

HOKLAS Supplementary Criteria No. 24

“Medical Testing” Test Category - Cytopathology

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 cytopathology 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 Gynaecological cytology (GYN cytology)
- 2.2 Non-gynaecological exfoliative cytology (non-GYN cytology)
- 2.3 Fine needle aspiration cytology

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 (including cytology) of the Hong Kong College of Pathologists, or equivalent as advised by the College.
- 3.1.2 Medically qualified individuals in specialties other than anatomical pathology shall have adequate cytology training equivalent to the level as advised by the Hong Kong College of Pathologists and similar to that of a fellow under the specialty of anatomical pathology.
- 3.1.3 Additional certification in cytology is desirable.
- 3.1.4 All medical personnel shall have continuous working experience after completion of training. Proof of proficiency is required if there is a break of service for more than 2 years. Evidence of participation in continuous cytology education is expected.
- 3.2 Technical personnel (referred to as “cytotechnologist”):
- 3.2.1 A qualified cytotechnologist shall have registration with the Hong Kong Medical Laboratory Technologists (MLT) Board, certification by passing CT (International Academy of Cytology) examination or equivalent, and continuation of work in cytology after certification. Proof of proficiency is required if there is a break of service for more than 2 years. Evidence of participation in continuous cytology education is expected.
- 3.2.2 A supervisory-level cytotechnologist shall be a qualified cytotechnologist with at least 5-year continuous working experience in cytology and Part I registration with the MLT Board.
- 3.3 Workload
- 3.3.1 There shall be a written workload policy with evidence of documentation. There shall be sufficient qualified personnel available to handle the volume and variety of cytology cases submitted to the laboratory.

3.3.2 Screening workload limits for GYN cytology:

3.3.2.1 A cytotechnologist performing either primary screening or re-screening without other duties shall screen no more than 100 slides per 24 hours (in no less than an 8-hour working period) or average 12.5 slides per hour.

3.3.2.2 An anatomical pathologist should aim to report a minimum of 20 abnormal cases per month in order to maintain diagnostic acumen.

3.3.2.3 If there is no screener in the laboratory and the anatomical pathologist performs primary screening as well as reporting, he or she shall be bound by the same workload limits as for cytotechnologist screeners.

3.3.3 An anatomical pathologist should aim to report no less than 750 cytology (GYN and non-GYN together) cases per year in order to maintain diagnostic acumen.

4 Accommodation and environmental conditions

4.1 For laboratories running an FNA clinic, there shall be a rest area for patients after the procedure and simple resuscitation equipment shall be available.

5 Laboratory equipment

5.1 Manual back up shall be available 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 able to handle similar workload should be in place.

6 Pre-examination procedures

- 6.1 A manual for the operation of FNA clinics shall be available, including the nature of the procedure, instructions to the patient, the role of assisting technician, the need for female chaperon and consent form, etc.
- 6.2 All glass slides on receipt shall be properly and adequately identified with patient's name and one other identifier on the slides. These shall be identical to those on the request forms.

7 Examination procedures

- 7.1 There shall be a hierarchical system for cytology screening (sequential review of the same case, when indicated, by individuals with increasing levels of experience/responsibility).
- 7.2 Peer review on difficult cases before reporting should be encouraged and facilitated.
- 7.3 In cases of apparent discrepancy in diagnosis with prior samples received from the patient, previous cytologic and histologic results shall be searched for and reviewed.

8 Assuring the quality of examination procedures

8.1 General

- 8.1.1 There should be a mechanism for feedback to the cytotechnologist when the final diagnosis in the report is different from the cytotechnologist's interpretation.

8.2 Non-gynecological cytology cases

- 8.2.1 The immediate preceding negative test results from the same site or organ

should be reviewed when significant abnormalities are identified in the current sample.

8.2.2 An effort shall be made to obtain cytology/histology correlation in cases with positive cytologic findings.

8.2.3 If significant disparities exist between the histologic and cytologic diagnoses that might affect current patient management, these shall be reconciled in the report with appropriate recommendations.

8.3 Gynecologic cervical cytology cases

8.3.1 The method for assessing specimen adequacy shall be standardized and consistently applied. The current Bethesda system is recommended.

8.3.2 All disparities found that might have impact on current patient management shall be reconciled in the report with appropriate recommendations or actions.

8.3.3 Statistical records that should be maintained include proportion of unsatisfactory specimen, proportion of negative, atypical cellular changes, low grade and high-grade lesions.

8.3.4 The number of cases with significant discrepancy found on re-screening of cytology slides or histology-cytology correlation should be recorded.

8.3.5 There shall be a re-screening of 10% randomly selected negative cases prior to reporting or rapid re-screening of all negative cases prior to reporting.

8.3.6 There shall be a policy for rescreening of current negative smears or slides in high risk cases by a supervisory level cytotechnologist or an anatomical pathologist or a pathology trainee under supervision.

9 Post-examination procedures

9.1 The minimum retention periods for the following records and specimens shall be:

Materials	Minimum Retention period
Request forms	3 years
Copies of cytology reports	20 years
Cytology slides for GYN screening	6 years
Cytology slides (all others)	10 years
Residual cytology material	7 days after reporting

10 Reporting of results

10.1 Report sign-out policy:

10.1.1 All non-GYN exfoliative cytology with the exception of “saliva only” sputum shall be re-screened and signed out by a qualified anatomical pathologist or a pathology trainee under supervision.

10.1.2 GYN cervical cytology

10.1.2.1 Negative cases can be reported by a cytotechnologist. All other cases shall be reported by a qualified anatomical pathologist or a pathology trainee under supervision.

10.1.2.2 Current negative smears or slides with previous high risk history shall be reported by a supervisory level cytotechnologist, or a qualified anatomical pathologist or a pathology trainee under supervision. (see clause 8.3.6)

10.1.3 Only qualified cytotechnologists (see clause 3.2.1) who are Part I registered with the MLT Board can sign out cytology reports. Qualified

cytotechnologists with Part II or Part III registration with the MLT Board can only sign out reports under supervision.

10.2 A descriptive diagnosis shall be used for cytology reporting. The current Bethesda system should preferably be used for gynecologic cytology reporting.

10.3 There shall be provision for comments and recommendations as required.

10.4 There should be a consistent system for diagnostic coding.

HKAS Executive
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