HOKLAS Supplementary Criteria No. 27

'Medical Testing' Test Category – Clinical Microbiology and Infection

1. Introduction

1.1 This document is an application document for the requirements of HKAS 002 and HOKLAS 015 for accrediting examinations in clinical microbiology and infection 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 Bacteriology

2.2 Miscellaneous Microbiology Tests

2.3 Mycobacteriology

2.4 Mycology

2.5 Parasitology

2.6 Syphilis Serology

2.7 Virology

Note: HKAS also provides accreditation for miscellaneous cross-discipline tests, such as urinalysis. When they are accredited, they are listed under the discipline where the test is performed by the laboratory.

3. Personnel

3.1 Technical personnel

3.1.1 The technical management of the laboratory shall include at least one member who has knowledge experience of microbiological testing for at least three years and who holds a certificate of registration (Part 1) and a valid practicing certificate issued by the Medical Laboratory Technologists Board, Hong Kong. He/she is a supervisory personnel responsible for the technical operation of the laboratory with respect to microbiological testing.

3.1.2 The relevant educational and professional qualification records, training and competence assessment records shall be readily available to confirm the competence of staff members. A training log should include, in addition to testing procedures, evidence of training in biosafety precautions, procedures for sample collection and handling, media preparation, sterilisation and data handling. Staff members shall be allowed to analyse clinical samples only after their competence has been assessed to be satisfactory. Their performance shall be evaluated regularly to ensure their continuing competence.

3.2 Medical personnel

3.2.1 A qualified clinical microbiologist (or qualified pathologist as advised by the Hong Kong College of Pathologists) shall be required to provide clinical interpretation of test results.

3.2.2 A qualified clinical microbiologist shall be a pathologist who has obtained postgraduate qualification in clinical microbiology, such as the Fellowship of Hong Kong College of Pathologists, or equivalent as advised by the College.

3.2.3 A qualified clinical microbiologist shall fulfil the CME/CPD requirement of the Hong Kong Academy of Medicine or specialist registration of the Hong Kong Medical Council or equivalent bodies, as advised by the Hong Kong College of Pathologists.

4. Accommodation and environmental conditions

4.1 General

A distinct space, in line with biosafety level requirements, shall be used for medical microbiological testing in a laboratory complex with good housekeeping and strict control of traffic. The laboratories shall lay down procedures and precautions to be taken to prevent risks of cross-contamination. Instructions shall be available for procedures such as washing of labware, generation of distilled, deionised or reagent water, waste disposal, sterilisation, wiping down of bench tops and handling spills of contaminated materials.

4.2 Laboratories shall document and implement an exposure control plan which identifies the appropriate safety practices for handling infectious materials and pathogens of different risk levels. Risk assessment must take into account the agent, the host and the work activity in the development of a comprehensive safety plan.

4.3 Laboratories shall devise an appropriate environmental monitoring programme such as the use of air settling plates to measure trends in levels of contamination for work places where clean operation is expected. Acceptable background counts shall be assigned and there should be a documented procedure for dealing with situations in which these limits are exceeded. Records of such situations and corrective actions taken shall be maintained.

4.4 Biological safety cabinets (BSCs) shall be available and used for procedures where an aerosol risk exists. The class of BSCs suitable for use in handling infectious materials or pathogens of various risk levels shall be considered and included in the exposure control plan.

4.5 Separate locations or clearly designated areas should be provided for the following processes:

a) sample receipt;
b) sample processing;
c) manipulation of pathogens (in conditions relevant to their hazard level);
d) preparation and sterilisation of culture media;
e) cleaning of labware;
f) decontamination of contaminated materials (recommended to be performed in separate room using appropriate methods); and

g) clinical waste storage.

4.6 Separate storage compartments shall be provided for the following materials:

a) reference cultures and working stocks;
b) samples;
c) reagents/prepared media; and
d) dehydrated media.

4.7 Biosafety levels

4.7.1 For all microbiology laboratories, there shall be ample space provided for the safe conduct of laboratory work and for cleaning and maintenance. Facilities for storing outer garments and personal items should be provided outside the laboratory working area.

4.7.2 The accommodation and facilities of the microbiology laboratory shall be designed to a biosafety level commensurate with the activities conducted therein. Laboratories may refer to the World Health Organisation's Laboratory Biosafety Manual (2004) for the appropriate biosafety level and details of the biosafety requirements. A few critical points are highlighted hereafter.

4.7.3 There are no specific ventilation requirement for laboratories handling Risk Group 1 and 2 microorganisms. Considerations should be given to provision of mechanical ventilation systems that provide an inward flow of air when new microbiology laboratories are designed. Doors should have vision panels, be self-closing and have appropriate fire ratings.

4.7.4 Biosafety Level 2 requirements include but are not limited to (1) laboratory personnel shall have specific training in handling pathogenic agents and are directed by competent scientists / pathologists; (2) only authorised persons are allowed to enter the laboratory working area and appropriate international biohazard warning symbols and signs displayed on the doors of rooms, access to the laboratory is limited when work is being conducted; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets. Plastic disposable transfer loops or electric transfer loop incinerators should be used inside the biological safety cabinets to avoid the generation of air turbulence.

4.7.5 For additional safety and protection for staff working in laboratories that have to handle respiratory tract specimens, other measures such as wearing of appropriate PPE and putting up of all cultures and preparing smears in a properly maintained biological safety cabinet shall be required. For identification and sensitivity tests of *Mycobacterium tuberculosis* isolates, Biosafety Level 3 laboratory set up is mandatory.

