



## Quidel Receives FDA Clearance for Its Molecular PCR Assay for the Detection of Herpes Simplex Virus 1+2 and Varicella Zoster Virus

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SAN DIEGO, CA -- (Marketwired) -- 05/14/14 -- **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, via the *De Novo* Request process, from the United States Food and Drug Administration (FDA) to market its Lyra™ Direct HSV 1+2/VZV multiplex real-time PCR assay. This new molecular test detects and differentiates herpes simplex viruses 1 and 2 (HSV 1+2) and varicella-zoster virus (VZV) nucleic acids isolated and purified from swab specimens taken from cutaneous (skin) or mucocutaneous (e.g., mouth, lips, or genitals) lesions on symptomatic patients.

Quidel's latest assay for HSV 1+2/VZV is part of its exciting new Lyra brand of ready-to-use, molecular PCR reagent kits specifically designed to be compatible with a laboratory's existing thermocycler.<sup>1</sup> The Lyra reagent kits provide attractive features that include a short time to result, ready-to-use master mix, and refrigerated, non-frozen storage of key reagents, as well as other benefits.

Lyra Direct HSV1+2/VZV Assay distinguishes between three pathogenic viruses: HSV 1, the virus responsible for most cold sores and some genital herpes transmissions; HSV 2, the virus primarily responsible for most genital herpes and some cold sores; and VZV, the virus responsible for chicken-pox in children and shingles among adults. The Centers for Disease Control and Prevention (CDC) estimates 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>2</sup>

The Lyra Direct HSV 1+2/VZV Assay kit includes an extraction-free, three-step sample preparation process that does not require time-consuming automated extraction. This fast and easy direct-to-amplification procedure allows the assay to generate a result in approximately 50 minutes.

"We are pleased to receive FDA clearance for our Lyra Direct HSV 1+2/VZV Assay," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "Our Lyra assay allows us to offer a molecular diagnostic alternative to our widely used cell-based ELVIS assay for the detection and identification of herpes simplex viruses. The inclusion of varicella-zoster virus to the multiplex assay provides the clinician with a rapid and sensitive tool not previously available to aid in the differential diagnosis of herpes simplex virus 1, herpes simplex virus 2 and varicella-zoster virus in humans."

Quidel also offers FDA-cleared, molecular diagnostic assays under the Lyra brand for the accurate detection of other infectious diseases, such as those caused by Influenza A+B, Respiratory Syncytial Virus, Human Metapneumovirus, *Clostridium difficile*, and Group A and pyogenic Group C or G Streptococcus.

Quidel's AmpliVue product line offers FDA-cleared, hand-held molecular diagnostic assays for the accurate detection of *Clostridium difficile*, Group B *Streptococcus*, and herpes simplex viruses 1 and 2.

The four Lyra and three AmpliVue assays are now available for sale throughout the U.S. and Europe, with several other assays currently in development.

### **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™ 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, 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.*

<sup>1</sup> Life Technologies QuantStudio™ Dx, Applied Biosystems® 7500 Fast Dx, Cepheid SmartCycler® II

<sup>2</sup> <http://www.cdc.gov/std/Herpes/STDFact-Herpes.htm>

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