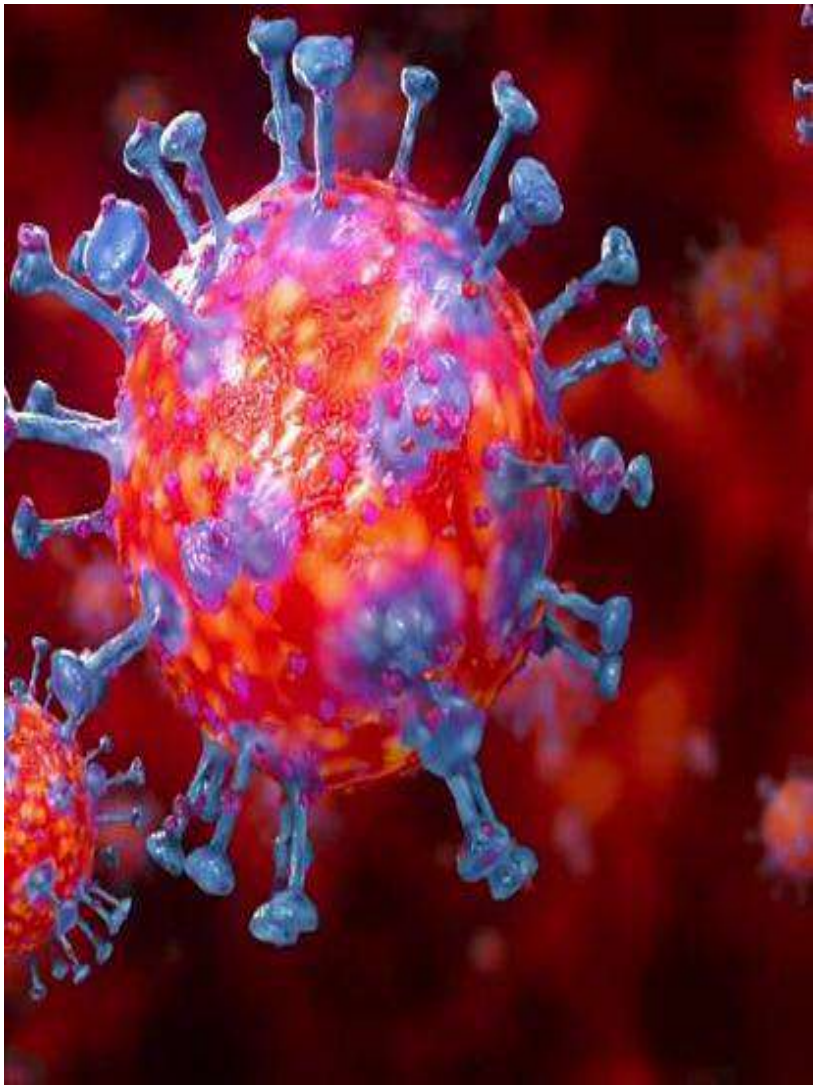

NATA
WORLD RECOGNISED
ACCREDITATION
NATA Human Pathology
ZOOM Forum
Thursday 18th June
12-1.00pm
Anyone joining the meeting please
mute your microphone



NATA/RCPA Human Pathology

Accreditation in the time of Corona Virus

- If attendees have any questions please use the chat function below – this will be monitored
- Will do a FAQ email post meeting
- Any specific questions please get in contact with your Client Coordinator

