

H1N1 Testing in America: H1N1 the Dominant Flu of 2009-2010

Quest Diagnostics, the world's leading diagnostic testing company, is uniquely positioned to provide insights into the impact of the 2009 H1N1 influenza virus (H1N1) on Americans. Quest Diagnostics is the only company in the U.S. that performs H1N1 laboratory testing and, through its Focus Diagnostics business, provides two H1N1 test kits that the FDA has authorized for emergency use by other qualified molecular laboratories.*

In this Quest Diagnostics Health Trends™ Report, we summarize analyses of more than 195,000 de-identified lab tests performed by five of our laboratories that perform H1N1 flu testing. Our H1N1 tests, the first of which were released on May 11, 2009, report whether a patient's specimen is positive for influenza A and/or H1N1. Our analysis supplements CDC reporting: cdc.gov/flu/weekly/.

**These H1N1 tests have not been FDA cleared or approved. These H1N1 tests have been authorized by FDA under an Emergency Use Authorization (EUA). These H1N1 tests are only authorized for the duration of the declaration of emergency under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1). Emergency-use authorization was recently renewed by the FDA through June 23, 2010.*

H1N1 “Crowds Out” Other Flu Viruses

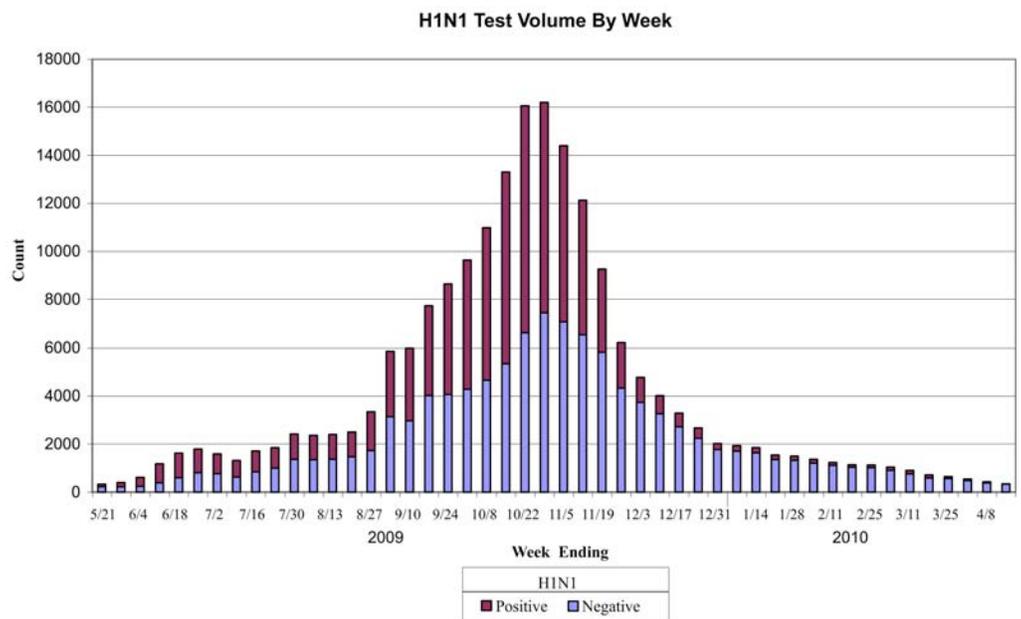
According to an analysis of our national testing data since May 2009, when we launched our first H1N1 test, more than 99 percent of specimens that tested positive for influenza A were positive for H1N1. Our laboratory testing data also show an absence of influenza B viruses. These findings suggest the H1N1 virus has “crowded out” other flu viruses, to be virtually the only influenza virus circulating in the U.S. since it was first identified in April 2009.

Two Major Waves of H1N1 Infection

Pandemic influenza viruses often occur in waves of infection. In the case of H1N1, two waves have occurred, according to an analysis of our national testing data (Graphic: “H1N1 Test Volume By Week”).

- The first wave occurred between May and mid-August 2009. (The CDC indicates the first wave began in April 2009; however, we introduced our first H1N1 test in May 2009 and do not have data for April 2009.)
- A second wave began in late August and peaked in late October 2009. Both testing volume and positivity rates have declined steadily since the second wave's peak.
- There is no evidence of a third wave. According to the CDC, flu season can last as late as May.

