HOKLAS Supplementary Criteria No. 30

"Medical Testing" Test Category – Molecular Pathology

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 molecular pathology examinations in 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 Nucleic Acid Amplification Testing (NAT)
- 2.1.1 Polymerase Chain Reaction (PCR)
- 2.1.2 Ligase Chain Reaction (LCR)
- 2.1.3 Strand Displacement Amplification (SDA)
- 2.1.4 Branch DNA technology (bDNA)
- 2.1.5 Quantitative PCR (qPCR)

2.2 Hybridization assay
- 2.2.1 Dot blot hybridization
- 2.2.2 Southern blot hybridization
- 2.2.3 In situ hybridization (ISH)

2.2.4 Fluorescence In situ hybridization (FISH)

2.2.5 Comparative genomic hybridization (CGH)

2.3 Electrophoresis

2.3.1 Single Strand Conformation Polymorphism (SSCP)

2.3.2 Restriction Fragment Length Polymorphism (RFLP)

2.3.3 DNA sequencing

3 Accommodation and environmental conditions

3.1 For nucleic acid amplification testing (NAT), areas for preparation of reagents, sample preparation and post-amplification analysis shall be located in separate rooms (especially for nucleic acid amplification set-up), distinct separation of these activities is to be maintained and appropriate procedures and control should be adopted to prevent cross-contamination.

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

a) sample reception;
b) sample preparation and extraction;
c) preparation of reagents and dispensing of master mix; and
d) amplification and product detection.

The movement of nucleic acid samples or specimens should as far as possible be unidirectional i.e. from pre-amplification to post-amplification areas.

3.2 For nucleic acid amplification testing (NAT), nucleic acid samples should be kept in designated refrigerated compartments after sample preparation. They should not be kept at areas where activity such as gel electrophoresis or PCR work is conducted.

4 Laboratory equipment

4.1 There shall be no sharing of general instruments (micropipettes, vortex mixers, heating block and micro-centrifuges) among designated areas as listed in 3.1 Aerosol resistant pipette tips or positive displacement pipettes are strongly recommended.

5 Reporting of results

5.1 When the presence of inhibitors is detected in NAT, an indication of the reporting limits should be given in test reports.

5.2 The final report shall be reviewed and signed by approved personnel with appropriate qualification, training and experience. Normally one-year training in molecular pathology is recommended. Medical testing requiring clinical interpretation should normally be signed by a qualified pathologist with appropriate training and experience.

HKAS Executive
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