Co-Diagnostics Continues Global Expansion With Africa Alliance, New India Facility

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NEW YORK – Molecular diagnostic kit developer Co-Diagnostics has begun a new collaboration in Africa and has officially opened its manufacturing site in India, continuing its international expansion efforts.

The Salt Lake City, Utah-based firm also continues to develop a menu of mulitplexed PCR kits for infectious diseases and recently added a liquid biopsy test to its pipeline.

Co-Diagnostics' core technology, called CoPrimers, reduces the formation of primer-dimers by 2.5-million fold and enables the firm to perform true multiplex PCR in a single tube, said Dwight Egan, the firm's CEO. The kits are also instrument agnostic, allowing them to be run on standard lab equipment.

"Part of Co-Diagnostics' mission is to provide US-engineered products … to the nations and people of the world that need it the most," Egan said. These customers have not had access to high-quality products at a price that would make them relevant, he added.

Indeed, Egan said the firm's goal is to provide quality testing to high-burden developing countries at a price that enables wide adoption, which usually means $10 or less per test.

The Africa market entry has begun with a toe hold in Ghana. The firm is collaborating with Dare Labs, a private diagnostic firm in Ghana's second most populous city, Kumasi, initiating the collaboration with a large order for Co-Diagnostics' malaria test kits.

In 2017, malaria killed an estimated 10,000 people in Ghana, accounting for nearly 20 percent of deaths in the county. This was actually an improvement, as the country has seen a 24 percent reduction in malaria deaths between 2012 to 2017, in part attributed to aggressive international and local control measures that incorporate diagnostic testing.

In India, meanwhile, Co-Diagnostics received regulatory clearance last week from the Central Drug Standard Control Organization for five diagnostic tests through its joint venture, CoSara Diagnostics. The clearance also enables the tests — for detecting tuberculosis, malaria, hepatitis B and hepatitis C viruses, and human papillomavirus — to be manufactured and sold from the CoSara facility in Ranoli, India.

The Ranoli facility is in line with a government initiative called "Make in India," which was launched in 2014 and is intended to encourage companies to manufacture products in India. Under that initiative, Cepheid last year announced plans for a new manufacturing site for its GeneXpert Edge battery operated system and production of certain test cartridges.

Co-Diagnostics is now developing a drug-resistant TB test, which will be the next test to go before the CDSCO, Egan said. It has also been developing a test that uses its multiplex technology paired with next-generation sequencing to detect 24 resistance-associated targets. The single-step, single-tube library preparation is compatible with both Illumina and Ion Torrent sequencers, he said.

"We're looking at that for India and other countries that have expressed interest in having a more robust product for testing resistance," Egan said.

Through CoSara, Co-Diagnostics is also planning to submit for regulatory approval in India an HIV test and a test for blood bank screening that will cover HIV, hepatitis B, and hepatitis C, he said.

The joint venture has the exclusive manufacturing rights in India for the complete menu of Co-Diagnostics' infectious disease molecular diagnostics kits. The CoSara tests use the same core CoPrimer technology as the ones Co-Diagnostics makes, branded Logix Smart.

Co-Diagnostics has also been inspired by successes with collaborators in the AgBio and applied markets, where CoPrimer-based tests have been used by partners LGC and its subsidiary BioSearch for multiplex SNP detection.

Egan said the ability to multiplex rare allele detection means the CoPrimer technology has a place in liquid biopsy testing, and the firm has been doing research that he said may culminate in PCR-based, or even NGS-based, cancer screening and monitoring tests.

Specifically, in July the firm announced it had completed a study of a 10-target multiplex test on circulating free DNA reference materials in which it demonstrated highly specific detection of mutations associated with non-small cell lung cancer.

Competing instrument-agnostic multiplexing is available from companies like Fast Track Diagnostics, a firm Siemens Healthineers acquired in 2017, and ChromaCode.

However, Egan said that Co-Diagnostics' kits are different from those of its competitors because the they take a more "purist" approach to multiplexing by performing many reactions in a single tube.

The Fast Track Diagnostics tests are limited to detecting four targets per reaction, with a 32-plex test requiring eight tubes, for example, while the ChromaCode technology multiplexes by increasing the fluorescence detection capabilities of standard equipment.

Co-Diagnostics has a CE mark on a tuberculosis test and a triplex test for Zika, chikungunya, and dengue viruses. It also recently released a suite of vector control products that multiplex detection of pathogens like West Nile virus and Eastern Equine Encephalitis.

Egan said that the company will continue to target international markets. "That's where we can make the most difference by providing high-grade but low-cost diagnostic products," he said.

Seeking clearance from the US Food and Drug Administration is a significant hurdle, on the other hand, and not terribly useful for targets that are not common in the US, Egan said. But the firm may consider pursing FDA clearance some day, particularly with respect to a nine-target sexually transmitted infections test it is currently developing. In the meantime, it is selling its vector control products stateside in a handful of counties, Egan said.

Co-Diagnostics is publicly traded in the US on the Nasdaq but has struggled on the market and currently has a market cap of around $17 million. It was issued a non-compliance warning from the Nasdaq last year regarding net equity in the company, though Egan said that the firm solved the problem by doing a registered direct equity offering in January of this year. In addition, an unnamed investor converted the firm's $2 million of debt into equity and also put in another $1 million. "All in all, we did about an $8.5 million financing, which certainly satisfied the issue with Nasdaq," Egan said.

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