

# HOKLAS Supplementary Criteria No. 24

## ‘Medical Testing’ Test Category - Cytopathology

### 1. Introduction

- 1.1 This document is an application document for the requirements of HKAS 002 and HOKLAS 015 accrediting cytopathology 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 Fine needle aspiration (FNA) cytology
- 2.2 Gynaecological cytology (GYN cytology)
  - General
  - Screening
- 2.3 Non-gynaecological cytology (excluding FNA)

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

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### 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 (including cytology), 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.
- 3.1.3 Medically qualified specialists in disciplines 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.
- 3.1.4 A non-trainee medically qualified individual shall be a person medically trained but not registered with the Hong Kong College of Pathologists as specialists, who have adequate cytology training and experience and working under supervision of a qualified pathologist.
- 3.1.5 Additional certification in cytology is desirable for all medical personnel.
- 3.1.6 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. A technically qualified approved signatory for cytopathology examinations shall be a qualified cytotechnologist in addition to the basic requirements described in HOKLAS Policy on Personnel, HOKLAS 015. The examinations for which a qualified cytotechnologist could sign-out are detailed in section 10.

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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 manually 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. A part-time cytotechnologist shall observe the same workload limits.

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 at reporting no less than 750 cytology (GYN and non-GYN together) cases per year in order to maintain diagnostic acumen.

3.3.4 A cytotechnologist should aim at examining no less than 3000 (GYN and non-GYN together) cases per year in order to maintain screening skill.

3.3.5 If the minimum number respectively stated in clause 3.3.3 and 3.3.4 is not met, the laboratory should design other systems that verify the attainment of screening skill of the cytotechnologist(s) and/or the maintenance of diagnostic acumen of the anatomical pathologist(s).

3.3.6 To ensure adequate exposure to a wide variety of cases, the laboratory should handle a minimum of around 500 abnormal smears per year. If this number is not met due to the setting of the laboratory, the laboratory should

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design other systems to maintain the screening skills and diagnostic acumen. The recommended standards as stated above in clauses 3.3.2 to 3.3.4 should be followed.

#### 3.4 Continuing education programme

3.4.1 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.

3.4.2 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 For laboratories running a fine needle aspiration (FNA) clinic, there shall be an area for patients to rest after undergoing the procedure. Simple resuscitation equipment shall be available at that area.

4.2 The screening area shall be well-lit and suitable for work requiring a high degree of concentration. The workstation design shall satisfy ergonomic principles.

4.3 All fresh non-GYN specimens and FNA materials shall be handled in a biosafety cabinet.

4.4 When the laboratory is responsible for operating a FNA clinic, appropriate safety instructions shall be provided to the sample collectors and operators to handle all aspirates for smear preparation in a biosafety cabinet when available. Where the aspirate has been collected at sites where a biosafety cabinet is not installed, the laboratory shall provide appropriate safety instructions to the collectors and operators to ensure that appropriate personal protective equipment shall be worn during operation and precautionary measures are also taken to protect other personnel in the surrounding area. Wherever possible, the laboratory is recommended to provide similar safety instructions to sample collectors or operators who are not laboratory staff.

### 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.

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- 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 that permit simultaneous viewing of microscopic slides by at least two persons.
- 5.4 Performance of all equipment, reagents and consumables that would affect the quality of examination results (e.g. autostainers and stains), shall be validated or verified before putting into service.

## **6. Pre-examination processes**

- 6.1 A manual for the operation of FNA clinic shall be available. The manual should cover 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 Upon receipt of every glass slide, it shall be properly and adequately identified by marking the patient's name and another identifier on it. The identifiers shall be identical to those on the request form.

## **7. Examination processes**

- 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 between the current sample and previous samples from the patient, previous cytologic and histologic results shall be retrieved and reviewed.

## **8. Ensuring quality of examination results**

### **8.1 General**

- 8.1.1 There should be a feedback mechanism to inform the cytotechnologist

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when the final diagnosis in the report is different from the cytotechnologist's interpretation.

## 8.2 Non-gynaecological cytology cases

- 8.2.1 The immediate preceding negative examination 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. The definition of significant discrepancy used by the laboratory shall be defined and documented. The performance of the laboratory shall be monitored according to its defined percentage of acceptable performance. The laboratory should make reasonable efforts in obtaining correlation of all positive non-gynaecological cases, with record of actions taken if not achieved.
- 8.2.3 If significant disparities exist between the histologic and cytologic diagnoses that may affect current patient management, these shall be reconciled in the report with appropriate recommendations or actions.