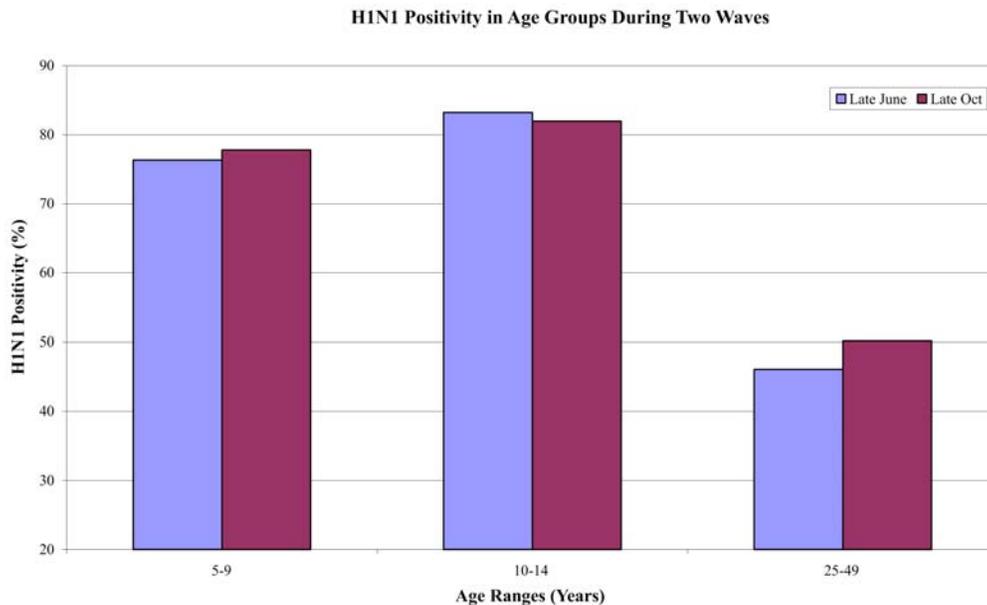
The Quest Diagnostics investigators believe the declines in testing and positivity rates may be due primarily to lower rates of infection from millions of Americans having already been infected with H1N1 and millions more having received the H1N1 vaccine, which have reduced the number of people susceptible to infection. In addition, changes in physician test-ordering practices may influence testing patterns.



This report is based on 100 percent of Quest Diagnostics' H1N1 testing between the seven days ending Thursday, May 21, 2009, and the seven days ending Thursday, April 8, 2010, and about 95 percent of testing volume for the seven days ending Thursday, April 15, 2010. Seven day periods ending Thursday, July 9, September 10, December 3, December 31, 2009, and January 7, 2010, include holidays when testing volume was reduced.

High Rate of H1N1 Positives Among Children Ages 5 to 14 During H1N1 Waves

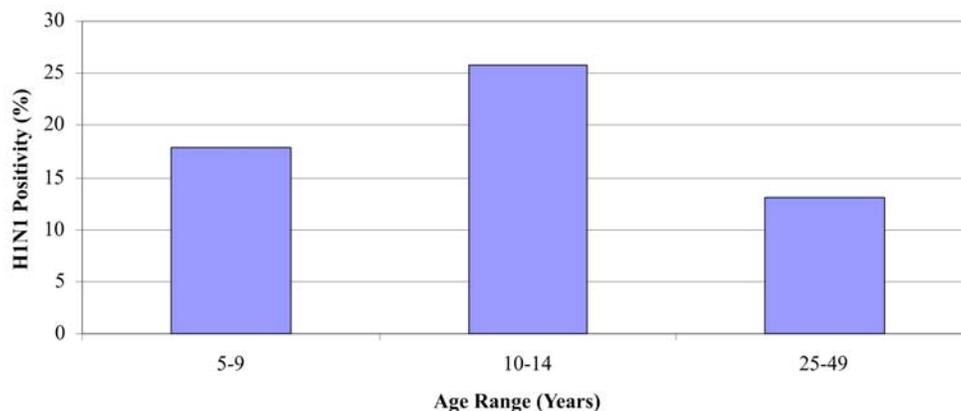
Our data also show that H1N1 positivity was highest among children during each of the two H1N1 waves that occurred in 2009 (Graphic: “H1N1 Positivity in Age Groups During Two Waves”). Among those aged 5 to 9 years who were tested, 76 percent were H1N1 positive in late June and 78 percent were positive in late October. Among children aged 10 to 14 years, 83 percent of tests performed were positive for H1N1 in late June and 82 percent were positive for H1N1 in late October. By comparison, positivity for adults aged 25 to 49 years tested was 46 percent in late June and 50 percent in late October.



As we reported in a prior H1N1 Health Trends™ Report (published October 20, 2009), children aged 10 to 14 years experienced a sharp increase in positive H1N1 results when school resumed across the nation in late August and early September. By October 2009, H1N1 positivity rates began to increase for other age groups. This trend – where children are the first to suffer from a new influenza virus that then spreads to other age groups – is consistent with the behavior of prior flu viruses. Our data suggest that the return of children to school in the fall was likely the trigger for a second wave of H1N1 infection.

