General checklist for HOKLAS Supplementary Criteria for Medical Laboratories –

In general, a separate checklist should be completed and returned for each medical discipline. A completed checklist may also be used for more than one discipline if their practice is identical. In any case, the discipline/s to which this completed checklist applies should be shown by ticking the box/es shown below.

Information provided in this general checklist represents the following disciplines / laboratories (please tick):

Anatomical Pathology	☐ :	**Autopsy**	☐	**Histology**	☐	**Cytology**	☐
Chemical Pathology	☐						
Clinical Microbiology and Infection	☐ :	**General Microbiology**	☐	**Virology**	☐	**Mycobacteriology**	☐
Haematology	☐ :	**General Haematology**	☐	**Blood Bank**	☐		
Immunology	☐						
Medical Genetics	☐ :	**Molecular Genetics**	☐	**Cytogenetics**	☐		

HOKLAS Supplementary Criteria – General Checklist

Management requirements	Clause (HOKLAS 015, 4th edition and relevant SC)	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**
Examination by referral laboratories	**4.5**	**4.5**		☐	☐	☐		
Has each referral laboratory to which the specimens are sent been approved by the person-in-charge?	4.5.1	4.5.1		☐	☐	☐		
Is there a written procedure on specimens or confirmatory tests referral, including which types of tests are to be referred to which laboratory?	4.2.1	4.5.1		☐	☐	☐		
Are extra-departmental cases that are submitted for consultation properly recorded and a written report issued?	4.5.3	4.5.2		☐	☐	☐		

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Are extra-departmental cases submitted for review accessioned according to the standard practices of the laboratory, a written report issued and a copy of this report sent to the original laboratory?	4.5.4	4.5.2		☐	☐	☐		
Advisory services	**4.7**	**4.7**						
Does the laboratory hold meetings with or contact laboratory users to obtain their feedback on services provided, appropriateness of reference ranges, critical/alert values etc.?	4.7	4.7		☐	☐	☐		
If the institution operates a blood bank, does it have a Blood Transfusion Committee?	4.7	4.7		☐	☐	☐		
Identification and control of nonconformities	**4.9**							
Are there any records of actions taken when daily QC results are out of limit?	4.9.1	4.9 (h)		☐	☐	☐		
Have actions been taken to review test results released between current QC failure and last successful QC event?	4.9.3	4.9 (e), (f)		☐	☐	☐		
Are there instructions for acceptance and rejection of test results when QC results indicate problems or deficiencies?	4.9.3	4.9 (d), (e), (f) and 5.6.2.3		☐	☐	☐		

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HOKLAS Supplementary Criteria – General Checklist

Management requirements	Clause (HOKLAS 015, 4th edition and relevant SC)	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
Quality and technical records / Control of records	**4.13**	**4.13**						
Are there documented policies and operating procedures to guide the proper storage and handling of records (such as retrieval and disposal) so as to ensure their integrity and confidentiality?	4.13.1	4.13.1		☐	☐	☐		
Are all quality control records retained for at least 3 years as required by HKAS (including those QC data kept electronically)?	4.13.3	4.13.H (g)		☐	☐	☐		
Is the operator performing the test and checking the result traceable from the laboratory records?	4.13H (d)	4.13H (d)		☐	☐	☐		
Are raw data/original observations kept for the test results?	4.13H (b)	4.13H (c)		☐	☐	☐		
If computer systems are used, are there procedures for checking transcription, calculation, or data entry errors?	4.13H (g)	4.13H (f)		☐	☐	☐		
Does the laboratory retain records (electronic and/or hardcopy format) for an appropriate time interval pursuant to the professional, statutory, legislative and HOKLAS requirements? N.B. In general, HOKLAS requires all records to be retained for at least three years. Please refer to respective supplementary criteria for those otherwise specified.	4.13.H SC-23 5.1 SC-24 9.1 SC-25 8.1 SC-26 6 SC-28 Table 1 SC-29 4 SC-30 Table 1 SC-35 Table 1	4.13.H SC-23 5.1 SC-24 9.1 SC-25 8.1 SC-26 6 SC-28 Table 1 SC-29 4 SC-30 Table 1 SC-35 Table 1		☐	☐	☐		

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Technical requirements	Clause (HOKLAS 015, 4th edition and relevant SC)	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**
Personnel	**5.1**	**5.1**						
Are staff qualifications appropriate?		5.1.2		☐	☐	☐		
N.B. Please pay attention to specific requirements for personnel under respective supplementary criteria.	SC-23 2 SC-24 3 SC-25 3 SC-26 3 SC-27 3 SC-28 3 SC-29 3 SC-30 3 SC-35 3	SC-23 2 SC-24 3 SC-25 3 SC-26 3 SC-27 3 SC-28 3 SC-29 3 SC-30 3 SC-35 3						
Does the supervisor in charge of a test area have relevant experience in medical testing for at least three years and experience in that responsible area for at least one year and is Part-I registered for at least one year?	5.1.H	5.1.H		☐	☐	☐		
Is training given to staff for specific assigned duties?	5.1.4 (g)	5.1.5		☐	☐	☐		
Is the competency of staff assessed following training, and reassessed periodically, especially for tests that required professional judgment and skills?	5.1.11	5.1.6	•	☐	☐	☐		
Has a continuing education programme been devised for managerial and technical staff and is it periodically reviewed for its effectiveness?	NA	5.1.8						
Accommodation and environmental conditions	**5.2**	**5.2**						
Is there adequate space allotted to :	5.2.1							

