HOKLAS Supplementary Criteria No. 25

'Medical Testing' Test Category – Histopathology

1. Introduction

1.1 This document is an application document for the requirements of HKAS 002 and HOKLAS 015 accrediting histopathology examinations within the test category of 'Medical Testing'. This document only details those requirements that require further elaboration but does not include all the accreditation requirements. Therefore, it has to be read in conjunction with HKAS 002, HOKLAS 015, HOKLAS SC-33 and relevant HOKLAS supplementary criteria.

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

HKAS provides accreditation under HOKLAS for the following areas:

2.1 Electron microscopy

2.2 Histopathology

2.3 Immunohistochemistry

Note: For molecular testing in histopathology, please refer to HOKLAS Supplementary Criteria No. 30 'Medical Testing' - Molecular Genetics.

3. Personnel

3.1 Medical personnel

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

3.1.2 Pathologist trainee shall be a registered medical practitioner who is enrolled and is undergoing active training 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 programme

3.3.1 A qualified anatomical pathologist shall fulfil 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 programme/activities, and the laboratory shall keep records of all such activities.

4. Accommodation and environmental conditions

4.1 Biological hazards

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

4.1.2 Biosafety cabinets shall be available and used for procedures where an aerosol risk exists.

4.2 Chemical hazards

4.2.1 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.

4.2.2 The workplace shall be maintained free from hazardous air impurities as far as possible. The laboratory shall assess and monitor the exposure of staff to ensure that the exposure level is below the ceiling limit. Where formaldehyde and xylene are used, their vapour concentrations shall be

maintained below the ceiling limit of 0.3 ppm and time weighted average (defined as the average concentration of a chemical substance over an eight-hour working day for a five-day workweek, to which nearly all workers can be exposed day after day without adverse health effects) of 100 ppm respectively as recommended by the Labour Department. The laboratory shall monitor the exposure level periodically as required. A recommended frequency of monitoring is every 1-3 months for formaldehyde and 3-6 months for xylene. More frequent monitoring is required if the level of formaldehyde and/or xylene is exceeded or after any procedural or environmental change.

4.3 Compressed gases and liquid nitrogen hazards

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

4.4 Physical hazards

4.4.1 The hand wheel of the rotary microtome shall be locked and the knife shall be removed or covered with a knife guard when the microtome is not in use. 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. Laboratory equipment, reagents and consumables

5.1 Manual staining system shall be available as back up if auto-stainer and auto-coverslipper are used.

5.2 If the laboratory uses high throughput automated specimen processing machines, suitable back up system or arrangement capable of handling similar workload should be in place.

5.3 There shall be adequate facilities to permit simultaneous viewing of microscopic slides by at least two persons.

5.4 Performance of all equipment, reagents and consumable that would affect the quality of examination results (e.g. autostainers and antibodies), shall be individually verified or validated before putting into service.

5.5 Under circumstances when expired antibodies are to be used for immunohistochemistry or other similar examinations, there shall be adequate performance evaluation record to confirm that the reagent(s) concerned continued to be acceptable for use without compromising the quality of examination results.

6. Examination processes

6.1 Surgical specimens shall be examined grossly by a qualified anatomical pathologist (or qualified pathologist as advised by the Hong Kong College of Pathologists), pathologist trainee or appropriately trained personnel under the direct supervision of a qualified anatomical pathologist.

7. Ensuring quality of examination results

7.1 For every case, previous cytologic and histologic diagnoses and slides shall be retrieved for review when appropriate. Significant disparities in diagnoses shall be reconciled in the report, if there is implication on current patient management.

7.2 There shall be correlation between frozen and paraffin section diagnoses. The laboratory shall define the acceptable percentage for discrepancy between diagnoses from the two types of sections and monitor its performance accordingly. The laboratory could consider using a level of less than 5% of discrepancy calculated by dividing the number of discordant cases with the number of frozen section cases excluding the number of deferral.

7.3 There shall be a documented program for retrospective random peer review of a defined number or percentage of cases. A random review of at least 1% cases should be performed on a quarterly basis at least. Whenever discrepancies are detected, appropriate actions shall be taken and recorded.

7.4 Appropriate positive control shall be included in each batch of histochemical, immunohistochemical and immunofluorescence examinations wherever practicable.