4.7.6 Biosafety Level 3 laboratory is an area where manipulation is done on indigenous or exotic agents that can cause lethal or serious disease. Because of the potential hazards of these agents, there are criteria for laboratories handling them. This area shall be separated from traffic areas in the building by two sets of self-closing doors. Biohazard warning signs on laboratory access doors must identify the microorganisms handled and the name of the laboratory supervisor who controls access, and indicate any special conditions for entry into the area e.g. Immunisation. The hand-wash sink shall be located next to the door and shall have hands-free controls. Eyewashes are required in each of these areas.

4.7.7 For all laboratory personnel who work in Biosafety Level 3 laboratories, a baseline serum sample should be obtained and stored for future reference.

4.7.8 No individual shall work unobserved in the Biosafety Level 3 laboratories.

4.7.9 There shall be a ventilation system that establishes a directional air flow into the Biosafety Level 3 laboratory room. Staff shall at all times ensure that proper directional air flow into the laboratory room is maintained. Air from the Biosafety Level 3 laboratory shall not be recirculated to other areas within the building. Air could be HEPA filtered, reconditioned and recirculated within the laboratory. Exhaust air from the laboratory shall be discharged to the outside of the building, so that it is dispersed away from occupied buildings and air intakes. It is recommended that this air is discharged through high efficiency particulate air (HEPA) filters.

4.7.10 Biosafety Level 4 laboratory is necessary when handling Risk Group 4 organisms. The requirements are more stringent than for Level 3.

4.8 For nucleic acid amplification tests, there shall be compartmentalisation and appropriate procedures and controls to prevent cross-contamination. Requirements to use separate rooms do not apply if reagent preparation, sample preparation, amplification, and detection are performed on the same

instrument system. Separate rooms or clearly designated areas should be provided for the following processes:

- preparation of reagents and dispensing of master mix,
- sample preparation and extraction,
- amplification, and
- manipulation of amplified product e.g. gel electrophoresis or sequencing

The movement of nucleic acid samples should as far as possible be unidirectional, i.e. from pre-amplification to post-amplification areas. Arrangements shall be made to ensure that printouts from post-amplification areas are protected from cross contamination.

4.9 The primary specimens, nucleic acid extracts and post-amplification products shall be stored in separate compartments or refrigerators. Nucleic acid samples shall be kept in designated refrigerated compartments after sample preparation. They shall not be kept in areas where activity such as gel electrophoresis or PCR work is conducted.

5. Laboratory equipment, reagents, and consumables

5.1 Autoclaves

5.1.1 Sterilisation of clean equipment and decontamination of used equipment should not be carried out during the same sterilisation cycle. It is preferable to use separate autoclaves for these two processes. Records of autoclave operations, including temperature and time shall be maintained. Acceptance and rejection criteria for operation conditions shall be defined and implemented.

5.1.2 The adequacy of each cycle shall be documented by either use of:

a) recorder to produce a printout of temperature against time;
b) chemical indicators such as Brownes tubes, thermalog strips, etc.;
c) biological indicators such as spore strips; or
d) reading of temperature against time obtained from panel of autoclave.

5.1.3 In addition to monitoring of temperature, the effectiveness of operation of the autoclave shall be checked monthly with biological

indicators. A periodic scheduled overhaul maintenance record shall be maintained. Temperature-sensitive tape shall be applied for each load. However, it is used simply as an indicator that the load has reached a designated temperature but not as a monitor of the actual process applied and shall not be regarded as a substitute of chemical indicator.

5.2 Hot-air ovens

Temperature-sensitive tape shall be used to indicate that materials have been exposed to sterilisation temperatures.

5.3 Incubators (water bath, air, water jacketed, or aluminium block)

The temperature of incubators shall be verified to conform to the requirements of the test standards. Temperature checks on the shelves in use shall be recorded. The temperature in course of incubation shall be monitored.

5.4 Biological safety cabinets or laminar flow cabinets

5.4.1 Laboratories shall establish a program to check the rate of airflow and particle count in the hood/cabinet.

5.4.2 Criteria shall be defined and records of checks shall be maintained.

5.4.3 The cabinets should be maintained and serviced in accordance with the manufacturer's recommendations. Such services include monitoring the usage time of UV lamps and HEPA pre-filters/filters and their regular replacement.

5.4.4 A written protocol and record of the decontamination of the safety cabinet by trained staff should be established.

5.5 Media preparation

5.5.1 The laboratory shall document the procedure for media preparation. Records shall be kept of the details of preparation. All media produced in-house or purchased from manufacturers shall be checked for performance. Where appropriate, quality control tests using known positive and negative control strains shall be included on each new batch of media. Records of performance testing shall be maintained and be traceable.

5.5.2 Preparation, storage and quality control of media shall be performed in accordance with documented methods from suitable manuals. Modifications from standard methods shall be validated.

5.5.3 Standard organisms shall be used to perform quality control for in-house media. An appropriate range of organisms from a reliable source shall be available. The stock of organisms shall be maintained under appropriate long-term storage conditions.

In-house media

5.5.4 The laboratory shall establish and maintain media preparation and quality control programs designed to suit the scope of testing.

5.5.5 The preparation protocol, procedures and quality control shall be documented as part of the laboratory quality system.

5.5.6 Records shall be kept of the preparation details for all types of media including:

a) Name of media;
b) Batch number for unique identity;
c) Responsible staff for preparation;
d) Date of preparation and expiry;
e) Volume of media/solutions made;
f) Media ingredients, manufacturer, manufacturer's batch number and quantity of each component;
g) Method of sterilisation, including time and temperature as appropriate;
h) Volume dispensed for diluent or other ingredients when the volume is critical; and
i) Pre- and post-sterilisation pH record for culture media prepared in-house according to formulation.

5.5.7 All media produced shall be checked for performance and records maintained including:

a) Physical appearance;
b) Sterility results after incubation;
c) Performance checks using positive and negative control organisms;

d) Records of other acceptance tests performed as required e.g. thickness of agar media for antibiotic disk susceptibility tests; and
e) Records of performance testing shall be traceable to batch preparation records.