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- administration and clerical functions?		5.2.2	•	☐	☐	☐		
- specimen collection areas, where applicable?		5.2.5	•	☐	☐	☐		
- specimen accessioning area?		5.2.2	•	☐	☐	☐		
- work benches?		5.2.2	•	☐	☐	☐		
- storage for records, specimens, preparation and supplies (including refrigerated storage)?		5.2.3	•	☐	☐	☐		
- glassware washing, drying and storage?		5.2.3	•	☐	☐	☐		
- equipment, e.g. microscopy and/or photomicroscopy, photographic processing or darkroom, fume cupboard (for reagent preparation where necessary) and safety cabinets?		5.2.3	•	☐	☐	☐		
Are first-aid facilities readily available? N.B Even for hospitals with A&E Department, first aid dressing is expected to be available in readily accessible location for treating cuts/wounds.	5.2.2	5.2.2 (d) 5.2.5	•	☐	☐	☐		
Specimen collection area for patients:								
- Is patient privacy protected at the specimen collection area?	5.2.3	5.2.5	•	☐	☐	☐		
- Is there a rest area for patients after the FNA procedure?	5.2.2	5.2.5	•	☐	☐	☐		
- Is simple resuscitation equipment available close to the FNA clinic?	5.2.2	5.2.5	•	☐	☐	☐		

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Are vessels containing flammable liquid kept covered at all times?	5.2.2	5.2.6	•	☐	☐	☐		
Where corrosive solutions are used, are there emergency overhead shower facilities located in appropriate areas?	5.2.2	5.2.6	•	☐	☐	☐		
Are there emergency eye wash facilities available and located in appropriate areas?	5.2.2	5.2.2 (e)	•	☐	☐	☐		
Is there a maintenance record of these emergency facilities (shower or eyewash)?	5.2.2	5.2.2 (e)	•	☐	☐	☐		
Does the laboratory provide a comfortable working environment with respect to	5.2.4	5.2.6						
- lighting?			•	☐	☐	☐		
- temperature?			•	☐	☐	☐		
- ventilation?			•	☐	☐	☐		
- noise level?			•	☐	☐	☐		
Are utilities (water, sink, electrical) sufficient?	5.2.4	5.2.6	•	☐	☐	☐		
Is the environmental condition monitored, where appropriate, with respect to the following	5.2.5	5.2.6						
- the vapour concentrations of formaldehyde (ceiling limit <0.3ppm) at the recommended frequency of every 1-3 months?			•	☐	☐	☐		

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- the vapour concentrations of xylene (time weighted average <100 ppm) at the recommended frequency of every 3-6 months?			•	☐	☐	☐		
- the environmental temperature and humidity where sensitive instruments are in use?			•	☐	☐	☐		
- the microbiological air quality of work places where clean operation is expected e.g. media preparation room for microbiology			•	☐	☐	☐		
Are adequate power points available (the use of double adapters and long extension cords is undesirable)?	5.2.5	5.2.6	•	☐	☐	☐		
Are voltage regulators / stabilizers / uninterruptible power supply used on instruments that require these items?	5.2.5	5.2.6	•	☐	☐	☐		
Is essential electrical supply available?	5.2.5	5.2.6	•	☐	☐	☐		
Is there a dedicated and/or adequate electricity supply provided for automated instruments which have special electrical criteria?	5.2.5	5.2.6	•	☐	☐	☐		
Are incompatible activities such as the following segregated?	5.2.6	5.2.6						
- cutting areas for fresh and fixed specimen from the rest of the work areas			•	☐	☐	☐		
- bulk flammable liquids stored in a separate storage room or chemical safety cabinet and in volumes in compliance with regulations?			•	☐	☐	☐		
- a distinct space, in line with the biosafety requirements, for performing microbiological testing?			•	☐	☐	☐		

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- a separate room dedicated for processing mycobacteriology?			•	☐	☐	☐		
If radioactive substances are handled in the laboratory:								
- does the laboratory carry a valid license?	5.2.H	5.2.H	•	☐	☐	☐		
- is the background radiation checked?	5.2.5	5.2.6	•	☐	☐	☐		
- are monitoring badges in use, and the exposure records kept?	5.2.2	5.2.2	•	☐	☐	☐		
- are radioactive substances properly disposed of to ensure that they pose no hazard to laboratory workers or to the community?	5.3.6	5.2.3	•	☐	☐	☐		
- are guidelines for safe handling of radioactive substances available	5.2.H	5.2.H	•	☐	☐	☐		
- Are there conventional signs to indicate the presence of radioactive materials in all areas or rooms where radioactive materials are being used or stored?	5.2.2	5.2.2	•	☐	☐	☐		
- Are areas for radionuclide handling, storage and decay properly shielded?	5.2.2	5.2.2	•	☐	☐	☐		
Are there adequate freezers and refrigerators for storing reagents, unfixed specimens, processed and unprocessed specimens, cultured plates and microorganisms?	5.2.9	5.2.3	•	☐	☐	☐		
Are specimens and reagents stored segregated in different compartments in freezers and refrigerators?	5.2.9	5.2.3	•	☐	☐	☐		
Is there a deep freezer (-80°C) available for long-term storage of fresh tissues, cultures, extracted RNA and extracted DNA?	5.2.9	5.2.3	•	☐	☐	☐		

