ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes MED 002

Specific Criteria for Microbiology Section

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1 Introduction & Scope

1.1 This document describes the specific requirements for clinical microbiology laboratory to be accredited.

1.2 The document shall be read in conjunction with ISO 15189 Medical laboratories – Requirements for quality and competence', SAC-SINGLAS documents, Proficiency Testing Technical Note 001, and other MEDICAL Series Technical Notes published by SAC-SINGLAS.

1.3 Microbiology includes bacteriology, mycobacteriology, mycology, parasitology, virology and serology. The tests may be performed in subspecialty laboratories, in general microbiology laboratories, or as part of a general or core laboratory. Laboratories shall be accredited according to their scope of tests.

2 Facilities and Environmental Conditions

2.1 Highly hazardous (RG3) organisms and agents of bioterrorism

a) There shall be written procedures for staff handling microbiological cultures to ensure that they recognize potential risk groups 3 (RG3) and agents of bioterrorism, and take further action to ensure safety of personnel and correct identification of the pathogen. Provisions for the safe packaging and transport to a reference laboratory for definitive identification (if necessary) shall also be made.

b) There shall be procedures for handling suspected RG3 agent and other agents with special hazard of serious laboratory-acquired infection suspected e.g. *Burkholderia pseudomallei, Neisseria meningitidis, Brucella spp., Bacillus anthracis (anthrax), Clostridium botulinum, Francisella tularensis, Yersinia pestis* and variola major. A risk management plan for suspected RG3 agents should be available.

c) The procedures pertaining to the recognition and safe handling of agents of bioterrorism are incorporated as part of an institution-wide plan to prepare and respond to a bioterrorism event. The laboratory is recognized in the institution's bioterrorism response plan and the role of the laboratory is outlined in the plan.

d) Procedures must also cover the safe handling and processing of samples that are suspected to contain highly infectious emerging pathogens. These agents may be of unconfirmed transmissibility and pathogenicity. Guidance from the local public health authority should be sought in drawing up these procedures.

2.2 Mycobacteriology

2.2.1 The laboratory shall be assessed according to the types of tests offered: acid-fast smear, molecular diagnosis and mycobacterial culture and identification. A risk assessment should be done and safe work practices, accommodation and environment provided to minimize risk of laboratory-acquired infection This includes work practices and use of facilities at appropriate biocontainment level.

3 Equipment

3.1 Centrifuge: Sealed buckets shall be used in centrifuges when infectious organisms are present or are likely to be present. Where infection may be acquired by aerosolisation, the bucket shall be unloaded in a biological safety after waiting for a suitable time before opening the sealed buckets.

3.2 Autoclave: All persons using the autoclave should have been trained and demonstrate competence in its operation. Face shields and protective aprons should be used for unloading liquids. Heat-proof gloves should be available for unloading the autoclave. There should be written procedures to verify autoclave effectiveness while handling RG3 agents based on risk assessment.

3.3 Campylobacter incubation conditions are checked using QC organisms or other appropriate methods.

3.4 A calibrated ocular micrometer is required for the measurement of eggs, cysts and larva.

3.5 <u>Matrix-Assisted Laser Desorption Ionization Time-Of-Flight (MALDI-TOF) Mass Spectrometry</u>

a) There are written procedures for the operation and calibration of the mass spectrometer. The laboratory should carefully follow the manufacturer's instructions for processing isolates and culture, including extraction methods and the consumables used. Any modifications or alternations from manufacturer's instructions should be validated and documented.

b) Acceptable tolerance limits for calibration parameters must be defined. A calibration control is run each day of patient testing, with each change in target plate, or according to manufacturer's recommendations and these records are maintained.

c) Appropriate control organisms or calibrators are tested on each day of patient testing. Appropriate controls would include at least one bacterium, with a representative yeast and mycobacterium also being run if these organisms are being tested for that day/routinely.

