



## Quidel Receives 510(k) Clearance for Quidel Triage® TOX Drug Screen, 94600 Toxicology Test for Use With Quidel's Triage® MeterPro Instrumented System

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**Quidel Corporation (NASDAQ: QDEL) ("Quidel")**, a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today that Quidel has received 510(k) clearance from the United States Food and Drug Administration (FDA) to market the Quidel Triage® TOX Drug Screen, 94600, a fluorescence immunoassay for the qualitative determination of the presence of drug and/or metabolites in human urine of up to 9 drug assays. The test is to be used with Quidel's Triage® MeterPro instrumented system.

Drug abuse in the United States continues to be an increasingly significant social and economic problem. Opiates, cocaine, THC and amphetamines are recognized by the Substance Abuse and Mental Health Services Administration (SAMHSA) as the most frequently abused illicit drugs. Benzodiazepines, tricyclic antidepressants, barbiturates and opiate compounds are among a group of prescription drugs that also are frequently abused.

Urine-specific screening tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most accepted method for screening urine for the presence of drugs.

The Quidel Triage TOX Drug Screen, 94600 uses distinct immunoassays for the simultaneous detection of drug and/or the urinary metabolites of up to 9 different drug classes. The use of monoclonal antibodies that are specific for the metabolites of the 9 drug classes ensures a high degree of sensitivity and specificity. The positive or negative results are typically displayed on the Quidel Triage MeterPro screen in approximately 15 minutes from the addition of specimen. All results are stored in the Meter memory to display or print when needed. If connected, the Meter can transmit results to the laboratory or hospital information system.

"We believe that our latest diagnostic screening test can play an important role in providing fast, diagnostic answers to healthcare providers in the emergency and urgent care settings," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "We are very pleased to receive clearance from the FDA for our Quidel Triage TOX Drug Screen, 94600 toxicology test and are optimistic that this assay will drive growth in the Triage business by delivering a more reliable, higher quality product to the customer, as well as creating further growth in the installed base of MeterPro instruments out in the field."

### 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, Thyretain®, Triage® and InflammDry® 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 recently acquired Triage® system of tests comprises a comprehensive test menu that provides rapid, cost-effective treatment decisions at the point-of-care (POC), offering a diverse immunoassay menu in a variety of tests to provide diagnostic answers for quantitative BNP, CK-MB, d-dimer, myoglobin, troponin I and qualitative TOX Drug Screen. Quidel's research and development engine is also developing a continuum of diagnostic solutions from advanced immunoassay 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).

### Forward-Looking Statements

*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, 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, our reliance on sales of our influenza diagnostic tests, 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, 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 exposure to claims and litigation, including litigation currently pending against us involving Beckman Coulter; intellectual property risks, including but not limited to, infringement litigation; 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") or other regulatory authorities or loss of any previously received regulatory approvals or clearances; changes in government policies; costs of or our failure to comply with government regulations in addition to FDA regulations; compliance with government regulations relating to the handling, storage and disposal of hazardous substances; third-party reimbursement policies; our failure to comply with laws and regulations relating to billing and payment for healthcare services; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance; failure in our information technology and storage systems; our exposure to cyber-based attacks and security breaches; 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; changes in tax rates and exposure to additional tax liabilities or assessments; risks relating to the acquisition and integration of the Triage and BNP Businesses; Alere's failure to perform under various transition agreements relating to our acquisition of the Triage and BNP Businesses; that we may incur substantial costs to build our information technology infrastructure to transition the Triage and BNP Businesses; that we may have to write off goodwill relating to our acquisition of the Triage and BNP Businesses; that we our ability to manage our growth strategy; the level of our indebtedness; the amount of, and our ability to repay, renew or extend, our outstanding debt and its impact on our operations and our ability to obtain financing; that substantially the Senior Credit Facility is secured by substantially all of our assets; our prepayment requirements under the Senior Credit Facility; the agreements for our indebtedness place operating and financial restrictions on the Company; that an event of default could trigger acceleration of our outstanding indebtedness; that we may incur additional indebtedness; increases in interest rate relating to our variable rate debt; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents, Delaware law and the indenture governing 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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