September 6, 2017

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

From: Barbara Haller, MD, PhD  
      Director, ZSFG Clinical Laboratory

Re:  Recall Notice for HIV Viral Load Test Results

Background: We have received a Field Correction Recall/Safety Notice from Abbott Diagnostics regarding the HIV-1 Viral Load Assay performed by ZSFG Clinical Laboratory.

Certain reagent lot numbers for HIV-1 viral load testing have the potential to exhibit false "Not Detected" results for HIV-1 samples less than 120 copies/mL. At 120 copies/mL and above, the percent detection is in accordance with the HIV-1 package insert, and accuracy is not affected.

Patient samples collected between 5/31/2017 and 6/27/2017 were tested at ZSFG Clinical Laboratory for HIV-1 viral load using the affected reagent lots.

Necessary Actions:

1. Providers should consider retesting patients who had HIV-1 viral load assays performed between 5/31/2017 and 6/27/2017, if the result was “Not Detected,” and knowing a more accurate quantitative result would have a significant effect on patient management and care. Accuracy was not affected for specimens with HIV-1 viral load results of ≥ 120 copies/mL.

2. To re-test a patient, please send 2 pearl-top EDTA tubes for HIV-1 viral load testing.

The specific reagent lot numbers affecting the HIV-1 Viral Load assay are no longer in use.

Please contact Beatrice Marcelo, Microbiology Supervisor at 415-206-8578, or Dr. Barbara Haller, Microbiology Division Chief and Director of ZSFG Clinical Laboratory at 415-206-8588 with any questions or concerns.