September 28, 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: Recall of Rapid Group A Strep Test Kits

The manufacturer of the Rapid Group A Strep Test Kit currently in use by the SFGH Clinical Laboratory (BD Directigen™ EZ Group A Strep Test) has recalled this product over concerns about an elevated incidence of false positive results. We are currently using this test kit to detect the presence of Group A Streptococcus in throat swab specimens.

1. As of Wednesday, September 28, 2011, the Clinical Laboratory will temporarily stop offering the rapid Group A Strep test, for which results are usually reported within one hour after receipt of specimens in the lab. Standard culture for Group A Streptococcus from throat swab specimens will still be available. If a rapid Group A Strep test is ordered, a culture will automatically be performed. Please continue to use the Double Swab Kit for Rapid Group A Strep Test (red top double swabs) for Group A strep culture.

2. The performance of a replacement kit will be verified by the Laboratory so the rapid test can again be offered for patients who may have strep throat. Notification will be sent when a new test kit is available and the rapid test can again be performed.

Please contact Dr. Barbara Haller (206-3595), Marguerite Roemer (206-3597), or Patricia Nassos (206-8578) with questions or concerns.