5.5.8 Laboratories producing media for their in-house use and distribution to satellite laboratories shall have a system in place for checking the integrity of their distribution chain. The suitability and efficacy of such a system will be reviewed at assessment.

Media and identification kits purchased from manufacturers

5.5.9 Performance of the first two lots of commercial media and identification kits newly used by the laboratory service shall be evaluated with reference strains.

5.5.10 The laboratory shall obtain information from the manufacturer which includes comprehensive quality control data for each batch of media. These shall include:

a) quality control protocols;
b) name and code of media;
c) purpose/scope of media;
d) ingredients;
e) quality control result (e.g. organisms, pH, etc); and
f) shelf life and expiry date.

Where necessary, additional performance check with the use of appropriate reference control strains should be carried out upon receipt to ensure proper performance of the media. The laboratory should determine if additional performance verification is necessary based on past experience, composition of the media, shipment length, storage condition during transport, etc.

5.5.11 Media shall be stored and used in accordance with the manufacturer's instructions. These instructions need to be documented and include inventory control.

5.5.12 Laboratories shall keep a record detailing the type of media, batch number and date received.

5.5.13 For commercial identification kits, a quality control plan shall be established to verify performance and records shall be kept.

5.5.14 Limitations of commercial media/test kits shall be acknowledged and addressed in quality control plans.

5.5.15 Laboratories shall periodically review the reliability of purchased media and document the results of this review. Records relating to media quality control shall be kept for three years.

5.6 For general equipment (e.g. micropipettes, vortex mixers, heating block and micro-centrifuges) used for molecular testing, there shall be no sharing of equipment among designated areas listed in 4.8 unless reagent preparation, sample preparation, amplification, and detection are performed on the same instrument system. Aerosol resistant pipette tips are mandatory and positive displacement pipettes are strongly recommended.

6. Examination processes

6.1. Evaluation and validation of methods

6.1.1 Commercial systems

6.1.1.1 The laboratory shall evaluate any new commercial systems to ensure its performance is suitable for the intended use before putting them into routine service. Verification of the manufacturer's claim shall be included as part of the evaluation. Records of these evaluations shall be kept.

6.1.1.2 For semi-quantitative tests, verification of the cut-off value is expected in the evaluation study. The evaluation shall include at least a strong positive control, a weak positive control close to cut-off value and a negative control. EQAP reference materials may be used for the verification.

6.1.1.3 An appropriate quality control plan shall be in place to ensure proper performance of the commercial system. This includes the use of appropriate reference control strains in accordance with the manufacturer's recommendation; or appropriate quality control materials. The laboratory shall pay attention to the limitations and precautions, and follow the exact procedural steps specified in the package insert of

the kits.

6.1.1.4 For commercial diagnostic assays using molecular testing techniques and approved by international or national regulatory bodies (e.g. FDA or CE-IVD), verification of assay performance shall, at least, cover analytical sensitivity (limit of detection), analytical specificity, precision and linear range (applicable only for quantitative assays such as viral load monitoring for HBV, HCV, HIV and CMV), if information on assay performance is provided by the manufacturers. Clinical samples shall be included where applicable. The method verification study shall include each type of specimens for the test and the amount of material sufficient for testing shall be verified.

6.1.2 In-house methods

6.1.2.1 In-house examination procedures shall be appropriately evaluated and documented. Changes shall be dated and documented.

6.1.2.2 For in-house developed nucleic acid amplification assays, the development and validation of the assay shall be well documented to include primer and probe design (re-evaluated at least once a year), target gene, analytical sensitivity (limit of detection), analytical specificity, precision, linear range (applicable only for quantitative assays such as viral load monitoring for HBV, HCV, HIV and CMV), accuracy, cut-off values, diagnostic sensitivity, diagnostic specificity, pre-nucleic acid amplification decontamination procedures, detection of inhibitors and interfering substances (optional). The method validation study shall include each type of specimens for the test and the amount of material sufficient for testing shall be validated.

6.1.2.3 For modified protocols of FDA and CE-IVD approved kits, research use only (RUO) or investigation use only (IUO) diagnostic kits using molecular testing techniques, validation shall be conducted as extensive as for in-house developed assays (see 6.1.2.2). Similarly, modification of any of the reagents used or platform used by the laboratory for any procedural steps from the adopted method or from

those recommended by the in vitro diagnostic manufacturer shall be re-validated to ensure that the modification is fit for the intended use.

6.2 Referral tests

If further identification of a bacterial isolate or confirmation of a test result cannot be completed in the laboratory, the laboratory shall have a procedure for sending out samples/isolates to referral laboratories. The laboratory shall keep records of all such samples which have been referred and shall state on the final report that such results are carried out by a referral laboratory.

6.3 Uncertainty of measurement

For quantitative and semi-quantitative tests where qualitative results are determined from a measured value, the laboratory shall determine the uncertainty of measurement and document the uncertainty components. Examples of such tests include antimicrobial drug assays, anti-HBs and rubella antibodies.

7. Ensuring quality of examination results

7.1 The laboratory shall have procedures for internal quality control for verifying that the intended result quality is achieved.

7.2 Appropriate controls should be performed and recorded using reference strains of appropriate range. See also 7.6 below.

7.3 Reference culture organisms shall be used to perform quality control checks in the areas of:

a) Direct examinations
b) Culture and identification tests
c) Antimicrobial susceptibility tests
d) Antimicrobial drug assays

Full history for each organism held by the laboratory for control purpose shall be retained.

