

Laboratory Accreditation-Role of Pathologist

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Synopsis of Talk

- Current Model of Accreditation
- Supervision Requirements
- On line review
- Surveillance visit
- (Re)Accreditation
 - Pre
 - During
 - Post



Laboratory Accreditation is a Continuous Process

- 4 Year Cycle
 - On line review at 12 & 36 months
 - Surveillance visit at 24 months
 - Reaccreditation visit at 48 months



On Line Review

- Follow up “C” from previous accreditation
- Limited Review of Management System
- Validation/Verification of new methods/equipment
- QAP Performance Review
- Changes in Governance/ Ownership-Incl Supervision
- Technical Assessors may be co-opted

Surveillance Visit

- Review previous “C &M” from previous assessment or online
- Management System-esp Quality Manual
- Technical Issues-QAP
- Staff-Supervision



Assessment (Reassessment)

- On site Peer Review
- Technical Assessors
- Management System
- Changes to Scope of Accreditation
- Supervision



The Role of the Pathologist(s) Providing Supervision is Ongoing

Focus is not only the (Re) Accreditation of
Laboratory



Supervision Requirements

- Outlined in NPAAC

*Requirements for Supervision of Pathology
Laboratories (2007 edition)*

*Requirements for Supervision in the Clinical
Governance of Medical Pathology
Laboratories(2018 edition)*

The Relevant Categories for Pathologists are GX GY B

Supervision Requirements

Designated Person

Medical Practitioner (*G&B= pathologist*) who has responsibility for Clinical Governance and ensures ethical Patient care

Supervising Pathologist

With relevant scope of practice delegated to supervise pathology in G&B laboratories

Ongoing Requirements

- Meet Supervision Requirements
- Familiar with NPAAC Requirements
- Yearly Management Review
- Regular Laboratory Meetings
- Clinical Liaison

Supervision Requirements must be met

- Evidence of Delegation from designated person
- Evidence of Scope of Practice and up to date CPD
- On site presence
- Risk management and mitigation



Supervision Activities

- Performance Management
- Review of Incidents/Audits/Corrective Action
- Risk Management Planning and Review
- EQA & IQC
- Validation /Verification
- Continuing Education
- Communication with Designated Person

Supervision Requirements

- Ethical Practice
 - Patient Rights Paramount
 - Open Disclosure
 - Confidentiality



Supervision Requirements

Risk Management

Clinical Governance

Scope of Practice



Supervision Requirements

- Clinical Governance ensuring service quality and Patient Safety is a prime responsibility of the Designated Person. However all Pathologists must take regard of this responsibility as they have a delegated role and responsibility
- Supervision Requirements are the minimum requirements and in some cases may not meet the Clinical Governance Responsibility.



Laboratory Accreditation is a Continuous Process

- 4 Year Cycle
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 - Surveillance visit at 24 months
 - Reaccreditation visit at 48 months



Pathologist and On line Review

- Meet supervision requirements-GX GY B
- Ensure submission is correct
- “C” are resolved/M are considered
- Validation/Verification of new methods
- QAP up to date and reviewed and corrective action(s) carried out and traceable

Survey Report
RN-1438199

[Printable View](#)

Survey Report Detail

[Edit](#)

Information

Participant Number	895.2	Discipline Name	CHEMICAL PATHOLOGY
Enrolment Year	2019	Program Name	General Chemistry and Therapeutic Drugs
Participant	Campbelltown Hospital	Cycle	110
Report Version	1	Run	0
Report ID	CPGC011000000008950200EOC01	File Link	End-of-Cycle
Amendment Notes	Initial Publication.	Attachment Link	

Participant Flag

Flag Green



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Reviews

[New](#)

Action	Created Date	Review Version	Review ID	Owner First Name	Owner Last Name	Status	# Attachments	# Notes	Comments	View
Edit	8/06/2019	1	CPGC011000000008950200EOC01	Ivo	Majurdic	Reviewed	0	0	Satisfactory performance.	View

Survey Report History

Date	User	Action
8/06/2019 2:16 PM	Ivo Majurdic	Changed Flag to Green.
16/05/2019 9:05 AM	Amazon API	Changed RCPA Report Number to RN-1438199.
		Created.

Always show me [more](#) records per related list

Review Edit Save Cancel

Information

Survey Report RN-1438199

Review Version 1

Review ID CPGC011000000008950200EOC01

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Review ID CPGC011000000008950200EOC01