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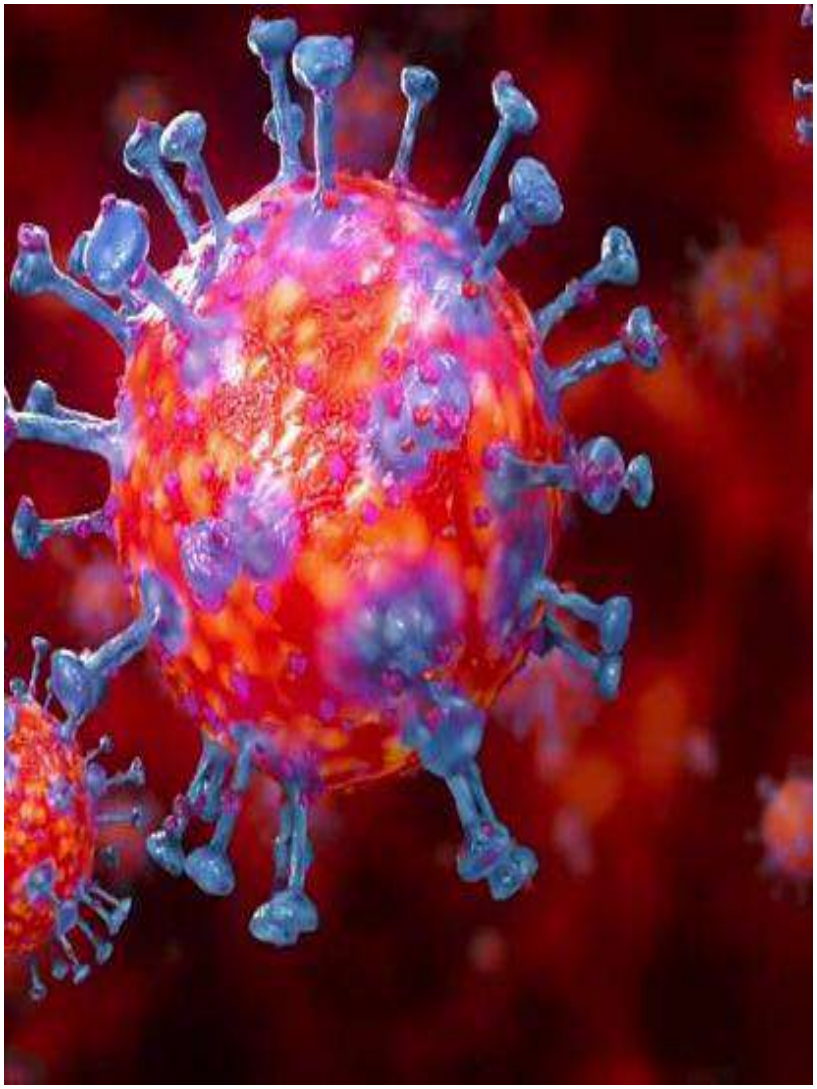

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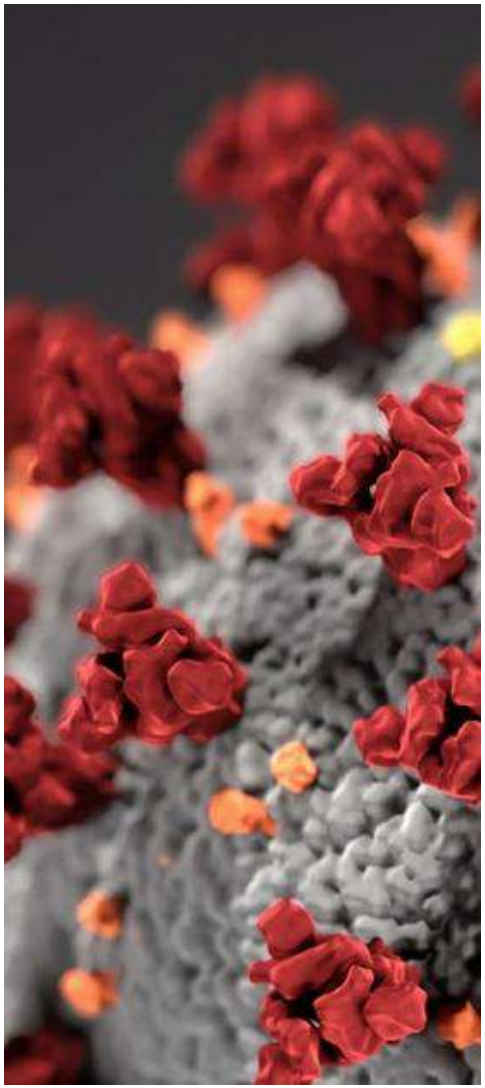
What we will cover today:

- Update on the accreditation process in 2020
- Accreditation a new way – the Reengineered accreditation model in Human Pathology
- Future forums



NATA Sars-Cov-2 Timeline (1)

NATA / TGA started dialogue about testing for the Novel corona-virus 2019-nCoV	22 January 2020
First Coronavirus case identified in Australia	25 January 2020
VIDRL successfully grew and sequenced the Coronavirus from a patient sample	29 January 2020
NATA informed by PHLN laboratories that they were developing assays and had started testing for the novel virus	3 February 2020
NATA starts discussions with Services Australia (Medicare)and the Department of Health regarding contingency plans for assessments	3 March 2020
WHO declares global pandemic	11 March 2020
NATA introduces a “No Travel” policy for Lead Assessors and Technical Assessors	13 March 2020
NATA brings together a team of Lead Assessors and Technical assessors to coordinate requests for scope extensions for SARS-CoV-2 testing. A decision is made that this will be a **non-chargeable** activity	18 March 2020
TGA lists SARS-CoV-2 tests on the ARTG	22 March 2020
NATA ceases all on-site activities and develops an alternative assessment policy	24 March 2020
“Pathology Accreditation Processes during Covid-19 Pandemic” released by the Commonwealth	7 April 2020
First lab NATA /RCPA accredited for Sars-Cov–2 testing	24 April 2020

