

2009 H1N1 INFLUENZA A REAL-TIME RT-PCR

Test #	277900
Synonyms	Influenza A H1N1 (2009); Novel Influenza A (H1N1); flu; H1N1
Category	Molecular Diagnostics
Indication	<ul style="list-style-type: none">• If identification of the 2009 H1N1 influenza virus is required to support diagnosis and patient care• Hospitalized patients with suspected influenza• Patients that are pregnant, severely immunosuppressed, or with severe lower respiratory tract disease (e.g., suspected viral pneumonia)¹

Specimen Requirements

Specimen	<ul style="list-style-type: none">• Nasopharyngeal swab or aspirate• Nasal swab, aspirate or wash• Throat swabs• Combined throat/nasopharyngeal swab
Container	<ul style="list-style-type: none">• Sterile swabs with synthetic tips (e.g., Dacron®, polyester, rayon) and aluminum or plastic shafts NOTE: Do NOT use calcium alginate-tipped swabs.• Place swab in 1 – 3 mL of viral transport medium (VTM), such as M5 transport media (MEDTOX #T60), M4 transport media, or other appropriate VTM
Handling	Ship and store refrigerated

Assay Parameters

Methodology	Real-Time RT-PCR (rRT-PCR) specific for 2009 H1N1 influenza
Turn Around Time	1-2 days
CPT code	87798x2
Interpretation	Positive or Negative for 2009 H1N1 Influenza A Virus

Clinical Information

This real-time reverse transcriptase polymerase chain reaction (rRT-PCR) test is the most sensitive and specific influenza diagnostic test available. The reagents, procedures and equipment used to perform this assay have been evaluated and approved by the FDA under CDC's emergency use authorization (EUA) to diagnose 2009 H1N1 influenza viral infections.²

Clinicians must use their clinical judgment to determine when to perform influenza diagnostic testing in patients who are not severely ill. Testing can assist with decisions regarding clinical care, infection control, as well as management of close contacts. When specific testing for 2009 H1N1 influenza virus is required, this rRT-PCR assay should be performed¹.

Limitations

Specimens should be collected during the first three days of illness at which time viral levels are highest and influenza diagnostic tests are more likely to be positive.

References

Centers for Disease Control and Prevention (CDC), *Interim recommendations for clinical use of influenza diagnostic tests during the 2009-2010 influenza season*. www.cdc.gov/h1n1/guidance/diagnostic_tests.htm, Sept 29, 2009.

Centers for Disease Control and Prevention (CDC), *Medical Devices for Flu Diagnosis and Protection 2009 H1N1 Flu Virus (Swine Flu)* <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>, Update: May 6 2009.