HOKLAS Supplementary Criteria No. 27

"Medical Testing" Test Category – Clinical Microbiology and Infection

1. Introduction

1.1 This Supplementary Criteria is an amplification and interpretation of the requirements of HKAS 002 and HOKLAS 015 for the accreditation of examinations in clinical microbiology and infection within the Medical Testing test category. This document sets out only those specific requirements that require further elaboration but does not include all the accreditation requirements. Therefore, this Supplementary Criteria needs to be read in conjunction with HKAS 002 and HOKLAS 015.

1.2 The checklist given in the Annex serves as guidance for laboratories to self-assess their management system and operation procedures against the requirements given in HOKLAS 015 and this document.

2. Scope of accreditation

The areas for which accreditation may be offered are listed below:

2.1 Direct Microscopic Examinations

2.2 Culture and Identification Tests

2.3 Antimicrobial Susceptibility Tests

2.4 Antimicrobial Drug Assays

2.5 Serology Tests

2.6 Non-culture Methods for Detection of Pathogens

3. Personnel

3.1 Technical personnel

3.1.1 The technical management of the laboratory shall include at least one member who has knowledge of microbiological testing and who holds a certificate of registration (Part 1) and a valid practicing certificate issued by the Medical Laboratory Technologist Board,

Hong Kong. He/she is responsible for the technical operation of the laboratory with respect to microbiological testing.

3.1.2 The relevant educational and professional 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, sterilization and data handling. Staff members should be allowed to analyse clinical samples only after their competence has been assessed to be satisfactory. Their performance should be evaluated regularly to ensure their continuing competence.

3.2 Medical personnel

3.2.1 A clinical microbiologist shall be required to provide clinical interpretation of test results.

3.2.2 A 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 clinical microbiologist shall fulfil the 3-year cycle of CME/CPD requirement of the Hong Kong Academy of Medicine or Hong Kong Medical Council or equivalent bodies.

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, deionized or reagent water, waste disposal, sterilization and wiping down of bench tops.

4.2 Laboratory bench area

The risk of contamination of both experiments and personnel rises with overcrowding. Sufficient bench space should be provided for each worker at one time. The space requirements should be commensurate with the volume of analyses handled. Provision of appropriate type and sufficient number of

properly installed biological safety cabinet is essential in situations where an aerosol risk exists.

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

a) sample receipt;
b) sample preparation;
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 culture media and samples (recommended to be performed in separate room using appropriate sterilizer); and
g) clinical waste storage.

4.4 Separate chambers or enclosures shall be provided for the following materials:

a) reference cultures, reference and working stocks (store pathogens under secure conditions);
b) samples;
c) serological and biochemical reagents/prepared media; and
d) dehydrated media.

4.5 Biosafety levels

(Ref.: NCCLS documents, GP18-A, Laboratory Design; Approved Guideline, 1998)

4.5.1 When designing the laboratory, the biosafety level of the activities must be considered according to the criteria outlined in the following:

Level 0: Where handling materials and performing tasks which do not involve contact with nor exposure to blood, body fluids, body secretions, or tissue.

Level 1: Where closed biological specimens as noted in Level 0 are handled, as with the receiving area in a laboratory.

Level 2: This is the level typically associated with clinical laboratory testing where there can be direct exposure to blood, body secretions, body fluids, or tissue. The risk to life due to inhalation or aerosol exposure is low.

Level 3: Where work is done using agents that cause lethal or serious diseases through inhalation.

Level 4: Where agents pose a high risk to life through aerosols.

4.5.2 Most clinical laboratory testing areas would be considered as level 2 while the receiving areas would be considered as level 1; neither of which requires the special design considerations of level 3 and 4 Biohazards.

4.5.3 Biosafety Level 2 is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) 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 or other physical containment equipment.

4.5.4 Level 3 is defined as areas which work is done with indigenous or exotic agents that can cause lethal or serious disease through inhalation. Because of the potential hazards of these agents there are layout criteria for laboratories handling them. This area must be separated from traffic areas in the building by two sets of self-closing doors. The hand-wash sink must be located next to the door and it must have hands free controls. Eyewashes are required in each of these areas.

4.5.5 Biosafety level 4 is necessary when the agents pose a high risk for life threatening disease. The layout requirements are more stringent than for level 3. The laboratory must be in a separate building or isolated zone. Changing rooms separated by a shower have to be provided. This may include a pressure suit area with a chemical shower. Materials that pass into and out of the laboratory must go through an airlock, fumigation chamber, or double door autoclave.

5. Laboratory equipment

5.1 Autoclaves

5.1.1 Autoclaves shall not be used to sterilize clean equipment and to decontaminate used equipment during the same sterilization 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 set and implemented.

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

a) thermocouple and recorder to produce a chart or printout;
b) maximum thermometer;
c) indicators such as Brownes tubes, thermalog strips, etc.;
d) spore strips; or
e) reading obtained from panel of autoclave.

5.1.3 In addition to monitoring of temperature, the effectiveness of operation of the autoclave may be checked monthly with biological indicators. Temperature-sensitive tape shall be applied for each load. However, it is used simply as an indicator that the load is "processed" but not as a monitor of the actual process applied.

5.2 Hot-air ovens

The performance of ovens shall be checked monthly with biological indicators. Temperature-sensitive tape shall be used to identify materials that have been exposed to sterilization temperatures.

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

The temperature of incubators shall be verified against the specifications of the test standards and checks on the shelves in use shall be recorded.

