



November 9, 2004

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Draft Pandemic Influenza Preparedness and Response Plan
Department of Health and Human Services, Office of the Secretary

Dear Sir or Madam:

Attached please find the comments prepared by Quidel Corporation to the Draft Pandemic Influenza Preparedness and Response Plan.

We sincerely appreciate the opportunity given to us to formulate comments to the Plan, and thereby, the opportunity to play a role in supporting the government's efforts to address the negative impacts that a flu pandemic might have on our country.

We will be happy to answer any question you may have and will consider any request to further participate to the finalization of the plan.

Sincerely,

A handwritten signature in cursive script, appearing to read "Caren Mason".

Caren Mason
President and CEO
Quidel Corporation

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Draft Pandemic Influenza Preparedness and Response Plan

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Quidel Corporation's comments

Quidel Corporation appreciates the opportunity to formulate comments to the HHS Flu Pandemic Preparedness and Response Plan, and thereby, the opportunity to play a role in supporting the government's efforts to address the negative impacts that a Flu pandemic might have on our country.

As the leading manufacturer of rapid diagnostic tests for the detection of Influenza infection, Quidel Corporation believes that the flu rapid test is a powerful, objective adjunct to the diagnosis of the disease, and therefore, that its use should be forcefully emphasized in the Flu Pandemic Preparation Plan.

The DHHS and CDC have come a long way in recent years in recognizing the performance and unique value of rapid flu testing. So long as a rapid test, like Quidel's, has the following two characteristics, it brings real practical value to clinicians trying to manage overflow clinics and ERs: (1) the test must have strong PPV and NPV, and (2) it must be very user friendly. The user friendly criterion is a real Quidel strength given the "lay user" test performance data accepted by the FDA in re-categorizing the Quidel test to CLIA-waived status. Anybody can run, interpret and report to triage clinicians reliable test results from nasal swabs with Quidel tests, thereby promoting timely treatment and disease containment objectives.

We acknowledge the prime importance of vaccination as a proactive method of disease prevention and control. We also agree that use of specific medications may reduce the impact of the disease. However, the events of the last flu season have shown that a new strain may appear that vaccination will only partially protect and the events of this year demonstrate the fragility of our vaccination program.

These events clearly indicate that rapid testing has a definite place in the care continuum of vaccination, surveillance, diagnosis and treatment, and that the Plan should reflect more forcefully the positive impact a rapid flu test will have.

The rapid flu diagnostic test would be most effective in the following situations:

1- **Surveillance**

We respectfully recommend that a report form similar to the SARS ILI case report form ([CDC | Supplement B: SARS Surveillance--Appendix B2: SARS Domestic Case Reporting Form](#)) be distributed to public and clinical personnel.

2- **Early diagnosis of the disease to allow judicious use of antiviral drugs**

Because antivirals are effective only when administered within 24-48 hours of the onset of illness, the only objective method available for rapid diagnosis is a rapid flu test. Using the rapid test will allow for judicious use of the drug stockpile, and will therefore make the drug available to more patients than if only subjective symptomatology is used.

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3- Strategies to limit transmission

- a. Symptomatic travelers coming from infected areas may be rapidly tested with a rapid flu test at the point of entry, isolated and treated. The travelers' companions, or the individuals present on the same flight may be rapidly isolated, and prophylactically treated with antivirals.
- b. Systematic, rapid testing of symptomatic patients at emergency sites will allow for rapid triage and isolation of those testing positive for flu, therefore reducing the contamination by exposure of the many non-infected individuals presenting with similar symptoms.
- c. Rapid testing of symptomatic healthcare, police, National Guard and military personnel: isolation of individuals testing positive, and prophylactic treatment of their colleagues will allow for rapid control of a situation that could result in the virtual paralysis of entire units.
- d. Rapid testing of symptomatic students allowing for their rapid isolation and that of their class mates. Similarly, rapid testing of workers will allow companies to quickly harness the impact of the disease, therefore reducing the economic burden of the pandemic on the entire nation.

About Quidel Corporation

Quidel Corporation has developed and is currently marketing two rapid flu tests: The QuickVue[®] Influenza rapid test produces a single positive result when detecting the presence of Flu A or Flu B antigen in a sample. QuickVue[®] Influenza A+B is our differentiated influenza test and produces a different positive result when detecting the presence of Flu A or Flu B antigen in a single sample.

In 2001, Quidel Corp. was the first company to obtain CLIA waiver for a rapid flu diagnostic test. Since the launch of QuickVue[®] Influenza rapid test during the 1999-2000 flu season, Quidel has gained a prominent position in the field of rapid flu testing, and our sales account for over 50% of the flu rapid test market in the professional arena. Within the emergency department, a 90% share and within the physician's office lab, 84%. Our test also holds a major position in Japan, where flu testing is encouraged by the government, and is widely used during the flu season. Because the antigen targeted by our test is common to all flu viral strains and does not change year after year, the QuickVue[®] Influenza rapid test has been, and is used by the CDC in studying flu infection in various countries around the world.

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