HOKLAS Supplementary Criteria No. 28

'Medical Testing' Test Category – Haematology

1. Introduction

1.1 This document is an application document for the requirements of HKAS 002 and HOKLAS 015 accrediting examinations in haematology 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, HOKLAS 015, HOKLAS SC-33 and relevant HOKLAS supplementary criteria.

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

HKAS provides accreditation under HOKLAS for the following areas:

2.1 General Haematology

2.2 Coagulation

2.3 Immunohaematology and Blood Bank

Note: For seeking accreditation of automated complete blood count (CBC), laboratories shall at a minimum include the following tests in the scope of accreditation:

- Haematocrit
- Haemoglobin
- Platelets
- Red blood cells (RBC)
- White blood cells (WBC)
- Mean corpuscular volume (MCV)

For molecular testing in haematology, please refer to HOKLAS SC-30 for molecular genetics; and for cancer cytogenetics, please refer to HOKLAS SC-35 for cytogenomics

For cross-discipline tests, laboratories could seek their accreditation under the discipline of the laboratory where they are performed.

3. Personnel

3.1 Where consultations and clinical interpretations of test results are required, they shall be provided by a qualified haematologist (or qualified pathologist as advised by the Hong Kong College of Pathologists (HKCPath)).

3.2 A qualified haematologist shall be a pathologist who has obtained postgraduate qualification in laboratory haematology, such as the Fellowship of the HKCPath, or equivalent as advised by the College.

3.3 A qualified haematologist 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.

4. Laboratory equipment, reagents, and consumables

4.1 Procedures to assure and verify the proper functioning of equipment (including critical reagents) shall meet acceptable professional standards, e.g.

4.1.1 For blood storage device, the laboratory shall have a system to monitor the storage temperature continuously, and an alarm system to alert laboratory staff of abnormal storage condition.

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

4.1.3 Critical reagents, such as antibodies, reagent cells and other reagent kits, shall be verified before putting into use and verification records shall be kept. Evaluation shall also be performed for in-house reagents if they affect the quality of the tests.

5. Control of records

5.1 Retention time of quality and technical records shall be in accordance with the requirements given in Table 1.

5.2 The laboratory shall retain records of original observations instead of interpreted results. For example, the scoring is expected to be retained for ABO-Rh grouping instead of positive and negative results.

6. Pre-examination processes

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 processes 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 independent identifiers for unique identification 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. Examination processes

7.1 For blood banks, the laboratory shall have procedures for emergency release of blood prior to completion of compatibility testing. The procedures shall include documenting a request for uncrossmatched blood by attending clinicians and collection of a pre-transfusion blood sample from the recipient for subsequent testing.

7.2 If a laboratory acquires a new methodology for any test, an evaluation study shall be carried out before it is put into routine service.

7.2.1 The extent of such evaluation study should commensurate with its intended use. Tests to be considered include within-batch and between-batch precisions, accuracy, linearity, carry over, correlation and bias studies with existing methods, etc.

7.2.2 Biological reference intervals to be used for tests conducted with this new methodology shall be verified, or established as appropriate, and verification records shall be kept. For verification of reference intervals from other sources, please refer to HOKLAS SC-32.

7.2.3 The laboratory shall document the evaluation protocol for new methodologies. Evaluation report including all studies done, test data, results and conclusions drawn shall be available.

7.3 The source of biological reference intervals should be documented. If the original

source is not traceable, the laboratory shall regularly review the continual suitability of the reference intervals for the examinations and maintain records of these evaluations.

7.4 If it is necessary to perform a second manual blood grouping, both the first and second blood groupings should be performed independently on the original sample by two qualified technical staff. The results should be read and recorded separately by two technical staff in such a way that neither staff is aware of the other's result until all the test results have been finalised. When only one qualified technical staff is available to perform the manual blood grouping, the first and second blood grouping shall be performed on the original sample on different occasions and the results shall be read and recorded independently.