7.4 For serology tests, a testing algorithm should be in place to reduce or eliminate the reporting of incorrect results. For non-culture methods for

detection of pathogens, suitable quality control shall be applied to assure the reliability of results.

7.5 The laboratory shall participate in interlaboratory comparisons that provide clinically relevant challenges that mimic patient samples and that check the entire examination process including pre- and post-examination processes.

7.5.1 Proficiency testing programmes should cover all test areas and techniques of the areas to be accredited.

7.6 Reference cultures

7.6.1 Laboratories shall demonstrate traceability by use of reference cultures of microorganisms issued by a recognised national collection such as the American Type Culture Collection (ATCC), or the National Collection of Type Cultures (NCTC), etc.

7.6.2 Reference culture of microorganisms not obtained directly from, but claimed to be traceable to a national collection may be used for quality control checks. However, it should be observed that working stocks may only be sub-cultured up to a defined maximum number of generations (normally no more than five passages from the original national collection culture as recommended by US Pharmacopoeia). They shall not be further sub-cultured if no information on passage number is available from the supplier, especially if they are used as quality controls for antimicrobial susceptibility tests and antimicrobial drug assays.

7.6.3 Laboratories shall have policies and procedures for purchase, handling, storage, preservation, maintenance and use of reference cultures and stocks.

7.6.4 Procedures for preparation and verification of working stocks shall be documented. Desired characteristics of the strains shall be verified by combinations of morphological, biochemical, serological, and/or molecular tests as appropriate. Reference cultures used beyond the five passages as recommended in US Pharmacopoeia may be acceptable provided that more extensive verifications satisfying quality control requirements shall be carried out before they are being used.

7.7 Laboratories offering molecular diagnostic testing shall participate in appropriate external quality assurance programme(s) for each specific

molecular test for each target gene/microorganism or interlaboratory comparison if this is not available.

7.8 If the molecular diagnosis is not based on definitive method or nucleotide sequencing, positive and negative controls of the interrogated nucleotide or nucleotides shall be included in the same run of the assay.

8. Post-examination processes

8.1 The primary sample, DNA and RNA extract, and amplified DNA products shall be retained for a minimum of one month after reporting.

8.2 Technical records to be retained for establishing traceability shall also include the gel images and hybridisation blots.

9. Reporting and release of results

9.1 Laboratories shall have clear documented procedures for 1) reporting of results, 2) handling of clinically significant results, and 3) handling of discrepant results.

9.2 All positive results for the following tests shall have direct input from a qualified clinical microbiologist (or qualified pathologist as advised by the HKCPath) before reporting. Direct input is referred to the personal review of the test request, data and results required of a specified test, and eventual sign-out of the relevant test report.

9.2.1 Based on their clinical significance and direct implication on patient management:

- Molecular quantitative tests (viral load) for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), cytomegalovirus (CMV) and Epstein-Barr virus (EBV)
- Antiviral resistance testing, including those for HIV, HBV, HCV and herpes viruses, etc.
- Qualitative detection of HIV ribonucleic acid (see 'Condition' below in 9.6)
- Antibody detection for HIV including combined test for HIV Ag/Ab
- Tests for all specimens from the central nervous system

- Abnormal blood levels for antibiotic assays
- Nucleic acid tests for the detection of infection with *Mycobacterium tuberculosis* and MTB complex
- Identification and anti-mycobacterial susceptibility tests of *Mycobacterium tuberculosis* isolates
- Tests for acute infection with CMV, Rubella, Toxoplasma, Parvovirus in pregnant women

9.2.2 Based on their relation to major outbreak investigation and/or current public concerns:

- Tests for non-seasonal Influenza A virus (i.e. not human seasonal Influenza A H1N1 nor H3N2)
- Tests for SARS coronavirus or any emerging pathogens of major public health concerns
- Tests for Japanese encephalitis virus and haemorrhagic fever viruses such as Dengue or Hantavirus, etc.
- Detection of multiple drug resistant organisms including, but not limited to, extremely-drug-resistant tuberculosis (XDR-TB), carbapenem-resistant Enterobacteriaceae (CRE), vancomycin-resistant enterococcus (VRE), vancomycin-resistant *Staphylococcus aureus* (VRSA), multi-resistant *Pseudomonas aeruginosa* (MRPA), and *Neisseria gonorrhoeae* resistant to 3rd generation cephalosporins, etc.

9.3 For tests listed in 9.2.1 and 9.2.2, an interim report may be issued where patient's conditions require and the final report shall be authorised promptly by a qualified clinical microbiologist (or qualified pathologist as advised by the HKCPath).

9.4 Laboratories shall have documented arrangement for obtaining input from a qualified clinical microbiologist (or qualified pathologist as advised by the HKCPath) for reporting of relevant test results.

9.5 For any test results of significant clinical and public health implication, input from a qualified clinical microbiologist (or qualified pathologist as advised by the HKCPath) is recommended.

9.6 **Condition for accrediting HIV ribonucleic acid qualitative test:**

In accordance with internationally accepted diagnostic algorithm, detection of HIV RNA shall not be used as first line screening test for the diagnosis of HIV. Test results of HIV RNA detection shall be reported together with

those of the serology test, regardless of the test result. POSITIVE result from any of the two tests shall be confirmed and require direct input from a qualified clinical microbiologist (or qualified pathologist as advised by the HKCPath). Alternatively, laboratories shall confirm any POSITIVE results by sending the original primary sample for confirmation to a referral laboratory with input from a qualified clinical microbiologist (or qualified pathologist as advised by the HKCPath). Requirements governing examination performed by referral laboratories (including reporting) stated in HOKLAS 015 shall apply (also refer to 6.2 of this supplementary criteria).