7.5 A laboratory may enroll in External Quality Assessment Schemes (EQAS) as a single entity. The reporting of EQAS results shall be in accordance with routine procedures for reporting patient samples. Reporting of consensus results is not recommended except for difficult cases where discussion among pathologists is a common practice in daily service.

7.6 All individuals involved in reporting results shall examine relevant EQAS slides independently and record his/her own results. A record of individual performance in examining these EQAS slides should be available to the Laboratory Director and be available for examination by the assessment team.

7.7 Laboratories should take part in EQAS that cover the accredited examinations. If EQAS is not available, interlaboratory comparisons should be arranged. Failing both, the laboratory should record the effort they have made in sourcing appropriate EQAS and their attempt to arrange interlaboratory comparisons.

8. Post-examination processes

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

Request forms	3 years
Wet tissue including fixed and fresh tissue	2 weeks after final report
Containers with/without residual tissue/fixative	2 weeks after final report
Control and case slides	20 years
Blocks	20 years
Immunofluorescence slides	7 days after reporting
Copies of reports	20 years or permanent if possible

8.2 The slides and blocks shall be properly filed and readily retrievable. All slides and blocks should preferably have double identifiers with at least one identifier originating from the primary sample.

8.3 The laboratory shall have a documented policy on return of loaned slides or blocks and there shall be records of loan of slides or blocks, whether to external or internal parties.

8.4 The residual fixative from primary samples shall be retained in the containers and be disposed only after the minimum retention period.

8.5 The same criteria shall apply to records held in electronic form, often as digital images. The laboratory shall ensure data security and prevent corruption or deterioration of data. Suitable back-up systems shall be employed and, as equipment becomes obsolete, re-recording or the production of durable hard copy may become necessary to maintain access.

9. Reporting and release of results

9.1 A histopathology report shall be authorised by a qualified anatomical pathologist (or qualified pathologist as advised by the HKCPath), or pathologist trainee under the direct supervision of a qualified anatomical pathologist.

9.2 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.

9.3 The terminology, tumor staging system, and minimum data set to be included in report shall follow recommendations of local or international professional bodies.

9.4 The intraoperative frozen section interpretation shall be included in the final report.

9.5 There shall be established policies for the procedure of communicating intraoperative frozen section interpretation.

9.6 Discrepancy in diagnoses from previous cytology, biopsy specimens or frozen section shall be explained and resolved.

9.7 Special examinations (such as immunohistochemistry, electron microscopy, molecular pathology) performed shall be recorded and significant results included in report. The results shall be correlated and integrated with the gross and light microscopic findings of the submitted specimen. Where the reporting of presence or absence of certain histological findings, e.g. presence or absence of polyps, contributed to the conclusion of the diagnosis, even significant negative findings shall be included in the report.

9.8 An indexing or cross-reference system shall be in place to allow retrieval of information through patient particulars and/or diagnosis.

9.9 There shall be a consistent encoding system for reporting.

- End -

HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Discipline Specific Technical Requirements							
Accommodation and environmental conditions	**5.2**						
Is there adequate space for:	5.2.1						
- Surgical specimen examination?		•	☐	☐	☐		
- Frozen section procedures?		•	☐	☐	☐		
Is a biological safety cabinet available and used for handling of fresh tissues that post aerosol risks?	SC-25 4.1.2	•	☐	☐	☐		
Are the vapour concentrations of formaldehyde and xylene maintained below the ceiling limit of 0.3 ppm and time weighted average of 100 ppm respectively as recommended by the Labour Department when they are used?	SC-25 4.2.2	•	☐	☐	☐		
Does the laboratory monitor the exposure level of formaldehyde at the recommended frequency of every 1-3 months and that of xylene in every 3-6 months where they are used (e.g. at the dissection table area and staining bench)?	SC-25 4.2.2	•	☐	☐	☐		
Is the hand wheel of the rotary microtome locked and knife guards used when it is not in use?	SC-25 4.4	•	☐	☐	☐		
Are all sharps stored, handled and discarded safely and securely?	SC-25 4.4	•	☐	☐	☐		
Are the cutting areas for fresh and fixed specimen effectively separated from the rest of the work areas?	SC-25 4.6	•	☐	☐	☐		
Are appropriate personal protective equipment such as gloves and goggles, or forceps, used; and precautions such as working inside a fume hood, taken when	5.2.2						

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2. Please put down the laboratory's document reference(s) where there are descriptions or procedures related to the requirement.

HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
- diluting concentrated formalin		•	☐	☐	☐		
- handling xylene to avoid inhalation and skin contact		•	☐	☐	☐		
- handling fixatives containing mercuric chloride to avoid skin contact and metal corrosion?		•	☐	☐	☐		
- handling chloroform to avoid inhalation		•	☐	☐	☐		
- handling osmium tetroxide and epoxy resin components to avoid skin contact and inhalation		•	☐	☐	☐		
- handling of compressed gases included liquid nitrogen		•	☐	☐	☐		
- knife sharpener is in operation		•	☐	☐	☐		
Dissection area							
Is the dissection area adequately ventilated by means of fume hood or other means?	5.2.6	•	☐	☐	☐		
Is the dissection area cleaned and disinfected at least daily?	SC-25 4.1.1	•	☐	☐	☐		
Is the exhaust system of a vented dissection table designed without connection to other systems, with proper sealing and with the exhaust vent in a safe location relative to the ventilation intake systems?	5.2.6	•	☐	☐	☐		
Laboratory equipment, reagents and consumables	**5.3**						
Bone saw							

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Are the safety measures checked according to the manufacturer's recommendation and documented?	5.3.1.5	•	☐	☐	☐		
Coverslipping machine							
Are fumes from the equipment vented adequately?	5.3.1.5	•	☐	☐	☐		
If auto-coverslipper is used, is manual back up readily available?	SC-25 5.1	•	☐	☐	☐		
Dissection table							
Is the dissection table checked for proper functioning on installation and then checked and documented at least annually to ensure that specifications are met e.g. airflow?	5.3.1.2 & 5.3.1.5	•	☐	☐	☐		
Embedding machine							
Is the temperature of the heating baths adjusted to correspond with the type of paraffin used?	5.3.1.5	•	☐	☐	☐		
Is the temperature of the paraffin baths checked regularly?	5.3.1.5	•	☐	☐	☐		
Floatation bath							
Is the temperature monitored regularly and documented clearly?	5.3.1.7 (j)	•	☐	☐	☐		
Is the water changed regularly?	5.3.1.5	•	☐	☐	☐		
Immunostainer							
If automatic immunohistochemistry staining equipment is used, are records of preventive and corrective maintenance kept in the laboratory?	5.3.1.7 (i)	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Is there documented evidence of corrective action when equipment malfunction has been detected?	5.3.1.7 (i)	•	☐	☐	☐		
Are wastes from the equipment properly disposed?	5.3.1.5	•	☐	☐	☐		
Microtome / Cryostat							
Are they clean and well-maintained?	5.3.1.5	•	☐	☐	☐		
Is the set temperature defined, monitored and documented clearly?	5.3.1.7 (j)	•	☐	☐	☐		
Are they mounted on rigid benches in a low traffic area, or one in which the traffic can be controlled while they are in use?	5.3.1.5	•	☐	☐	☐		
Is there a documented procedure for decontamination of the microtome in the cryostat when an infective case is inadvertently sectioned (eg, TB)?	5.3.1.5	•	☐	☐	☐		
Microwave processor							
Are fumes from the microwave processor vented adequately?	5.3.1.5	•	☐	☐	☐		
Paraffin bath and paraffin dispenser							
Is the temperature suitable for the type of paraffin, regularly checked and recorded?	5.3.1.5 & 5.3.1.7 (j)	•	☐	☐	☐		
Are temperature tolerance limits defined?	5.3.1.5	•	☐	☐	☐		
Is there documented evidence of corrective action when temperature tolerance limits are exceeded?	5.3.1.7 (k)	•	☐	☐	☐		

