# Quidel Receives FDA Clearance for Its Hand-Held Molecular Diagnostic Test for Group A Strep

July 28, 2014

SAN DIEGO, CA -- (Marketwired) -- 07/28/14 -- ***Quidel Corporation*** (NASDAQ: QDEL), a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today that it has received clearance from the United States Food and Drug Administration (FDA) to market its AmpliVue GAS Assay for the qualitative detection of Group A β-hemolytic Streptococcus (*Streptococcus pyogenes*) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat.

The AmpliVue GAS Assay is an easy-to-use, handheld disposable molecular diagnostic test that has superb clinical accuracy and does not require culture confirmation of negative results. The assay requires no upfront extraction of DNA and generates an accurate result in less than one hour. Like other previously FDA-cleared AmpliVue assays, the AmpliVue GAS Assay does not require the customer to invest in either expensive thermocycling equipment, or any other upfront testing costs. Using AmpliVue can therefore significantly lower a laboratory's cost to adopt and maintain molecular testing methods.

Group A streptococci are Gram-positive bacteria, primarily residing in the nose, throat and skin; they are responsible for several illnesses, ranging from mild illnesses (strep throat or skin infections) to severe illnesses (necrotizing fasciitis, or streptococcal toxic shock syndrome).[1] Strep throat, or streptococcal pharyngitis, is the most common illness from Group A streptococcal infections. These bacteria are spread through contact with airborne droplets from an infected person's cough, sneeze or via contaminated items such as eating utensils.[2]

"We are very pleased with the rapid pace of our AmpliVue assay development. Our AmpliVue assay for Group A Strep is our third AmpliVue product to be 510(k)-cleared by the FDA in the last seven months," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "Our sales force now has a broader suite of fast and accurate molecular assays that offer a compelling value, especially among smaller labs that generally do not test using molecular methods. With respect to diagnosing Group A streptococcal infections, Quidel now has a breadth of diagnostic offerings ranging from the Sofia immunofluoresence-based test to the hand-held AmpliVue molecular assay to the Lyra Strep A + C/G molecular product for higher throughput labs."

Quidel's AmpliVue platform now enables laboratories of all sizes to perform highly sensitive and specific molecular tests. The AmpliVue GAS Assay is Quidel's fourth molecular infectious disease assay to receive 510(k) clearance from the FDA in this hand-held, disposable AmpliVue format. Quidel now offers 510(k)-cleared, *in vitro* diagnostic products on this novel platform for the diagnosis of five pathogens: C. difficile, Group A Strep, Group B Strep, HSV1 and HSV2.

1. http://www.cdc.gov/ncidod/dbmd/diseaseinfo/groupastreptococcal_g.htm
2. http://www.cdc.gov/Features/strepthroat/

***About Quidel Corporation***

Quidel Corporation serves to enhance the health and well being of people around the globe through the development of diagnostic solutions that can lead to improved patient outcomes and provide economic benefits to the healthcare system. Marketed under the QuickVue®, D3® Direct Detection and Thyretain® leading brand names, as well as under the new Sofia®, AmpliVue® and Lyra™ brandsQuidel's products aid in the detection and diagnosis of many critical diseases and conditions, including, among others, influenza, respiratory syncytial virus, Strep A, herpes, pregnancy, thyroid disease and fecal occult blood. Quidel's research and development engine is also developing a continuum of diagnostic solutions from advanced lateral-flow and direct fluorescent antibody to molecular diagnostic tests to further improve the quality of healthcare in physicians' offices and hospital and reference laboratories. For more information about Quidel's comprehensive product portfolio, visit quidel.com and Diagnostic Hybrids at dhiusa.com.

*This press release contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, fluctuations in our operating results resulting from seasonality; the timing of the onset, length and severity of cold and flu seasons; government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses; adverse changes in competitive conditions in domestic and international markets; the reimbursement system currently in place and future changes to that system; changes in economic conditions in our domestic and international markets; changes in sales levels as it relates to the absorption of our fixed costs; lower than anticipated market penetration of our products; the quantity of our product in our distributors' inventory or distribution channels and changes in the buying patterns of our distributors; our development of new technologies, products and markets; our development and protection of intellectual property; our reliance on a limited number of key distributors; our reliance on sales of our influenza diagnostics tests; our ability to manage our growth strategy, including our ability to integrate companies or technologies we have acquired or may acquire; intellectual property risks, including but not limited to, infringement litigation; limitations and covenants in our senior credit facility; that we may incur significant additional indebtedness; our need for additional funds to finance our operating needs; volatility and disruption in the global capital and credit markets; acceptance of our products among physicians and other healthcare providers; competition with other providers of POC diagnostic products; changes in government policies; adverse actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA"); compliance with other government regulations, such as safe working conditions, manufacturing practices, environmental protection, fire hazard and disposal of hazardous substances; third-party reimbursement policies; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance; the loss of key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into US markets; our failure to maintain adequate internal control*

*over financial reporting; volatility in our stock price; dilution resulting from future sales of our equity; and provisions in our charter documents and Delaware law that might delay stockholder actions with respect to business combinations or the election of directors. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," and similar words, although some forward-looking statements are expressed differently. The risks described under "Risk Factors" in reports and registration statements that we file with the Securities and Exchange Commission (SEC) from time to time should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this press release. We undertake no obligation to publicly release the results of any revision or update of the forward-looking statements, except as required by law.*

Quidel Contact:
Quidel Corporation
Randy Steward
Chief Financial Officer
858.552.7931

Media and Investors Contact:
Quidel Corporation
Ruben Argueta
858.646.8023
Email Contact

Source: Quidel