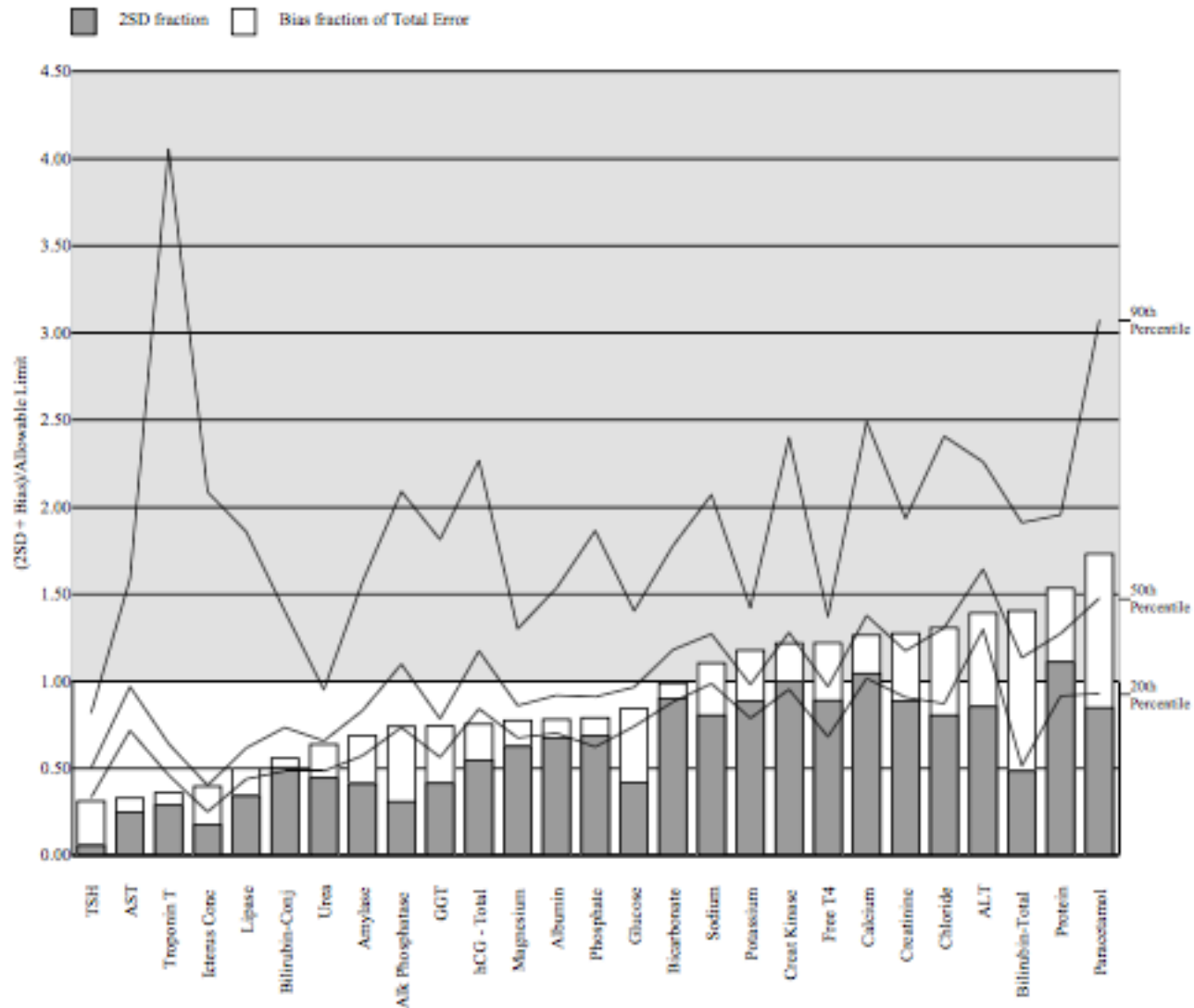
Status --None--

Comments

Save Cancel

PERFORMANCE SUMMARY FOR PARTICIPANT NO. 895.1

(2SD + Bias)/Allowable Limit Assessment - Compared to 20th, 50th & 90 Percentile Rankings



Results based on Labs Method Median - Albumin, Icterus Conc, hCG - Total, Free T4, TSH.
 General Chemistry and Therapeutic Drugs Cycle 110 - 7 January - 15 April 2019

Pathologist and Surveillance Visit

- Meet supervision requirements
- “C & M” are resolved
- Validation/Verification of new methods
- QAP up to date and reviewed
- Be Available if Possible

Pathologist and(Re) accreditation Visit

Prior to Visit

- Supervision meets requirements
- Review documentation before submission
- Review Scope of Testing
- Review Previous Accreditation Report
- Management Review
- Point of Care
- QAP

Pathologist and(Re) accreditation Visit

At Accreditation

BE THERE

It is Peer Review



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Pathologist and(Re) accreditation Visit

Opening Discussion

- Role of Pathologist
- Any clarifications required
- Discussion of laboratory services



Pathologist and(Re) accreditation Visit

Assessment

- Be available for queries (in person/ other methods)
- Meet with Technical Assessor(the pathologist)
- May be asked about CPD
- Risk Assessment

(G&B laboratories)

Pathologist and(Re) accreditation Visit

Assessment

- Be familiar with POC Service



Pathologist and(Re) accreditation Visit

Accreditation of Laboratory for RCPA Training



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Pathologist and(Re) accreditation Visit

Exit Discussion

- Receive Feedback
- Correct Any Misunderstandings
- Consider C&M Conditions
- Consider Risk Assignments



Pathologist and(Re) accreditation Visit

Exit Discussion

- Receive Feedback
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Pathologist and(Re) accreditation Visit

Post Visit

- Start addressing Cs (esp High Risk) before Final Report
- Develop Plan to meet the C&M in a timely fashion
- “Os” give opportunity for improvement

And Then the Cycle Starts Again



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