PHLN
Public Health Laboratory Network

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PHLN STATEMENT ON USE OF SALIVA AS AN ALTERNATIVE SPECIMEN FOR THE DIAGNOSIS OF SARS-CoV-2

Diagnostic testing for SARS-CoV-2 is central to controlling the COVID-19 pandemic as Australia moves into the next stage of response. On 18 May 2020, the Public Health Laboratory Network (PHLN) convened an extraordinary teleconference during which members discussed the use of saliva as an alternative specimen for the diagnosis of SARS-CoV-2.

In Australia, Polymerase Chain Reaction (PCR) is the gold standard test for the acute diagnosis of SARS-CoV-2 infection. This test is very sensitive and detects nucleic acid sequences specific to the virus. Traditionally, PCR testing is undertaken following collection of respiratory sample, typically using nasopharyngeal swab, which is somewhat invasive.

PHLN continues to monitor the emerging literature with regard to the performance of saliva collection as alternative specimen for use in PCR testing. Some early validation studies have been conducted both internationally and in Australia, which indicate promising results.[1][2][3][4]

Noting the current evidence, PHLN considers that advantages to this specimen collection method include:

- it is minimally invasive and can be reliably self-administered;
- it reduces the risk to health care workers and minimises the demand for personal protective equipment; and
- is consumable sparing, particularly noting the global supply pressures on high quality nasopharyngeal swabs.

However PHLN note there are constraints of a regulatory nature with using saliva and these must be considered when working with referring medical practitioners and advising on specimen collection methods which are not included in an In-Vitro Diagnostic (IVD) medical devices' instructions for use (i.e. a specimen type which has not been validated by the manufacturer for use with the device). Medical practitioners should be cognisant of the following:

- Currently none of the SARS-CoV-2 IVD medical devices included in the Australian Register of Therapeutic Goods are intended by the manufacturer to be used with saliva specimens.
- However use of alternative specimen types, such as saliva, for testing for SARS-CoV-2 can be readily validated by laboratories as an in-house IVD medical device.

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[1] Khurshid, Z., Zohaib, S., Joshi, C., Moin, S., Zafar, M. and Speicher, D. (2020). *Saliva as a non-invasive sample for the detection of SARS-CoV-2: a systemic review.* medRxiv. Doi: 10.1101/2020.05.09.20096354.

[2] Azzi, L. Carcano, G., Gianfangna, F. et al., *Saliva as a reliable tool to detect SARS-CoV-2*, Journal of Infection. Doi: 10.1015/jinf.2020.04.005

[3] To, K., Tsang, O., Leung,. W., Tam, W., Wu, T., Lung, D. et al. *Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study*. The Lancet Infectious Diseases. Doi: 10.1016/S1473-3099(20)30196-1.

[4] Williams, E., Bond, K., Zhang, B., Putland, M. and Williamson, D. A. (2020). *Letter to the Editor: Saliva as a non-invasive specimen for detection of SARS-CoV-2*. Journal of Clinical Microbiology. Doi: 10.1128/JCM.00776-20.