



ACCREDITATION SCHEME FOR LABORATORIES

Technical Note MED 002
Specific Criteria for Histopathology
Section

Technical Note MED 002- Histopathology, 29 March 2019
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1. Introduction & Scope

- 1.1 a) This document describes the specific requirements to be complied by histopathology section to be accredited.
- b) The International Standard 'ISO 15189 Medical laboratories – Particular requirements for quality and competence', other MEDICAL Series Technical Notes published by SAC-SINGLAS shall be studied in conjunction with this document.

2. General Technical Note : Medical 001

2.1 Please refer **General Technical Note: Medical - 001** for the following:

- Personnel
- Accommodation & Environmental Conditions
 - Physical Facilities and Laboratory Safety
- Laboratory Equipment – Calibration & Maintenance
- Pre-examination Procedures
 - Requisitions, Collection and Handling of Specimens
- Examination Procedures
 - Test Methods and Method Validation
- Assuring Quality of Examination Procedures
 - Quality Control, Proficiency Testing, Reagents and Reference Materials
- Post-examination Procedures
 - Retained Samples and Waste Disposal
- Reporting of Results

3. Personnel

3.1 Refer to Personnel in **General Technical Note: Medical - 001**.

4. Accommodation and Environmental Conditions

4.1 Refer to Accommodation & Environmental Conditions - Physical Facilities and Laboratory Safety in **General Technical Note: Medical - 001**. In addition to that, the histopathology laboratory shall comply with the following:-

4.2 Appropriate extraction systems shall be in place to minimize the levels of noxious vapours.

5. Laboratory Equipment

5.1 Refer to Laboratory Equipment in **General Technical Note: Medical - 001**.

6. Pre-examination Procedures

6.1 Refer to Pre-examination Procedures in **General Technical Note: Medical - 001**.

7. Examination Procedures

7.1 Refer to Examination Procedures in **General Technical Note: Medical - 001**.

8. Assuring Quality of Examination Procedures – Quality Control and Proficiency Testing

8.1 Refer to Assuring Quality of Examination Procedures - Quality Control, Proficiency Testing, Reagents and Reference Materials in **General Technical Note: Medical - 001**. In addition, quality control measures must be in place and documented to ensure good technical quality of slides produced.

8.2 If the laboratory is performing immunohistochemical stains, it shall be enrolled in a quality assurance programme for immunohistochemistry.

8.3 Workload statistics, audit activities and work improvement activities shall be documented and monitored regularly.

9. Post-examination Procedures

9.1 Refer to Post-examination Procedures in **General Technical Note: Medical - 001**.

10. Reporting of Results

10.1 Refer to Reporting of Results in **General Technical Note: Medical - 001**. In addition to that the following is applicable to histopathology laboratory.

10.2 All reports must be documented in writing. This includes intraoperative consultation.

10.3 A Pathologist or a designated qualified physician must verify all reports.

10.4 The reports must be timely and relevant to the medical management of the patients.

10.5 All intra-departmental and extra-departmental consultation of cases shall be recorded. All reports shall be easily retrievable by name or identification number or accession number.

10.6 All materials and reports should be retained for a minimum period as stated below:-

10.7 RETENTION OF LABORATORY RECORDS AND MATERIALS

10.7.1 The table below refers to the minimum retention period for materials and records. Laboratories are to retain records and materials for a longer period of time than specified, especially when patient care needs so

10.7.2 warrant it.

Microfilm and electronic records in place of hard copies are acceptable provided they are maintained securely, are readily accessible and are the exact duplicates of the reports sent out.

MATERIALS	SURGICAL PATHOLOGY	POST MORTEM	CYTOLOGY
Wet Tissue	4 weeks after final report	3 months after final report	-
Cytologic material e.g. sputum, fluid	-	-	7 days
Paraffin blocks (include E/M blocks)	10 years	10 years	-
Slides	10 years	10 years	5 years
IMF Slides	7 days	7 days	7 days
Records & Reports	20 years	20 years	20 years