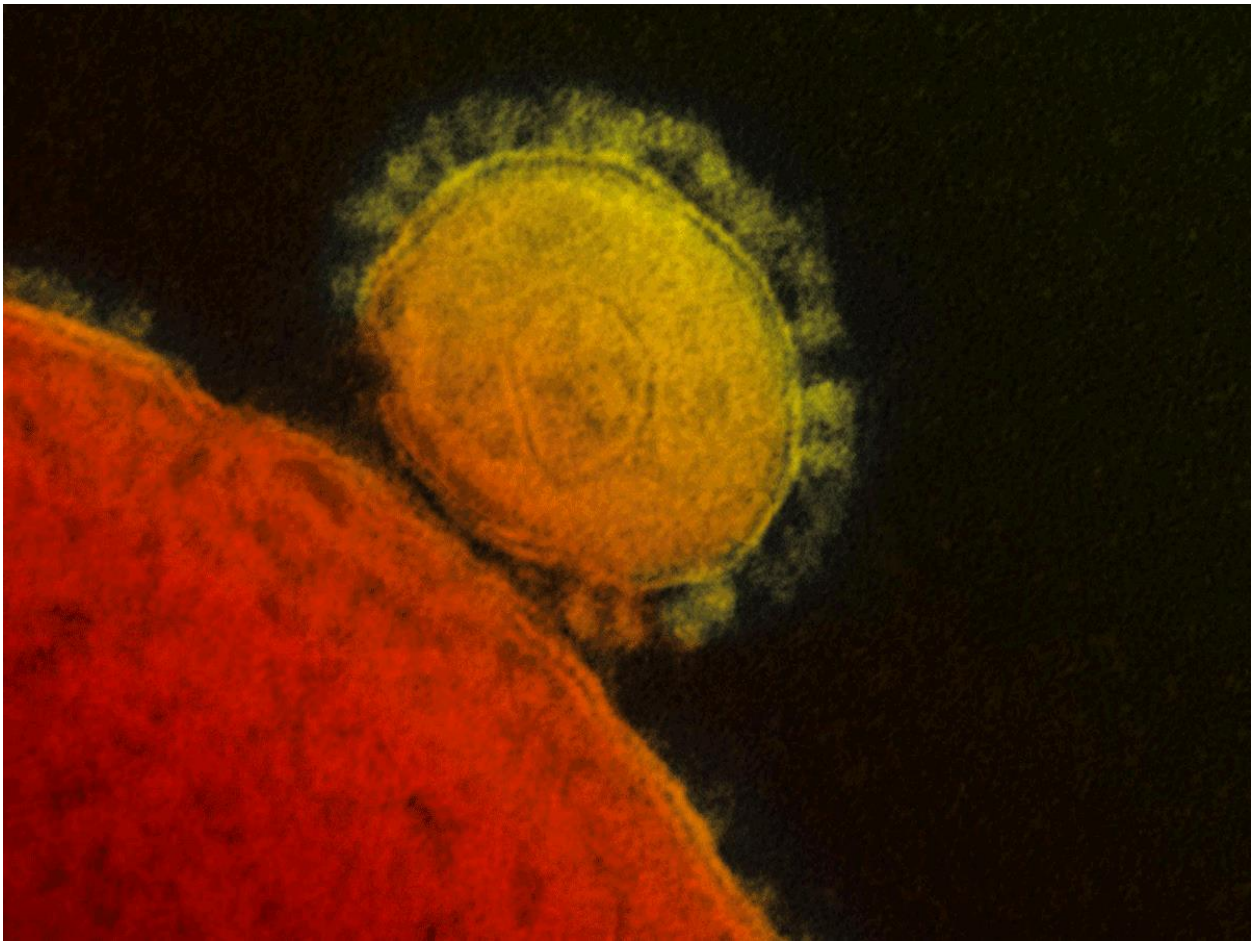
Co-Diagnostics completes critical step in developing coronavirus diagnostic



Under the electron microscope, coronaviruses appear to have a corona or halo. Credit: NIAID

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By Annette Boyle

Salt Lake City-based Co-Diagnostics Inc. has finished the principle design work for a polymerase chain reaction (PCR) screening test for the novel coronavirus that has sickened nearly 3,000 with an acute respiratory illness and killed more than 80 people in Wuhan, China. Known as 2019 novel coronavirus or 2019-nCoV, the virus has spread rapidly since it was first detected in late December 2019 to at least 16 countries. The U.S. has five confirmed cases and another 110 patients under investigation across 26 states, the Centers for Disease Control (CDC) reported on Jan. 27.

