



PHLN

Public Health Laboratory Network

Tuesday, 3rd March 2020

PHLN Statement on Emergency Testing Provisions for SARS-CoV-2 (the virus that causes COVID-19)

On 27 February 2020, the Australian Government announced the activation of the Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19). As a result, there is increasing pressure for the expansion of SARS-CoV-2 testing capability across Australia.

On 3 March 2020, the Public Health Laboratory Network (PHLN) convened an extraordinary teleconference to discuss the current and near future status of laboratory testing for SARS-CoV-2 across Australia. There was representation from at least one representative from each state and territory public health laboratory. Key outcomes of this meeting are described below:

Current status of SARS-CoV-2 testing in Australia

- Currently, the majority of SARS-CoV-2 diagnostic testing is being performed by state or territory PHLN laboratories.
- On 25 February 2020, PHLN updated the guidance on laboratory testing for SARS-CoV-2. This is available on the Australian Government Department of Health [website](#). This update recommended that as a minimum standard recommendation across all jurisdictions, a nasopharyngeal and an oropharyngeal swab should both be collected for testing.
- On 3 March 2020, members discussed the necessity for PHLN laboratories to conduct dual target laboratory testing: E gene; in combination with RNA-dependent RNA polymerase (RdRp) and/or N gene and/or another suitable target such as the ORF1ab.

TGA In Vitro Diagnostic Medical Devices (IVDs) Regulations and NATA/NPAAC Requirements

- PHLN state and territory member laboratories are permitted to use commercially supplied assays (labelled for in vitro diagnostic use) under an exemption from particular requirements of the *Therapeutic Goods Act 1989* (the Act), allowing the use of medical devices for the diagnosis, confirmatory testing, prevention, monitoring, treatment or alleviation of COVID-19 infection. A full copy of the '*Therapeutic Goods (Medical Devices—Novel Coronavirus) (Emergency) Exemption 2020*' can be found on the Federal Register of Legislation ([F2020N00015](#)).
- Under the emergency exemption, commercial sponsors cannot legally supply medical devices intended for the detection of COVID-19 infection in humans (labelled for in vitro diagnostic use) and which are not included on the Australian Register of Therapeutic Goods, to laboratories other than state and territory member laboratories of PHLN.
- For PHLN and non-PHLN laboratories, use of incompletely validated in-house IVDs is permitted under Clause 1.3 of the National Pathology Accreditation Advisory Council (NPAAC) Requirements for the Development and use of in-house IVDs (note that laboratory use of commercially available products labelled as being for research use only (RUO) are also considered in-house IVDs). Clause 1.3 stipulates such in-house IVDs may be used, 'only in matters of urgency for a disease that poses a serious risk to public health' and with a 'documented plan for validation'. Test results must also include a disclaimer as described in

Clause S1.3 of the NPAAC Standard and must also indicate that the test is not currently NATA accredited.

Validation of in-house IVDs (includes use of RUO reagents/products) and commercially supplied IVDs (i.e. intended for in vitro diagnostic use) by PHLN

- PHLN laboratories are in the process of validating both commercially supplied IVDs and in-house IVDs to ensure quality SARS-CoV-2 testing and to inform the potential expansion of testing capability across non-PHLN laboratories.
- Clinical experience and findings from validation processes are communicated within the network and with the Australian Government Department of Health to inform decision-making related to laboratory testing.

Non-PHLN laboratories planning to provide clinical diagnostic testing for SARS-CoV-2

- Non-PHLN laboratories planning to provide clinical diagnostic testing and reporting for SARS-CoV-2 must be accredited to the NPAAC standard for providing medical pathology services.
- PHLN strongly recommends that non-PHLN laboratories planning to provide clinical diagnostic testing and reporting for SARS-CoV-2 meet the following criteria to ensure quality testing is maintained across Australia:
 - Participation in the Royal College of Pathologists of Australasia Quality Assurance Program (RCPAQAP) for SARS-CoV-2 testing when available;
 - Access and utilise positive control material provided by a state or territory reference laboratory; and
 - Arrange for parallel testing to be conducted by a PHLN laboratory to validate the results. In the short term, this means referring all positive samples for confirmatory testing, and referring a subset of negative samples where a strong clinical or epidemiological suspicion exists.

Please note: this statement was amended on 16 March 2020 to note the accreditation requirements for laboratories planning to commence SARS-CoV-2 testing.