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QUIDEL'S QUICKVUE® AT-HOME OTC COVID-19 TEST RECEIVES EMERGENCY USE AUTHORIZATION FOR SCREENING USE WITH SERIAL TESTING

Easy-to-use at-home test provides results in ten minutes

SAN DIEGO--(BUSINESS WIRE)-- Mar 31, 2021 -- Quidel Corporation (NASDAQ: QDEL) ("Quidel"), a leading provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today that it has received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), allowing the company to market its new **QuickVue® At-Home OTC COVID-19 Test** for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two (or three days) with at least 24 hours (and no more than 36 hours) between tests. This test is authorized for nonprescription home use with self-collected (unobserved) direct anterior nares (NS) specimens from individuals aged 14 years and older or with adult-collected anterior NS samples from individuals aged 2 years or older. Additional information regarding the intended use of the **QuickVue® At-Home OTC COVID-19 Test** can be found at **www.quidel.com.**

The QuickVue® At-Home OTC COVID-19 Test shows excellent performance, with positive results agreeing with PCR 83.5% of the time, and negative results agreeing 99.2% of the time, delivering confidence to patients running the test and facilitating informed discussions with doctors. This EUA allows the QuickVue® At-Home OTC COVID-19 Test to be used among asymptomatic individuals and run without a prescription provided that individuals test twice within 24-36 hours. Routine testing by rapid antigen tests has shown to be effective in diagnosing COVID-19.[1]

"Quidel and the people we serve through our advanced diagnostic technologies all owe a debt of gratitude to the FDA, CDC and NIH for their tireless and thorough pursuit of the science and the algorithms to guide accurate and equitable COVID-19 testing protocols that will catch infections early and help contain virus spread," said Douglas Bryant, president and CEO of Quidel Corporation. "Studies are confirming that serial testing with rapid antigen tests is a crucial resource for people to know their current health status and make prudent decisions to protect themselves, their loved ones and their communities."

The QuickVue® At-Home OTC COVID-19 Test employs the same Quidel lateral flow technology used for decades by healthcare professionals and features the same SARS CoV-2 rapid antigen test strip and reagent solution that received an EUA from the FDA for use in professional settings in December 2020. Quidel's QuickVue® brand launched in 1986 with visually read rapid diagnostics focusing on women's health and respiratory diseases. In 1999, QuickVue® Influenza A+B was the first visually read rapid test approved by the FDA for professional use. QuickVue® was also the first flu test cleared by the FDA for

use in CLIA-Waived point-of-care facilities like doctors' offices, urgent care clinics and pharmacies. Today, QuickVue® is a market leading platform in the professional segment for visually diagnosing Influenza, respiratory syncytial virus, Strep A and a variety of other illnesses. Since the launch of the QuickVue® brand into the professional segment, more than 150 million QuickVue® diagnostic tests have been sold.

Quidel recently started the buildout of a new manufacturing facility in Carlsbad, CA. The 128,000 square foot facility is expected to be the company's highest-volume production facility and begin operations in the second half of 2021, initially with a mission to produce more than 50 million QuickVue® rapid antigen tests per month, or 600 million tests per year at full capacity.

The QuickVue® At-Home OTC COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization. The QuickVue® At-Home OTC Covid-19 Test has not been FDA cleared or approved. The test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Visit www.quickvueathome.com for more information. For media inquiries, contact media@quickvueathome.com.

1. https://www.medrxiv.org/content/10.1101/2021.03.19.21253964v2

About Quidel Corporation

Quidel Corporation (Nasdaq: QDEL) is a leading manufacturer of diagnostic solutions at the point of care, delivering a continuum of rapid testing technologies that further improve the quality of health care throughout the globe. An innovator for over 40 years in the medical device industry, Quidel pioneered the first FDA-cleared point-of-care test for influenza in 1999 and was the first to market a rapid SARS-CoV-2 antigen test in the U.S. Under trusted brand names Sofia®, Solana®, Lyra®, Triage® and QuickVue®, Quidel's comprehensive product portfolio includes tests for a wide range of infectious diseases, cardiac and autoimmune biomarkers, as well as a host of products to detect COVID-19. With products made in America, Quidel's mission is to provide patients with immediate and frequent access to highly accurate, affordable testing for the good of our families, our communities and the world. For more information about Quidel, visit quidel.com.

View *our story* told by *our people* at www.quidel.com/ourstory

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 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: the impact and duration of the COVID-19 global pandemic; competition from other providers of diagnostic products; our ability to accurately forecast demand for our products and products in development, including in new market segments; our

ability to develop new technologies, products and markets and to commercialize new products; our reliance on sales of our COVID-19 and influenza diagnostic tests; our reliance on a limited number of key distributors; quantity of our product in our distributors' inventory or distribution channels; changes in the buying patterns of our distributors; the financial soundness of our customers and suppliers; lower than anticipated market penetration of our products; third-party reimbursement policies and potential cost constraints; our ability to meet demand for our products; interruptions, delays or shortages in the supply of raw materials, components and other products and services; failures in our information technology and storage systems; our exposure to data corruption, cyber-based attacks, security breaches and privacy violations; international risks, including but not limited to, economic, political and regulatory risks; continuing worldwide political and social uncertainty; our development, acquisition and protection of proprietary technology rights; intellectual property risks, including but not limited to, infringement litigation; the loss of Emergency Use Authorizations for our COVID-19 products and failures or delays in receipt of reviews or regulatory approvals, clearances or authorizations for new products 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, clearances or authorizations or other adverse actions by regulatory authorities; our contracts with government entities involve future funding, compliance and possible sanctions risks; product defects; changes in government policies and regulations and compliance risks related thereto; our ability to manage our growth strategy and successfully identify, acquire and integrate potential acquisition targets or technologies and our ability to obtain financing; our acquisition of Alere's Triage® business presents certain risks to our business and operations; the level of our deferred payment obligations; our exposure to claims and litigation that could result in significant expenses and could ultimately result in an unfavorable outcome for us, including the ongoing litigation between us and Beckman Coulter, Inc.; we may need to raise additional funds to finance our future capital or operating needs; our debt, deferred and contingent payment obligations; competition for and loss of management and key personnel; business risks not covered by insurance; changes in tax rates and exposure to additional tax liabilities or assessments; and provisions in our charter documents and Delaware law that might delay or impede stockholder actions with respect to business combinations or similar transactions. 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 from time to time, should be carefully considered, including those discussed in Item 1A, "Risk Factors" and elsewhere in our Annual Report on Form 10 K for the year ended December 31, 2020 and in our subsequent Quarterly Reports on Form 10 Q. 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 any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.