d) Organisms or calibrator(s) required by the manufacturer must be used. In the absence of manufacturer recommendations, choice of control organisms is at the Laboratory Director's discretion.

e) Control organisms must be subjected to the same testing conditions throughout the testing procedure as patient specimens. An extraction control should be included if any of the organisms being tested are run with extraction.

f) In formats of testing where a target is reused, a blank control needs to be run after each cleansing to assess the cleanliness of the target (demonstrating a lack of peaks prior to testing).

g) Reagents and solvents are of appropriate grade. Only the manufacturer's specified grade of solvents are to be used for this procedure. This may be HPLC-grade or other reagent grades as indicated.

h) Consumables appropriate to the instrument and assay are required. Consumables utilized may be specified by the manufacturer. Deviation from the manufacturer's recommendation must be validated.

Verification / Validation of MALDI-TOF:

- For identification of isolates, in-house verification is required with a minimum of 200 representative bacterial isolates and 50 fungus/yeast isolates. Whenever possible, these isolates should include the most common species isolated from different sources in the laboratory.
- If different extraction methods are used for different scenario in the laboratory, validation should be performed by including at least 30 isolates for each extraction method as part of the total numbers of representative isolates that required.
- For bacterial identification directly from blood culture, at least 100 positive cultures should be included in the validation covering at least 10 of the major bacterial species commonly identified in blood culture in the laboratory. For validation of fungus/yeast identification from blood culture, minimum of 50 positive blood cultures should be included, which should cover minimum 5 of the major species commonly identified in blood cultures in the laboratory. In addition, minimum 5 negative blood culture specimens should be tested.
- Inter-assay reproducibility should be recorded by testing at least 3 clinical isolates, clinical sample or spiked clinical samples for at least 3 common species in triplicates on three different days.
- The validation should also include tolerance study and carry-over and cross contamination study to define the min and max quantity of colonies of the common species, plating plan and cleaning protocol.
- There should be written detailed protocols in the laboratory to define the steps and relevant quality control measures. It should include, but not limited to, the following:
  - Culture media
  - Sample preparation
  - Colony age
  - Sample stability on target plate
  - Reagent and consumable QC and reagent shelf life
  - Daily QC and calibration
  - Negative controls, including blank and extraction blank, for each run
  - Testing algorithm
  - Reporting cut-off and algorithm

3.6 <u>High Performance Liquid Chromatography (HPLC) for Mycobacterial Identification</u>

a) There are written procedures for operation and calibration of the HPLC instrument.
b) Appropriate calibrators or standards are run with each analytic batch.
c) Appropriate controls (positive and negative) are extracted and run through the entire procedure.
d) External chromatogram pattern controls are available.
e) New columns are verified for performance before use.

f) The performance of the column and detector are monitored on each day of use.
g) There is a written procedure for the detection and evaluation of potential carryover.
h) The laboratory policies define which growth media may be used for organisms to be analyzed by HPLC.
i) There is a procedure for (at least annually) verifying calibration of the peak-naming table, if used.
j) The HPLC method has been validated using known strains of bacteria, including strains expected to be encountered in routine clinical use.
k) There is a policy for review of HPLC results in conjunction with other laboratory data prior to reporting results.
l) There are procedures to check the purity of cultures used as a source for HPLC analysis.
m) Reagents and solvents are of appropriate grade, and solvent purity is assessed when needed.

4 Reagents and Consumables

4.1 Reagents / Stains / Media / Kits / Antimicrobials

4.1.1 All reagents, stains, media, kits and antimicrobials should be stored as recommended by the manufacturers and used within their indicated expiry dates.

4.1.2 They should be labelled, as applicable and appropriate, with the content and quantity, concentration or titre date received or prepared, date placed in service, storage requirements and expiry date. If there are multiple components of a reagent kit, the laboratory must use components of reagent kits only with other kits that are of the same lot number unless otherwise specified by the manufacturer.