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Is the storage area e.g. for processed specimens, slides, blocks, adequately ventilated with temperature and humidity suitable for storage of the material?	5.2.9	5.2.3	•	☐	☐	☐		
Are reagents correctly kept according to manufacturer's recommendations, especially where special storage conditions are required (refrigeration, flammable store, dark storage)?	5.2.9	5.2.3	•	☐	☐	☐		
Is the laboratory space clean and well-maintained?	5.2.10	5.2.6	•	☐	☐	☐		
Is the specimen reception area clean and disinfected at least daily?	5.2.10	5.2.6	•	☐	☐	☐		
Is waste segregated, bagged and disposed of according to relevant regulations?	5.2.10	5.2.3	•	☐	☐	☐		
Are sharps, microtome knives, contaminated needles discarded in clearly labeled, puncture resistant containers?	5.2.10	5.2.3	•	☐	☐	☐		
Is there adequate drainage/sewerage for solvent and biological waste disposal which are conformed to relevant local authorities' requirements?	5.2.10	5.2.3	•	☐	☐	☐		
Are washrooms, a supply of drinking water and facilities for storage of personal protective equipment and clothing provided to staff?	N/A	5.2.4	•	☐	☐	☐		
Equipment / Laboratory equipment, reagents, and consumables	**5.3**	**5.3**						
Are new lots of reagents validated and critical reagents verified before being used?	5.3.2	5.3.2.3	•	☐	☐	☐		

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Is planned preventive maintenance available for all instruments in use?	5.3.2	5.3.1.5	•	☐	☐	☐		
Is there any instruction and documentation for routine checking and maintenance of instruments?	5.3.2	5.3.1.3	•	☐	☐	☐		
Does the laboratory have copies of the Manufacturer's Work and Maintenance Manuals for each analyzer?	5.3.4	5.3.1.3	•	☐	☐	☐		
Are adverse incidents and accidents that can be attributed directly to specific equipment investigated and reported to the manufacturer and appropriate authority, as required?	N/A	5.3.1.6	•	☐	☐	☐		
Are records on calibration, performance verification and maintenance of all equipments available and ready for inspection?	5.3.4	5.3.1.7	•	☐	☐	☐		
Is performance of instruments recorded in a manner that may reveal trends of malfunctions?	5.3.4	5.3.1.7	•	☐	☐	☐		
Is there evidence of active review of instrument maintenance, function and temperature on all shifts?	5.3.4	5.3.1.5	•	☐	☐	☐		
Is there any record of actions taken whenever equipment malfunction has been detected?	5.3.4(j)	5.3.1.7	•	☐	☐	☐		
Is there a written procedure for the safe and proper operation of the equipment?	5.3.5	5.3.1.5	•	☐	☐	☐		
Are all equipment maintained under adequate and stable electrical supply?	5.3.6	5.3.1.5	•	☐	☐	☐		
Are specific areas or specially designed containers available for storage of volatile chemicals and flammable solvents?	5.3.6	5.3.1.5	•	☐	☐	☐		

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Are safety guidelines available for handling hazardous, toxic and caustic chemicals and appropriate spillage kits available?	5.3.6	5.3.1.5	•	☐	☐	☐		
Are the following instruments properly located in a low traffic area, or one in which traffic can be controlled while they are in use?	5.3.6	5.3.1.5						
- Biosafety cabinet			•	☐	☐	☐		
- Centrifuge			•	☐	☐	☐		
- Fume hood			•	☐	☐	☐		
- Laminar flow cabinet			•	☐	☐	☐		
- Pressure cooker			•	☐	☐	☐		
Is there a written routine maintenance procedure for decontaminating or routine cleansing of equipment?	5.3.8	5.3.1.5	•	☐	☐	☐		
Autoclave **Available** ☐ **Not available** ☐								
Are there records kept for autoclave operations, including cycle temperature and time, results of checking, materials autoclaved for that particular load.	5.3.2	5.3.1.7 (j)	•	☐	☐	☐		
Is the adequacy of each cycle recorded with one of the following:	5.3.2	5.3.1.7	•	☐	☐	☐		
- thermocouple and recorder to produce a chart or printout of temperature;								
- maximum thermometer to record the actual temperature the cycle attained;								

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- indicators such as Brownes tubes, thermalog strips, etc.;								
- biological indicators such as spore strips;								
- reading obtained from panel of autoclave?								
On top of monitoring each cycle, is the effectiveness of operation of the autoclave checked monthly with a biological indicator?	5.3.2	5.3.1.7	•	☐	☐	☐		
Are records kept for periodic overhaul maintenance of autoclaves?	5.3.4	5.3.1.7	•	☐	☐	☐		
Is there any temperature-sensitive tape used to identify materials that have undergone the heating process?	5.3.2	5.3.1.2	•	☐	☐	☐		
Automated machines and systems								
Available ☐ **Not available** ☐								
Is there a contingency plan or manual back up available in case the automated system is out of service?	5.3.1	4.1.1.4 (n)	•	☐	☐	☐		
Is the backup system commensurate with the workload handled by the laboratory?	5.3.1	4.1.1.4 (n)	•	☐	☐	☐		
Balance **Available** ☐ **Not available** ☐								
Is a beam balance available for balancing the load before centrifugation?	5.3.1	5.3.1.1	•	☐	☐	☐		
Are recognized standard weights available where necessary and the weights appropriately stored?	5.3.1 5.3.6	5.3.1.3	•	☐	☐	☐		
Are records available for periodic repeatability checks and regular checks with known mass?	5.3.4 (h)	5.3.1.7 (j)	•	☐	☐	☐		

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Are analytic balances mounted on vibration – free benches in areas free from draught?	5.3.6	5.3.1.5	•	☐	☐	☐		
Are balances clean, regularly serviced and records kept?	5.3.12	5.3.1.7 (j)	•	☐	☐	☐		
Biological safety cabinet and Laminar flow cabinets **Available ☐ Not available ☐**								
Is the biological safety cabinet available in the laboratory of appropriate class suitable for the intended use?	5.3.1	5.3.1.1	•	☐	☐	☐		
Are the exhaust systems of vented biological safety cabinets designed without connection to other systems, with proper sealing and with the exhaust vent in a safe location relative to the ventilation intake systems?	5.2.2	5.2.3	•	☐	☐	☐		
Are the biological safety cabinets/laminar flow cabinets checked at least annually to ensure that filters are functioning properly and that airflow meets specifications and documented?	5.3.2	5.3.1.5	•	☐	☐	☐		
Does the laboratory have a policy on when to change HEPA filters?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are all the controls, warning lights and alarms of the safety cabinet tested daily and recorded to ensure that they are working correctly?	5.3.2	5.3.1.5	•	☐	☐	☐		
Is the maintenance record of the cabinets, including change of pre-filters and HEPA filters, readily available?	5.3.4	5.3.1.5	•	☐	☐	☐		
Are HEPA filters or main filters changed only by trained engineers when indicated and documented?	5.3.5	5.3.1.5	•	☐	☐	☐		