9.7 It should be noted that, for laboratory investigation of HIV, HBV and HCV infections, qualitative molecular test results alone are inadequate for clinical management. The laboratory shall remind the physicians ordering the tests to take into account of other parameters such as serology findings and clinical features before initiating any definitive treatment.

- 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 the microbiology laboratory designed to have mechanical ventilation systems that provide an inward flow of air without recirculation?	5.2.1	•	☐	☐	☐		
For laboratories that have to handle requests for AFB smears and putting up AFB cultures, does the laboratory have evidence to demonstrate that a negative pressure is adequately maintained in the laboratory?	5.2.6	•	☐	☐	☐		
For handling identification and sensitivity tests of AFB isolates, are they carried out in a Biosafety Level 3 laboratory?	5.2.1	•	☐	☐	☐		
If your laboratory is a Biosafety Level 3 laboratory, are biohazard warning signs posted on laboratory access doors to identify the microorganisms handled and the name of the laboratory supervisor?	5.2.1	•	☐	☐	☐		
Does the laboratory have a policy of not allowing individual to work alone in the Biosafety Level 3 laboratory?	SC-27 4.7.8	•	☐	☐	☐		
Is the microbiological air quality of work places where clean operation is expected (e.g. media preparation room) monitored?	5.2.6	•	☐	☐	☐		
Has the laboratory documented and implemented an exposure control plan?	SC-27 4.2	•	☐	☐	☐		
For nucleic acid amplification test, are there separate rooms or clearly designated areas provided for the following processes: A. preparation of reagents and dispensing of master mix; B. sample preparation and extraction; C. amplification; and D. manipulation of amplified products	5.2.6	•	☐	☐	☐		

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, 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 a documented policy describing the movement of nucleic acid samples or specimens should as far as possible be unidirectional i.e. from pre-amplification to post-amplification areas?	5.2.6	•	☐	☐	☐		
Are nucleic acid samples kept in designated refrigerated compartments after sample preparation away from areas where activity such as gel electrophoresis or PCR work is conducted?	5.2.3	•	☐	☐	☐		
Laboratory equipment, reagents, and consumables	**5.3**						
Are reference cultures of microorganisms obtained from a recognised national collection such as the American Type Culture Collection (ATCC), or the National Collection of Type Cultures (NCTC), etc?	5.3.1.4	•	☐	☐	☐		
Are biosafety cabinets or laminar flow cabinets maintained and serviced according to the established programme and records are kept?	5.3.1.7	•	☐	☐	☐		
Are aerosol resistant pipette tips or positive displacement pipettes used in the whole process for nucleic acid amplification tests?	5.3.1.1	•	☐	☐	☐		
Is there a documented policy preventing the sharing of general instruments (e.g. micropipettes, vortex mixers, heating block and micro-centrifuges) among designated areas? A. preparation of reagents and dispensing of master mix; B. sample preparation and extraction; C. amplification; and D. manipulation of amplified product.	5.3.1.3	•	☐	☐	☐		

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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
Media preparation							
Are quality control tests using known positive or negative control strains included on each new batch of media?	5.3.2.3	•	☐	☐	☐		
Are standard organisms used to perform quality control tests for in-house media?	5.3.2.3	•	☐	☐	☐		
(A) For in-house media:							
Are the preparation procedures, protocols and quality control programs properly documented?	5.3.2.1	•	☐	☐	☐		
Are records kept for media prepared included name of media, batch number, responsible staff for preparation, date of preparation, date of expiry, volume of media/solution made, pH checking, and sterilisation records?	5.3.2.7	•	☐	☐	☐		
For each batch of culture media prepared, do quality control records kept include date of quality control testing, physical appearance, sterility results after incubation, performance checks using positive and negative control organisms?	5.3.2.7	•	☐	☐	☐		
Is there a system in place to check the integrity of the distribution chain if media prepared in-house are also supplied to satellite laboratories?	SC-27 5.5.8	•	☐	☐	☐		
(B) For media and identification kits purchased from manufacturers:							
When commercial media and identification kits are newly used by the laboratory service, is the performance of at least the first two lots of new media/kit evaluated and records kept?	5.3.2.7	•	☐	☐	☐		
Are quality control reports from manufacturers for respective lot/batch kept?	5.3.2.7	•	☐	☐	☐		

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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
Does the information provided in the reports include quality control protocols, name and code of media, purpose/scope of media, quality control results (e.g. organism, pH etc), shelf life or expiry date?	5.3.2.7	•	☐	☐	☐		
Are commercial media stored and used in accordance with the manufacturer's instructions?	SC-27 5.5.11	•	☐	☐	☐		
Are records available for type of media, batch number and date received?	5.3.2.7	•	☐	☐	☐		
For commercial identification kits, is there a quality control plan established to verify performance and are records kept?	5.3.2.7	•	☐	☐	☐		
Does the laboratory review the reliability of purchased media and document the review findings?	SC-27 5.5.15	•	☐	☐	☐		
Examination processes	**5.5**						
If commercial systems are used, does the laboratory evaluate the performance of the system to ensure its suitability before putting into service and validate the claim of the manufacturer?	5.5.1.2	•	☐	☐	☐		
For semi-quantitative tests, is the cut-off value evaluated with inclusion of at least a strong positive, a weak positive and a negative control?	5.5.1.2	•	☐	☐	☐		
Where quantitative test results are given e.g. antimicrobial drug assay, has the laboratory determined the uncertainty of measurement and document the uncertainty components?	5.5.1.4	•	☐	☐	☐		
Are manufacturer's instructions controlled?	4.3	•	☐	☐	☐		
Is there any written procedure for referrals, whether for confirmatory tests or	5.5.3	•	☐	☐	☐		