4.1.3 New reagent lots shall be checked against old reagent lots or with suitable reference material before being placed in service.

4.1.4 The use of commercial reagents and controls shall comply with manufacturer's instructions, or the requirements of this standard, whichever is the more stringent.

4.1.5 The laboratory shall have documented records of quality control results of test procedures, reagents, stains, media, kits, antimicrobials, etc. These should be checked prior to being placed in service and subsequently be monitored at least monthly for performance or limits of acceptability. All relevant QC results must be checked prior to reporting patient results. Corrective actions should be documented when such results are unacceptable.

4.1.6 All stains shall be checked with appropriate positive and negative controls for each new batch of preparation.

For stains like Gomori's methenamine silver, the slide itself serves as the negative control.

4.2 Media

4.2.1 The laboratory shall ensure that all media prepared in-house are sterile, able to support growth and are appropriately reactive biochemically. This will require that the laboratory maintains stock reference organisms and tests the media before or concurrent with use.

4.2.2 For purchased media, the manufacturer shall document to the user that their quality control activities meet the criteria described as above, 8.8.1 The laboratory should test media that are known to show significant variability in performance e.g. chocolate agar (for *H. influenzae*), campylobacter agar, Thayer-Martin medium

4.2.3 The user shall visually examine each batch of media for breakage, contamination, appearance, or evidence of freezing or overheating.

4.2.4 All the quality control procedures that are carried out in the laboratory shall be documented.

4.2.5 A record should be kept of all lot numbers and expiration dates of the media received for the past two years.

4.2.6 Reference cultures and sera should be maintained for the proper control of stains, media, reagents, antimicrobial susceptibility tests and serological tests.

4.3 Virology

4.3.1 Sterility of all culture media shall be ensured following the addition of ingredients post sterilization.

4.3.2 All cell cultures shall be tested for mycoplasma and endogenous viral contamination immediately upon receipt, after recovery from the deep freezer and at regular intervals as the cultures are maintained in the laboratory.

4.3.3 Animal sera for use in culture media shall be tested to exclude toxicity to cells.

4.3.4 Media and diluents shall be checked for sterility and pH.

5 Pre-examination Procedures

5.1 There must be procedures/policies for appropriate collection, transport and rejection of samples including how to deal with samples submitted after office hours. Requests for analysis are to include source of specimen, test or tests requested and, when appropriate, type of infection and/or organism expected.

5.2 Clients should be instructed to send microbiological specimens in appropriate leak-proof containment. Specimens sent to a referral laboratory should also be packaged and labelled with proper containment. The laboratory shall evaluate new specimen containers to ensure they are leak-proof and meet operational requirements. Sample identification should be traceable through all phases of analysis, such as specimen receipt, inoculation and plating.

5.3 There are written instructions for microbiology specimen collection and handling that include the following:

a) Method for proper collection of culture specimens from different sources
b) Proper labelling of culture specimens
c) Use of appropriate transport media when necessary
d) Policies for safe handling of specimens (tightly sealed containers, no external spillage)
e) Need for prompt delivery of specimens to ensure minimum delay and processing (e.g. CSF, wound cultures, anaerobes)
f) Method for preservation of specimens if processing is delayed (e.g. refrigeration of urines)
g) The number and/or timing of collection of stool specimens submitted for routine enteric pathogen and parasitology testing.

5.4 Specimens for viral culture should be collected appropriately (in suitable transport medium) and transported to the laboratory without delay.

5.5 The laboratory shall have written procedures for the handling of specimens that will be tested using molecular amplification methods. Special precautions must be taken to avoid sample cross-contamination that may not affect culture-based methods but may lead to false positive results when tested using molecular amplification methods.

6 Examination Procedures

6.1 General

6.1.1 The microbiology laboratory at least annually assesses morphologic observations among personnel performing Gram, trichrome and other organism stains, to ensure consistency.

