Point of Care Testing – Information Note for SAC

PHAC has undertaken a review of new technologies related to point-of-care (POC) testing for COVID-19. At present, the NML is considering a two-pronged approach for the deployment of POC diagnostic testing capabilities, which includes:

1. The Cepheid GeneXpert, to be initially placed within hospital laboratory settings. The GeneXpert platform had been previously approved by Health Canada for use in a laboratory testing, allowing for rapid deployment to support the COVID-19 response. Distribution to PT sites has commenced for the GeneXpert device along with a limited number of test kits (the specialized cartridges in which the test is run). Furthermore, in partnership with FNIHB, an analysis was undertaken to determine the optimal deployment of GeneXpert platforms to support POC testing given the limited number of platforms and tests currently available. The goal is to strategically place instruments where they can best support testing of remote Indigenous communities who experience challenges with accessing diagnostic testing services.

2. The Spartan Bioscience Cube, is undergoing validation testing, and if successful, will be considered for deployment placement at Nursing Stations, Health Centres, and within communities. The NML began the validation of the Cube's performance on April 11, contributed by approval of a clinical trial by Health Canada REB. These results will support the overall implementation of the Spartan Bioscience Cube, as multiple provincial laboratories have also placed orders for this platform. NML will assist in coordinating implementation plans. The Government of Canada has also amended its procurement contract with Spartan to secure supply of the devices and has requested 40,000 tests per month for April, May and June, and a further 200, 000 units per month for July to the following March. At present, the company is in a ramp-up phase so it is unclear whether it is feasible to receive the requested supply of devices and tests. The Government of Canada is working to rapidly with provinces and territories to determine the future allocation of these medical supplies.

The rationale behind a two-pronged approach is in light of concerns with global supply bottlenecks and to allow for a system where testing can continue if alternate testing platforms are required (i.e. there is both additional capacity and system redundancy).

<u>Further information</u>

To ensure that the platform performs properly, the NML will be deploying training materials to the site, along with a fit-for-purpose panel, that includes a non-infectious positive control, a negative control, and two cartridges. Given the limited cartridge inventory, the NML will initially be holding onto the balance of cartridges, to be deployed as needed. As supplies come to scale, it is anticipated that supplies can be delivered directly to sites. The NML undertook a validation of the GeneXpert technology the weekend of April 4, 2020 once the first test cartridges were received at the laboratory. In addition to the NML's validation of the GeneXpert technology for SARSCoV2/COVID-19 testing, the Vancouver General Hospital also completed a validation of the technology. It is felt that the test performance is in agreement with results generated from laboratory-based SARSCoV2 diagnostic testing methods.