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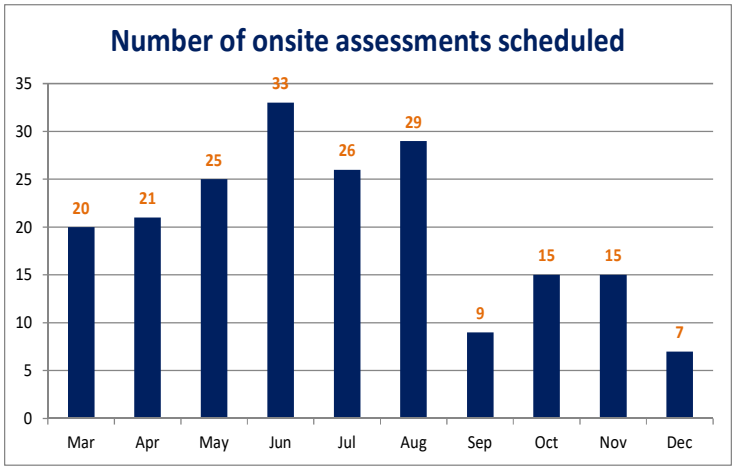
Statistics



- As previously noted NATA ceased all onsite assessments on the 24 March
- Significant backlog developing
- April > December approximately 110 OLNs due – Cancelled

- As per the Commonwealth the APL expiry date for labs before 30th Sept has been extended by 6 months
- **NATA has requested the Commonwealth give consideration to extending the option for remote assessments**

Laboratories whose Medicare Expires (and have not been issued a new ROLP)	
March - June	12
July- September	40
September - December	39

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Labs whose APLs will expire prior to 1 October 2020

Based on the Commonwealth DOH advice & effective until 30 Sept 2020

Option 1

Lab opts for Medicare expiry to be automatically extended by 6 months

- Assessment to be conducted prior to the new expiry date
- Assessment will be the delayed assessment type
- Contingent on relaxation of restrictions

NB: Accreditation must be continued before NATA can issue a new Medicare report

- Approximately 40% of labs have taken this option

Option 2

Laboratory opts to proceed with a **Remote** assessment

- As a result APL is extended by up to 36 months
- Option requires on-site visit within 12 months of the remote assessment
- The coverage of the onsite assessment at will be determined on a case by case basis

- Approximately 60% of labs have taken this option
- Approximately 30 remote assessments have been undertaken so far

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Ongoing process during Covid shutdown

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- Initial advisory visits and significant additions to scope are been reviewed on a case by case basis
  - Where practicable undertaken as a remote activity
- Initial assessments following the advisory visit for labs claiming MBS rebates will need to be on-site once in recovery phase
- Extra-ordinary visits e.g. follow up assessments will be considered on case by case basis.
  - On-site visits for these will be prioritised once the recovery phase begins.

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Return to "Normal"

- As per the NATA CEO communication on 6 May 2020 assessments up to **31 August** will need to be remote
- From 1 September we are set restart On-Site assessments
- Will need to take into consideration any travel restrictions and health and safety requirements
- NATA are getting an increasing numbers of requests for on-site assessments now as Australia transitions out of COVID-19 restrictions
- These requests can be considered on a case-by-case basis and will be subject to strict conditions and require management approval
- These timelines are subject to ongoing review – NATA management meeting weekly

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The Plan Moving Forward

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To address the backlog:

- Carefully monitoring developments and in ongoing communication with Services Australia and Department of Health
- Priority been be given to Laboratories whose Medicare expires soonest
- Mixture of “remote” style assessments
    - E.g. Satellite visits – NATA lead assessor onsite
- Increasing internal administration resources
- Communication

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Accreditation a new way

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Background

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The current human pathology assessment model was introduced in 2013

Drivers for change include:

- A move by standards writing and accreditation bodies toward risk based approach;
- Accreditation body ISO standard ISO 17011 now allows more flexible assessment models;
- advances in technology enabling different assessment activities to supplement physical on-site visits;
- Data driven trend and summary reporting from NATAs information system (AIMS);
- Introduction of risk rating and cause analysis.