“Let’s remember this virus was identified within the past month and there is much we don’t know yet. We are expecting more cases in the U.S., and we are likely going to see some cases among close contacts of travelers and human-to-human transmission,” said Nancy Messonnier, director of CDC’s National Center for Immunization and Respiratory Diseases.

Chinese health authorities posted the full genome of the virus to multiple international databases on Jan. 12. “The available sequences suggest a likely single, recent emergence from a virus related to bat coronaviruses and the SARS [severe acute respiratory syndrome] coronavirus,” according to the CDC.

Consistent with that analysis, early tracking of the disease suggested that the infections arose from contact with animals in a large market in Wuhan, however, Chinese officials recently reported fourth generation human-to-human transmission in Wuhan as well as second generation transmission elsewhere in the country to the World Health Organization.

“There are several challenges to developing a test for a virus so relatively new on the world stage, especially one with many closely related genetic cousins such as SARS and MERS [Middle East respiratory virus],” said Dwight Egan, CEO of Co-Diagnostics. “One of the most important advantages of our Coprimer platform is its ability to reliably and accurately differentiate between similar genetic sequences, in order to reduce the likelihood of a false positive diagnosis.”

Illustration demonstrating amplification of DNA segments. Source: Co-Diagnostics

The Coprimer multiplexing technology enables highly specific reactions that Co-Diagnostics says are 2.5 million times more effective in reducing amplification errors than other PCR methods. The platform works without use of primer dimers, which are the major source of false positives in diagnostic testing. It also reduces research, design, and development costs by 80%, according to the company, allowing Co-Diagnostics to provide a low-cost molecular diagnostic tool for use on the ground in areas of limited resources.

Increasing need for 2019-nCoV diagnostics

WHO declined to declare 2019-nCoV a public health emergency of international concern (PHEIC) on Jan. 23, but four days later, the organization raised the disease risk to “very high in China, high at the regional level and high at the global level.” It also noted that about one-quarter of confirmed cases appear to be severe.

“We believe that if the WHO takes the step of declaring the illness a global health emergency following collection of more data in the days and weeks to come, Co-

Diagnostics will be well positioned to quickly assist in providing these state-of-the-art tools to affected countries," Egan said.

As no vaccine or specific treatment for the virus is available at this time, quickly identifying infected patients is important to begin supportive care before the patient's condition deteriorates. Rapid identification can also minimize the spread of the disease, which now seems to be transmissible in the roughly two-week incubation period before symptoms appear.

Infected individuals may present with cough, fever or lower respiratory infection such as bronchitis or pneumonia, the CDC said. The CDC has developed its own diagnostic test that can identify the virus in respiratory and serum samples and publicly "posted a blueprint to make the test" on Jan. 24, Messonnier said. The federal agency plans to make the tests available to priority states shortly and to provide them to domestic and international partners in the coming weeks.

Impact on stock

Co-Diagnostics also expects to close a $5 million registered direct offering with undisclosed institutional investors on Jan. 28, 2020, which will be used to advance its infectious disease testing as well as other development, commercialization, and general corporate purposes.

While the broad U.S. stock market dipped downward on Jan. 27 on news of the increased spread of the coronavirus and containment-related travel lockdowns that have quarantined more than 50 million in China, the share price of Co-Diagnostics (NASDAQ:CODX) more than doubled to set a new 12-month high of $3.43 as investors balanced the news of the offering price of $1.45 for more than 3.4 million shares against the building demand for 2019-nCoV diagnostic.

In commentary on Becton Dickinson, Wells Fargo Managing Director for Medical Supplies and Devices Lawrence Biegelsen said, "our early take is that the current virus could boost near-term demand for diagnostic testing and vaccine development, and thus BDX sales." Co-Diagnostics appears to be benefitting from that sentiment as well.