



H1N1

Influenza A and 2009 A/H1N1 by rRT-PCR

GA Test Code	8191
Method	Real-time Reverse Transcriptase - Polymerase Chain Reaction (rRT-PCR)
PCR Targets	Flu A: qualitative detection of all known type A influenza viruses H1N1: qualitative detection of 2009 H1N1 subtype of influenza A
Specimens	Upper Respiratory Swab (e.g. nasopharyngeal): Swab specimens should be collected only on swabs with a synthetic tip (such as polyester or Dacron®) and an aluminum or plastic shaft. Do not use calcium alginate or wood-shafted swabs. Place the swab in 1-2 ml sterile saline or viral transport medium in a sterile leak-proof container. Ship ambient within 96 hours of collection. Bronchoalveolar Lavages, Respiratory Washes: 3.0 mL (1.0 mL), sterile leak-proof container. Ship ambient within 96 hours of collection. Other Samples: Please contact GA for questions about other specimens.
Causes for Rejection	Calcium alginate or wood-shafted swab; time and/or temperature instructions not followed as specified; quantity not sufficient (QNS) for analysis.
Reference Range	Not Detected
Turnaround Time	Monday through Saturday, results reported within 4-6 hours
CPT Code	87798 (x3)

Description

This assay uses real-time reverse transcriptase PCR to perform universal detection of all known type A influenza viruses, and specific detection of the 2009 H1N1 subtype of influenza A, also referred to as novel influenza A and swine flu. This assay was created in accordance with CDC protocol of real-time RT-PCR for influenza A (H1N1).¹

Clinical Utility

For the Flu A target, a “Detected” result indicates infection by the influenza A virus, but no subtype is specified. For the H1N1 target, a “Detected” result specifically indicates infection by the 2009 H1N1 subtype of influenza A. The results of the tests should be coupled with clinical presentation and other laboratory results to help determine appropriate patient management.

For detection of 2009 H1N1 influenza A, the sensitivity of rRT-PCR (99.3%) is far superior to the sensitivity of rapid influenza diagnostic tests (RIDTs), which ranges from 10-70%. Therefore, a negative RIDT result does not rule out 2009 H1N1 influenza A infection. Likewise, false positives can occur with RIDTs, especially during periods of low influenza activity (e.g. the very beginning of the season). When more conclusive testing is desired, follow-up confirmatory testing with rRT-PCR is warranted.²

1. CDC/WHO, [CDC protocol of realtime RT-PCR for influenza A \(H1N1\)](#), 28 April 2009, revision 1 (30 April 2009).

2. CDC, [Interim Guidance for the Detection of Novel Influenza A Virus Using Rapid Influenza Diagnostic Tests](#), 10 August 2009.

PCR is performed pursuant to a license agreement with Roche Molecular Systems, Inc.

Genetic Assays