HENRY SCHEIN ANNOUNCES THE AVAILABILITY OF A CORONAVIRUS 2019 (COVID-19) POINT-OF-CARE RAPID TEST

Q1: Does the SD Biosensor "Standard Q COVID-19 IgM/IgG Rapid Test" comply with FDA's guidance?

A1: Yes. It is our understanding that the test complies with FDA's guidance for distributing serology tests that identify antibodies. Because the coronavirus presents a public health emergency, serology tests for the coronavirus, like the Standard Q COVID-19 IgM/IgG Rapid Test, are not currently required to go through FDA's typical clearance or approval processes, nor do they require Emergency Use Authorization (EUA).

On March 16, 2020, FDA established a policy of not objecting to the development and distribution by commercial manufacturers of serology tests that identify antibodies to SARS-CoV-2, even if those tests do not have an EUA. FDA established this policy because "serology tests are less complex than molecular tests and are solely used to identify antibodies to the virus." FDA Guidance: Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (March 16, 2020), available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency

SD Biosensor has notified FDA that it has validated the "Standard Q COVID-19 IgM/IgG Rapid Test" and that the test is being offered as set forth in FDA's March 16, 2020 guidance. FDA has posted these notifications on its website.

Q2: Has it been validated?

A2: Yes. We understand that the manufacturer has validated the test in accordance with the recommendations in FDA's recent guidance, titled "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency," which was issued on March 16, 2020. That guidance recommends that serology tests, like the Standard Q COVID-19 IgM/IgG Rapid Test, be validated with the following validation studies:

- Cross-reactivity/Analytical Specificity
- Class Specificity
- Clinical Agreement Study

Q3: Who is the manufacturer of the Standard Q COVID-19 IgM/IgG Rapid Test?

A3: SD BioSensor, Inc., which is based in South Korea.

Q4: Can the test be used as a "sole basis" to diagnose or exclude SARS-CoV-2 (i.e., coronavirus) infection or to inform infection status?

A4: No. At this time, FDA's guidance recommends that the results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 (COVID-19) infection or to inform infection status. Follow-up testing with a molecular diagnostic should be considered to confirm or rule out infection.

Q5: Of what value are the tests?

A5: There is urgent need for rapid testing to quickly identify large numbers of previously infected patients, including asymptomatic carriers. This is important to reduce and prevent virus transmission, assure timely treatment of patients, and help return our citizens to the workforce.

These serology tests may help track the progression of the novel coronavirus, in individual patients or on a community level. They may also help health care professionals make more informed decisions regarding how to best to care for their patients, in addition to other information, such as confirmatory tests, medical history, and symptoms.

The serology test information may be useful in instances where medical resources need to be rationed. Because serology tests measure antibodies, they can help assess the likelihood of past as well as present infection, and are meant to be used as an aid to diagnosis in the mid- to later stages of the viral infection. Along with other information, such as the presence of symptoms, the tests may help health care professionals assess whether individuals (including health care workers) have recovered from the virus. Follow-up testing should be used for definitive diagnoses.

The serology tests also will help public health officials better understand how much of the U.S. population has been exposed. See Coronavirus Disease 2019 (COVID-19), https://www.cdc.gov/coronavirus/2019-ncov/about/testing.html.

And perhaps most importantly, the Standard Q COVID-19 IgG/IgM Rapid Tests are particularly helpful because they can provide results within 15 minutes, as distinguished from PCR tests, where it can take hours or days to get results. Rapid testing may help health care providers better protect patients and communities, and the test results, along with other medical information, may help health care professionals determine whether patients should be quarantined or whether they can return to normal activities.

Q6: How, where, and when will the tests be available?

A6: Henry Schein is working through multiple channels to distribute the tests to health care professionals in the U.S. as efficiently as possible, for use by physician offices, hospitals, and other relevant health care institutions. We anticipate having at least several hundred thousand tests available by March 30 and significantly increased availability beginning in April 2020.

Q7: Will these tests be made available outside of the U.S. once the rise in new cases has leveled off domestically?

A7: Our initial focus is on the U.S. market and we will address the potential to distribute the tests to other geographies at a later date. For questions about availability outside the U.S., please contact Tom Popeck, Vice President and General Manager, of Henry Schein's Healthcare Specialties Group, at tom.popeck@henryschein.com.

Q8: Will the tests be covered by insurance or the U.S. government?

