

**LAB ALERT**

**Date:** 01/24/14

**To:** Regional Pathology Services Clientele

**From:** Regional Pathology Client Services

**Test Code:** HEPCQ (HCV RNA Detect/Quant)

**RE: Reference Range Changes and Lower Limits of Detection for Hepatitis C RNA Quantitative Assay**

Effective January 27<sup>th</sup> the Molecular diagnostics laboratory will upgrade the Hepatitis C Quantitative Assay from version 1.0 (v1.0) to version 2 (v2.0), which will result in improved sensitivity and a larger dynamic range.

- HCV v1.0 was reported to under quantify certain genotype 4 strains of HCV. The design of v2.0 improves the accuracy of quantitation of these genotype 4 strains, resulting in higher viral loads for some patients.

Below is a table comparing the range of detection of the old methodology with the new methodology:

		Lower Limit of Quantitation	Upper Limit of Quantitation
HCV viral load IU/mL	Version 1.0	50	$2.5 \times 10^7$
	<b>Version 2.0(New)</b>	<b>15</b>	<b><math>1.0 \times 10^8</math></b>

**Test codes and specimen requirements will remain the same:**

**Specimen Requirements:** One 6.0 mL SST (Gold) tube. Centrifuge tube within 24 hrs, aliquot serum and store frozen. Minimum of 2ml serum required.

**Reference Range: Hepatitis C RNA not detected (<15 IU/ml)**

**Interfaced Clients:** This change will not affect any of the interfaces. The new reference range will be automatically transmitted through the interfaces.

**Please call Regional Pathology Services with any questions or concerns regarding this lab alert at 402.559.6420 or Toll free at 1-800-334-0459.**