Quidel QuickVue(R) Dipstick Strep A Test Receives CLIA-Waived Status

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SAN DIEGO, July 31 /PRNewswire/ -- Quidel Corporation (Nasdaq: QDEL), a leading provider of rapid point-of-care (POC) diagnostic tests, today announced that the U. S. Food and Drug Administration (FDA) has granted a CLIA waiver for the Company's QuickVue(R) Dipstick Strep A test for use in waived physician office laboratories. The CLIA-waiver greatly expands the test's potential user base because it allows the QuickVue test to be administered in more than 100,000 physician offices/laboratories in the United States rather than only in larger laboratories.

The QuickVue Dipstick Strep A test is intended for use as an aid in the diagnosis of Group A Streptococcal infection, a common bacterial infection associated with "strep throat." Classic symptoms include the abrupt onset of sore throat accompanied by fever, fatigue and headache. The test is simple to use and provides results in 5 minutes or less in an easy-to- read, user-friendly format.

The QuickVue Dipstick Strep A is the newest addition to Quidel's family of rapid strep A tests. The other tests include the first CLIA-waived rapid strep A test, the QuickVue(R) In-Line(R) Strep A as well as the QuickVue + (formerly CARDS(R) Q.S.(R)) Strep A.

CLIA Waived Diagnostics
The Clinical Laboratory Improvement Amendments (CLIA) of 1988 established national quality standards for most laboratories that 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.

About Quidel Corporation
Quidel Corporation discovers, develops, manufactures and markets rapid point-of-care, diagnostic tests for detection of medical conditions and illnesses. These products provide accurate, rapid and cost-effective diagnostic information for acute and chronic conditions associated with women's health, in areas such as reproduction and diseases of the elderly. Quidel also provides point-of-care diagnostics for infectious diseases, including influenza A and B, strep throat, H. pylori infection, chlamydia, infectious mononucleosis and bacterial vaginosis. Quidel's products are sold to healthcare professionals for use in physician 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. For more information, please visit Quidel's Web site at http://www.quidel.com.

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 business, 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 (both domestically and internationally) 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 report on Form 10-K and subsequent quarterly reports on Form 10-Q.

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