6.1.2 The laboratory has a defined protocol to periodically incorporate taxonomic changes into its organism database. This is especially important where the change in taxonomy may potentially affect the choice of appropriate antimicrobials to report and/or the interpretative breakpoints to use. Up to date taxonomic information may be obtained from any reliable and authoritative source at the discretion of the director.

6.2 Bacteriology

6.2.1 Every laboratory reporting bacterial culture results should have the ability to perform Gram stains as part of its bacterial identification process.

6.2.2 Suitable control strains, for identification and antibiotic susceptibility testing, should be traceable to type collections and the passage history documented. There should be procedures for maintenance of the control strains to preserve their bioreactivity, phenotypic characteristics and integrity, which should include when to change aliquots or re-characterize the controls.

6.2.3 Respiratory cultures: All sputa shall be assessed for adequacy of specimen (i.e. whether good quality sputum was obtained). Laboratories handling throat swabs should have facilities to identify *C. diphtheriae* in-house or via a referral laboratory, when that is requested by the physician.

6.2.4 Urine cultures: The laboratory should perform and report quantitative cultures and use media and procedures that permit isolation of clinically-relevant Gram positive and negative bacteria. Specimens should be processed in a timely manner so that bacterial overgrowth does not occur in the urine. Where delay in plating is expected, provision should be made to prevent overgrowth: viz. storing at 4 deg C, or by adding preservative to the container, and or using dip slide cultures. For dip slide cultures, there must be evidence that the estimated counts correlate with actual colony counts.

6.2.5 Urethral and Cervical cultures: Transport and culture conditions should be satisfactory for the isolation of *N.gonorrhoeae.*

a) Group B Streptococcus prenatal screening for pregnant women should include an enrichment broth procedure.
b) When Gram stains are performed to make the laboratory diagnosis of bacterial vaginosis, the smear is scored and interpreted according to published criteria.

6.2.6 Stool cultures: The procedure should permit isolation and identification of enteric pathogens in patients with diarrhoea (using appropriate selective media and enrichment media). The range of pathogens detected by the culture should be indicated to lab users and stated in the final report. Procedures should be in place to cater to requests for gastroenteritis agents not routinely detected. The policy for reporting susceptibility test results should not lead to inappropriate antibiotic use. Testing for toxigenic *Clostridium difficile* should be offered where appropriate. There are written policies for the number and/or timing of collection of stool specimens submitted for routine bacterial testing.

6.2.7 CSF and other sterile body fluids: If only plated media are used for sterile body fluids, fluid is centrifuged and the sediment used to inoculate media unless the entire specimen is plated. Cerebrospinal fluid specimens should be processed and cultured immediately on receipt. A Gram stain should be performed routinely on sediments and results reported directly to the physician. There should be procedures to check and resolve discrepancies between Gram stain and culture. Media and incubation conditions must permit recovery of fastidious bacteria (e.g. *Neisseria meningitidis*, *H. influenzae*) and cultures should be performed on both smear positive and negative CSF specimens. If bacterial antigen-detection methods are used, back-up cultures are performed on both positive and negative CSF specimens.

6.2.8 Blood cultures: Sterile technique for drawing and handling blood cultures should be defined and made available to those drawing blood cultures. Blood culture contamination rates and adequacy of fill volumes should be regularly monitored and feedback should be given, wherever indicated, to those drawing blood cultures. The blood culture system shall be designed to recover both aerobic and anaerobic organisms. Sub-cultures and/or stains need not be done on blood cultures performed by automated methods if the bottles are monitored as recommended by the vendors. There shall be a policy for immediate notification of positive blood results.

6.2.9 Wound cultures: When indicated, Gram stain of direct smears should be examined and reported. Both aerobic and anaerobic cultures should be performed on specimens from appropriate sites.

6.2.10 Anaerobic cultures: Specimens and cultures should be placed in an anaerobic atmosphere as soon as practicable. There should be a process to ensure that plates are not left exposed to room air for too long.

