

SENSITIVE PCR DETECTION OF H1N1 VIRUS — TEST CODE # 6874

The H1N1 influenza virus is one subtype of the Influenza A virus. It is a new infectious virus that can cause a range of diseases of the respiratory tract. The 2009 H1N1 pandemic influenza virus has affected millions of people in the US; the CDC estimates that nearly 14,000 people may have died from the infection.



■ RT-PCR TEST

Enzo Clinical Laboratories performs the RT-PCR test to detect the virus. This test was validated in the laboratory, using the US Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) kit manufactured by Roche, with the MagNaPure and Lightcycler Instrument (Roche). The test differentiates between the seasonal flu virus and the H1N1 virus, and reports positive or negative results for the RNA present in both, the seasonal flu type A, and the H1N1 subtype of the flu A virus. The Roche assay for the 2009 H1N1 influenza virus detects RNA from the 2009 H1N1 Influenza A virus and provides a rapid means of identification of patients infected with this virus. This test is similar in performance and sensitivity to the one used by the Centers for Disease Control and Prevention (CDC), since both tests use the PCR method of amplification. The CDC website describes the current status of the H1N1 flu pandemic, the testing guidelines, the evaluation of treatment options, and the methods available for the detection of H1N1.

■ REPORTING OF RESULTS

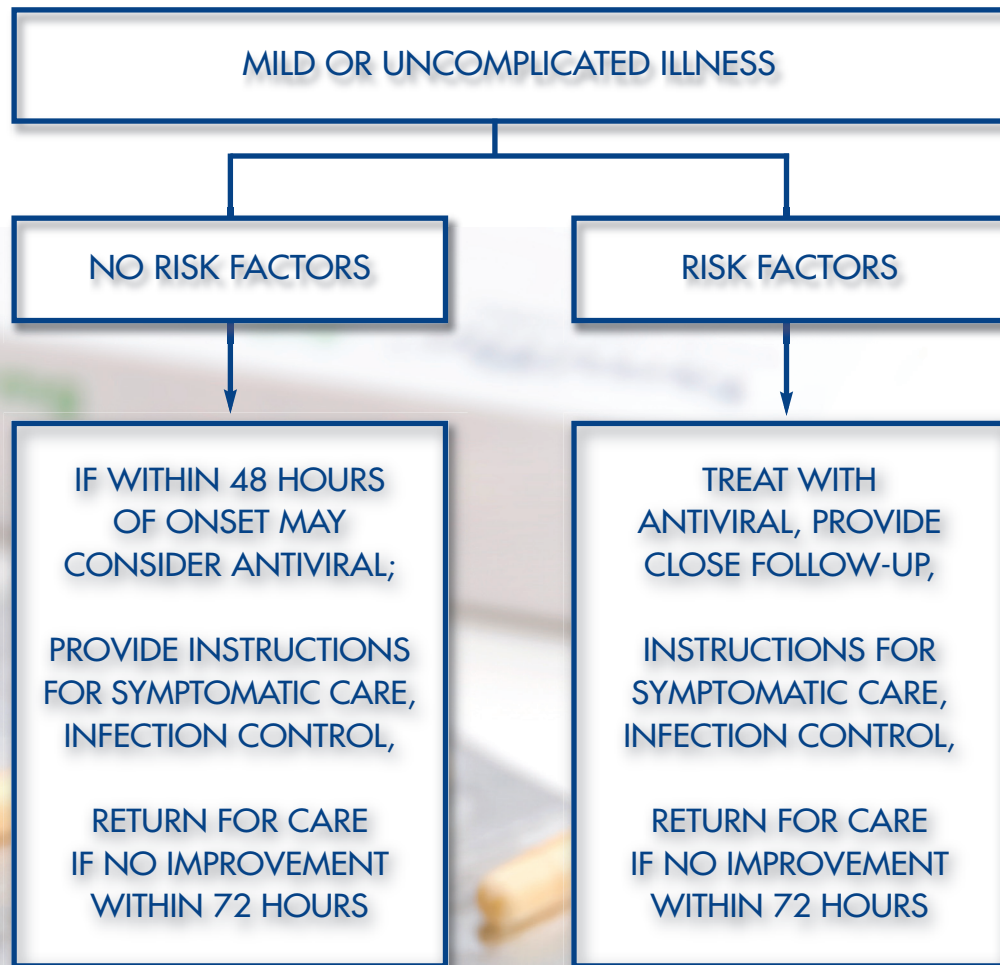
The results for the H1N1 influenza virus testing are usually reported within one day of receipt of samples by Enzo. This is the fastest turnaround time for any clinical laboratory.

The results of this test from nasopharyngeal swabs, nasal swabs, nasal washes, or nasal aspirates, along with other information, can help physicians take better care of their patients. Knowing the test results may help patients to prevent the spread of the virus to others.

■ TREATMENT OPTIONS AS RECOMMENDED BY THE CDC

This test is useful for patients who are hospitalized with suspected influenza, or patients for whom a diagnosis of influenza will allow management or control of the infection. The CDC also recommends antiviral treatment early. The algorithm used by the CDC for treatment purposes is shown on the next page.

CLINICAL ALGORITHM FOR CONSIDERATION IN THE ASSESSMENT OF PERSONS WITH MILD OR UNCOMPLICATED INFLUENZA ILLNESS.



Test Name:	H1N1 Virus by RT-PCR
Test Code:	#6874
Setup Time:	A.M.
Setup Days:	Monday thru Friday
Report Available:	Reports Same Day
Reference Range:	Not Detected

SPECIMEN REQUIREMENTS:

Specimen:	Nasopharyngeal swabs, nasal swabs, nasal aspirates, or nasal washes
Specimen Tube Requirements:	Viral Transport, Viral Culture or Universal Transport Media
Storage:	Refrigerated
Stability:	14 Days