



Coyote Bioscience Co., Ltd.

www.coyotebio.com

Molecular diagnostics in a box

Coyote Biosciences has developed a range of miniaturized, portable and battery-powered molecular diagnostics instruments that provide point-of-care testing solutions—from detecting infectious diseases to profiling cancer—for health care providers and patients globally.

Molecular detection of disease, whether based on the identification of specific pathogens or of disease-related genes, has evolved rapidly over the past two decades. One of the key detection technologies is the polymerase chain reaction (PCR), a simple and inexpensive method to make billions of copies of a target piece of nucleic acid—the disease-related gene. Today, very sophisticated PCR-based tests exist, but their implementation often requires complex equipment and highly trained personnel.

Since its establishment in 2009, Coyote Biosciences has strived to design and manufacture solutions for PCR-based diagnostics that make the process simpler and ultimately allow for the tests to be performed at the point of care (POC) in the shortest time possible to provide real-time results to doctors and patients. This philosophy guided Coyote through its first five years, in which it developed a solid R&D capability and a reputation for the development and commercialization of top-of-the-line PCR reagents and devices, and it continues to shape the company's strategy for developing innovative PCR solutions to address new diagnostics challenges.

Coyote is expanding its offerings and looking to partner with other companies or organizations in need of efficient PCR-based diagnostics for a variety of applications such as cancer patient stratification (e.g., detection and quantitation of single-nucleotide polymorphisms), women's health issues (e.g., HPV, chlamydia and gonorrhea) and emerging infectious diseases (e.g., Ebola and Zika viruses).

"Our goal is to technologically take molecular diagnostics to the next level and provide access to this high-quality testing to everyone in the world," said Sabrina Li, Coyote's CEO.

Rapid on-site quantification

The first PCR-based diagnostic tools developed by Coyote were a series of miniaturized, integrated, quantitative PCR (qPCR)-based solutions, referred to as 'lab-in-a-box', for the detection of Ebola, dengue fever and other pathogens. Like all of Coyote's products, the lab-in-a-box solutions are portable—one to two kilograms in weight—and fit in a small, hand-carry-size case that contains a battery to power the system.

qPCR is a variation of PCR that relies on monitoring of the number of DNA copies as they are generated. Coyote simplified the multi-step process and turned it into a one-step qPCR testing method by eliminating the traditional sample-preparation and nucleic acid-extraction steps. Using as little starting material as a drop (5–50 µl) of blood, saliva, serum or urine, the system takes only 20 minutes to identify and quantify

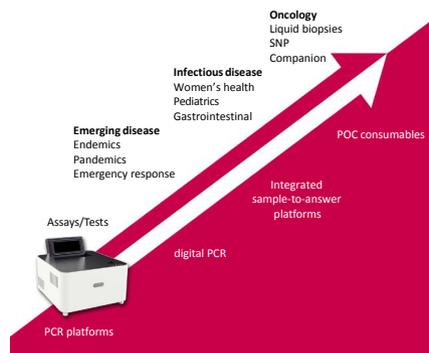


Figure 1: The Coyote miniaturized, portable and self-contained qPCR platform affords high flexibility and adaptability for a wide range of current and future molecular diagnostics applications.

target nucleic acids. This simplified qPCR platform—arguably the simplest one on the market—affords an ideal solution for fast medical screening and POC deployment.

A second generation of instruments currently in development at Coyote is based on digital PCR (dPCR), an absolute quantitative variation of PCR. In dPCR, samples are diluted to a point where small subsamples of the original volume contain either one copy or no copies of the target nucleic acid. After PCR, the output signal is binary—any subsample will be either positive or negative for the target molecule, with the number of positive readouts representing the original number of target molecules in the sample.

Coyote is developing dPCR in a portable format that is self-contained and rapidly deployable. And just like Coyote's qPCR platforms, the dPCR device will represent a low-cost solution for clients worldwide.

"Coyote will be introducing next-generation, dPCR-based diagnostic platforms in the second half of this year with POC consumables," said Jesus Ching, Coyote's CTO.

Emerging diseases and Zika

With its self-contained, battery-powered and highly portable platforms, Coyote's unique solution for performing accurate and cost-effective molecular detection can be rapidly deployed to any geographic area. As a result, one of its principal potential uses is the detection of emerging diseases.

In 2015, Coyote's Mini8 Real Time PCR system was included among the World Health Organization's (WHO) Emergency Quality Assurance Mechanisms

for Ebola virus testing in Africa. Since then, Coyote has developed a gene sensor, InstantGene, to obtain a molecular diagnosis of this disease from a drop of blood within 20 minutes.

The recent worldwide outbreak of the Zika virus offered Coyote another chance to demonstrate the versatility and adaptability of its platform. In this case, working in close collaboration with the Chinese Center for Disease Control and Prevention, Coyote implemented a solution for the diagnosis and general screening of the Zika virus in China based on the company's qPCR system.

The Zika virus diagnostic kit is under review by the Chinese Food and Drug Administration (FDA), and applications for registration with the US FDA and the WHO prequalification program will be submitted in the second quarter of 2016. Immediate application of the test kit and qPCR devices in Brazil is under discussion with the Brazilian government to help prevent the spread of the virus.

Partnering PCR

Whether reacting to a public health emergency or building a network of POC molecular diagnostics for routine health monitoring, Coyote offers its potential partners a tool for the rapid development and deployment of needed analytical capabilities in the form of its PCR platforms and testing kits.

Coyote will entertain a variety of partnership opportunities, from codevelopment agreements to collaborate on a new test or application, to regional or national distribution deals to commercialize any of the company's products.

According to Li, "Coyote is interested in partnering, collaborating or codeveloping with companies or institutions that are aligned with our vision on providing high-quality molecular testing to everyone."

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