



Australian Government

Department of Health

Dear Pathology Stakeholder

ACCREDITATION REQUIREMENTS FOR SARS-COV-2 TESTING

Pathology laboratories have played an important role in the response to the COVID-19 pandemic. The Australian Government is committed to supporting the pathology sector and ensuring patient access to quality pathology services during the response to COVID-19.

The National Pathology Accreditation Program is aimed at ensuring there is a quality framework for the safe performance and delivery of quality pathology services, and pathology services performed by appropriately accredited laboratories are eligible for Medicare rebates. The Department is focussed on supporting the performance of pathology laboratories conducting SARS-CoV-2 testing and would like to ensure that all pathology laboratories are appropriately accredited for SARS-CoV-2 testing, particularly when claiming Medicare benefits for the testing.

The Department understands that NATA wrote to Authorised Representatives in all laboratories in March 2020 to notify them of the requirement for laboratories performing SARS-CoV-2 testing to be assessed and accredited and the option of remote assessment.

The Department is writing to all Approved Pathology Authorities and all Accredited Pathology Laboratories to draw attention to the requirement that all laboratories must notify Services Australia and NATA, as the independent accreditation assessment body, of any change in the laboratory's testing which may affect its scope of accreditation. For example, laboratories performing SARS-CoV-2 testing must be specifically accredited for SARS-CoV-2 testing in order to be eligible to claim Medicare rebates for this test. This is the case even if a pathology laboratory is already accredited to perform microbiology and/ or serology testing.

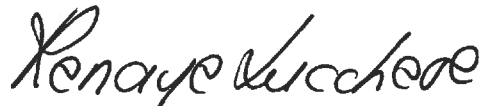
As part of the assessment process, the laboratory needs to demonstrate that it meets the pathology accreditation requirements, including that the tests have been validated, the supervising pathologist has the relevant qualifications and scope of practice to oversee the testing performed and report test results appropriately. The accreditation requirements also require that laboratories are enrolled and actively participate in a relevant External Quality Assurance Program for SARS-CoV-2 testing.

The Department recommends that pathology laboratories performing SARS-CoV-2 testing contact NATA to confirm their accreditation status for this test. The Department expects that all laboratories performing SARS-CoV-2 testing will be NATA/RCPA accredited **by 20 December 2020**. NATA has indicated that it is progressing all requests for SARS-CoV-2 testing as a matter of priority.

The Department is monitoring SARS-CoV-2 testing activities and is working closely with Services Australia, NPAAC and NATA. Please note that the Department may conduct future compliance activities in relation to pathology laboratories claiming MBS rebates in accordance with the accreditation requirements under the *Health Insurance Act 1973* and the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017*.

Please contact your Client Coordinator at NATA to discuss the laboratory's status of accreditation for SARS-COV-2 testing. NATA can be contacted on Ph – 1800 621 666 or Email - sector.lcs@nata.com.au

Yours sincerely

A handwritten signature in black ink that reads "Renaye Lucchese". The signature is written in a cursive, flowing style.

Renaye Lucchese
Assistant Secretary
Diagnostic Imaging and Pathology Branch

3 November 2020