

30 April 2020

Dear Authorised Representative

NATA/RCPA ACCREDITATION DURING THE COVID-19 PANDEMIC

Approved Pathology Laboratories

By now I am sure you are aware of the advice provided by the Commonwealth Department of Health (DoH) regarding the COVID-19 pandemic exceptional circumstance provision for Approved Pathology Laboratories (APLs).

Laboratories whose APLs will expire prior to 1 October 2020

Two options are available.

- 1) The provision allows for the APL to be automatically extended for a further 6 months from the current expiry date. When the pandemic recovery phase commences, an assessment and continuation of accreditation will be required prior to the new expiry date. The assessment type will be that which was delayed i.e. Surveillance or Reassessment. The ability for NATA to perform this assessment will obviously be contingent on the relaxation of current restrictions. Should this visit be unable to proceed, it is unknown at this stage whether a further APL extension will be granted by the Commonwealth.
- 2) A laboratory may opt to proceed with a remote assessment* during this time in lieu of an on-site assessment to allow an extension of its APL for a period up to 36 months. This arrangement will necessitate a further on-site visit to occur within 12 months of the date of the remote assessment. The coverage of the remote assessment activity will be dependent on the type of assessment which was due. The management and technical laboratory activities selected for review will be determined on a case by case basis taking into consideration each laboratory's specific circumstances and assessment history.
 - a) Surveillance visit

Where the assessment activity was scheduled as a surveillance visit, the coverage of this assessment will follow as closely as possible the activities performed at an on-site surveillance visit and as described in the *Specific Accreditation Criteria: Human Pathology - NATA/RCPA Accreditation Surveillance Model for Human Pathology*. The assessment team will comprise a NATA lead assessor(s) but will not routinely include a technical assessor. Selected technical areas and the management system will be reviewed.

b) Reassessment

Where the assessment activity was scheduled as a reassessment, the coverage of this assessment will follow as closely as possible the activities performed at an on-site reassessment visit and as described in the *Specific Accreditation Criteria: Human Pathology - NATA/RCPA Accreditation Surveillance Model for Human Pathology*. Selected management system elements and all technical areas (as far as is practical) will be reviewed.

* Remote Assessment (ISO/IEC 17011:2017 clause 3.26):

Assessment of the physical location or virtual site of a conformity assessment body, using electronic means.

Note 1: A virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.

Note 2: Examples of electronic means include: teleconferencing, webinars, on-line video/audio services such as Skype, audio or video recordings, remote access to an organisation's data processing and management systems, databases, etc.

Laboratories whose APL will expire after 30 September 2020

The advice from the DoH does not cover APLs which will expire after 30 September 2020.

NATA has requested that the DoH give consideration to extending the option for a remote assessment with the granting of APL approval for up to 36 months (option 2 above), to include APLs whose NATA/RCPA assessment is due on or prior to 30 September 2020 but whose APL expires after this date.

For facilities in this position NATA is able to offer the option of a remote assessment now should facilities have capacity to accommodate this. Whether a targeted follow up on-site visit will be required prior to the APL being extended will depend on the advice to be received from the DoH.

Facilities that are not Approved Pathology Laboratories

Facilities that are not recognised by the Commonwealth as APLs may opt to proceed with a remote assessment in lieu of an on-site assessment on this occasion only. The coverage of the remote assessment activity will be dependent on the type of assessment activity which was due. In general, the assessment activity following the remote assessment will be scheduled in accordance with the facility's routine assessment cycle, however, NATA reserves the right to perform an on-site assessment at anytime after the recovery phase begins taking into consideration each laboratory's specific circumstances and the outcome of the remote assessment.

Facilities that do not opt for a remote assessment will require an on-site visit as soon as the recovery phase begins, the coverage of which will be dependent on the type of assessment activity which is overdue.

Facilities scheduled for a routine On-line activity in 2020

On-line assessments of all facilities which are scheduled but have not yet commenced will be cancelled for the remainder of 2020.

Advisory visits

NATA is able to offer advisory visits by remote assessment when requested.

Extensions to scopes of accreditation

NATA is able to offer additions to scopes of accreditation by desk top variations in accordance with normal procedures. Where the scope extension would normally require an on-site visit, NATA is able to offer a remote assessment wherever practical to do so. As the recovery phase begins, NATA will evaluate the feasibility of performing on-site assessments. Should you be seeking accreditation for SARS-CoV-2 testing, please contact your client coordinator.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Jennifer Evans', written in a cursive style.

Jennifer Evans
CHIEF EXECUTIVE OFFICER