November 22, 2011

To: Chiefs of Service, Attending Physicians, Housestaff, Nurses and Other Concerned Personnel

From: Barbara Haller, MD, PhD
Division Chief, Microbiology

Eberhard Fiebig, M.D.
Director, Clinical Laboratory

Re: A New Hepatitis C Virus Quantitative RNA Assay (HCV Viral Load Assay)

Beginning November 28, 2011, the San Francisco Clinical Laboratory will offer a real-time PCR quantitative RNA assay for Hepatitis C virus on the Abbott m2000 instrument, replacing the current bDNA method. Results from the new assay can be used to monitor therapy, including treatment with the new protease inhibitors. The lower limit of quantitation for this real-time PCR assay is 12 IU/mL, or 1.08 log IU/mL. If HCV RNA is detected below the linear range of the assay, the result will be reported as “Detected < 12 IU/mL” and “Detected < 1.08 log IU/mL.”

Important information about this new, real-time PCR assay includes the following:

1. For each patient, collect 2 (5mL) PPT-EDTA (white top) tubes.
2. NOTE: Serum (gold top tubes) will no longer be accepted for the HCV viral load assay.
3. Specimens must be delivered to the Clinical Laboratory within 4 hours after collection.
4. The linear range of this assay is 12 IU/mL (1.08 log IU/mL) to 100 million IU/mL (8.00 log IU/mL).
5. NOTE: Results will no longer be reported as copies/mL. Results will only be reported as IU/mL and log IU/mL.
6. Results will be reported as shown below:

<table>
<thead>
<tr>
<th>IU/mL</th>
<th>Log IU/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Detected</td>
<td>Not Detected</td>
</tr>
<tr>
<td>Detected &lt; 12 IU/mL</td>
<td>Detected &lt; 1.08 log IU/mL</td>
</tr>
<tr>
<td>12 to 100,000,000 IU/mL</td>
<td>1.08 to 8.00 log IU/mL</td>
</tr>
<tr>
<td>&gt; 100 million IU/mL</td>
<td>&gt; 8.00 log IU/mL</td>
</tr>
</tbody>
</table>

7. A result reported as “Detected < 12 IU/mL” and “Detected < 1.08 log IU/mL,” indicates that HCV RNA can be detected, but it is not quantifiable (i.e., it is below the limit of quantitation).
8. A result of “> 100 million IU/mL” and “> 8.00 log IU/mL” indicates that HCV RNA was detected and it is greater than the upper limit of quantitation.
9. This assay will be performed one time per week (turn-around-time is 7-10 days).

For questions or concerns, please contact Dr. Barbara Haller (206-3595) or Patricia Nassos (206-8578).