6.2.11 Direct antigen testing: For direct antigen tests on patient specimens, positive and negative controls are tested and recorded at least daily, or more frequently if specified in the manufacturer's instructions or laboratory procedure. Examples include, but are not limited to: Group A Streptococcus antigen, *C. difficile* toxin, fecal lactoferrin and immunochemical occult blood tests. For panels or batteries, controls must be employed for each antigen sought in patient specimens. External control materials should be used wherever available; if such controls are not available and an internal quality control process (e.g. electronic/procedural/built-in) is used instead, justification must be provided in the quality control plan drawn up by the laboratory director.

6.2.12 A negative direct antigen test for Group A Streptococcus is always confirmed by culture or other method.

6.3 Mycobacteriology

6.3.1 Rapid and reliable methods shall be used for microscopic examination, isolation, identification and antimycobacterial susceptibility testing of *Mycobacterium tuberculosis* complex.

a) Where clinically indicated, results of acid-fast stains are reported within 24 hours of specimen receipt by the testing laboratory.
b) Fluorochrome staining is performed on mycobacterial smears prepared from primary respiratory specimens, either in the laboratory or by the reference laboratory.

6.3.2 There is a written policy defining those specimens (e.g. sputum) requiring concentration before AFB smear examination and culture.

Molecular tests for M. tuberculosis should be used for the intended purpose, and appropriate evaluation done or comment given where it is used outside manufacturer’s indication.

6.3.3 Specimens (other than blood) are routinely inoculated on media that support optimal growth of the majority of clinically relevant mycobacterial species. The use of two types of media (including one liquid medium) is recommended.

6.3.4 Mycobacterial cultures are maintained at 35 to 37°C. Exceptions to this include specimens obtained from skin or soft tissue suspected to contain *M. marinum* (incubate at 30 to 32°C) or *M. xenopi* (incubate at 42°C). These specimens should be held at 35 to 37°C in addition to the lower or higher temperature.

6.3.5 Nucleic acid probes, chromatography, the NAP test, or other rapid method (e.g. nucleic acid amplification or sequencing) is employed for identification of mycobacterial isolates.

6.3.6 Temperature growth requirements and photo-reactivity studies shall be done when appropriate if complete identification of mycobacterial organisms cultured is performed by conventional methods. Alternative methods for species identification e.g. HPLC (see HPLC subsection below), MALDI-TOF, DNA sequencing, should have been verified for accuracy.

6.3.7 Differential biochemical tests are appropriate for the extent and manner of mycobacterial identification.

6.3.8 Susceptibility test results for *M. tuberculosis* are available in a timely manner. Ideally, results should be available within 28 days of receipt, but this is a goal, not a requirement.

6.3.9 Identification

6.3.9.1 A known strain of *M. tuberculosis* should be run whenever identification of *M. tuberculosis* complex is performed.

6.3.9.2 Biochemical tests used for identification should be checked each day of use with appropriate positive controls.

a) Nucleic acid probes or nucleic acid amplification technique for mycobacterial identification should be accompanied by appropriate positive and negative controls on each day of use.

6.3.10 Susceptibility Testing

A control strain of *M. tuberculosis*, which is sensitive to all antimycobacterial agents, should be included with each run.

6.4 Antimicrobial Susceptibility Testing

6.4.1 There shall be written policies to ensure that only antimicrobial agents appropriate for the organism and body site are routinely reported.

a) Reported antibiotics should be clinically relevant and the policy should include suppressing the results of selected antibiotics to encourage prudent antibiotic use and testing supplemental agents when needed on isolates resistant to routinely tested agents.

b) If the laboratory is unable to perform susceptibility testing on-site, there is a mechanism to refer clinically significant isolates for which susceptibility testing is deemed necessary (e.g. isolates obtained from blood or other sterile sites).