## 8.3 Gynaecologic cervical cytology cases

- 8.3.1 The method for assessing specimen adequacy shall be standardised and consistently applied. The current version of the Bethesda system is recommended.
- 8.3.2 All disparities found between the histologic and cytologic diagnoses that may have impact on current patient management shall be reconciled in the report with appropriate recommendations or actions.
- 8.3.3 Statistical records to be maintained shall include proportion of unsatisfactory specimens, proportion of negative, atypical cellular changes, low grade and high-grade lesions.
- 8.3.4 An effort shall be made to obtain cytology/histology correlation in cases with HSIL or above. The laboratory shall define its target percentage of correlation ( $\leq 1$  tier difference) for cases with a definite cytologic diagnosis of HSIL to be confirmed on cervical histology within 6 month's time. The laboratory should aim to obtain 100% correlation of all gynaecologic cervical cytology cases with HSIL or above, with record of actions taken if not achieved.

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- 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. For automated screening or re-screening, appropriate evidence-based protocol should apply.
- 8.3.6 There shall be a policy for re-screening of negative smears or slides in high risk cases by a supervisory level cytotechnologist or a qualified anatomical pathologist as defined in clause 3.1.1 or a pathologist trainee under the direct supervision of a qualified anatomical pathologist.
- 8.3.7 The number of cases with significant discrepancy in diagnoses found on re-screening of cytology slides or histology-cytology correlation shall be recorded.
- 8.4 A laboratory may enroll in External Quality Assessment Schemes (EQAS) as a single entity. The return of EQAS results shall be in accordance with routine procedures for reporting patient samples.
- 8.5 All individuals involved in reporting examination 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.
- 8.6 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.

## 9. Post-examination processes

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

<b>Materials</b>	<b>Minimum Retention period</b>
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

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

## 10. Reporting of results

### 10.1 Report sign-out policy:

#### 10.1.1 Non-GYN exfoliative cytology

10.1.1.1 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 qualified pathologist as advised by the HKCPath) or a pathologist trainee under the direct supervision of a qualified anatomical pathologist.

10.1.1.2 Non-GYN exfoliative cytology negative reports can also be signed out by non-trainee medically qualified individuals as defined in clause 3.1.4 with appropriate experience and under supervision of a qualified anatomical pathologist.

#### 10.1.2 GYN cervical cytology

10.1.2.1 Negative cases can be delegated to a qualified cytotechnologist or non-trainee medically qualified individuals with appropriate experience and under supervision of a qualified anatomical pathologist for signing reports. All other cases shall be reported by a qualified anatomical pathologist (or qualified pathologist as advised by the HKCPath) or a pathologist trainee under the direct supervision of a qualified anatomical pathologist.

10.1.2.2 Negative smears or slides with previous high risk history shall be reported by a supervisory level cytotechnologist, or a qualified anatomical pathologist (or qualified pathologist as advised by the HKCPath) or a pathologist trainee under the direct supervision of a qualified anatomical pathologist.

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

10.3 There shall be provision for comments and recommendations as required by a qualified anatomical pathologist in the reports.

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10.4 The laboratory shall use a consistent diagnostic coding system for reporting.

- End -

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<b>Discipline Specific Technical Requirements</b>							
<b>Personnel</b>							
<i>Medical Personnel</i>							
Have the laboratory's medical personnel had continuous working experience after completion of training and is there proof of proficiency if there is a break of service for more than 2 years?	SC-24 3.1.6	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<i>Technical Personnel</i>							
Have the laboratory's cytotechnologists obtained registration with the Hong Kong MLT Board, certification by passing CT (International Academy of Cytology) examination or equivalent, and continued to work in cytology after certification?	SC-24 3.2.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there any proof of proficiency when a cytotechnologist has a break of service for more than 2 years?	SC-24 3.2.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory's supervisory-level cytotechnologist obtained Part I-registration under the Hong Kong MLT Board, certification by passing CT (International Academy of Cytology) examination or equivalent, and had continuous working experience in cytology for at least 5 years?	SC-24 3.2.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<i>Workload</i>							
Is there a written workload policy with evidence of documentation to demonstrate that there are sufficient qualified personnel available to handle the volume and variety of cytology cases submitted to the laboratory?	SC-24 3.3.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