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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
further identification of an isolate?							
Bacteriology							
Throat and Nasopharyngeal Cultures							
Are adequate procedures available for the isolation and identification of pathogens, including *Streptococcus species, Neisseria gonorrhoeae, Candida species, Bordetella pertusis,* expected from these types of specimens?	5.5.1.1	•	☐	☐	☐		
Sputum Cultures							
Is a gram-stained smear performed routinely on all expectorated sputa to determine acceptability of a specimen for bacterial culture or the extent of culture work-up?	5.5.1.1	•	☐	☐	☐		
Are test procedures suitable for the isolation and identification of lower respiratory tract pathogens including *Strep. pneumoniae, H. influenzae*, and other less common pulmonary pathogens such as *Cryptococcus, Aspergillus spp.* and *Nocardia spp.* when they appear to be relevant*?*	5.5.1.1, 5.5.1.2	•	☐	☐	☐		
Are other Gram-negative bacilli identified when they appear to be relevant?	5.5.1.1	•	☐	☐	☐		
Urine Cultures and Microscopy							
Are semi-quantitative cell counts done for urine microscopy?	5.5.1.1	•	☐	☐	☐		
Are semi-quantitative cultures or colony counts done?	5.5.1.1	•	☐	☐	☐		
Do the media used allow the isolation of both Gram-positive and Gram-negative bacteria as well as yeast?	5.5.1.1	•	☐	☐	☐		

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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
Urethral-cervical cultures for N. gonorrhoeae							
Are all cultures received either inoculated directly or in transport medium?	5.5.1.1	•	☐	☐	☐		
Are the media and means of incubation suitable for isolation of *N. gonorrhoeae*?	5.5.1.1	•	☐	☐	☐		
Faeces Cultures, Rectal Swabs, etc							
Do routine procedures allow both rapid isolation and identification of enteric pathogens, including *Salmonella typhi, Salmonella spp., Shigella spp Campylobacter* species*, Vibrio cholerae and other Vibrio* species, *Y. enterocolitica,* EHEC (*Escherichia coli* O157:H7), *Aeromonas species,* and some specific Gram-positive bacteria such as *C. difficile,* when indicated in patients with appropriate clinical picture?	5.5.1.1	•	☐	☐	☐		
Do routine procedures allow recovery of small numbers of enteric pathogens in asymptomatic carriers?	5.5.1.1	•	☐	☐	☐		
Cerebro-Spinal Fluid Cultures							
Are specimens processed immediately on receipt?	5.5.1.1	•	☐	☐	☐		
Is the macroscopic appearance of the specimen and supernatant recorded?	5.5.1.1	•	☐	☐	☐		
Is a differential cell count done?	5.5.1.1	•	☐	☐	☐		
Are all specimens centrifuged and a Gram stain done on the sediment?	5.5.1.1	•	☐	☐	☐		
Does the routine procedure allow recovery and identification of common disease-producing microorganisms with fastidious requirements? (e.g. *N. meningitides, H. influenzae, Cryptococcus neoformans)*	5.5.1.1	•	☐	☐	☐		

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Blood Cultures							
Are blood cultures incubated to recover organisms, including fungus, with different atmospheric requirements?	5.5.1.1	•	☐	☐	☐		
Are blood cultures kept long enough (e.g. at least 5 to 7 days) to recover slow-growing pathogens?	5.5.1.1	•	☐	☐	☐		
Are adequate volumes of blood collected for detection of sepsis?	5.5.1.1	•	☐	☐	☐		
Are protocols set for recovery of SBE (IE) and Brucellosis infection?	5.5.1.1	•	☐	☐	☐		
Wound Cultures and Aspirates							
Are special procedures established to minimise loss of anaerobes from specimens?	5.5.1.1	•	☐	☐	☐		
Are Gram stains of specimens examined and results reported routinely when indicated?	5.5.1.1	•	☐	☐	☐		
Are selective methods used to detect / recover strict anaerobes?	5.5.1.1	•	☐	☐	☐		
Beta Lactamase Production							
Are procedures available to detect beta lactamase production by *Neisseria gonorrhoeae*, *Haemophilus influenzae, Enterobacter* species and other organisms, when relevant?	5.5.1.1	•	☐	☐	☐		
Isolations of Anaerobes							
Are there adequate arrangements for preventing or minimizing exposure to oxygen of specimens to be examined for anaerobes?	5.5.1.1	•	☐	☐	☐		

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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
Is a direct Gram stain done on all specimens requiring for anaerobic culture?	5.5.1.1	•	☐	☐	☐		
Are specimens for anaerobes inoculated directly onto solid media?	5.5.1.1	•	☐	☐	☐		
Are cultures on solid media put into an anaerobic environment immediately?	5.5.1.1	•	☐	☐	☐		
Are liquid media such as thioglycollate media or cooked meat broth, used for putting up specimens for anaerobes?	5.5.1.1	•	☐	☐	☐		
If disposable commercial hydrogen – CO_2 generators are used, is the brand known to be reliable in maintaining a supply of CO_2 ?	5.5.1.1	•	☐	☐	☐		
If hydrogen is supplied from an external source (e.g. cylinder) for anaerobiosis, is CO_2 also added to the anaerobic apparatus?	5.5.1.1	•	☐	☐	☐		
If a palladium catalyst is used, is there a procedure to ensure that it is dry?	5.5.1.1	•	☐	☐	☐		
Is the catalyst replaced after incubation of H_2S-producing organisms?	5.5.1.1	•	☐	☐	☐		
During and after incubation, is anaerobiosis assessed by an indicator such as Methylene blue, Resazurine or by the culture of a strict aerobe (e.g. *Pseudomonas aeruginosa*) or strict anaerobe (*Clostridium tetani*)?	5.5.1.1	•	☐	☐	☐		
Antibiotic Testing							
(A) Susceptibility testing							
Are methods of proven reliability used for susceptibility testing?	5.5.1.1, 5.5.1.2	•	☐	☐	☐		
Are antimicrobials used within their specified shelf life and properly stored?	5.5.1.1	•	☐	☐	☐		
Is inoculum size standardised?	5.5.1.1	•	☐	☐	☐		

