response (EVR, defined as a 2-log or greater decrease in HCV RNA or undetectable HCV RNA after 12 weeks). Treatment duration of combination therapies can be tailored based upon the virologic response at these time points. Several clinical trials have shown that use of new FDA approved DAA (Direct-acting Antiviral Agents such as telaprevir and boceprevir) with the combination therapy have better outcomes (70-80% response rate) with chronic HCV genotype 1. The threshold for viral suppression is defined as <10-15 IU/mL in these trials. The new version of HCV viral load assay that we are offering will have a wider reportable range of 15- 100,000,000 IU/mL. This change will help physicians to optimize the treatment regimens.

TEST CODES: HCVQT, HCVQTR

METHODOLOGY: Roche COBAS AmpliPrep/COBAS TaqMan® HCV Test, v2.0; if reflexed Siemens Versant 2.0, INNO-LiPA Reverse Blot

NEW REPORTABLE RANGE: 15 to 100,000,000 IU/mL ($\log_{10}$ 1.18 to $\log_{10}$ 8.00 IU/mL)

IMPORTANT NOTE: **Please note that there is <u>NO CHANGE</u> in ordering, specimen collection, transport and stability, testing schedule and billing with this test enhancement.**

ORDER/CONTACT INFORMATION: *ClearPoint Client Services: 972-966-7700 | Fax: 972-966-7799*