Quidel Rapid Flu Test Now Available for Widespread Use in the U.S.

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SAN DIEGO, Oct. 12 /PRNewswire/ -- Quidel Corporation (Nasdaq: QDEL) today announced that the U.S. Food and Drug Administration (FDA) has granted a CLIA waiver for the Company's QuickVue(R) Influenza Test in time for this winter's flu season. Previously, only a limited number of physicians were able to access this diagnostic tool. Now an estimated 100,000 U.S. physicians' office laboratories will have access to this test, allowing more patients to benefit from rapid diagnosis and to receive the most appropriate treatment for their condition.

Every year more than 90 million people have flu-like symptoms, but many do not have influenza. The widespread use of Quidel's rapid diagnostic test will aid physicians to rule in or rule out influenza which is important because:

- Rapid diagnosis avoids unnecessary medications including overuse of antibiotics
- Prompt diagnosis of the disease allows for treatment with a variety of antiviral medications
- Flu-like symptoms can be indicative of other illnesses including potentially more serious conditions

"Accurate diagnosis of influenza is especially important in infants and young children because it can mimic other serious illnesses. With a rapid test to determine if a child has influenza, we can avoid painful procedures and ineffective therapies," said Kathryn M. Edwards, M.D., Professor of Pediatrics, Vanderbilt University School of Medicine. "After evaluating Quidel's rapid diagnostic test during last winter's flu season, it is clear that this test reliably provides a yes or no answer in minutes. Although this test is very useful, influenza prevention through vaccination remains our most important weapon."

Seventy to 76 million people in the U.S. are at high risk for influenza infections. The high risk populations include approximately 35 million persons aged 65 years or older, 39 million persons less than 65 years of age with high risk conditions and 2 million pregnant women. These infections cause an average of 114,000 excess hospitalizations and 20,000 deaths annually according to the U.S. Center for Disease Control and Prevention (CDC).

Rapid Test
The QuickVue(R) Influenza Test detects influenza types A and B within 10 minutes using a simple nasal swab, and is the only CLIA waived test on the market today. As a result of the CLIA waiver, a patient can now be tested and treated in one office visit.

"The combination of using our QuickVue(R) Influenza Test in the diagnosis of the virus and providing available treatment options represents a stronger line of attack against influenza than ever before," said Andre de Bruin, President and Chief Executive Officer of Quidel Corporation. "We are very excited about receiving a CLIA waiver for our QuickVue(R) Influenza Test as last flu season only a small fraction of physicians had access to this diagnostic tool."

CLIA Waived Diagnostics
The Clinical Laboratory Improvement Amendments (CLIA) of 1988 established national quality standards for most laboratories which perform testing on human specimens to ensure the reliability of test results regardless of where the test is performed. CLIA-regulated laboratories must meet specified quality standards to be eligible for payment from the Medicare and Medicaid programs. Diagnostic test systems are classified into one of three CLIA regulatory categories based on their potential risk to public health. Waived tests are the lowest regulated category and those most used in physician offices.

The Flu
Influenza is a highly contagious, acute viral infection of the upper respiratory tract. The virus can be dangerous and even deadly, particularly in high-risk patients and patients with underlying respiratory disease. According to the CDC, pneumonia and influenza were the 6th leading cause of death in the U.S. in 1996. Total direct and indirect costs of a severe flu epidemic have ranged between $12-$14.5 billion.

Quidel Corporation discovers, develops, manufactures and markets point-of-care, rapid diagnostic tests for detection of medical conditions and illnesses. These products provide accurate, rapid and cost-effective diagnostic information for acute and chronic conditions that affect women's health throughout the phases of their lives including reproductive status, pregnancy management and osteoporosis. Quidel also provides point-of-care diagnostics for infectious diseases, including influenza A and B, strep throat, H. pylori infection, chlamydia and infectious mononucleosis. Quidel's products are sold to healthcare professionals for use in physicians' offices, clinical laboratories and pharmacies, and to consumers through organizations that provide private label, store brand products. These tests provide diagnostic information to enable rapid treatment and improve health outcomes, lower costs, and increase patient satisfaction.

This press release contains forward-looking statements regarding Quidel's future activities within the meaning of the federal securities laws. These forward-looking statements involve material risks and uncertainties. Many possible factors could affect the future results and performance of Quidel's products, such that actual results and performance may differ materially. If Quidel's products fail to perform as expected, or if there is lower consumer demand for these products than expected, Quidel's financial condition and operating results may be materially and adversely affected. Quidel's financial condition and operating results may also be materially and adversely affected by a number of other factors, including, without limitation, seasonality, adverse changes in competitive and economic conditions, actions by the Company's distributors, manufacturing and production delays or difficulties and adverse actions or delays in product reviews by the FDA. Please see the discussion of these and other factors in Quidel's annual reports on Form 10-K and subsequent quarterly reports on Form 10-Q. For more information, please visit Quidel's web site at http://www.quidel.com.

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