

HOKLAS Supplementary Criteria No. 29

“Medical Testing” Test Category – Immunology

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 immunology 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 Immunochemistry – this area has substantial overlap with chemical pathology
- 2.2 Autoantibody detection
- 2.3 Immune cell function and enumeration

3 Personnel

- 3.1 Medical personnel

3.1.1 A qualified pathologist in immunology shall be a pathologist who has obtained postgraduate qualification in immunology such as Fellowship of Hong Kong College of Pathologists or equivalent as advised by the College.

3.1.2 Where consultations and clinical interpretation of immunology test results are required, they shall be provided by a qualified pathologist in immunology.

3.1.3 A qualified pathologist in immunology shall fulfill the 3-year cycle of CME/CPD requirement of the Hong Kong Academy of Medicine or Hong Kong Medical Council or equivalent bodies.

3.2 Technical personnel

3.2.1 Technical personnel who run a test independently shall be registered under Part I of the Medical Laboratory Technologists Board (or with equivalent qualifications and exempted by the Supplementary Medical Professions Ordinance Cap. 359), and with at least 1-year post-Part 1 registration medical testing experience, 6 months of which shall be in immunology. For tests requiring interpretative skill (e.g. IIF, electrophoresis), 1-year training in the specific area is also needed.

4 Post-examination procedures

4.1 Electrophoresis films and copies of reports should be kept for at least 30 years.

5 Reporting of results

5.1 For all immune cell functions, results of normal control shall be reported in parallel with patient results

5.2 Copies of reports of immune cell functions shall be kept for at least 30 years.

HKAS Executive
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