HOKLAS Supplementary Criteria No. 29

'Medical Testing' Test Category – Immunology

0 Introduction

(a) This document is an application document for the requirements of HKAS 002, as well as either (1) HOKLAS 015 (5th edition), or (2) ISO 15189:2022 and HKAS PD002, accrediting examinations in immunology 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, either (1) HOKLAS 015 (5th edition), or (2) ISO 15189:2022 and HKAS PD002, as well as HOKLAS SC-33 and relevant HOKLAS supplementary criteria.

1 Scope

HKAS provides accreditation under HOKLAS for the following areas:

(a) Immunochemistry – this area has substantial overlapping with chemical pathology

(b) Autoantibody detection

(c) Immune cell function and enumeration

(d) Allergy tests (e.g. allergen-specific IgE)

(e) Molecular tests for immunological diseases

(i) The scope of immunological diseases covers the following:
  (I) Primary immunodeficiencies
  (II) Autoimmune diseases
  (III) Allergic diseases
  (IV) Malignancies of the immune system (overlapped with Haematology)

Note: For molecular testing in immunology, laboratories shall follow HOKLAS SC-30 for general requirements of molecular genetics.
For cross-discipline tests, laboratories could seek their accreditation under the discipline of the laboratory where they are performed. For example, immunophenotyping and lymphocyte subsets may be listed under 'Immune cell

function and enumeration' of Immunology or 'Special haematology' of Haematology.

2 Normative references

(No additional explanation)

3 Terms and definitions

(No additional explanation)

4 General requirements

(No additional explanation)

5 Structural and governance requirements

(No additional explanation)

6 Resources requirements

6.2 Personnel

6.2.2 Competence requirements

(a) Medical personnel

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

(ii) Where consultations and clinical interpretation of immunology test results are required, they shall be provided by a qualified pathologist in immunology (or qualified pathologist as advised by the HKCPath).

(iii) A qualified pathologist in immunology 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.

(b) Technical personnel

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 I registration medical testing experience, 6 months of which shall be in immunology.

7 Process requirements

7.4 Post-examination processes

7.4.1 Reporting of results

(a) For all immune cell function tests, results of normal control shall be reported in parallel with patient results.

(b) Interpretation of molecular tests for immunological disorders shall be correlated with clinical findings and results of other immune function tests.

(c) All immune cell function tests and enumeration shall be reported by a qualified pathologist in immunology (or qualified pathologist as advised by the HKCPath) with the following being exempted:

(i) Single T Lymphocyte enumeration (e.g. CD3+, CD4+, CD8+ and CD34)
(ii) T Lymphocyte ratio (e.g. CD4+/CD8+ ratio)

(d) All allergy tests shall be reported by a qualified pathologist in immunology (or qualified pathologist as advised by the HKCPath) with the following being exempted:

(i) Test for specific IgE to single allergen (whole extract)
(ii) Total IgE assay

(e) For any test results of significant clinical implication, input from a

qualified pathologist in immunology (or qualified pathologist as advised by the HKCPath) is recommended.

7.4.2 Post-examination handling of samples

(a) Electrophoresis films (either as softcopy or hardcopy) and copies of their reports should be kept for at least 30 years.

(b) Copies of reports of immune cell functions shall be kept for at least 30 years.

(c) EDTA blood samples for flow cytometry should be kept at room temperature for 24 hours after examination.

8 Management system requirements

(No additional explanation)

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