- Note:
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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, 5 <sup>th</sup> edition and relevant SC)	*1	Y	N	NA	Lab's Document Reference or Remarks <sup>2</sup>	Assessment Team's remarks / questions to be asked at the laboratory
Does a cytotechnologist performing either primary screening or re-screening manually without other duties 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? Does a part-time cytotechnologist observe the same workload limits?	SC-24 3.3.2.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If there is no screener in the laboratory and the pathologist performs primary screening as well as reporting, is he or she bound by the same workload limits as for cytotechnologist screeners?	SC-24 3.3.2.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does each pathologist report a minimum of 750 cytology (GYN and non-GYN together) cases per year in order to maintain diagnostic acumen?	SC-24 3.3.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does each cytotechnologist screen a minimum of 3000 (GYN and non-GYN together) cases per year in order to maintain screening skill?	SC-24 3.3.4	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If the minimum no. of cases per year is not met, is there any other system established to verify the attainment of screening skill of the cytotechnologist and/or the maintenance of diagnostic acumen of the anatomical pathologist(s)?	SC-24 3.3.5	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory handle a minimum of around 500 abnormal smears per year?	SC-24 3.3.6	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If this minimum number is not met, is there any other system established to maintain the screening skills and diagnostic acumen?	SC-24 3.3.6	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Accommodation and environmental conditions</b>	<b>5.2</b>						
Specimen collection area for patients:							
Is there a rest area for patients after the FNA procedure?	SC-24 4.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Is simple resuscitation equipment available at the FNA clinic?	SC-24 4.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the screening area of the laboratory well-lit and conducive to concentrated work with ergonomic workstation?	SC-24 4.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are fresh non-GYN specimens and FNA materials handled in a biosafety cabinet?	SC-24 4.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When the laboratory is responsible operating a FNA clinic:							
Are appropriate safety instructions provided to sample collectors and operators to handle all aspirates for smear preparation in a biosafety cabinet?	SC-24 4.4	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Where the aspirates are collected at sites where a biosafety cabinet is not installed, does the laboratory provide appropriate safety instructions to the collectors and operators to ensure that appropriate personal protective equipment are worn during operation and precautionary measures are also taken to protect other personnel in the surrounding area?	SC-24 4.4	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Laboratory equipment, reagents and consumables</b>	<b>5.3</b>						
<i>Automated Machines and Systems</i>							
If computer-assisted automatic screening and re-location machines for cervical cytology operated both for primary screening or quality assurance purpose, is the quality control in the laboratory maintained in accordance to the manufacturer's manual and in strict compliance with prevailing standards established by professional bodies and evidence based studies?	5.6.2.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<i>Reagents</i>							