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Is the paraffin bath located at least 2 metres away from open volatile solvents?	5.3.1.5	•	☐	☐	☐		
Reagents – for immunohistochemistry							
Are records maintained for evaluation of new antibody lots, expired antibodies and new antibodies introduced into the laboratory?	5.3.2.7 (g)	•	☐	☐	☐		
Is the pH of the buffers used in immunohistochemistry routinely monitored?	5.3.2.7 (h)	•	☐	☐	☐		
Are records maintained regarding reactivity of control tissue blocks?	5.3.2.7 (g)	•	☐	☐	☐		
Staining machine							
Where appropriate, are staining programs defined and change of solutions monitored?	5.3.1.5	•	☐	☐	☐		
Are fumes from the equipment vented adequately?	5.3.1.5	•	☐	☐	☐		
If an auto-stainer is used, is manual back up readily available?	SC-25 5.1	•	☐	☐	☐		
Tissue Processors							
Is the temperature of the paraffin baths adjusted to correspond with the type of paraffin used?	5.3.1.5	•	☐	☐	☐		
Is the temperature of the paraffin baths checked regularly and recorded?	5.3.1.7 (j)	•	☐	☐	☐		
Are tissue processor solutions changed at regular intervals?	5.3.1.5	•	☐	☐	☐		
Where appropriate, are tissue processing temperatures defined and monitored?	5.3.1.5 & 5.3.1.7(j)	•	☐	☐	☐		
Are fumes from the tissue processor vented adequately?	5.3.1.5	•	☐	☐	☐		

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Is there documented evidence of corrective action when equipment malfunction has been detected?	5.3.1.7 (k)	•	☐	☐	☐		
Pre-examination processes	**5.4**						
If an intraoperative frozen section service is available,							
- is the frozen section slide permanently labelled prior to staining and examination by a pathologist?	5.4.6	•	☐	☐	☐		
- is there a written method to ensure that specimens for frozen section will not be mixed up?	5.4.6	•	☐	☐	☐		
- are there written instructions and guidelines for preparing frozen sections?	5.5.3	•	☐	☐	☐		
Examination processes	**5.5**						
Are surgical specimens grossly examined by a qualified anatomical pathologist?	SC-25 6.1	•	☐	☐	☐		
Are surgical specimens grossly examined by pathologist trainee or appropriately trained personnel under the direct supervision of a qualified anatomical pathologist (or qualified pathologist as advised by the HKCPath)?	SC-25 6.1	•	☐	☐	☐		
Is there a list indicating specimens that may be grossly examined by non-medical trained personnel?	SC-25 6.1	•	☐	☐	☐		
If yes, to the above item, then:							

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- is there a specimen dissection manual for designated personnel to refer to for these specimen types?	5.5.1.1	•	☐	☐	☐		
- does this dissection manual include specific indications when these personnel must contact the pathologist for advice or assistance?	5.5.1.1	•	☐	☐	☐		
Is there a manual for the detailed dissection, description and histological sampling of all specimen types handled by the laboratory?	5.5.1.1	•	☐	☐	☐		
Is the dissection manual regularly reviewed and updated?	4.3	•	☐	☐	☐		
For histological preparations:							
Is the identity of every specimen and piece of tissue maintained through each step in processing and slide preparation?	5.4.6	•	☐	☐	☐		
Are blocks labeled adequately?	5.4.6	•	☐	☐	☐		
Are slides labeled adequately?	5.4.6	•	☐	☐	☐		
Are slides of sufficient quality for diagnosis?	5.6.2.1	•	☐	☐	☐		
Are all blocks or stained slides identified by an accession number and / or the patient's name?	5.4.6	•	☐	☐	☐		
Are all slides prepared checked to ensure they are correctly labelled with the right accession numbers during preparation?	5.4.6	•	☐	☐	☐		
For special stains (histochemistry):							
Are positive controls run routinely on all special stains performed?	5.6.2.2	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Are they verified for acceptability prior to reporting results with documentation?	5.6.2.3	•	☐	☐	☐		
Do methods using the special stains satisfactorily demonstrate the desirable tissue substance?	5.5.1.1	•	☐	☐	☐		
For immunohistochemistry:							
Are positive controls used for each antibody?	5.6.2.2	•	☐	☐	☐		
Are negative controls used for each antibody? (Negative control or equivalent measures to ascertain that the reagents do not produce nonspecific staining is not mandatory)	5.6.2.2	•	☐	☐	☐		
Are the controls verified for acceptability prior to reporting results with documentation?	5.6.2.3	•	☐	☐	☐		
Are the immunohistochemical stains produced of acceptable technical quality, and do they satisfactorily demonstrate the desirable tissue substance?	5.5.1.1	•	☐	☐	☐		
Ensuring quality of examination results	**5.6**						
Are previous cytologic and histologic diagnoses searched for and reviewed when appropriate?	SC-25 7.1	•	☐	☐	☐		
Are significant disparities reconciled in the report?	SC-25 7.1	•	☐	☐	☐		
Is there correlation between frozen and paraffin section diagnoses with documentation?	SC-25 7.2	•	☐	☐	☐		

