



Influenza A H1N1/09 Real-Time RT-PCR

Advanced Diagnostic Laboratories (ADx) now offers a laboratory test for the pandemic 2009 H1N1 influenza A virus (H1N1/09)¹, with rapid reporting time.

In April 2009, the Centers for Disease Control (CDC) reported the first cases of “swine influenza A (H1N1) virus” containing unique genetic segments, not previously recognized in human influenza A viruses. By June, the World Health Organization (WHO) declared a flu pandemic, the first in 40 years. Illness caused by this virus is still commonly referred to as “swine flu”. CDC’s Flu Update reports that almost all of the influenza viruses identified so far this season are H1N1/09, and that reported influenza illnesses are much higher than expected.

The test offered by ADx Molecular Diagnostic Laboratory has been authorized by the FDA under an Emergency Use Authorization (EUA).² At present only one other test, developed by the CDC, has been authorized by EUA, and its availability from public health laboratories is limited. The ADx test is offered to supplement and extend H1N1 confirmatory testing to all physicians and patients.

Performance Benefits

- Employs real-time PCR to amplify and detect H1N1/09
- Detects all Influenza A strains (including H1N1/09) and specifically confirms H1N1/09
- Highly sensitive and specific: 98% concordance vs. CDC molecular test³
- Much more sensitive than other influenza tests, especially rapid tests (Table 1)
- Results reported within one business day of receipt (Mon through Fri)

Clinical Utility

- Confirms infection with H1N1/09
- Separately detects seasonal influenza A
- May aid in treatment decisions (Table 2)
- May aid in infection control⁵

Related Tests

- Respiratory Virus Panel by PCR
- Mycoplasma Pneumoniae PCR
- Chlamydomphila Pneumoniae PCR

For questions or to request a sample report please contact
ADx Client Services at
800.550.6227, Option 6

Table 1: Test Sensitivities for H1N1/09

Method	Sensitivity ⁴
Rapid Influenza →	17 – 69%
Direct Immunofluorescence →	47 – 93%
Real-Time PCR →	98 – 100%

Table 2: Influenza Antiviral Sensitivity⁶

	H1N1/09	Seasonal A/H1N1	Seasonal A/H3N1	Influenza B
Oseltamivir	Sensitive	Resistant	Sensitive	Sensitive
Amantidine/ Rimantidine	Resistant	Sensitive	Resistant	Resistant
Zanamivir	Sensitive	Sensitive	Sensitive	Sensitive

Test Information

Test Code:	H1N1
Test Description:	Influenza A H1N1/09 Real-Time RT- PCR
Intended Use:	<p>Aids in the detection and differentiation of seasonal influenza A virus and H1N1/09 virus.</p> <p>Please refer to the Health Care Provider and Patient Fact Sheets at www.NJlabs.org, under Laboratory Tests and Documents or contact ADx Client Services at 800.550.6227, Option 6</p>
Methodology:	Nucleic acid extraction followed by Real-time RT-PCR technology. Matrix gene from influenza A viruses is targeted in one set of reactions to identify both seasonal human influenza A virus and 2009 H1N1 influenza virus in the specimen. Two separate regions of the hemagglutinin gene of the 2009 H1N1 influenza virus are targeted also to differentiate the presence of seasonal human influenza A virus from the 2009 H1N1 influenza virus.
Reference Range:	Not Detected
Preferred Specimen:	Throat, nasal, or nasopharyngeal swab, in at least 2mL of M4 viral transport media, or equivalent universal transport media (UTM) or nasal aspirates in saline.
Specimen collection:	Use only sterile swabs: Dacron, nylon, or rayon with plastic shafts. DO NOT USE calcium alginate swabs. Collect nasal aspirates into sterile container
Transport Temperature:	2-8°C (refrigerated)
Results Available:	Within one business day of receipt. Results will include health care provider and patient fact sheets, which are also available online at www.NJlabs.org , under Laboratory Tests and Documents.
CPT Code:	87798 x 2
Disclaimers:	<ul style="list-style-type: none">• The FDA authorized this test under an Emergency Use Authorization• This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc• This test has not been FDA cleared or approved• This test is not available for New York patient testing

References:

- (1) H1N1/09 is also known as "pandemic flu virus" and S-OIV (swine-origin influenza virus)
- (2) This test is only authorized for the duration of the declaration of emergency (section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b). The declaration of emergency will expire on April 26, 2010, unless it is terminated or revoked sooner or renewed.
- (3) H1N1 Test Package Insert
- (4) Pollock et al. Clinical Infectious Diseases 2009; 49:e66–8. CDC. MMWR Morb Mortal Wkly Rep. 2009 Aug 7;58(30):826-9. Ginocchio et al. Journal of Clinical Virology 45 (2009) 191–195. http://www.accessdata.fda.gov/cdrh_docs/pdf8/k080570.pdf. Faix et al. NEJM 361;7 august 13, 2009
- (5) CDC infection control recommendations: (see http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm).
- (6) Adapted from CDC guidelines <http://www.cdc.gov/h1n1flu/recommendations.htm>.