January 25, 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:     New Real-Time PCR Assay for Detection of Influenza A and Influenza B

Beginning February 1, 2012, SFGH Clinical Laboratory will implement a molecular assay for detection of influenza A and B viruses (Cepheid Xpert® Flu assay). The rapid assay currently in use for detection of influenza A and B (BD Directigen EZ Flu A+B) will be discontinued.

The Cepheid Xpert Flu assay is a reverse transcriptase polymerase chain reaction (RT-PCR) assay that can detect the presence of influenza A and B viruses in respiratory specimens (see specimen requirements below) with much greater sensitivity (85-100%) and specificity (98-99%) than the current assay.

Important information about the new real-time PCR assay for influenza viruses:

1. **Specimen Requirements:** Nasopharyngeal aspirates/washes or nasopharyngeal swab specimens sent in tubes with Universal Viral Transport Medium.

2. **Test availability:** 24 hours a day, seven days a week, including holidays.

3. **Turn-around-time:** 2 hours from the time the specimen is received in the lab.

4. Due to the significantly higher cost of the new test it is imperative that it only be ordered for patients with influenza-like symptoms who fall into at least one of the following categories:
   - will be admitted or treated with neuraminidase inhibitors
   - are at a higher risk of complications from influenza virus infection (people 65 years and older, people of any age with chronic medical conditions such as asthma, diabetes, or heart disease, pregnant women, children < 5 years old, immunocompromised patients, or morbidly obese patients – for comprehensive list see CDC website at cdc.gov/flu/about/disease/high_risk.htm).

5. **Xpert Flu assay results will be reported as follows:**
   a. POSITIVE. Influenza A or B target RNA detected. Report will specify which is detected.
   b. NEGATIVE. Influenza A and influenza B target RNA not detected.
   c. Presence or absence of influenza A and influenza B target RNA cannot be determined. Resubmit if clinically indicated. (Reported if the instrument result is either “invalid” or “error.” This result suggests the presence of inhibitors in the specimen).
6. If the RT-PCR assay result is negative for influenza A and influenza B virus, repeat testing can be performed after 14 days, or if approved by the Microbiology Laboratory Medicine Resident.

7. If the RT-PCR assay result is positive for influenza A or influenza B virus, repeat testing will not be performed during the current respiratory season, unless approved by the Microbiology Laboratory Medicine Resident.

8. Viral Culture with or without CMV testing can still be ordered for detection of influenza viruses and other viruses.

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