



Date	November 19, 2009
To	All Physicians and Clients
From	Denise Facaros, Manager, HealthCare Clinical Laboratories
Subject	H1N1 Update
Copies to	Stephen Connolly, M.D., Medical Director and Teresa Bryant, Sr. Director, HCCL

memorandum

H1N1 Timeline:

Spring 2009: Novel H1N1 flu, a respiratory infection caused by an influenza virus is first recognized.

July 24, 2009: FDA grants first authorization of Focus Diagnostics Commercial 2009 H1N1 Flu Test for use during Pandemic Flu Emergency. The test kit is authorized for use during the declaration of emergency, which is set to expire on April 26, 2010

September 28, 2009: HealthCare Clinical Lab announces H1N1 testing utilizing the Focus Diagnostics assay.

October 16, 2009: FDA issues a second emergency use Commercial Kit also from Focus Diagnostic, trademarked Simplexa.

About the Influenza A H1N1 (2009) Test

The Influenza A H1N1 test is a Real Time RT-PCR (real-time reverse transcriptase assay) for human influenza A virus, and the differential detection of 2009 H1N1 influenza virus in nasopharyngeal swabs, nasal swabs, throat swabs and nasal aspirates only. This is the most accurate laboratory test available which detects the viral RNA, by using a highly complex methodology.

Other more common tests are the rapid influenza test which has low sensitivity and specificity for influenza. The ability to detect the flu with the rapid test can vary greatly. Rapid tests do not distinguish 2009 H1N1 flu from other flu viruses.

Result Availability

From the time the specimen arrives in the laboratory, the results are generally available within 24-48 hours.

Please note, the current turn-around time will be reduced once HCCL validates the second emergency kit mentioned above, which provides the ability for higher throughput in less time.

CDC Recommendations

The following recommendations are for clinical use of influenza diagnostic testing:

1. People who are hospitalized with suspected flu.
2. People such as pregnant women or with weakened immune systems, for whom a diagnosis of flu will help their doctor make decisions about their care.

For any questions concerning this test please contact Dr. Stephen Connolly at 209-461-3468 or Denise Facaros at 209-467-6389.