

August 29<sup>th</sup>, 2014

## TEST CHANGE NOTIFICATION

Dear Physicians and Staff,

Effective September 2<sup>nd</sup> 2014, Enzo Clinical Laboratory will replace the current Roche COBAS AmpliPrep/TaqMan HCV Test with a new version of test, the **COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0**. The differences between the current and new HCV RNA viral load tests are summarized below:

	<b>NEW</b>	<b>CURRENT</b>
<b>TEST NAME:</b>	COBAS AmpliPrep/TaqMan HCV,v2.0	COBAS AmpliPrep/TaqMan HCV
<b>TEST CODE:</b>	6385	6385
<b>REFERENCE RANGE:</b>	< 15 IU/mL	< 43 IU/mL
<b>REPORTABLE RANGE:</b>	15 - 100,000,000 IU/mL (1.18 - 8.00 log <sub>10</sub> IU/mL)	43 - 69,000,000 IU/mL (1.63 - 7.00 log <sub>10</sub> IU/mL)
<b>SPECIMEN REQUIREMENTS:</b>	Serum	Serum
<b>TURN AROUND TIME:</b>	5 days	5 days

***\*\*Please note that the reference range will be changed from < 43 IU/mL to < 15 IU/mL\*\****

The new HCV RNA Test, v2.0 accurately detects and quantitates HCV genotypes 1 through 6 in patient plasma samples. It can be used to confirm an active infection and monitor treatment response to HCV therapies. With its improved sensitivity and expanded reportable range, this new test will help improve the diagnosis and management of patients with HCV infections.

We appreciate the continued opportunity to serve you and your patients and welcome any questions or concerns you may have. You can reach us at 631-755-5500 or talk to your ECL sales or service representative for more information.

*Sincerely,*



**Dieter Schapfel, MD**  
**Medical Director**