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Is intrinsic resistance to beta-lactam drugs (e.g. Methicillin resistance) tested at 35℃ or on hypertonic salt media?	5.5.1.1	•	☐	☐	☐		
Which drug is used to detect Methicillin resistance?_____		•					
Which method is used for ESBL detection? _____		•					
Which drug is used to detect insensitive pneumococcus? _____		•					
If disc tests are used:							
Are disc stored in a desiccated state:	5.5.1.1						
(a) for current use at room temperature?		•	☐	☐	☐		
(b) for stock, under vacuum and refrigeration?		•	☐	☐	☐		
Are zone sizes of tests measured and used for recording sensitivity resistance?	5.5.1.1	•	☐	☐	☐		
If automated tests are used, are the manufacturer's instructions followed exactly?	5.5.1.1	•	☐	☐	☐		
Molecular Testing							
Does the laboratory verify the performance of commercial diagnostic assays (e.g. analytical sensitivity, analytical specificity, precision, linear range if applicable, accuracy and cutoff values)?	5.5.1.2 SC-27 6.1.1.4	•	☐	☐	☐		
Does the laboratory include all specimen types it normally encounters in the verification study? Is the amount of material sufficient for testing determined?	5.5.1.2 SC-27 6.1.1.4	•	☐	☐	☐		
Are in-house developed methods validated and documented to include primer and probe design (re-evaluated at least once a year), target gene, analytical sensitivity, analytical specificity, precision, linear range if applicable,	5.5.1.3 SC-27 6.1.2.2	•	☐	☐	☐		

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accuracy, cutoff values, diagnostic sensitivity, diagnostic specificity, pre-nucleic acid amplification decontamination procedures, detection of inhibitors and interfering substances (optional)?							
Does the laboratory include all specimen types it normally encounters in the validation study? Is the amount of material sufficient for testing determined?	5.5.1.3 SC-27 6.1.2.2	●	☐	☐	☐		
Are modified protocols of FDA and CE-IVD approved kits, research use only (RUO) or investigation use only (IUO) diagnostic kits validated as extensive as for in-house developed methods?	5.5.1.3 SC-27 6.1.2.3	●	☐	☐	☐		
Ensuring quality of examination results	**5.6**						
Are reference cultures used within five passages? If not, have relevant verification procedures been performed?	SC-27 7.6.2	●	☐	☐	☐		
Is there any documented policy and procedure for handling, storage, preservation, maintenance and use of reference cultures and stocks?	5.3.2.1	●	☐	☐	☐		
Is there any documented procedure for preparation and verification of working stocks?	SC-27 7.6.4	●	☐	☐	☐		
Control of staining procedure							
Are controls run and results recorded routinely with all infrequently used stains?	5.6.2.1	●	☐	☐	☐		
Is the Gram staining procedure checked and recorded for each new batch of stains and at least weekly against known gram-positive and gram-negative control organisms?	5.6.2.1	●	☐	☐	☐		
Control of differential tests							
Are controls run each day of use and results recorded for all differential tests, e.g.	5.6.2.1	●	☐	☐	☐		

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coagulase, catalase, oxidase, etc.?							
Control of serologic typing procedures							
Are contaminated antisera discarded?	5.6.2.1	•	☐	☐	☐		
Are positive and negative controls run routinely and recorded?	5.6.2.1	•	☐	☐	☐		
Is the date that reagents are brought into use recorded on the label?	5.3.2.7	•	☐	☐	☐		
Does the laboratory participate in external quality assurance programme(s) covering each of the molecular tests for each target gene/microorganism?	5.6.3.1	•	☐	☐	☐		
Are positive and negative controls of the interrogated nucleotide or nucleotides included in the same run of the assay for molecular diagnosis, which is not based on definitive method or nucleotide sequencing?	5.6.2.1	•	☐	☐	☐		
Control of antibiotic testing							
For disc susceptibility tests:							
Are zone sizes of controls measured and recorded?	5.6.2.1	•	☐	☐	☐		
Are QC programs used to detect disc potency?	5.6.2.1	•	☐	☐	☐		
Are control strains of known susceptibility included with each batch of antibiotic susceptibility tests and results recorded?	5.6.2.1	•	☐	☐	☐		
If dilution tests are used:							
Is there adequate control of the strength and identity of the diluted drugs?	5.6.2.1	•	☐	☐	☐		
For measuring drug levels in blood:							
Are adequate controls run with each batch of tests?	5.6.2.1	•	☐	☐	☐		

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Are serum controls stored deep-frozen as single use aliquots?	5.6.2.1	•	☐	☐	☐		
For susceptibility testing of anaerobes:							
Are control organisms included with each batch of susceptibility tests performed for anaerobes?	5.6.2.1	•	☐	☐	☐		
Post-examination processes	**5.7**						
Are the primary samples, DNA extracts, RNA extracts and amplified DNA products retained for a minimum of 1 month after reporting?	SC-27 8.1	•	☐	☐	☐		
Are gel images and hybridisation blots kept as part of the technical records retained?	SC-27 8.2	•	☐	☐	☐		
Reporting of results	**5.8**						
Reports for drug levels in blood							
Are the safe trough and therapeutic peak levels shown in the report to aid interpretation?	5.8.3 (j)	•	☐	☐	☐		
Release of results	**5.9**						
Are final negative reports normally available within 48 hours (except for blood culture reports)?	4.14.7	•	☐	☐	☐		
Are preliminary reports issued if final reports are not available within 48 hours?	5.9.1	•	☐	☐	☐		
Reports for blood cultures							