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Is the cabinet at least 4 feet away from any supply air grilles (downward airflow)?	5.3.6	5.3.1.5	•	☐	☐	☐		
Is there a documented protocol and a record of decontamination of the biological safety cabinet at defined interval and before changing filters or maintenance available?	5.3.7	5.3.1.5	•	☐	☐	☐		
Does the supervisor check on details of the maintenance report provided by the contractor before filing?	5.3.10	5.3.1.5	•	☐	☐	☐		
Is a full maintenance check done and recorded whenever the cabinet has been relocated or after filters have been changed?	5.3.10	5.3.1.5	•	☐	☐	☐		
Is the cabinet interior free from clutters that may interfere with adequate airflow?	5.3.14	5.3.1.4 (f)	•	☐	☐	☐		
Centrifuge **Available ☐ Not available ☐**								
Are operating speeds and timing regularly checked and recorded to ensure that they meet the test specifications?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are there written instructions for measures controlling aerosol generation?	5.3.5	5.3.1.3	•	☐	☐	☐		
Are safety buckets in use or tubes spun with caps on?	5.3.5	5.3.1.5	•	☐	☐	☐		
Are these instruments properly mounted with rigid support and in a convenient position for operation?	5.3.6	5.3.1.5	•	☐	☐	☐		
Are sealed containers used in centrifuges and/or are centrifuges vented to avoid contamination of the work area?	5.3.6	5.3.1.5	•	☐	☐	☐		
Is there a written procedure for decontaminating or handling spills or breakage?	5.3.6	5.3.1.5	•	☐	☐	☐		

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Is there a written procedure and record for decontaminating centrifuge buckets routinely?	5.3.6	5.3.1.5	•	☐	☐	☐		
Compressed gas **Available** ☐ **Not available** ☐								
Are compressed gas cylinders kept away from flame or heat sources?	5.3.6	5.3.1.5	•	☐	☐	☐		
Are the cylinders secured in position and prevented from falling?	5.3.6	5.3.1.5	•	☐	☐	☐		
Are cylinders transported on specially designed trolleys?	5.3.6	5.3.1.5	•	☐	☐	☐		
Electrophoresis equipment **Available** ☐ **Not available** ☐								
Is the displayed voltage reading confirmed by a voltmeter?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are the electrodes and buffer tank intact, power supply electrodes of snug fit and free from build up of dried buffer?	5.3.6	5.3.1.5	•	☐	☐	☐		
Film processing / Photographic equipment **Available** ☐ **Not available** ☐								
Is the film processing (developing) equipment under a regular service and repair system?	5.3.4(i)	5.3.1.5	•	☐	☐	☐		
Are the fixed camera mountings secured and leveled?	5.3.6	5.3.1.5	•	☐	☐	☐		
Flow cytometer **Available** ☐ **Not available** ☐								
Are guidelines adopted and implemented for laser safety, carcinogenic dyes and infectious biohazard risks?	5.2.2 5.3.6	5.2.6 5.3.1.5	•	☐	☐	☐		

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Are there actions and documentations to monitor optical alignment and laser sensitivity of flow cytometer each time prior to analysis?	5.3.2	5.3.1.7 (j)	•	☐	☐	☐		
For flow cytometer, are fluorochrome standards run each day prior to analysis as part of calibration process; and are results documented for quality control purposes?	5.3.2 5.6.1	5.3.1.5 5.6.2.2	•	☐	☐	☐		
Are there processes to ensure acceptable and constant laser current of flow cytometry?	5.3.2	5.3.1.3	•	☐	☐	☐		
Are there regular procedures for determining appropriate colour compensation settings of flow cytometer?	5.3.2	5.3.1.3	•	☐	☐	☐		
Are logs of flow cytometer calibrations and laser integrity checks regularly reviewed and audited?	5.3.4	5.3.1.7	•	☐	☐	☐		
Fluorescence microscope **Available** ☐ **Not available** ☐								
Are the barrier filters appropriate and adequate?	5.3.2	5.3.1.3	•	☐	☐	☐		
Are bulb hours recorded for the fluorescent microscopes?	5.3.4 (k)	5.3.1.7 (j)	•	☐	☐	☐		
Are the microscopes properly mounted on vibration – free benches?	5.3.6	5.3.1.5	•	☐	☐	☐		
Is the fluorescent light source shielded to protect personnel from direct light?	5.3.8	5.3.1.5	•	☐	☐	☐		
Fume hood **Available** ☐ **Not available** ☐								
Are they certified annually to ensure that filters are functioning properly and that the airflow rates are appropriate and documented?	5.3.2	5.3.1.7 (j)	•	☐	☐	☐		