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Has the laboratory defined its criteria of acceptable performance and monitor its performance accordingly?	SC-25 7.2	•	☐	☐	☐		
Is there any documented program for retrospective random peer review by pathologists for a defined number or percentage of cases?	SC-25 7.3	•	☐	☐	☐		
Are appropriate action(s) taken and documented when discrepancies are detected?	SC-25 7.3	•	☐	☐	☐		
Post-examination processes							
Do gross descriptions and microscopic findings, if included, support the pathologic diagnosis?	5.7.1	•	☐	☐	☐		
Where relevant, are photographs (physical or digital) of the gross specimens taken for proper documentation?	4.13	•	☐	☐	☐		
Storage of the primary sample and other laboratory samples							
Is there a log of all stored specimens maintained to permit retrieval for further testing?	5.7.2	•	☐	☐	☐		
Safe disposal of samples							
Are body parts and organs disposed of by incineration, in accordance with local regulations?	5.7.2	•	☐	☐	☐		
Are minimum retention periods of the following met:							
- wet tissues and containers with/without residual tissue/fixative – 2 weeks after final report?	SC-25 8.1	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
- control and case slides and blocks – 20 years?	SC-25 8.1	•	☐	☐	☐		
- immunofluorescence slides – 7 days after reporting?	SC-25 8.1	•	☐	☐	☐		
- copies of reports – 20 years (permanent if possible)?	SC-25 8.1	•	☐	☐	☐		
N.B. Other records are required by HKAS to be retained for at least three years.							
Are the slides and blocks properly filed and readily accessible?	SC-25 8.2	•	☐	☐	☐		
Do stored slides and blocks have double identifiers?	SC-25 8.2	•	☐	☐	☐		
Are loan of slides or blocks documented to ascertain that the transfer to be traced as necessary?	SC-25 8.3	•	☐	☐	☐		
Reporting and release of results	**5.8 & 5.9**						
In the reports on surgical specimens, are there clear and concise descriptions on the macroscopic appearance, including the type, size and/or weight of specimen, how blocks are taken, a pathologic diagnosis as well as other pertinent information for patient care?	SC-25 9.2	•	☐	☐	☐		
In the gross description for surgical specimens, are the blocked margins explicitly stated (circumferential versus perpendicular)?	SC-25 9.2	•	☐	☐	☐		
On reporting excision specimens of tumour, are terminology, staging, grading, and minimum data set provided following recommendations of local or international professional bodies?	SC-25 9.3	•	☐	☐	☐		
Is intraoperative frozen section interpretation included in the final report?	SC-25 9.4	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Are guidelines in place regarding the procedure for verbal reporting of intraoperative frozen sections, such as to whom the verbal report given, means of patient identification, and ascertaining that the message is accurately transmitted?	SC-25 9.5	•	☐	☐	☐		
Is any discrepancy in diagnosis from previous cytology, biopsy specimens or frozen section explained and resolved in the reports on surgical specimens?	SC-25 9.6	•	☐	☐	☐		
Are special examinations performed documented, and results indicated in the report?	SC-25 9.7	•	☐	☐	☐		
Are reports on special examinations, such as immunohistochemistry, electron microscopy and molecular studies correlated and integrated with the gross and light microscopic findings of the submitted specimen?	SC-25 9.7	•	☐	☐	☐		
If intradepartmental or interdepartmental consultations are made on the case, are they documented in the report?	5.8.3 (l)	•	☐	☐	☐		
Is there an indexing or cross-reference system (such as SNOMED, ICD-10) in place to allow retrieval of information by patient particulars and/or diagnosis?	SC-25 9.8	•	☐	☐	☐		
Is there a consistent encoding system?	SC-25 9.9	•	☐	☐	☐		

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