



## Quidel Receives FDA Clearance for Its AmpliVue(R) Hand-Held Molecular Diagnostic Test for Herpes Simplex Virus Types 1 and 2

March 27, 2014

SAN DIEGO, CA -- (Marketwired) -- 03/27/14 -- **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 510(k) clearance from the United States Food and Drug Administration (FDA) for the sale of its AmpliVue HSV 1+2 Assay for the differentiation and detection of herpes simplex viruses 1 and 2.

The AmpliVue HSV 1+2 Assay is easy-to-use, handheld and disposable. The assay requires no upfront extraction of DNA and generates an accurate result in approximately one hour. Like other previously FDA-cleared AmpliVue assays, the AmpliVue HSV 1+2 Assay does not require investment in expensive thermocycling equipment. Using AmpliVue can therefore significantly lower a laboratory's cost to adopt and maintain molecular testing methods.

The Centers for Disease Control and Prevention (CDC) estimate that there are almost 800,000 new cases of herpes in the United States each year, and about 1 in 6 Americans aged 14 to 49 have a genital HSV 2 infection.<sup>1</sup>

"We are pleased to launch our third AmpliVue assay and are certainly delighted by the acceleration in the pace of AmpliVue product development by our organization since BioHelix's acquisition in May of last year," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "Hospitals are becoming increasingly aware of the AmpliVue brand, and we plan to build on that momentum with even more AmpliVue product introductions later this year."

The AmpliVue product line now enables laboratories of all sizes to perform highly sensitive and specific molecular tests for four pathogens -- two viruses and two bacterial species -- without incurring the significant expense that is usually required to adopt and maintain molecular testing methods on-site. The AmpliVue HSV 1+2 is Quidel's third assay to launch in its hand-held, disposable format. The AmpliVue C. difficile assay for the molecular detection of toxigenic *Clostridium difficile* bacterial DNA received FDA clearance in December of 2012. The AmpliVue GBS Assay for the molecular detection of Group B *Streptococcus* infections received FDA clearance in December of 2013. All three assays are now available for sale throughout the U.S. and Europe, with several other assays currently in development.

<sup>1</sup> <http://www.cdc.gov/std/Herpes/STDFact-Herpes.htm>

### About Quidel Corporation

Quidel Corporation serves to enhance the health and wellbeing 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™ 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](http://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, seasonality, the timing of onset, length and severity of cold and flu seasons, the level of success in executing on our strategic initiatives, our reliance on sales of our influenza diagnostic tests, uncertainty surrounding the detection of novel influenza viruses involving human specimens, our ability to develop new products and technology, adverse changes in the competitive and economic conditions in domestic and international markets, our reliance on and actions of our major distributors, technological changes and uncertainty with research and technology development, including any molecular-based technology, the medical reimbursement system currently in place and future changes to that system, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA"), our ability to comply with FDA, environmental and other regulations, our ability to meet unexpected increases in demand for our products, our ability to execute our strategy, including the integration of new companies or technologies, disruptions in the global capital and credit markets, our ability to hire key personnel, intellectual property, product liability, environmental or other litigation, potential required patent license fee payments not currently reflected in our costs, adverse changes in our international markets, potential inadequacy of booked reserves and possible impairment of goodwill, and lower-than-anticipated acceptance, sales or market penetration of our new products. 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 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.*

2593ID0214D (02/14)

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Source: Quidel