8. Ensuring quality of examination results

8.1 All blood banks offering compatibility testing for blood transfusion purposes shall participate in an appropriate external quality assessment programme. This shall involve all staff taking part in the compatibility testing activities.

8.2 There shall be a documented programme to ensure that all technical staff members involved in blood film examination have an opportunity to test external quality assessment programme samples and have their results submitted to the programme provider.

8.3 There shall be a documented daily quality control plan detailing the levels of quality control materials run each day, frequency of performing QC, types of QC materials, and the QC acceptance criteria to be observed by the laboratory staff. As a general guide, at least two levels of QC run daily are expected. The selection of QC levels should be appropriate for clinical decision and patient management. The laboratory shall provide clear and easily understood information for the actions to be taken in case the QC result falls outside the acceptance limit. All actions taken shall be recorded.

8.4 For those examinations performed using more than one analyser, e.g. CBC analyser or coagulator, the laboratory shall have a defined mechanism to ensure comparability of results throughout the reportable ranges. The established procedures of correlation should address both routine comparison and data review at defined intervals. The number of samples to be used and the frequency of run should commensurate with the performance of the equipment. Criteria of acceptance, e.g. maximum allowable percentage of difference, shall be clearly documented. The laboratory shall record and review results from these comparisons using appropriate statistical analysis, e.g. regression analysis and bias estimation. Problems identified shall be acted upon.

8.5 The laboratory shall have guidelines for the determination of measurement uncertainty (MU). For tests that give quantitative results, the laboratory shall determine the MU and document the uncertainty components. Some examples of these tests include complete blood count (automated), prothrombin time (PT), activated partial thromboplastin time (APTT). The measurement uncertainty shall be estimated at the clinical decision level. The estimated MU shall be available to laboratory users upon request, but are not expected to be included routinely in test reports.

9. Post-examination processes

9.1 Storage of the primary sample and other laboratory samples shall be in accordance with the requirements given in Table 1. 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. Secondary sample meeting the required retention period shall have at least one identifier originating from the primary sample.

10. Reporting of results

10.1 The following is a list of tests whereby the reports shall have direct input from a qualified haematologist (or qualified pathologist as advised by the HKCPath):

10.1.1 Bone marrow examination

10.1.2 Cytochemistry (for diagnosis of haematolymphoid malignancies)

10.1.3 Immunophenotyping (for diagnosis of haematolymphoid malignancies)

10.1.4 Haemoglobin pattern (abnormal results)

10.1.5 Investigation of suspected haemolytic transfusion reaction

10.2 For any test results of significant clinical implication, input from a qualified haematologist (or qualified pathologist as advised by the HKCPath) is recommended.

10.3 As appropriate, the description of examinations performed and their results should follow the vocabulary and syntax recommended by one or more of the following organisations:

- International Council for Standardisation in Haematology (ICSH);
- International Society of Haematology (ISH);

- International Society on Thrombosis and Haemostasis (ISTH);
- European Committee for Standardisation (CEN).

As appropriate, the description and results should follow the nomenclature recommended by the World Health Organisation (WHO).

11. Release of results

11.1 For computer auto-validated reports, the laboratory shall define and document the person(s) authorising the use of the particular algorithm for automatic release of results. The reports shall be traceable to the person(s) who authorise and release the results; and the requesters shall be informed on such reports that the results are auto-validated by computer system.

- End -

Table 1 - Retention of Laboratory Records and Materials

	Record/material	Requirement
General	Records of employee signatures, initials, and identification codes	10 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.
Haematology	Reported blood films	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
Blood Banks	Copies of reports	3 years Type-and-screen results: Indefinite
	Blood samples	Post-analysis (other than compatibility testing): 7 days at 2-8°C Pre-transfusion: 7 days at 2-8°C Post-transfusion: 7 days at 2-8°C
	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 (for records only)
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.

HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Discipline Specific Technical Requirements							
General Haematology and Coagulation							
External services and supplies	**4.6**						
Coagulation Systems							
Is sensitivity of factor VIII and IX re-determined when there is a change in APTT reagent lot?	5.3.2.3	•	☐	☐	☐		
Examination processes	**5.5**						
Are measures taken to ensure that anticoagulated blood is adequately mixed before sampling?	5.5.1.1	•	☐	☐	☐		
Manual Haematocrit							
Has the constant packing time (minimum spin to reach maximum packing of cells) been determined and recorded for each instrument?	5.5.1.3	•	☐	☐	☐		
Manual Platelet, Red and White Blood Cell Count							

Note: 1. The assessor should concentrate on items marked with a •; other items will be checked by the team leader.
2. Please put down the laboratory's document reference(s) where there are descriptions or procedures related to the requirement.

HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Are counting chambers for blood cells examined regularly to ensure that the lines are bright and free of scratches?	5.5.1.1	•	☐	☐	☐		
Are correct standard thick glass cover slips used?	5.5.1.1	•	☐	☐	☐		
Is the diluting fluid filtered before use, checked periodically for background count and changed when necessary?	5.5.1.1	•	☐	☐	☐		
Is the number of cells counted statistically valid for the test (100 for white cell counts, 1000 for red cell counts, 100 for platelet counts)?	5.5.1.1	•	☐	☐	☐		
Automated Haematology System: Cell Counting, Cell Size Measurement and Haemoglobin Determination							
For semi-automatic systems, is the minimum/maximum time for lysing determined at regular intervals?	5.5.1.1	•	☐	☐	☐		
Are background counts performed on the diluent and lysing agent to check for contamination?	5.5.1.1	•	☐	☐	☐		
Are procedures available to verify white cell counts that fall outside the action limits?	5.5.1.1	•	☐	☐	☐		
Are adequate measures taken to prevent the possibility of 'carry over'?	5.5.1.1	•	☐	☐	☐		
Are performance or tolerance limits defined for each instrument, component or procedure of the system?	5.5.1.1	•	☐	☐	☐		
Blood Film Examination							