A8: We understand that Congress is working to ensure that the tests should be reimbursed by third-party insurance, including private health plans, self-insured plans, and federal health care programs.

Q9: Can you comment on price point, anticipated quarterly sell-through, and gross profit for this test?

A9: Unit pricing is available through our Henry Schein Medical sales organization. As for sales and gross profit, as is customary, we don't comment on sales and gross profit by individual product lines.

Q10: Will you distribute an antigen test in the future?

A10: Henry Schein intends to add other tests from VelocityDX and other suppliers specific to COVID-19, with the goal of offering a wide array of point-of-care tests for health care professionals, including an antigen test.

Q11: What are the potential risks associated with the serology (antibody) test?

A11: Potential risks include: (1) Possible discomfort or other complications that can happen during sample collection, and (2) Possible incorrect test result.

- Negative results do not rule out SARS-CoV-2 (COVID-19) infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E, or past or present infection with SARS virus (no. 6).

Q12: Have these tests been independently tested by a third party?

A12: No. Under normal circumstances, the validation of the test would be independently reviewed by FDA. But, because of the public health emergency, FDA has issued guidance where it has effectively waived its opportunity to conduct an independent review. FDA issued that guidance to ensure that the tests can get to health care professionals and patients quickly.

FDA has not suggested that third-party validation of serology tests is required, and that type of third-party validation would prevent the tests from getting to health care professionals and patients quickly.

Cautionary Note Regarding Forward-Looking Statements

In accordance with the "Safe Harbor" provisions of the Private Securities Litigation Reform Act of 1995, we provide the following cautionary remarks regarding important factors that, among others, could cause future results to differ materially from the forward-looking statements, expectations and assumptions expressed or implied herein. All forward-looking statements made by us are subject to risks and uncertainties and are not guarantees of future performance. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance and achievements or industry results to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. These statements are identified by the use of such terms as "may," "could," "expect," "intend," "believe," "plan," "estimate," "forecast," "project," "anticipate," “to be,” “to make”, “understand or understanding” “understand,” or other comparable terms. Forward looking statements include the number of tests intended to be made available and the timing for availability, the nature of the target market, as well as the efficacy or relative efficacy of the test results given that the test efficacy has not been independently verified under normal FDA procedures. A full discussion of our operations and financial condition, status of litigation matters, including factors that may affect our business and future prospects, is contained in documents we have filed with the United States Securities and Exchange Commission, or SEC, and will be contained in all subsequent periodic filings we make with the SEC. These documents identify in detail important risk factors that could cause our actual performance to differ materially from current expectations.

Risk factors and uncertainties that could cause actual results to differ materially from current and historical results include, but are not limited to: effects of a highly competitive and consolidating market; increased competition by third party online commerce sites; our dependence on third parties for the manufacture and supply of our products; our dependence upon sales personnel, customers, suppliers and manufacturers; our dependence on our senior management; fluctuations in quarterly earnings; risks from expansion of customer purchasing power and multi-tiered costing structures;

increases in shipping costs for our products or other service issues with our third-party shippers; general global macro-economic conditions; risks associated with currency fluctuations; risks associated with political and economic uncertainty; disruptions in financial markets; volatility of the market price of our common stock; changes in the health care industry; implementation of health care laws; failure to comply with regulatory requirements and data privacy laws; risks associated with our global operations; risks associated with the Novel Coronavirus Disease 2019 (COVID-19); risk associated with the United Kingdom's withdrawal from the European Union; transitional challenges associated with acquisitions, dispositions and joint ventures, including the failure to achieve anticipated synergies/benefits; financial and tax risks associated with acquisitions, dispositions and joint ventures; litigation risks; new or unanticipated litigation developments and the status of litigation matters; the dependence on our continued product development, technical support and successful marketing in the technology segment; our dependence on third parties for certain technologically advanced components; risks from disruption to our information systems; cyberattacks or other privacy or data security breaches; certain provisions in our governing documents that may discourage third-party acquisitions of us; and changes in tax legislation. The order in which these factors appear should not be construed to indicate their relative importance or priority.

We caution that these factors may not be exhaustive and that many of these factors are beyond our ability to control or predict. Accordingly, any forward-looking statements contained herein should not be relied upon as a prediction of actual results. We undertake no duty and have no obligation to update forward-looking statements.

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