Quidel Receives FDA Clearance for Its New Solana(R) Molecular Assay for the Detection of Clostridium difficile (C. difficile) Infections

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SAN DIEGO, CA -- (Marketwired) -- 05/11/17 -- ***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 510(k) clearance from the United States Food and Drug Administration (FDA) to market its Solana® C. difficile Assay for the direct, qualitative detection of the *Clostridium difficile* DNA in unformed stool specimens of patients suspected of having *Clostridium difficile*-infection (CDI).

Clostridium difficile is the most frequently identified enteric pathogen in patients with antibiotic-associated diarrhea and colitis. Per the Centers for Disease Control and Prevention (CDC), *C. difficile* was responsible for approximately half a million infections in the United States in 2011, with 29,000 patient deaths occurring shortly after the initial diagnosis.[1]

Clostridium difficile bacterial infections are life threatening, especially for the elderly, for the immunocompromised, and for patients on a prolonged antibiotic regimen. Typical CDI symptoms include nausea, fever, watery diarrhea and abdominal pain due to inflammation of the colon.

Traditional methods for diagnosing CDI, such as glutamate dehydrogenase (GDH) or toxin antigen tests, can lack sensitivity and increase lab costs due to additional confirmation testing. In addition to significant technical expertise, cytotoxicity assays and toxigenic culture require 24 to 48 hours and 3 to 5 days, respectively, before reliable results can be obtained. The Solana *C. difficile* assay will now enable laboratories to offer a fast and sensitive result generated by molecular methods, without an upfront nucleic acid extraction step.

The Solana *C. difficile* Assay is an easy-to-use, accurate, molecular diagnostic test that generates an accurate result in about 35 minutes.

The Solana molecular platform leverages the Helicase-Dependent Amplification (HDA) technology that is resident in Quidel's AmpliVue® molecular product line to generate a fast and accurate test result. Solana can process up to 12 different assays or patient samples in each batched run, and provides time-saving workflow advantages to healthcare professionals in moderately complex settings.

"We are excited to introduce a Solana assay that can make a profound difference in the lives of people that are affected by CDI through a quick and accurate diagnosis. The laboratorian will benefit from the Solana platform's ability to address the particular workflow needs of the moderately complex laboratory setting in a cost-effective manner by neatly balancing higher volume sample testing at scale with customizable, on-demand assay processing," said Douglas Bryant, president and chief executive officer of Quidel Corporation.

The Solana® C. difficile Assay is Quidel's first molecular diagnostic test to receive 510(k) clearance from the FDA in the scalable and versatile Solana format for diagnosis of a Healthcare Associated Infection (HAI). Other 510(k) cleared Solana molecular diagnostic assays include:

Solana® HSV 1+2/VZV Assay	STI	Cleared 11/28/16
Solana® Complete (Strep A + C/G) Assay	Respiratory	Cleared 10/25/16
Solana® Influenza A+B Assay	Respiratory	Cleared 09/27/16
Solana® Trichomonas Assay	STI	Cleared 08/15/16
Solana® Group A Strep Assay	Respiratory	Cleared 06/23/15

With the Solana franchise, Quidel has broadened its molecular strategy to include instrumented systems, and grown the number of its molecular platforms that are both 510(k) cleared and available commercially. Quidel's other FDA cleared molecular solutions include the AmpliVue® non-instrumented system for lower-volume moderately complex labs, and Lyra® reagents for higher throughput, highly complex laboratories that are compatible with existing PCR infrastructure.

1. https://www.cdc.gov/hai/organisms/cdiff/cdiff_infect.html

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 Sofia®, QuickVue®, D3® Direct Detection and Thyretain® leading brand names, as well as under the new Solana®, AmpliVue® and Lyra® molecular diagnostic brands, Quidel'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.

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, our reliance on development of new technologies, fluctuations in our operating results resulting from the timing of the onset, length and severity of cold and flu seasons, seasonality, 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, lower than anticipated market penetration of our products, the quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors, and changes in the healthcare market and consolidation of our customer base; our development and protection of proprietary technology rights; our development of new technologies, products and markets; 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; our inability to settle conversions of our Convertible Senior Notes in cash; the effect on our operating results from the trigger of the conditional conversion feature of our Convertible Senior Notes; our need for additional funds to finance our capital or operating needs; the financial soundness of our customers and suppliers; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; adverse actions or delays in new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the "FDA"); changes in government policies; 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 and exposure to other litigation claims; interruption to our computer systems; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations and foreign currency exchange risk sharing arrangements, 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 U.S. markets; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents, Delaware law and the indenture covering our Convertible Senior Notes that might delay or impede stockholder actions with respect to business combinations or similar transactions; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although some forward-looking statements are expressed differently. The risks described in reports and registration statements that we file with the Securities and Exchange Commission (the "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. Except as required by law, we undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.

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