ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes MED 002

Specific Criteria for Cytopathology Section

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1. Introduction & Scope

1.1 This document describes the specific requirements to be complied by cytopathology laboratory to be accredited.

1.2 The document shall be read in conjunction with ISO 15189 Medical laboratories – Requirements for quality and competence', SAC-SINGLAS documents, Proficiency Testing Technical Note 001, and other MEDICAL Series Technical Notes published by SAC-SINGLAS.

2. Personnel

2.1 The Pathologist will be responsible for cytology and histology reports. They shall be SAB certified in pathology.

2.2 The Pathologist and Cytotechnologist must participate in continuing education in cytology dedicated training and updates.

2.3 The pathologist or a designated alternative must be available every working day.

2.4 Each screener whether Cytotechnologist or Pathologist involved in primary screening shall not screen more than 70 slides / per person / 24 hours.

2.5 An in-house refresher programme should be undertaken if the Cytotechnologist has not screened smears for 3 months or more. For an absence from screening for more than 6 months, a formal (external) update programme is recommended.

2.6 The pathologist should see a minimum number of 20 abnormal smears per month.

2.7 The Cytotechnologist should read a minimum of 3000 slides per year.

3. Facility and Environmental Conditions

3.1 Safety

3.1.1 The laboratory shall maintain the quantity of flammable and dangerous chemicals within the allowable limit, as stipulated in its SCDF license and NEA certification.

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

4. Laboratory Equipment

4.2 Automated Screening

4.2.1 The laboratory shall ensure that automated systems, including AI applications used for cytology are validated and verified for their intended scope of testing.

4.2.2 The laboratory shall understand the limitations of these systems, ensure their appropriate application, and implement ongoing monitoring and quality control of automated screening processes.

5. Examination Procedures

5.1 There shall be a documented policy for ensuring that non-gynaecologic specimens with a high potential for cross-contamination are processed and stained separately from other specimens.

6. Ensuring the Validity of Examination Results

6.1 Quality control measures must be in place and documented to ensure good technical quality of slides produced.

6.3 The Laboratory shall be enrolled in SAC-SINGLAS recognised quality assurance programmes or its equivalent.

6.4 A rescreen of 10% of the normal cervical smears shall be done regularly by a suitably trained Cytotechnologist or Pathologist.

6.5 Correlation of cervical smears with biopsies shall be done whenever the biopsies are available.

6.6 A review of all cervical cytology within the preceding five years should be carried out, especially in cases of high grade squamous intraepithelial lesions, and the reviews should be documented.

6.7 All non-gynaecologic slides shall be reviewed and the report signed by a pathologist.

6.8 Effort shall be made to correlate non-gynaecologic cytopathology findings with histological and clinical findings.

9. Reporting of Results

9.1 In the case of a cervical smear, conventional and liquid based tests should be stated if they are used.

9.2 Only non-malignant (normal and inflammatory) cervical smears may be reported by suitably trained Cytotechnologist.

9.3 All abnormal cervical smears and non-gynaecological smears shall be reported by a Pathologist or a designated qualified physician.

9.4 The cervical PAP smear shall be reported using current standard terminology and classification.

9.5 All reports shall be easily retrievable by name or identification number or accession number.

9.6 <u>Retention of Laboratory Reports and Materials</u>

9.6.1 Slides should be archived in or by the reporting laboratory. If these are archived outside the laboratory, there must be a documented procedure for the retrieval of slides.

9.6.2 Should a laboratory cease business, the laboratory should take all measures as are reasonable and necessary to ensure that the medical records of every patient are properly transferred to the healthcare establishment indicated by the patient's clinician to patient; or the stewardship of another accredited laboratory.

9.6.3 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 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	**CYTOLOGY**
Cytologic material e.g. sputum, fluid	7 days
Gynaecologic and non-gynaecologic glass slides	5 years
Fine needle aspiration glass slides	10 years
Reports	15 years