Diagnostic Test Kit: Integration of Patented Technologies

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Since the beginning of the pandemic, the Food and Drug Administration (FDA) has been at a rapid pace in evaluating COVID-19 related diagnostic tests, amongst which include those that utilize patented technologies. As of January 2022, the FDA has authorized over 400 COVID-19 related tests and collection kits, including over 200 molecular tests, over a dozen at-home tests performed at user's home with a self-collected sample, over 60 home collection tests and kits where samples are collected at home and sent to a lab for processing, and over 50 point-of-care tests that quickly return a result at a health care setting.

Diagnostic test kits are often simple to operate for the home users and health care providers. However, beneath the veneer of simplicity in operation is the integration of a myriad of different technologies. For example, Lucira™ CHECK-IT COVID-19 Test Kit has received FDA Emergency Use Authorization for nonprescription over-the-counter home use as of April 9, 2021 (also authorized by Health Canada as of April 23, 2021), and it only requires the home user to collect test sample with a nasal swab, insert the swab into a sample vial on the diagnostic test device to release the test sample from the swab, discard the swab and then press down the closed sample vial and essentially just let the device run its course.

The device detects RNA of a SARS-CoV-2 gene by reverse transcription loop mediated isothermal amplification (RT-LAMP) reaction which requires enzymes, halochromic agents, and heat. An internal electronic heating element within the device automatically turns on when reaction mixture enters the reaction chambers. As the RT-LAMP reaction proceeds, color change in the reaction mixture is detected by optical and electronic sensors within the device, and an on-board microprocessor analyzes the color change data to detect the presence of amplification, *i.e.* the presence of SARS-CoV-2 RNA – in real time. The device firmware also includes a diagnostic algorithm that interprets the data and the result regarding infectivity status is displayed accordingly via LED indicators on the device.

This diagnostic test kit takes advantages of technologies that are protected by patents, that is, US Patents 10,146,909, 10,253,357 and other pending US and international patents, that cover different aspects of the device. In particular, US 10,146,909 is directed to image-based disease diagnostics using a mobile device, which includes system, method and computer program product claims that cover the diagnostic test kit, whereas US 10,253,357 is directed to colorimetric detection of nucleic acid amplification which includes method and kit claims for colorimetric detection of a nucleic acid (*e.g.* RNA) amplification. Thus, an under the hood look of the Lucira test kit shows us how the seamless operation of a modern diagnostic test kit relies on the integration of distinct technologies from patented inventions.