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Are initial positive cultures given to the physician as soon as this information is available?	5.9.1 (b)	•	☐	☐	☐		
Are records of such early notifications kept, including name of laboratory staff, name of person who has received the notification, date and time of notification?	5.9.1 (e)	•	☐	☐	☐		
Mycology							
Accommodation and environmental conditions	**5.2**						
Is a biological safety cabinet available and used for the handling of all specimens requested for fungal smear and culture?	5.2.1	•	☐	☐	☐		
Laboratory equipment, reagents, and consumables	**5.3**						
Is an incubator in the range of 25-30°C provided specifically for fungal culture?	5.3.1.1	•	☐	☐	☐		
Examination processes	**5.5**						
Is the direct microscopic examination of fungal smear with stains e.g. 20% KOH, Indian Ink, lacto phenol cotton blue, etc., performed?	5.5.1.1	•	☐	☐	☐		
Are the media and procedures used suitable for the isolation of yeast, dermatophytes and systemic fungi?	5.5.1.1	•	☐	☐	☐		
Parasitology							
Laboratory equipment, reagents, and consumables	**5.3**						

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Is an ocular micrometer available for determining the size of eggs, larvae, cysts and trophozoites?	5.3.1.1	•	☐	☐	☐		
Has the ocular micrometer been calibrated?	5.3.1.4	•	☐	☐	☐		
Examination processes	**5.5**						
Is there a written procedure manual specific for parasitology?	5.5.3	•	☐	☐	☐		
Are reference materials, such as permanent mounts, slides, printed atlases or similar illustrations and descriptions available at the workbench?	5.6.2.2	•	☐	☐	☐		
Does the procedure manual include:	5.5.3						
(i) Instructions for the proper collection and handling of specimens		•	☐	☐	☐		
(ii) Methods		•	☐	☐	☐		
(iii) Staining methods		•	☐	☐	☐		
(iv) Criteria for identification of eggs and parasites?		•	☐	☐	☐		
Are permanent stains routinely used for screening faecal sediments?	5.5.1.1	•	☐	☐	☐		
Virology							
Laboratory equipment, reagents, and consumables	**5.3**						
Are records kept of all cell types, passage number, source, media used for their growth and maintenance, and quality control testing results?	5.3.2.7	•	☐	☐	☐		

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Pre-examination processes	**5.4**						
Does the laboratory request form for viral studies include clinical history, relevant vaccination, source of specimen, type of infection and / or virus expected, and test requested?	5.4.3	•	☐	☐	☐		
Are there written instructions for the collection, handling and transportation of specimens for viral studies and adequate supplies of materials to enable the instructions to be carried out?	5.4.4.3	•	☐	☐	☐		
Examination processes	**5.5**						
Is complement titrated in the presence of each test antigen where appropriate?	5.5.1.1	•	☐	☐	☐		
Are red cell suspensions being standardised where appropriate?	5.5.1.1	•	☐	☐	☐		
Are antigen titrations being done with each haemagglutination test run where appropriate?	5.5.1.1	•	☐	☐	☐		
Where quantitative test results are given for antibody levels e.g. anti-HBs, rubella antibody, has the laboratory determined the uncertainty of measurement and document the uncertainty components?	5.5.1.4	•	☐	☐	☐		
Ensuring quality of examination processes	**5.6**						
Are antigen controls, complement heterophile, rheumatoid factor and autoantibody controls included and run with each test where appropriate?	5.6.2.1	•	☐	☐	☐		
Are continuous cell lines checked for mycoplasmas?	5.6.2.1	•	☐	☐	☐		
Are animal sera used for growth media checked for absence of toxicity to cells?	5.6.2.1	•	☐	☐	☐		

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Are uninoculated culture controls set up with each set of culture tubes for viral isolation?	5.6.2.1	•	☐	☐	☐		
Are all results with clinical or epidemiological significance confirmed with another test method or sent to a reference laboratory for confirmation?	SC-27 8.1	•	☐	☐	☐		
Mycobacteriology							
Accommodation and environmental conditions	**5.2**						
Are there Health and Safety manuals (or list of special precautions) available for all personnel engaged in mycobacteriology?	4.2.2.1	•	☐	☐	☐		
Is there a suitable biological safety cabinet furnished and used routinely for handling specimens and culture for mycobacteriology?	5.2.1	•	☐	☐	☐		
Is there a separate room dedicated for processing mycobacteriology?	5.2.1	•	☐	☐	☐		
Examination processes	**5.5**						
AFB Smear							
Are AFB smears prepared and examined for all clinical specimens submitted for mycobacterial evaluation?	5.5.1.1	•	☐	☐	☐		
Culture							
Are suitable digestion-decontamination procedures used for recovering mycobacteria? Specify the method: _____	5.5.1.1, 5.5.1.2	•	☐	☐	☐		

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Are incubation temperatures for the growth of mycobacteria defined and followed under culture conditions of different species? Specify the temperature (s): _____	5.5.1.1, 5.5.1.2	•	☐	☐	☐		
Ensuring quality of examination processes	**5.6**						
Is control slide included with each run of staining?	5.6.2.1	•	☐	☐	☐		
Are media routinely checked with reference control strains for each new shipment or preparation?	5.3.2.3	•	☐	☐	☐		
Are control strains of known susceptibility included with each batch of susceptibility test?	5.6.2.1	•	☐	☐	☐		
Release of results	**5.9**						
Does the reporting turnaround time for positive and negative microscopy report upon receipt of the specimen meet the clinical needs?	4.14.7	•	☐	☐	☐		
Is interim report issued for culture-positive specimen before identification of the AFB is available?	5.9.1	•	☐	☐	☐		

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