PHLN Recommendations for Non-PHLN Laboratories Undertaking Testing for SARS-CoV-2 (the virus that causes COVID-19)

Revision History

Version	*Date Endorsed by PHLN*	*Revision note*
1.0	30 March 2020	Initial document

Testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019, is being performed by a number of accredited public, private and hospital laboratories across Australia, with the support of state and territory Public Health Laboratory Network (PHLN) laboratories.

PHLN continues to maintain guidance on laboratory testing for SARS-CoV-2. This is available on the Australian Government Department of Health website.

Early in the outbreak, PHLN, Australia's leading network of expert microbiological laboratories led the establishment of testing capability nationwide by developing in-house designed tests, following the release of the genome sequence of the virus, and through trialling emerging commercial tests under an emergency exemption provided by the Therapeutic Goods Administration (TGA).

Therapeutic Goods Administration Emergency Use Exemption

On 22 March 2020, the TGA repealed the *Therapeutic Goods (Medical Devices – Novel Coronavirus) (Emergency) Exemption 2020* which was specific to PHLN laboratories only, and replaced it with the *Therapeutic Goods (Medical Devices – Accredited Pathology Laboratories) (COVID-19 Emergency) Exemption 2020* (the TGA exemption).

The TGA exemption permits commercially supplied assays (labelled for in vitro diagnostic use) to be provided to any Australian laboratory accredited to provide medical pathology services. A full copy of the TGA exemption can be found on the Federal Register of Legislation (F2020N00032). Further information is available on the TGA website.

National Pathology Accreditation Advisory Council (NPAAC) Requirements for In-House IVDs

For PHLN and non-PHLN laboratories, use of incompletely validated in-house IVDs is permitted under Clause 1.3 of the 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 National Association of Testing Authorities, Australia (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 continued 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 providing clinical diagnostic testing for SARS-CoV-2

- Non-PHLN laboratories providing, or 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 providing, or planning to provide, clinical diagnostic testing and reporting for SARS-CoV-2 meet the following criteria to ensure quality testing is maintained across Australia:
    1. Participation in the Royal College of Pathologists of Australasia Quality Assurance Program (RCPAQAP) for SARS-CoV-2 testing when available;
    2. Access and utilise positive control material provided by a state or territory reference laboratory; and
    3. Arrange for parallel testing to be conducted by a PHLN laboratory to validate the results. This means referring:
        a) all positive samples for confirmatory testing until a level of confidence is reached, determined by the jurisdictional PHLN laboratory;
        b) referring a subset of negative samples where a strong clinical or epidemiological suspicion exists; and
        c) referring all indeterminate samples for confirmatory testing.