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Is there an alarm system to indicate when function is impaired?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are they located at least 4 feet away from any supply air grilles (downward air flow)?	5.3.6	5.3.1.5	•	☐	☐	☐		
Are they free from obstruction that may interfere with adequate airflow?	5.3.14	5.3.1.5	•	☐	☐	☐		
Incubators (water bath, air, water jacketed, aluminium block, thermocycler, oven) **Available** ☐ **Not available** ☐								
Is spatial temperature distribution determined annually for large incubators such as warm rooms and records kept?	5.3.2	5.3.1.7 (j)	•	☐	☐	☐		
Is the set temperature and allowable temperature range of each incubator defined?	5.3.2	5.3.1.5	•	☐	☐	☐		
Is the temperature of each incubator checked and recorded at least daily?	5.3.2	5.3.1.5	•	☐	☐	☐		
For water baths or heating blocks which are switched on only at use, is the temperature checked at time of use? Are records kept?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are individual wells of a thermocycler checked for temperature accuracy before being placed in service and periodically thereafter?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are there clear instructions prohibiting the use of these equipment to store substances with flash point lower than the set temperature?	5.3.5	5.3.1.3	•	☐	☐	☐		
Microscopes **Available** ☐ **Not available** ☐								

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Are suitable attachments (e.g. phase contrast, darkfield) available when necessary, and appropriately used?	5.3.1	5.3.1.1	•	☐	☐	☐		
Are polarizing filters available for use, when necessary?	5.3.1	5.3.1.1	•	☐	☐	☐		
Are the laboratory's microscope regularly cleaned and well maintained?	5.3.2	5.3.1.5	•	☐	☐	☐		
For anatomical pathology laboratory, is there any conference microscope or multi-head facility or video monitors enabling simultaneous viewing, discussion and consultation by more than one personnel?	5.3.2	5.3.1.1	•	☐	☐	☐		
Is illumination sufficient for all powers of magnification in use?	5.3.2	5.3.1.1	•	☐	☐	☐		
Microscope, Electronic **Available ☐ Not available ☐**								
Is the electron microscope suitable for the type of services being offered?	5.3.1	5.3.1.1	•	☐	☐	☐		
Is the electron microscope checked for x-ray leakage at the time of installation and after major repair?	5.3.2	5.3.1.1	•	☐	☐	☐		
Are instrument maintenance, service and repair records (or copies) promptly available to, and usable by, the technical staff operating the equipment?	5.3.4	5.3.1.5	•	☐	☐	☐		
Is the electron microscope under a regular maintenance and repair system?	5.3.6	5.3.1.5	•	☐	☐	☐		
Is the electron microscope adequately shielded to prevent irradiation?	5.3.8	5.3.1.5	•	☐	☐	☐		

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Is radiation from the electron microscope checked periodically and after major repair?	5.3.10	5.3.1.5	•	☐	☐	☐		
Is the magnification calibrated after major maintenance?	5.3.10	5.3.1.5	•	☐	☐	☐		
Are there policies and procedures established for electron microscopy preparations and operation?	5.3.12	5.3.1.3	•	☐	☐	☐		
pH meters **Available** ☐ **Not available** ☐								
Are high quality buffers (certified assay of content) used for calibration of the pH meters?	5.3.2	5.3.1.4?	•	☐	☐	☐		
Is a record of calibration kept on days of use?	5.3.2	5.3.1.7	•	☐	☐	☐		
Are there written instructions for the proper operation, calibration and functional checks of pH meters?	5.3.5	5.3.1.3	•	☐	☐	☐		
Pipettes and pipetting devices **Available** ☐ **Not available** ☐								
Are volumetric pipettes certified or verified? (i.e. Gravimetric)	5.3.2	5.3.1.5	•	☐	☐	☐		
Are there written procedures for calibration of pipettes?	4.2.1	5.3.1.3	•	☐	☐	☐		
Are automatic/semi-automatic pipettors checked for accuracy and reproducibility before being placed in service, and intermediate checks carried out regularly to confirm their ongoing acceptability for use :	5.3.2	5.3.1.5	•	☐	☐	☐		
- e.g. every three months or less frequent with justification?	5.3.4(h)		•	☐	☐	☐		
- after major service and/or repair?	5.3.10		•	☐	☐	☐		

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- whenever necessary for troubleshooting?	5.3.10		•	☐	☐	☐		
Are there records of all calibrations and checking?	5.3.4 (i)	5.3.1.7	•	☐	☐	☐		
Radio assay instrumentation **Available ☐ Not available ☐**								
Is the spectrometer's high voltage calibrated and recorded using calibrated reference standards ("peaking") and compared to previous values?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are daily background counts taken and recorded at discriminator values (windows) for the intended radioisotope use prior to each use of the instrument?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are there written criteria for unacceptable background levels?	5.3.2	5.3.1.7	•	☐	☐	☐		
Are counting times sufficiently logged for statistical accuracy?	5.3.2	5.3.1.7	•	☐	☐	☐		
Are recovery studies performed when setting up an assay and at regular intervals thereafter?	5.3.2	5.5.1.3 and 5.6.2.1	•	☐	☐	☐		
Are regular radiation area surveys and wipe tests carried out and records maintained?	5.3.4	5.2.6	•	☐	☐	☐		
Are radiation survey equipments calibrated regularly?	5.3.4 (i)	5.3.1.4	•	☐	☐	☐		
Are there written procedures for handling radioactive waste?	5.3.6	5.3.1.5	•	☐	☐	☐		
Reagent, General **Available ☐ Not available ☐**								
Are reagents properly labeled with content, concentration (if applicable), date of preparation or date opened, and expiry date?	5.3.2	5.3.2.7	•	☐	☐	☐		

