Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Editorial

Rapid COVID-19 testing: Speed, quality and cost. Can you have all three?

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ABSTRACT

Key Messages:

- Consider safety precautions and infection control processes, particularly in remote testing locations when using rapid SARS-CoV-2 devices.
- Seek oversight and partnership with an accredited clinical laboratory for guidance on setting up a quality assurance framework.
- Rapid-testing for SARS-CoV-2 requires method verification prior to clinical implementation.

1. Choose any two

As the old saying goes, "better, faster, cheaper… you can have any two". Under a COVID-19 lens and with the proliferation of rapid-testing options, the advocacy for "better" is amplifying strongly, which translates into tests conducted with robust quality, safety, and appropriate interpretation.

The Canadian government has procured millions of rapid molecular and antigen test kits for detection of SARS-CoV-2 that are approved under the Health Canada interim order. Among the attractive attributes of these rapid-testing kits is their ability to produce a result in under one hour (faster), and potentially at the point-of-care (POC), outside traditional laboratories. It is anticipated that their distribution across Canada will be valuable to assist public health officials in identifying cases, managing outbreaks, and improving access to testing, especially where laboratory diagnostic testing is limited.

POCT is a key component in the diagnostic tools available to health care providers. Clinical biochemists are partners in POCT quality management and oversight for simple to higher complexity tests. This partnership is as essential for COVID-19 testing, not only by virtue of the testing complexity itself, but also due to the profound implications for getting the correct answer. As recently illustrated by commentary on social media (e.g. @elonmusk 13Nov2020), public trust in testing quality can be damaged at "warp-speed" when results and interpretation are unclear.

Rapid-tests for detection of SARS-CoV-2 span categories of complexity in the testing itself. Lateral flow rapid antigen tests approximate less complex parallels such as urine pregnancy tests, while the rapid molecular tests employing nucleic acid amplification testing (NAAT) are more akin to moderate complexity parallels such as blood glucose testing at the point-of-care. However, unlike a blood glucose or urine pregnancy test, SARS-CoV-2 rapid-testing carries additional considerations including: (1) infection control risk, (2) appropriate selection of testing population (e.g. symptomatic), and (3) individual/patient management implications of false positives or false negatives. Appropriate oversight and partnership with specifically trained laboratory professionals provides the best opportunity for robust quality management to optimize the "better" aspects of these "faster" tests.

2. Partners in quality

POCT of any type and in any location requires oversight from an accredited clinical laboratory and under the guidance of a Laboratory Director. For rapid-testing programs to be implemented in locations not directly associated with hospital laboratories, the institution planning to implement POCT should seek oversight and partnership with an accredited clinical laboratory (hospital or community) in their local area. The partnership provides a valuable resource and facilitates improvements in test device selection, method verification and ongoing performance evaluations, as well as to ensure a framework for quality assurance is in place [1,2]. This framework at minimum should include 1) method verification of tests and devices prior to clinical use, 2) training of healthcare workers to perform the rapid-tests, 3) adequate measures to prevent the spread of infectious diseases for both blood borne and respiratory diseases, 4) quality control (QC) testing prior to patient testing, 5) reporting and documentation of results (e.g. how results be documented and when results require follow-up laboratory testing) and 6) troubleshooting guidance (e.g. QC failures, device errors etc.). The quality assurance framework will ensure POCT results are as accurate as possible within the given limitations of each test method and meets the intended clinical use.

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3. Trust but verify

The POCT Interest group of the Canadian Society of Clinical Chemists (CSCC) recently published a practical guidance for quality assurance practices related to POCT performed in hospital and outside hospital environments [2]. This guidance document provides practical information on development of a quality assurance framework for POCT implementation. Based on this guideline, rapid antigen testing would be considered low complexity and rapid molecular testing as moderate complexity.

Method verification studies should include precision or repeatability, depending on the nature of the test, method comparison to laboratory-based NAAT, and clinical performance evaluation in collaboration with a consulting centre (i.e. clinical sensitivity, specificity, negative and positive predictive values) with predefined acceptance criteria. It is key to evaluate clinical sensitivity and specificity in proposed testing populations, for understanding the false positive and negative rates, to inform decisions around the risks of acting upon POCT results. Depending on availability of resources and time constraints, both minimal and optimal verification criteria have been recommended [2]. More details on these recommendations are also available in the CSCC consensus guidance for testing, selection, and quality management of SARS-CoV-2 Point-of-Care tests in this edition of Clinical Biochemistry.

Ideally, sites should evaluate the device prior to implementation of clinical testing, which will require collection of two swab specimens from patients; however, this may not be possible in remote areas or areas with low incidences of COVID-19. In these situations, a prospective method verification with parallel NAAT testing by a reference laboratory may be considered with consultation with the Laboratory Director.

Processes must be in place for verification of each new lot and shipment of reagents received by a testing site. This will ensure proper functioning of reagents prior to clinical use, as performance can differ between manufactured lots and materials can become damaged during transport (eg. the shipment sat on the loading dock in −30 °C weather for a long time). Recommendations for reagent verification are available [2] and are more specifically considered for SARS-CoV-2 testing in the Consensus Guidance in this issue of Clinical Biochemistry.

Like their laboratory-based counterparts, non-laboratory healthcare workers at the point-of-care require training prior to clinical implementation of SARS-CoV-2 testing and all POCT. Training must include how to use the test device, how and why QC is performed, how to troubleshoot, perform routine maintenance, required personal protective equipment, cleaning of testing area and device to prevent contamination, infection control risks associated with the testing process, interpretation of results, and where and how to chart results and processes for downstream reporting to public health officials.

4. “We are all in this together”

While it is acknowledged that, in general, rapid-testing options for detection of SARS-CoV-2 may have documented performance limitations compared to laboratory-based NAAT, addressing in advance the essential quality, safety, and interpretation considerations protects Canadians as we navigate use of these testing modalities.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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