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Are all working solutions of cytology stains properly labelled and dated?	5.3.2.7	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all cytology stains and reagents stored as recommended by the manufacturer and used within their indicated expiration date?	5.3.2.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are Papanicolaou staining solutions, alcohol and xylene filtered or replaced regularly?	5.3.2.7	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Pre-examination processes</b>	<b>5.4</b>						
Is there a manual for the operation of the FNA Clinic, including the nature of the procedure, instructions to the patient, the role of assisting technician, the need for female chaperon and consent form, etc.?	SC-24 6.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
In the primary sample collection manual, do the instructions include the preferred method for smear preparation and proper fixation of slides (FNA and GYN specimens)?	5.4.2 (d)	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do the instructions include the method of collection and proper fixation of all non-gynaecological specimens (sputum, urine, gastric washings, body fluids, bronchial aspirations, fine needle aspirations, etc.)?	5.4.2 (d)	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
For primary specimens received in the form of microscopic slides (e.g. conventional PAP smear), is the slide (not the mailer) labelled properly and adequately with the patient identity?	5.4.6	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all stained slides identified by a unique accession number and / or the patient's name?	5.4.6	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Are all prepared slides checked to ensure that they are correctly labeled with the right accession numbers during preparation?	5.4.6	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Examination processes</b>	<b>5.5</b>						
<i>Preparation of diagnostic smears/slides</i>							
Are all stains checked for predicted staining characteristics each day of use?	5.5.1.2 / 5.3.2.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there a written policy ensuring that non-gynaecologic specimens with a high potential for cross-contamination are processed and stained separately from other specimens?	5.5.3 (I)	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the cellular and nuclear details of sufficient quality for diagnosis?	5.5.1.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there a documented evidence of daily review of the technical quality of cytologic preparations by the supervisory cytotechnologist or pathologist and that the problems identified are documented and investigated?	5.6.2.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<i>Screening</i>							
Are there adequate and up-to-date references in cytopathology?	5.5.1.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there a hierarchical method of cytology screening (sequential review of same specimen, when indicated, by individuals with increasing levels of experience/responsibility)?	SC-24 7.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are there written criteria for referring specimens to a supervisory level cytotechnologist or a qualified pathologist?	5.5.1.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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In case of apparent discrepancy in diagnosis with prior samples received from the patient, are the previous cytologic and histologic results searched for and reviewed?	SC-24 7.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Ensuring quality of examination results</b>	<b>5.6</b>						
Is there a system in place to evaluate and document the ongoing performance of individuals who perform cytology screening against the overall annual statistics for the laboratory as a whole?	5.6.2.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there a documentation of each individual's diagnostic discrepancies and corrective action taken?	5.6.2.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there any feedback mechanism in place when the final diagnosis in the report is different from the cytotechnologist's interpretation?	SC-24 8.1.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<i>For non-gynaecological cytology cases</i>							
Has the laboratory reviewed the immediate preceding negative examination results from the same site or organ when significant abnormalities are identified in the current sample?	SC-24 8.2.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory made an effort to obtain cytology/histology correlation in cases with positive cytologic findings?	SC-24 8.2.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory defined and documented "significant discrepancy"?	SC-24 8.2.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the laboratory monitor its own performance in accordance to the defined percentage of acceptable performance with respect to cytology/histology correlation?	SC-24 8.2.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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If disparities are found between the histologic and cytologic diagnoses that may have an impact on current patient management, are they reconciled in the report with appropriate recommendations or actions?	SC-24 8.2.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<i>For gynaecologic cervical cytology cases</i>							
Is the method for assessing specimen adequacy standardized and consistently applied?	SC-24 8.3.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Regarding specimen adequacy, are there guidelines for comments and follow-up recommendations and are these consistently applied?	5.6.2.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If disparities are found that may have impact on current patient management, are they reconciled in the report with appropriate recommendations or actions?	SC-24 8.3.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are statistical records maintained which include proportion of unsatisfactory specimen, proportion of negative, atypical cellular changes, low grade and high-grade lesions?	SC-24 8.3.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory made an effort to obtain cytology/histology correlation in cases with HSIL or above?	SC-24 8.3.4	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Has the laboratory defined its target percentage of correlation?	SC-24 8.3.4	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
For quality control of cervical cytology, does the laboratory has a system of re-screening of 10% randomly selected negative cases prior to reporting or rapid re-screening of all negative cases prior to reporting?	SC-24 8.3.5	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If automated screening or re-screening is carried out, does it apply an evidence-based protocol?	SC-24 8.3.5	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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HOKLAS Requirement	Clause (HOKLAS 015, 5 <sup>th</sup> edition and relevant SC)	*1	Y	N	NA	Lab's Document Reference or Remarks <sup>2</sup>	Assessment Team's remarks / questions to be asked at the laboratory
Is there a policy for re-screening of current negative smears or slides in high-risk cases by a supervisory level cytotechnologist or a qualified anatomical pathologist (or qualified pathologist as advised by the HKCPath) or a pathologist trainee under the direct supervision of a qualified anatomical pathologist?	SC-24 8.3.6	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the number of cases with significant discrepancy found on re-screening of cytology slides or histology – cytology correlation recorded?	SC-24 8.3.7	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are the available negative smears and histologic material for the prior 3 years reviewed whenever significant atypia (HSIL or above, AG-US favor neoplastic or above, etc.) is identified?	5.6.2.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Post examination processes</b>	<b>5.7</b>						
<i>Are minimum retention periods for the following met:</i>	SC-24 9.1						
Cytology report copies – 20 years?		•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Cytology slides for GYN screening – 6 years?		•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Cytology slides (all others) – 10 years?		•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Residual cytology material – 7 days after reporting?		•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
N.B. Other records are required by HKAS to be retained for at least three years.							

- Note:
1. The assessor should concentrate on items marked with a •; other items will be checked by the team leader.
  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, 5 <sup>th</sup> edition and relevant SC)	*1	Y	N	NA	Lab's Document Reference or Remarks <sup>2</sup>	Assessment Team's remarks / questions to be asked at the laboratory
<b>Reporting of results</b>	<b>5.8</b>						
Are all non-GYN exfoliative cytology with the exception of "saliva only" sputum re-screened and signed out 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?	SC-24 10.1.1.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do non-trainee medically qualified individuals who sign out non-GYN exfoliative cytology negative reports have appropriate experience and are they under supervision of a qualified anatomical pathologist?	SC-24 10.1.1.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all GYN cervical cytology except negative cases without previous high-risk history reported 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?	SC-24 10.1.2.1	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are current negative cases with previous high-risk history reported by a supervisory level cytotechnologist, or a qualified anatomical pathologist (or qualified pathologist as advised by the HKCPath) or pathologist trainee under the direct supervision of a qualified anatomical pathologist?	SC-24 10.1.2.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is specimen adequacy for diagnostic purposes indicated in the report?	5.8.3 (I)	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is a descriptive diagnosis used for cytology reporting?	SC-24 10.2	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there any provision for comments and recommendations as required by a qualified anatomical pathologist?	SC-24 10.3	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there a consistent system for diagnostic coding?	SC-24 10.4	•	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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