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Are reagents stored at a condition according to manufacturer's instructions?	5.3.2	5.3.2.2	•	☐	☐	☐		
Are reagents used within their shelf life?	5.3.2	5.3.2.2	•	☐	☐	☐		
Are outdated reagents quarantined or discarded?	5.3.2	5.3.2.4	•	☐	☐	☐		
Refrigerators & Freezers **Available ☐ Not available ☐**								
Is emergency power available for each blood storage refrigerator/freezer in blood banks?	5.2.4	5.3.1.2	•	☐	☐	☐		
Is emergency power or a contingency plan available to cater for electricity failure for refrigerators and freezers storing critical reagents and samples?	5.2.4	4.1.1.4 (n)						
Are they free of improper items (i.e. food, open bottles, etc.)?	5.2.10	5.3.1.5	•	☐	☐	☐		
Are all refrigerators/freezers used for storing blood products equipped with a temperature recorder for continuous monitoring of the storage condition?	5.3.1	5.3.1.5	•	☐	☐	☐		
Are temperatures monitored regularly and recorded?	5.3.2	5.3.1.7 (j)	•	☐	☐	☐		
Are records of temperature recorder checked daily?	5.3.2	5.3.1.7 (j)	•	☐	☐	☐		
Is the temperature sensor of blood refrigerator placed in 150-250 mL of fluid?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are temperature tolerance limits defined?	5.3.2	5.3.1.7 (j)	•	☐	☐	☐		
Is spatial temperature distribution determined annually for large refrigerators and cold rooms, and records kept?	5.3.2	5.3.1.7 (j)	•	☐	☐	☐		

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Are there documented procedures to ensure that temperature sensitive reagents are placed in non-defrosting refrigerators as far as possible; otherwise, are records kept for evaluating whether their qualities are affected by the storage condition?	5.3.2	5.3.2.2	•	☐	☐	☐		
Are only non-temperature sensitive reagents stored in refrigerators/freezers without temperature monitoring?	5.3.2	5.3.2.2	•	☐	☐	☐		
Are refrigerator and freezer doors free from temperature sensitive reagents?	5.3.2	5.3.2.2	•	☐	☐	☐		
Is there documented evidence of corrective action when temperature tolerance limits are exceeded?	5.3.4 (j)	5.3.1.7 (j)	•	☐	☐	☐		
Are protective mitts available for use when loading and unloading the deep freezers?	5.3.12	5.2.2	•	☐	☐	☐		
Spectrophotometers **Available** ☐ **Not available** ☐								
Are absorbance and photometric linearity checked periodically with filters or standard solutions as required by the instrument manufacturer?	5.3.2	5.3.1.5	•	☐	☐	☐		
Is spectrophotometer wavelength calibration checked and documented regularly with appropriate solutions, filters or emission line source lamps as required by the manufacturer?	5.3.2	5.3.1.5	•	☐	☐	☐		
Is stray light checked periodically with extinction filters or appropriate solutions as required by the manufacturer?	5.3.2	5.3.1.5	•	☐	☐	☐		
Are all curves rerun regularly and/or verified after servicing or recalibration of the instrument for procedures using calibration curves?	5.3.10	5.3.1.5	•	☐	☐	☐		

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Thermometers **Available** ☐ **Not available** ☐								
Are all thermometers calibrated against a calibrated "reference thermometer" before being placed into service?	5.3.2	5.3.1.4	•	☐	☐	☐		
Are they recalibrated at defined interval against "reference thermometers"?	5.3.2	5.3.1.4	•	☐	☐	☐		
Have all correction factors been taken into account when the working thermometers are used for measuring temperature?	5.3.13	5.3.1.4	•	☐	☐	☐		
Water **Available** ☐ **Not available** ☐								
Is the type of water used in the laboratory appropriate for the intended use?	5.3.2	5.4.6	•	☐	☐	☐		
Is the quality of the reagent water checked periodically and the results documented?	5.3.2	5.4.6 (a)	•	☐	☐	☐		
Is the bacterial content of purchased water tested monthly once the container is opened and results recorded?	5.3.4(h)	5.4.6	•	☐	☐	☐		
Pre-examination procedures / processes	**5.4**	**5.4**						
Does the request form include :	5.4.1	5.4.3						
- unique identification of the patient/body?			•	☐	☐	☐		
- a second unique identifier?			•	☐	☐	☐		
- date and approximate time of death (for autopsy)?			•	☐	☐	☐		

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- date of sample collection and where relevant, time of collection?			•	☐	☐	☐		
- name or unique identification of requesting doctor?			•	☐	☐	☐		
- test requested? (in case of autopsy, limited or full autopsy?)			•	☐	☐	☐		
- relevant clinical information and diagnosis?			•	☐	☐	☐		
- type of sample and anatomical site of origin			•	☐	☐	☐		
Is this manual readily available at all collection sites?	5.4.2	5.4.2	•	☐	☐	☐		
Does the user manual for the proper collection and handling of specimens include the following:	5.4.3	5.4.2	•	☐	☐	☐		
- personal safety and spill handling?			•	☐	☐	☐		
- request for relevant clinical information such as drug history?			•	☐	☐	☐		
- instructions to patients for proper collection of random/timed urine specimens and information on the content in the container for special tests?			•	☐	☐	☐		
- instructions to patients for the need to fast or other special requirements such as dietary and drugs restriction?			•	☐	☐	☐		
- instructions for the sample collector to record his/her identity?			•	☐	☐	☐		

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- special sample handling requirement such as need for protection from light, immediate delivery, transportation in low temperature or no refrigeration, etc.?			•	☐	☐	☐		
- guidelines for the number and/or timing of collection of specimens sent for bacterial testing, where relevant?			•	☐	☐	☐		
Are there written instructions for specimen reception?	5.4.2 5.4.7	5.4.6	•	☐	☐	☐		
Are there documentations detailing methods for specimen labeling, specimen preservation and storage before testing?	5.4.3	5.4.4.3	•	☐	☐	☐		
Are specimens on receipt properly and adequately identified with two unique identifiers (e.g. the patient's name, identity card number, clinic/hospital number, passport number, etc) on the slides or on the primary containers and are these identical to those on the request forms?	5.4.5 5.4.H	5.4.6 (a) 5.4.H	•	☐	☐	☐		
For primary specimens received in the form of microscopic slides (e.g. tissue slides, conventional PAP smear), is the slide (not the mailer) labeled with the patient identity?	5.4.5	5.4.6	•	☐	☐	☐		
Is there any procedure to handle sample(s) with uncertainty?	5.4.5	5.4.6 (b)	•	☐	☐	☐		
If multiple samples are taken from the same patient on the same day, or by the same procedure, can they be identified with an appropriate system?	5.4.7	5.4.6 (a)	•	☐	☐	☐		
Are samples checked for the appropriate type and volume of fixative being added, as necessary?	5.4.8	5.4.6 (b)	•	☐	☐	☐		