NATA has reviewed the Human Pathology assessment model to reflect a more contemporary governance & risk based approach.

A new accreditation model that sees you the way you see yourselves

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Key Changes

- NATA will move to recognise organisations identified as having a **Single Governance Framework** as one accreditation - regardless of accreditation number, site number or name.
- Assessments will take a holistic approach to the organisation
- The Governance of an organisation will become a major focus of the assessment - across all levels
- Tailored assessment program to be developed for each organisation with a variety of assessment types – including the introduction of **remote assessments**

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Key Changes

- All levels of the Governance structure will be assessed
- Types of visit to include
  - Governance assessments
  - Full and partial technical assessments
  - On-site and remote assessments
- All “main” labs - Cat GX, large GY and Cat S labs will undergo full technical assessment each cycle
- Sampling of the Scope and Sites for Category B, POCT and Cat SB labs

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Key Changes

- All visits to include a technical assessor(s)
- QMS will be assessed across the network
- Ceasing Surveillance and On-line activities as a routine activity
- Focus on risk rather than compliance based assessments
- Applicants treated as a special case

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Overview

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Level 1 Organisation Review

Level 2 Designated Person Assessment

Level 3 Discipline Specific Assessments

Level 4 Branch Sampling

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Level 1 Organisation Review

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- Review of the highest level of interaction, cooperation and direction in an organisation
- How is this managed?
- Review focused at the level above the designated person
- With the person(s) responsible for the overall Governance of the organisation
- Review to focus on the **4 pillars** of Governance
    - Responsibility
    - Communications
    - Policy development
    - Risk management
- Outcome used to provide guidance on organisations approach to Governance

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Level 2 Designated Person Assessment

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- Designated Person (DP) framework was introduced by NPAAC in 2018
- Every lab must be under the control of a DP who is responsible and accountable for the Clinical Governance & Risk Management of the service
- Assessment will focus on:
  - The overarching clinical governance structure (incl Level 1) and supervision arrangements
  - Risk management plans
  - Clinical incident management systems
  - Policy implementation -including the quality management system
  - Range of tests and consultation provided

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Level 3
Discipline Specific Assessments

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- The Designated Person delegates supervision of testing to Pathologists with the relevant Scope of Practice.
- Assessment focuses on the day to day supervision of the disciplines - including B/GY laboratories for which the laboratory takes responsibility.
- To be completed over 4 years with yearly assessment of discrete disciplines.
- Associated B / GY will be considered as part of the GX lab and records for these labs will be reviewed as part of the GX assessment.
- Assessment to focus on high risk points including;
    - Pre and Post analytics e.g. Collections, couriers etc.
    - Clinical handover
    - Introduction of new testing, especially In-house IVDs
    - Assessment of staff competency, including talking to staff rather than simply reviewing records
    - Main site supervision of remote sites at “bench” level

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Level 4
Branch Sampling

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- B / GY labs with the same accreditation number but different site numbers
    - will be considered as part of the GX laboratory and records for these labs will be reviewed as part of the GX assessment.
    - B/GY labs will be sampled with visits a mixture of onsite and remote activities
    - Sampling will vary depending on network performance and assessment history

Framework :

- For B / GY Labs - where there is a pathologist who is **IN CHARGE** of supervision or where the scope is complex assessment will be as per a GX discipline
- For B/GY Labs - Where there is no pathologist and where the scope is simple assessment will be a per a B lab and will be sampled

Non-networked / Single discipline labs will have a reassessment every 2 years (Highest risk)

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Transition plans

- Currently undertaking stakeholder engagement
- Building the framework / rules around the changes
- Developing the required changes in AIMS
- Each Organisation will be different but current intent is to link the new process to the GX lab
- Ongoing role out over a number of years
- Client managers

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Future Forums

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NATA is planning a series of future forums addressing areas of interest including:

- *Clinical Governance - including how governance will be assessed as part of the new program*
- *Risk management - including examples of how labs have built a risk framework*
- *Further details on the new assessment model*
- *Remote assessments including experiences of the NATA Lead Assessor, the lab and the technical assessor*
- *Details of the "Scope Project"*
- *6 Months of assessment findings - including a discussion on the most common assessment findings*
- *Cause analysis - labs approach to cause analysis and how this is reviewed*

Dates are yet to be finalised.

Thankyou

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