6.4.2 Only single isolates or pure cultures shall be used for the final performance of antibiotic susceptibility testing. Each new lot of antibiotic discs should be checked for activity before being placed in service and at least weekly thereafter with reference cultures.

6.4.3 Inoculum density should be controlled using a turbidity standard or other acceptable method and tolerance limits for potency of antimicrobials (criteria for out of control) should be established.

6.4.4 Written criteria shall be available for interpretation of the end point or zone size.

6.4.5 For antimicrobial susceptibility testing by either disk or gradient diffusion strips or broth dilution (MIC) methods, quality control organisms are tested with each new lot number or shipment of antimicrobials or media before or concurrent with initial use, and each day the test is performed thereafter.

6.4.6 For hospital-based microbiology laboratories, cumulative antimicrobial susceptibility test data are maintained and reported to the medical staff at least yearly.

6.4.7 There is a written policy to address unusual or inconsistent antimicrobial testing results. The policy must cover recognition of unusual phenotypes and the relevant actions to take, such as repeating identification via the same or an alternative method, repeating susceptibility testing via the same or an alternative method, and/or sending the isolate for further testing by a reference laboratory.

6.5 Serology for Infectious Diseases

6.5.1 In addition to the general requirements described in the “Diagnostic Immunology and Serology” section under MED 002 General Chemistry, the following points apply to infectious disease serology.

6.5.2 Red cell suspensions that are used for quantitative serologic procedures are standardized (photometrically or with some other equivalent procedure).

6.5.3 Criteria for degrees of agglutination and lysis are defined for quantitative serologic procedures.

6.5.4 Reactive and nonreactive controls are processed in serologic reactions for detection of antibodies or antigens.

6.5.5 There are written policies for the acceptance and rejection of samples for CMV antigenemia testing.

6.5.6 The method used should be appropriate to the clinical indication. Relevant interpretive comments should be inserted, and request for a follow up specimen made where necessary.

6.5.7 Worksheets and/or records indicate actual titers, when known, of reagents and control sera.

6.6 Mycology

6.6.1 Technical procedures for isolation and identification of fungi directly from specimens and cultures shall be available.

6.6.2 These include the use of microscopy, stains, selective media, biochemical tests, serological tests and nucleic acid tests.

6.6.3 If cryptococcal antigen-detection methods are used on CSF, back-up cultures are performed on positive CSF specimens submitted for diagnosis.

6.6.4 Suitable selective media are used for the growth and isolation of dermatophytes and/or systemic fungi.

6.6.5 Media with antimicrobial agents are used to suppress the growth of contaminants.

6.6.6 Incubation temperatures for the growth and isolation of dermatophytes and systemic fungi are defined and followed under culture conditions.

6.6.7 If cultures are incubated at room temperatures, actual ambient temperature (22 to 26°C) is recorded daily to determine if proper growth conditions are being maintained.

6.6.8 Slide cultures are used as part of the identification protocol where appropriate.

6.6.9 The identification of dimorphic fungal isolates is confirmed by exo-antigen, molecular, yeast-mould conversion or tissue phase detection tests.

6.6.10 If plate culture media is used in mycology, appropriate safety precautions are taken (such as taping lid to plate on both sides when not in use or other appropriate measures) to prevent the accidental opening of a plate.

6.6.11 When working with a colony exhibiting mycelial growth, all transfers are performed within a biologic safety cabinet, and the use of slide culture techniques is limited, whenever possible, to work with low virulence organisms.

6.6.12 When preparing teased preparations or "scotch" tape preps, mycelia are always submerged in liquid medium (such as lactophenol cotton blue).

6.7 Parasitology

6.7.1 Reference materials, such as permanent mounts, photomicrographs, CLSI/NCCLS documents M15-A and M28-A2, or printed atlases should be available at the work bench to assist with identifications.

