HOKLAS Supplementary Criteria No. 28

"Medical Testing" Test Category – Haematology

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 tests and examinations in haematology within the Medical Testing Test Category. This document sets out only those specific requirements which require further elaboration but does not include all the accreditation requirements. This Supplementary Criteria needs to be read in conjunction with HKAS 002 and HOKLAS 015.

1.2 The checklists given in the Annex serve 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

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

2.1.1 General Haematology
2.1.2 Coagulation
2.1.3 Cancer Cytogenetics
2.1.4 Immunohaematology and Blood Bank
2.1.5 Molecular Pathology

3 Personnel

3.1 Where consultations and clinical interpretations of test results are required, they shall be provided by a haematologist.

3.2 A haematologist shall be a pathologist who has obtained postgraduate qualification

in laboratory haematology, such as the Fellowship of Hong Kong College of Pathologists, or equivalent as advised by the College.

3.3 A haematologist 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.

4 Laboratory equipment

4.1 Procedures to assure and verify the proper functioning of equipment shall meet acceptable professional standards, eg

4.1.1 Blood storage device shall have a system to monitor the temperature continuously, and an alarm system to alert abnormal storage condition.

4.1.2 The optical alignment and instrument sensitivity of flow cytometry shall be documented on each day of use, and there shall be procedures to ensure that the laser current is acceptable and constant.

5 Quality and technical records

5.1 Retention time of quality and technical records shall be in accordance with the requirements given in the Annex.

6 Pre-examination procedures

6.1 There shall be established procedures to prevent specimens taking from the wrong patient and to ensure correct labelling of the specimens.

6.2 The laboratory shall define relevant pre-examination procedures including specimen handling and storage conditions to assure stability and suitability for proper testing.

6.3 The laboratory shall have a policy and specification for the maximum interval during which a specimen may be used for the specified test.

6.4 The request forms and specimens submitted for compatibility tests for blood transfusion shall contain at least two unique and independent identifiers of the patient. The identifying information on the request form shall be identical to that on the specimen tube label. There shall be a system to identify the person collecting the specimen for such tests.

7 Post-examination procedures

7.1 Storage of the primary sample and other laboratory samples shall be in accordance with the requirements given in the Annex.

8 Reporting of results

8.1 The tests that shall have clinical interpretation by haematologists include:

8.1.1 Bone marrow examination
8.1.2 Cytochemistry (for diagnosis of haematolymphoid malignancies)
8.1.3 Immunophenotyping (for diagnosis of haematolymphoid malignancies)
8.1.4 Cancer cytogenetics
8.1.5 Investigation of suspected haemolytic transfusion reaction

8.2 The description of test results for cytogenetic study shall follow the International System for Human Cytogenetics Nomenclature.

HKAS Executive
June 2003

Annex I

Retention of Laboratory Records and Materials

The document describes the recommendations for the minimum requirements for the retention of laboratory records and materials. Laboratories may retain records and/or materials for a longer period of time than specified when such is appropriate for patient care, education, quality improvement needs or legal requirements, etc.

	Record/material	**Requirement**
General	Personnel records	Employment + 3 years
	Records of employee signatures, initials, and identification codes	10 years
	Laboratory methods/procedures	While methods current + 3 years
	Maintenance and problem records	Life of machine + 3 years
	External QA records	3 years
	Internal QC records	3 years
	Referring doctor's request	3 years after dispatch of final report. Indefinite for request form which contains clinical information not readily accessible in the patient's notes but used in the interpretation of test result. Where the request form is used to record working notes or as a worksheet, it should be retained as part of the laboratory record.
	Accreditation documents; records of inspections	10 years
Haematology	Copies of reports	3 years
	Reported blood film	1 year if findings significant; 7 days if film normal
	Blood samples/serum/plasma	48 hours, under appropriate storage conditions
	Bone marrow samples	5 days, at 2-8^{o}C storage
	Bone marrow -slides and copies of reports	20 years

	Record/material	Requirement
Blood Banks	Copies of reports	3 years Type-and-screen results: Indefinite
	Blood for pre-transfusion test	EDTA Whole blood: 7 days at 2-8°C. Plasma/Serum: 7 days at 2-8°C; 5 years at -30 °C
	Samples of material examined	7 days post-transfusion, at 2-8°C storage
	Laboratory records of blood donations and/or administration of blood and blood products	20 years
	Blood typing difficulty, clinically significant antibodies, significant unexpected adverse reactions to transfusion and special transfusion requirements	Indefinite
Cytogenetics	Copies of reports	Indefinite
	Patient information/karyotypes	Indefinite
	Slides	2 years after final report, if photographic record kept; 5 years otherwise, unless degeneration evident
	Original specimen and container /wet specimen/tissue	Until report is authorized
	Fixed chromosome preparation (blood, bone marrow)	Abnormal - indefinite Normal - 6 months
	Tissue cultures/cell cultures lines	Cryopreservation, when appropriate - indefinite
	Diagnostic images (digitized or negatives)	Indefinite
Immunophenotyping	Copies of reports and slides	Indefinite
	Blood samples	7 days under appropriate storage condition

N.B.: Indefinite means without limit of time, but not less than 30 years.