In 2010, children have continued to experience higher rates of positive H1N1 test results (Graphic: “H1N1 Positivity by Age Group for the Four Weeks Ending April 15, 2010”). Eighteen percent of children aged 5 to 9 years tested and 26 percent of children aged 10 to 14 years tested were positive for H1N1 during the four weeks ending April 15, 2010. By comparison, 13 percent of adults aged 25 to 49 years were positive for H1N1 when tested during the same period.

H1N1 Positivity by Age Group for the Four Weeks Ending April 15, 2010



Southern U.S. Experienced Higher Rates of H1N1 Positives in Early 2010

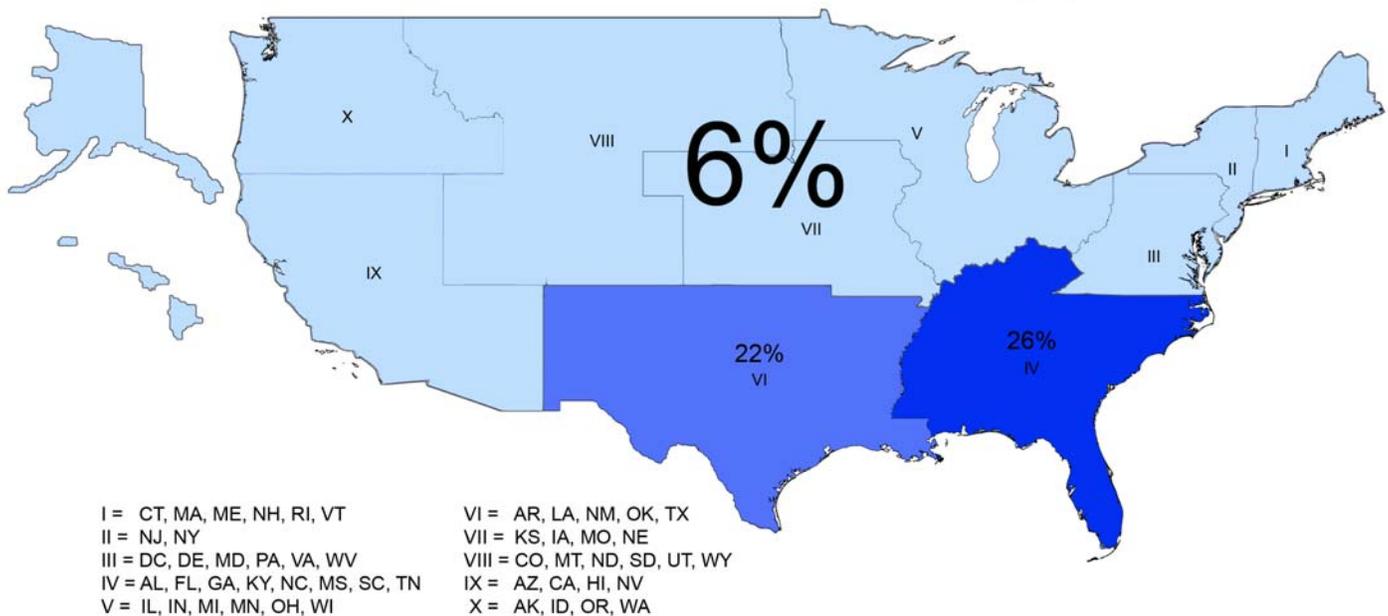
The Quest Diagnostics Health Trends™ Report also suggests that the rate of positive H1N1 tests in the south was higher than in other parts of the U.S. during the four weeks ending April 15, 2010 (Graphic: “H1N1 Positivity in the U.S. for the Four Weeks Ending April 15”).

- In the southeast region, 26 percent of patients in all age groups tested were positive for H1N1. The southeast includes Alabama, Florida, Georgia, Kentucky, Mississippi, North and South Carolina and Tennessee.
- In the central south region, 22 percent of patients in all age groups tested were positive for H1N1. The central south region includes Arkansas, Louisiana, New Mexico, Oklahoma and Texas.
- All other regions in the U.S. combined experienced positivity rates of 6 percent during the same time period.

The regions characterized below are based on regional breakdowns provided by the U.S. Department of Health & Human Services. For more information, please refer to: www.hhs.gov/about/regionmap.html.

Regional differences may be due to factors that include differences in test ordering practices by physicians and hospitals as well as changes in the spread of the virus. Our regional analysis is based on an analysis of approximately 85 percent of our total national data during the time period we evaluated, for a total of nearly 1,300 test results.

H1N1 Positivity in the U.S. for the Four Weeks Ending April 15



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