6.7.2 A concentration method and a permanent mount should be used to examine stools for optimal detection of parasites. The method should fit the purpose according to clinical indication. If a wet mount is performed, the limitation should be communicated in the report.

6.7.3 Both thick and thin blood films should be used in the examination for malarial parasites in suspected cases of malaria.

6.7.4 Stained films should be washed with a buffer of known pH (6.8 - 7.2). Thick film examination should include at least 100 oil immersion fields (approximately 10-15 mins).

6.7.5 The physician shall be informed immediately of a blood film positive for malaria. Where infection by P. *knowlesi* is suspected, there should be a process for identification that does not depend on microscopic morphology alone.

6.8 Virology

6.8.1 This section applies to any laboratory providing facilities for the diagnosis of viral infections, which include cell culture, antigen detection, serology or molecular diagnosis. (Refer to “MOLECULAR PATHOLOGY” section).

6.8.2 Appropriate cell lines should be available to support the services offered by the laboratory.

6.8.3 Tube monolayer cultures should be incubated for a sufficient time to recover the relevant viruses. Tube cultures should be checked for cytopathic effect every other day for the first two weeks, unless other additional diagnostic methods are used (e.g. shell vials), in which case the observation schedule may be modified as appropriate.

6.8.4 There shall be documentation of cell types, source, passages and media used in their propagation.

6.8.5 Worksheets or records shall indicate titres, when known, of reagents and control sera.

7 Ensuring the Validity of Examination Results

7.1 Results of control tests shall be reviewed before reporting patient results.

7.2 There shall be records of at least monthly review of quality control results by the head or designee.

If the laboratory performs test procedures for which control materials are not commercially available, there are written procedures for an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be recorded.

7.3 The laboratory shall perform and record results with positive and negative controls at specified periodic. Recording of qualitative observations e.g. colour change, should be unambiguous with respect to the expected result.

7.4 Serological (antibody and antigen) and nucleic acid tests should be run with known positive and negative control organisms or sera with each new batch of preparation and when appropriate.

7.5 There shall be known positive and negative controls with each run of test specimens for all direct antigen tests on patient specimens.

7.6 Parasitology

7.6.1 Quality control checks of the specific gravity of concentrating solution (e.g. Zinc sulphate) should be done periodically.

7.6.2 All permanent stains shall be checked, together with controls, for intended staining results at least monthly, or with each test if test is performed less frequently. Special stains used to detect specific organisms (e.g. acid-fast, fluorescent stains) shall be checked with appropriate control organisms each time the stain is used.

7.7 External quality assurance (proficiency testing) specimens shall be tested in the same manner and by the same personnel as patient specimens. Organisms in proficiency testing specimens are identified to the same level as those from patient samples. Identifications in proficiency testing submissions should not be less specific than that in routine patient testing.

If any susceptibility testing is performed on-site, the laboratory participates in a proficiency testing program for the related subspecialty (e.g. bacteriology, mycology).

7.8 Corrective actions taken when errors or unacceptable results are detected or when tolerance limits are exceeded shall be documented. Any impact on test methods or reporting procedure should be addressed.

8 Post-examination Procedures

8.1 Sample Storage

There should be suitable facilities for storage of samples that may need re-testing. There should be a policy on the duration of storage, to allow retrieval of samples or significant isolates for re-testing or further testing. This includes a policy on retention of serum when paired titres are expected to be performed in the future.

9 Reporting of Results

9.1 Reports with abnormal results shall be reviewed by senior personnel and evaluated for conformity with the clinical information available

9.2 Reports should be available in a timely manner, and preliminary reports issued if specimens take a longer time to work up. Written procedures define when preliminary results are issued.

9.3 Results of control tests shall be reviewed before reporting patient results. Tests are not to be released if controls are unacceptable. Unacceptable control results shall be reported to the supervisor and corrective action documented.

9.4 Qualified personnel shall be available to provide consultation regarding the interpretation of results.