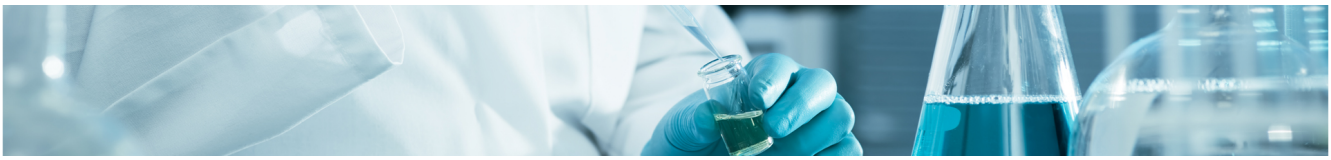

Chasing the Enemy – Major Breakthroughs in COVID-19 Diagnostics IP

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By Noel Courage

Innovations in diagnostic testing are key to fighting COVID-19. Countries that have had initial success in controlling the extent of viral outbreaks, such as South Korea and Singapore, were rigorous testers. Countries that have had poor availability and speed of testing have had less success containing the virus. Public health authorities in North America have said that key steps in fighting the COVID-19 epidemic are identify, isolate and trace contacts of carriers. Testing is the gateway step to efficiently determine which suspected cases to keep in isolation and trace, so it cannot become a bottleneck.

Building Capacity, Filling the Pipeline

Many governments struggled with testing backlogs, as they worked to increase testing capacity. As a result, initial testing was focused on specific, narrow groups, such as persons returning from a high risk country or that had contact with a known COVID-19 carrier. The undertesting and backlogs in processing of tests led to delayed reporting of cases, potentially giving the general public an impression that there are fewer cases and less community transmission than actually exist (i.e. false sense of security).

As one example of the growing pains in testing, Ontario had a backlog of over 10,000 unprocessed tests in late March. It also limited tests throughout March to specific groups such that many suspected cases could not get tested. Capacity to do diagnostic tests was built by supplementing public health lab work with private labs[1]. Substantial excess capacity then developed, but the number of tests per day dipped[2]. The Ontario government called its testing rate unacceptable (lowest per capita in Canada), and it is now focusing on filling the pipeline. Test qualification criteria have also evolved and broadened.

Diagnostic Test Innovations

The diagnostic tests for COVID-19 have evolved quickly in a matter of months. Innovations in the speed and ease of testing will be a game-changer, once they are fully scaled and embraced by public health authorities.

The earliest diagnostic tests were typically based on detecting viral nucleic acids based on nose or throat swabs administered by a health care worker. Each test could take hours to produce a result. Other tests are being developed that detect proteins from swabs or human antibodies developed in response to infection. In a dramatic improvement, test times that were formerly measured in hours are now measured in minutes. Abbott recently launched a nucleic acid test that it says can diagnose individuals with the virus in five minutes. This is a significant development for virus testing, and it may also become a very valuable piece of intellectual property for Abbott[3] in selling its test machines and future diagnostic kits for other conditions. FDA has also recently approved a self-administered nose swab test. Abbott's main challenge is scaling and rolling out the technology as quickly as possible.

Antibody-based diagnostics are now coming on stream. These will help identify those who have had the COVID-19 virus, including those who had it and now appear recovered. This can potentially be helpful to identify plasma antibody donors, as well as to potentially clear post-virus people to return to work.

A key task for Canada will be getting diagnostics companies to get regulatory approval and roll out new technologies in Canada quickly (or otherwise make them available, for example through licensing or open-source initiatives). The hot diagnostic tests described on the evening news probably do not have Health Canada regulatory approval and marketplace

availability in Canada yet[4]. Health Canada publishes a list of currently approved tests in Canada[5]. The fastest test in Canada appears to be a newly approved test from Spartan Bioscience in Ottawa which provides results in under an hour.

There have also been developments in the mode of testing. The FDA recently approved a self-administered nose swab test. A physician recently suggested that, as part of our new normal, rapid diagnostic testing may become a regular and routine activity in daily life before going on mass travel or to special events. An early example of this approach is Ontario giving COVID-19 tests to all long term care residents being transferred into retirement homes. In Wuhan, workers at some companies are required to have a COVID-19 test before returning to work.

The new technology and IP in diagnostics are increasingly being recognized as a key way to control virus spread. More healthcare resources will be focused on rolling out these fast diagnostics in the coming weeks.

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[1] Eg. Dynacare and LifeLabs. https://www.thestar.com/news/canada/2020/04/04/how-ontario-turned-the-tide-on-a-huge-backlog-of-covid-19-tests.h

[2] For example, on Tuesday, April 7, it was reported that 2930 tests were processed, under the target of 5,000 per day for the first week of April, and well under the stated daily capacity of 13,000.

[3] It is quite likely that Abbott quickly filed a patent application prior to releasing the technology.

[4] Health Canada is expediting review of COVID-19 diagnostic tests.

[5] The 5 minute test, called Abbott ID NOW COVID-19 test does not appear to be approved in Canada yet at the time of writing. Another test called, Abbott Realtime SARS-COV-2, was approved on an expedited basis in March 2020.