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Are specimens checked for the appropriate type of anticoagulant in use and in the correct final concentration?	5.4.8	5.4.6 (b)	•	☐	☐	☐		
Are there criteria for rejection of specimens due to incorrect labeling, inadequate specimen, unidentified specimens, or unauthorized requests?	5.4.8	5.4.6 (b)	•	☐	☐	☐		
Is the integrity of specimens inspected upon receipt and are they rejected when they fail to meet the predefined criteria e.g. delayed delivery, inappropriate containers or preservation and leaking containers?	5.4.8	5.4.6 (b)	•	☐	☐	☐		
Is there a record system for rejected sample(s)?	5.4.8	5.4.6 (b)	•	☐	☐	☐		
Is the identity of every specimen and/or piece of tissue maintained through each step in processing, including aliquots and portions, and/or slide preparation?	5.4.5 5.4.12	5.4.6	•	☐	☐	☐		
Are all blocks or stained slides identified by an accession number and/or the patient's name?	5.4.12	5.4.6	•	☐	☐	☐		
Are all slides prepared checked to ensure they are correctly labeled with the right accession numbers during preparation?	5.4.12	5.4.6	•	☐	☐	☐		
Examination procedures / processes	**5.5**	**5.5**						
Is the following information included in the procedure manual :								

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(i) principle and clinical purpose of the method?	5.5.3	5.5.3 (a) 5.5.3 (b)	•	☐	☐	☐		
(ii) performance specifications/ characteristics?	5.5.3	5.5.3 (c)	•	☐	☐	☐		
(iii) type of specimens appropriate for the method used?	5.5.3	5.5.3(d)						
(iv) patient preparation	N/A	5.5.3 (e)						
(v) type of containers and additives used?	5.5.3	5.5.3 (f)	•	☐	☐	☐		
(vi) preparation of reagents, standards and controls (methods, source of supplies, catalogue numbers)?	5.5.3	5.5.3 (g)	•	☐	☐	☐		
(vii) environmental and safety control?		5.5.3 (h)						
(viii) calibration procedures, if applicable?	5.5.3	5.5.3 (i)	•	☐	☐	☐		
(ix) step by step procedures written clearly?	5.5.3	5.5.3 (j)	•	☐	☐	☐		
(x) methods for calculations and estimation of measurement uncertainty, where relevant?	5.5.3	5.5.3 (m)	•	☐	☐	☐		
(xi) include requirements for quality control and criteria for accepting quality control results?	5.5.3	5.5.3 (k)	•	☐	☐	☐		
(xii) include clear instructions for reporting results, with reference intervals where appropriate?	5.5.3	5.5.3 (n) 5.5.3 (o)	•	☐	☐	☐		
(xiii) reference notes (e.g. special requirements, drug/other interference, potential source of variation etc.)?	5.5.3	5.5.3 (l)	•	☐	☐	☐		

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(xiv) history of authorized changes for each method?	5.5.3	5.5.3	•	☐	☐	☐		
(xv) criteria for identifying and dealing with seriously abnormal results?	5.5.3	5.5.3 (q)	•	☐	☐	☐		
(xvi) the appropriate units to be used e.g. SI and/or Conventional?	5.8.3	5.8.3 (i)	•	☐	☐	☐		
(xvii) source of references for the methods, acceptance criteria, reference intervals, comments or interpretations?	5.5.1	5.5.3 (t)	•	☐	☐	☐		
Are there documented procedures for handling and examination of highly infectious cases?	4.2.1	4.2.1	•	☐	☐	☐		
If a new methodology is used in the laboratory, has it been evaluated and records kept for all tests done, test data, results and conclusions?	5.5.2	5.5.1.2 5.5.1.3	•	☐	☐	☐		
Where applicable, has the biological reference interval used for this new method been validated or established as appropriate?	5.5.2	5.5.1.3	•	☐	☐	☐		
Does the laboratory regularly review the biological reference intervals for their continual suitability and has the source of the biological reference intervals been documented?	5.5.5	5.5.2	•	☐	☐	☐		
Assuring the quality of examination procedures / Ensuring quality of examination results	**5.6**	**5.6**						

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Technical requirements	Clause (HOKLAS 015, 4th edition and relevant SC)	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 there written records of all quality assurance results?	5.6.1		•	☐	☐	☐		
Is there documented evidence of active review by designated person(s) of the following:	5.6.1	5.6.2.1						
a. internal quality control procedures			•	☐	☐	☐		
b. results of controls in tests			•	☐	☐	☐		
c. instrument function checks			•	☐	☐	☐		
d. temperature records			•	☐	☐	☐		
e. performance in the proficiency testing programmes?			•	☐	☐	☐		
Are quality control results verified for acceptability before test results are reported?	5.6.1	5.6.2.1	•	☐	☐	☐		
Where quantitative test results are given, has the laboratory made an effort to estimate the uncertainty of measurement and document the uncertainty components? Examples of tests where estimation of MU are expected are provided in relevant Supplementary Criteria.	5.6.2 SC-27 7.2 SC-28 8.4 SC-30 7.1 SC-35 7.1	5.5.1.4 SC-27 7.2 SC-28 8.4 SC-30 7.1 SC-35 7.1	•	☐	☐	☐		
Are appropriate reference material, microbial reference strains and quality control materials available and used? Are they stored under proper conditions?	5.6.3	5.3.1.4	•	☐	☐	☐		
If the reporting of test results involved subjective judgment and professional competency of staff, has arrangement been made for individual staff to participate in external quality assurance programs?	5.6.4	5.6.3.1	•	☐	☐	☐		

