

HOKLAS Supplementary Criteria No. 25

“Medical Testing” Test Category – Histopathology

1. Introduction

- 1.1 This Supplementary Criteria is an amplification and interpretation of the requirements of HKAS 002 and HOKLAS 015 for the accreditation of examinations in histopathology within the Medical Testing Test Category. This document sets out only those specific requirements that require further elaboration but does not include all the accreditation requirements. Therefore, this Supplementary Criteria needs to be read in conjunction with HKAS 002 and HOKLAS 015.
- 1.2 The checklist given in the Annex serves as guidance for laboratories to self-assess their management system and operation procedures against the requirements given in HOKLAS 015 and this document.

2. Scope of accreditation

The areas for which accreditation may be offered are listed below:

- 2.1 Surgical pathology
- 2.2 Intraoperative frozen section
- 2.3 Immunohistochemistry
- 2.4 Electron microscopy
- 2.5 Molecular pathology

3. Personnel

- 3.1 Medical personnel (referred to as “anatomical pathologist”):

3.1.1 A qualified anatomical pathologist shall be a pathologist who has obtained postgraduate qualification in anatomical pathology, such as the Fellowship of Hong Kong College of Pathologists, or equivalent as advised by the College.

3.1.2 Pathology trainee shall be a registered medical practitioner who is enrolled in a training programme recognised by the Hong Kong College of Pathologists, or equivalent as advised by the College.

3.2 Workload

There shall be adequate staff resources taking into account the time required for laboratory management, audit, teaching and continuous professional development. The degree of case complexity should also be considered.

3.3 Continuing education program

3.3.1 Pathologist shall fulfill the 3-year cycle of CME/CPD requirement of the Hong Kong Academy of Medicine or Hong Kong Medical Council or equivalent bodies.

3.3.2 Technical staff shall actively participate in continuing education program, and supported by documentation.

4. Accommodation and environmental conditions

4.1 Biological hazards

The specimen reception area and dissection area shall be clean and disinfected at least daily.

4.2 Chemical hazards

Adequate precautions shall be taken (e.g. fume hood, gloves and goggles used) when handling and storage of toxic or volatile chemicals such as xylene, chloroform and heavy metals to prevent inhalation or skin contact.

4.3 Compressed gases and liquid nitrogen hazards

Appropriate safety devices shall be available for safe handling of compressed gases and liquid nitrogen.

4.4 Physical hazards

All sharps shall be stored, handled and discarded safely and securely.

4.5 Radiation hazards

4.5.1 The electron microscope shall be adequately shielded to prevent irradiation to operators.

4.5.2 Radiation from the electron microscope shall be checked periodically and after major repair.

4.6 The cutting area for fresh and fixed specimens shall be effectively separated from the rest of the work area.

5. Examination procedures

5.1 Surgical specimens shall be examined grossly by an anatomical pathologist, pathology trainee or appropriately trained personnel under the direct supervision of a qualified pathologist.

6. Assuring the quality of examination procedures

- 6.1 Previous cytologic and histologic diagnoses shall be searched for and slides retrieved for review when appropriate, for each case. Significant disparities shall be reconciled in the report, if there is implication on current patient management.
- 6.2 There shall be correlation of frozen and paraffin section diagnoses.
- 6.3 There shall be a documented program for peer review of a defined number or percentage of cases. Whenever discrepancies are detected, appropriate actions shall be taken and documented.

7. Post-examination procedures

- 7.1 The minimum retention period for request forms and other materials shall be as follows :

Request forms	3 years
Wet tissues	2 weeks after final report
Containers with no residual tissue	2 weeks after final report
Slides	20 years
Blocks	20 years
Immunofluorescence slides	7 days after reporting
Copies of reports	20 years or permanent if possible

- 7.2 The slides and blocks shall be properly filed and readily retrievable.

- 7.3 There shall be documentation of loan of slides or blocks.

8. Reporting of results

- 8.1 The histopathology report shall be authorised by a qualified pathologist, or pathology trainee under the direct supervision of a qualified pathologist.
- 8.2 With the exception of small biopsies, reports on surgical specimens shall include adequate description on the macroscopic appearance, how blocks are taken, and a pathologic diagnosis.
- 8.3 The terminology, tumor staging system, and minimum data set to be included in report shall follow recommendations of local or international professional bodies.
- 8.4 The intraoperative frozen section interpretation shall be included in the final report.
- 8.5 There shall be established policies for the procedure of communicating intraoperative frozen section interpretation.
- 8.6 Discrepancy in diagnosis from previous cytology, biopsy specimens or frozen section shall be explained and resolved.
- 8.7 Special examinations (such as immunohistochemistry, electron microscopy, molecular pathology) performed shall be documented and results indicated in report. The results shall be correlated and integrated with the gross and light microscopic findings of the submitted specimen.
- 8.8 An indexing or cross-reference system shall be in place to allow retrieval of information by patient particulars and/or diagnosis.
- 8.9 There should be a consistent encoding system.