5.4 Refrigerators, freezers or cold-storage rooms

The allowed range of temperature fluctuation shall be specified and records of daily checks of temperature shall be maintained.

5.5 Temperature monitoring devices

Where the accuracy of temperature measurement has a direct effect on the result of an analysis, the temperature measuring devices used in incubators and autoclaves shall be of the appropriate quality to achieve the specifications in the test methods. The graduation of the device shall be appropriate for the required accuracy. Traceability of measurement of the temperature measurement device has to be established and overall uncertainty of measurement shall be estimated and appropriate for the measurement.

5.6 Biohazard hoods or laminar flow cabinets

Laboratories shall establish a program to check the rate of airflow and particle count in the hood/cabinet. Criteria shall be defined and records of checks shall be maintained. The hood or cabinet should be maintained and serviced in accordance with the manufacturer's recommendations. Such services include monitoring the use of UV lamps and HEPA filters and their regular replacement.

5.7 Media preparation

5.7.1 The laboratory must maintain the procedure for media preparation. Records must be kept of the details of preparation. All media produced in-house or purchased from manufacturers must be checked for performance. Quality control tests using known positive and negative control strains should be included on each new batch of media. Records of performance testing must be maintained and be traceable.

5.7.2 Preparation, storage and quality control of media must be performed in accordance with the documented method from suitable manuals. Modifications from the standard method must be validated.

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

In-house media

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

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

5.7.6 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;
e) Volume of media/solutions made;
f) Media ingredients, manufacturer, manufacturer's batch number and quantity of each component;
g) Initial pH (pre-sterilisation);

h) Final pH (post-sterilisation);
i) Method of sterilization, including time and temperature as appropriate;
j) Volume dispensed for diluent or when the volume is critical for other reasons.

5.7.7 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 performance testing must be traceable to batch preparation records.

5.7.8 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 purchased from manufacturers

5.7.9 The laboratory shall obtain a customer report from the manufacturer with a comprehensive quality control report for each batch of media. The report 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);
f) shelf life and expiry date.

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

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

5.7.12 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.

6. Examination procedures

6.1. Validation of methods

The laboratory shall perform and record the performance characteristics of the commercial test systems (kits) by using appropriate reference control strains or according to manufacturer's recommendation. The laboratory shall pay attention to the limitations and precautions, and follow the exact procedural steps specified in the package insert of the kits.

6.2. Tests for referral

The laboratory shall send isolates to other accredited referral laboratories for identification, if identification cannot be completed in the laboratory. The laboratory shall have a written procedure for referral tests. The laboratory shall keep records of all tests for referral and shall state the referral laboratory in the formal report.

7. Assuring the quality of test results

7.1 The laboratory shall have procedures for internal quality control that verify that the intended quality of results is achieved.

7.2 Appropriate controls should be performed and recorded using reference strains (e.g. NCTC, ATCC) of appropriate range. The stock of organisms must be maintained under appropriate long-term storage conditions. Working cultures can be sub-cultured a limited number of times, after which organisms from the stock must be obtained.

7.3 A full history must be retained of each quality control organism held. These organisms would be used to perform quality control in the areas of:

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

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 should be applied to assure the reliability of results.

7.5 The laboratory shall participate in organized inter-laboratory comparisons, such as external quality assessment schemes. External quality assessment program should, as far as possible, provide clinically relevant challenges

that mimic patient samples and that check the entire examination process including pre- and post-examination procedures.

7.5.1 The materials to be tested should:

a) represent patient samples;
b) span the concentrations of clinically important ranges for serology and anti-microbial agents assays;
c) be transported and stored without significant deterioration in assay values, in numbers of viable bacteria and not be bacterially contaminated;
d) be packaged for transport against damage;
e) be labeled unambiguously;
f) include clear, concise and unambiguous instructions.

7.5.2 General programs should cover the areas of

a) Direct microscopic examinations;
b) Culture and identification tests;
c) Antimicrobial susceptibility tests;
d) Antimicrobial drug assays;
e) Serology tests;
f) Non-culture methods for detection of pathogens.

7.6 Reference cultures

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

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

7.6.3 Procedures for preparation and verification of working stocks shall be documented. Desired characteristics of the strains shall be verified by serological, biochemical and/or morphological tests.

8. Reporting of results

8.1 The following is a tentative list of tests that shall have clinical interpretation by clinical microbiologist:

Virology:

- HIV: PCR, viral load, antiviral resistance typing;

- HCV: PCR, viral load
- HBV: viral load
- Herpes simplex: PCR, serology
- SARS coronavirus: PCR, serology

Bacteriology, Parasitology and Mycology:

- CSF for all microbiological investigations
- Bactericidal and fungicidal activity of body fluids
- MIC, MBC or MFC determination for bacteria and fungal isolates
- Sterile body fluid and tissue for parasitological investigations
- Blood for antibiotic assay

8.2 For the following tests, in addition to appropriate testing strategy with mandatory confirmatory testing, positive results should be accompanied by the statement "*Interpretation by qualified pathologist is recommended*":

Positive results for the following virology testings:

- HIV antibody
- CMV in pregnant women
- Rubella in pregnant women
- Toxoplasma in pregnant women
- Parvovirus in pregnant women
- Dengue

Positive results for the following microbiology testings:

- Blood culture
- Sterile body fluids

Isolation of the following organisms:

- Unusual isolates of uncertain clinical significance
- Multiple drug resistant isolates of uncertain clinical significance

HKAS Executive
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