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Are there records kept for individual performance in EQAPs?	5.6.4	5.6.3.4	•	☐	☐	☐		
Are the reports of the quality assurance program checked and reviewed by laboratory director or designates?	5.6.4	5.6.3.4	•	☐	☐	☐		
Have the EQAP results been circulated to participating staff and those working in the area for information and education?	5.6.4	5.6.3.4	•	☐	☐	☐		
If some analyses are done by more than one method or equipment, are there procedures and records to show that the results are comparable? Are there written criteria for acceptance of results?	5.6.6	5.6.4	•	☐	☐	☐		
Is there any documented record for corrective measures in response to problems or deficiencies identified from QC results?	5.6.7	5.6.3.4	•	☐	☐	☐		
Post-examination procedures / processes	**5.7**	**5.7**						
Is there a regular review of the reports to ensure that all required data are present?	5.7.1	5.7.1	•	☐	☐	☐		
Are results routinely reviewed by authorized personnel with supervisory responsibilities for clerical errors, absurd results, internal consistency, clinical relevance or results requiring special notification before they are released?	5.7.1	5.7.1	•	☐	☐	☐		
Are the results of examinations reviewed by authorized personnel with appropriate qualification, training and experience in the relevant examination?	5.7.1	5.7.1	•	☐	☐	☐		

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Are there policies and procedure in place to ensure safe packaging, labeling, transportation and disposal of various types of hazardous waste?	5.7.3	5.7.2	•	☐	☐	☐		
Reporting of results	**5.8**	**5.8**						
When diagnostic reports are generated by computer or telecommunications equipment, the actual signature or initials of the authorized person may not appear on the report. Does the laboratory have a procedure to ensure and document that the responsible person reviewed and approved the complete report before its release?	5.8.3	5.7.1	•	☐	☐	☐		
When computer systems are used, are there procedures to check for transcription, calculation, or data entry errors?	5.8.3	5.8.1	•	☐	☐	☐		
Are the test results from referral laboratories properly kept and referral results provided to requester by the referring laboratory?	5.8.6, 4.5.4	4.5.2	•	☐	☐	☐		
Are the reports specified in relevant supplementary criteria to require direct input from qualified pathologist of the appropriate specialty, authorized by the appropriate person?	SC-23 6.1 SC-24 10.1.1 SC-24 10.1.2 SC-25 9.1 SC-26 7.1 SC-27 8.1 SC-28 10.1 SC-30 9.1, 9.2 SC-35 9.2, 9.3	SC-23 6.1 SC-24 10.1.1 SC-24 10.1.2 SC-25 9.1 SC-26 7.1 SC-27 8.1 SC-28 10.1 SC-30 9.1, 9.2 SC-35 9.2, 9.3	•	☐	☐	☐		

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Do reports include the appropriate age-, sex- specific biological reference intervals, where applicable?	5.8.3 (i)	5.8.3 (j)	•	☐	☐	☐		
Is a documented procedure available for expedited handling of seriously abnormal results?	5.8.7	5.9.1 (b)	•	☐	☐	☐		
Is the turnaround time set within a reasonable time frame and has users' need been taken into consideration?	5.8.11	4.14.7	•	☐	☐	☐		
Are the requesters informed on the reports that the results are auto-validated by computer system?	SC-26 6.3 SC-28 10.3	SC-26 7.3 SC-28 10.3	•	☐	☐	☐		
Release of results	**N/A**	**5.9**						
For computer auto-validated reports, does the laboratory define and document the person(s) authorizing the use of the particular algorithm for the automatic release of the results? Is the authorization for release of auto-validated reports traceable?	SC-26 6.3 SC-28 10.3	5.9.2 (a)	•	☐	☐	☐		
Laboratory information management	**N/A**	**5.10**						
Is/Are the responsible personnel who can approve new information system(s) or changes to information system(s) in the laboratory defined?	N/A	5.10.2	•	☐	☐	☐		
Have security roles and responsibilities of employees, contractors and third party users been clearly defined and documented?	N/A	5.10.2	•	☐	☐	☐		
Are there documented procedures for collecting, processing, recording, reporting, storing, and retrieving examination data and information?	N/A	5.10.3	•	☐	☐	☐		

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Is there any back-up system for information?	N/A	5.10.3	•	☐	☐	☐		
Is the laboratory aware of the sources of information from the relevant authorities concerning information security?	N/A	5.10.3	•	☐	☐	☐		
Are there any protective measure on information assets, including facilities and storage media, against loss, damage, and theft?	N/A	5.10.3	•	☐	☐	☐		
Has the laboratory identified secure areas and adopted proper access controls to prevent unauthorized physical access, damage and interference to the laboratory's premises and information?	N/A	5.10.3	•	☐	☐	☐		
Has a contingency plan(s) been established to maintain services in the event of failure or downtime in a computerized information system?	N/A	5.10.3	•	☐	☐	☐		
Have measures been taken to ensure the integrity (e.g. accuracy, completeness, etc.) of information transmitted (e.g. via computer systems, fax, e-mail, etc.) to and/or from systems external to your laboratory?	N/A	5.10.3	•	☐	☐	☐		

End of General checklist

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