September 10, 2012

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

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

Eberhard Fiebig, MD
Director, Clinical Laboratory

Re: A New Hepatitis B Virus Quantitative Assay (HBV Viral Load)

Beginning the week of September 10th, 2012, the San Francisco General Hospital Clinical Laboratory will offer an in-house real-time PCR quantitative assay for Hepatitis B virus on the Abbott m2000 instrument, replacing the real-time assay currently sent to the ARUP reference laboratory. The new HBV Viral Load assay has an increased quantitative range compared to the ARUP assay. The lower limit of quantitation is 10 IU/mL, or 1.0 log IU/mL, and the upper limit of quantitation is 1 billion IU/mL, or 9.0 log IU/mL.

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

1. For each patient, collect 2 (5mL) PPT-EDTA (pearl-top) tubes.

2. Specimens must be received in the Clinical Laboratory within 4 hours after collection.

3. The linear range is 10 IU/mL (1.0 log IU/mL) to 1 billion IU/mL (9.0 log IU/mL).

4. When HBV viral load results on patient specimens from the new PCR assay were compared to results from the ARUP PCR assay, the correlation was 0.99. It should not be necessary to establish a new baseline viral load for patients being monitored for viral load changes.

5. 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; 10 IU/mL</td>
<td>Detected &lt; 1.0 log IU/mL</td>
</tr>
<tr>
<td>10 to 1,000,000,000 IU/mL</td>
<td>1.0 – 9.0 log IU/mL</td>
</tr>
<tr>
<td>&gt; 1 billion IU/mL</td>
<td>&gt; 9.0 log IU/mL</td>
</tr>
</tbody>
</table>

6. A result reported as “Detected < 10 IU/mL” and “Detected < 1.0 log IU/mL” indicates that HBV DNA can be detected, but it is not quantifiable (i.e., it is below the limit of quantitation).

7. A result of “> 1 billion IU/mL” and “> 9.0 log IU/mL” indicates that HBV DNA was detected and it is greater than the upper limit of quantitation.

8. The turn-around-time for assay results will be 2-14 days.

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