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Are slides for blood film examination adequately identified, i.e. traceable to original sample?	5.4.6	•	☐	☐	☐		
Is the quality of blood films satisfactory in respect of (a) staining, (b) debris, (c) morphology and (d) distribution of cells?	5.5.1.1	•	☐	☐	☐		
Does the report include an evaluation of red cell morphology?	5.5.1.1	•	☐	☐	☐		
Is an estimation of platelets made from the blood film?	5.5.1.1	•	☐	☐	☐		
When the platelet count falls outside the action limits, are quantitative counts correlated with an estimate from a blood film?	5.5.1.1	•	☐	☐	☐		
Reticulocyte Counts – Manual							
Are slides for reticulocyte counts adequately identified, i.e. traceable to original sample?	5.4.6	•	☐	☐	☐		
Are blood films stained and examined within 24 hours?	5.5.1.1	•	☐	☐	☐		
Is the reticulocyte stain filtered before use?	5.5.1.1	•	☐	☐	☐		
Is the percentage of reticulocytes based on a count of at least 1000 red cells?	5.5.1.1	•	☐	☐	☐		
Reticulocyte Counts – Automated							
Are procedures available to verify reticulocyte counts when they fall outside the action limits?	5.5.1.1	•	☐	☐	☐		
Are there adequate safeguards to prevent the possibility of 'carry over'?	5.5.1.1	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Are performance or tolerance limits defined for each instrument, component or procedure of the system?	5.5.1.1	•	☐	☐	☐		
Blood Films for Malarial Parasites							
Are blood films for examination of malarial parasites adequately identified, i.e. traceable to original sample?	5.4.6	•	☐	☐	☐		
Are both thick and thin films made?	5.5.1.1	•	☐	☐	☐		
Are appropriate staining techniques used (e.g. Field's stain for thick films, Wright, Giemsa stains for thin films; appropriate buffers etc.)?	5.5.1.1	•	☐	☐	☐		
For thick films, are at least 100 fields examined under oil immersion before a negative report is issued?	5.5.1.1	•	☐	☐	☐		
Bone Marrow Preparations							
Are slides of bone marrow preparation adequately identified, i.e. traceable to original sample?	5.4.6	•	☐	☐	☐		
Is the quality of bone marrow films satisfactory with respect to (a) staining, (b) debris, (c) morphology and (d) distribution of cells?	5.5.1.1	•	☐	☐	☐		
Are histological sections of marrow specimens prepared routinely (marrow clot and/or trephine biopsy)?	5.5.1.1	•	☐	☐	☐		
Is iron stain routinely performed for iron store assessment?	5.5.1.1	•	☐	☐	☐		
Are facilities available for further investigation (cytochemistry and/or immunophenotyping, etc.)?	5.5.1.1	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Cytochemical Studies							
Are slides for cytochemical studies adequately identified, i.e. traceable to original sample?	5.4.6	•	☐	☐	☐		
Is the quality of blood/bone marrow films satisfactory with respect to (a) staining, (b) debris, (c) morphology and (d) distribution of cells?	5.5.1.1	•	☐	☐	☐		
Are there appropriate controls (internal and/or external) for cytochemical studies?	5.6.2.1	•	☐	☐	☐		
Immunocytochemical Studies (Flow cytometry)							
Are slides for immunocytochemical studies adequately identified, i.e. traceable to original sample?	5.4.6	•	☐	☐	☐		
Is the quality of blood / bone marrow / cytospin films satisfactory with respect to (a) staining, (b) debris, (c) morphology and (d) distribution of cells?	5.5.1.1	•	☐	☐	☐		
Are there appropriate controls (internal and/or external) for immunocytochemical studies?	5.6.2.1	•	☐	☐	☐		
Automated Coagulation Systems							

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
If an automated coagulation instrument is used for routine coagulation studies (e.g. PT, APTT):							
- Are guidelines available for determining when other procedures should be performed (e.g. specimens that have significant degree of lipaemia, hyperbilirubinaemia, turbidity, etc.)?	5.5.3	•	☐	☐	☐		
- Are reference intervals re-established when there is a change in reagent lot?	5.5.2	•	☐	☐	☐		
- Is the automated system checked with different levels of control material at the start of each shift, and when there is a change in reagent?	5.6.2.2	•	☐	☐	☐		
Manual Coagulation Systems							
If routine coagulation studies (e.g. PT, APTT) are performed by manual technique:							
- Is the temperature of water bath or incubator verified with a certificated thermometer (or equivalent technique)?	5.3.1.4	•	☐	☐	☐		
- Are criteria for accepting duplicate testing results available?	5.5.3	•	☐	☐	☐		
- Is the manual coagulation system checked with different levels of control material in duplicate during each 8-hour period of patient testing, and when there is a change of reagent?	5.6.2.2	•	☐	☐	☐		
Coagulation Factor Assays							

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
If factor assays are performed:							
- Are at least three points plotted for the standard curve?	5.5.1.1	•	☐	☐	☐		
- Are at least two points plotted for the patient's factor assay curve?	5.5.1.1	•	☐	☐	☐		
Ensuring quality of examination results	**5.6**						
Does your laboratory's documented daily quality control plan clearly state the levels of QC materials run per day, frequency of performing QC, types of QC materials, and the QC acceptance criteria?	5.6.2.2 SC-28 8.2	•	☐	☐	☐		
Has your laboratory provided information for the actions taken in case the QC results falls outside the acceptance limit? Are the actions recorded?	SC-28 8.2	•	☐	☐	☐		
If your laboratory uses more than one analyser to perform a test,							
- Are there established procedures to compare results from the analysers throughout the reportable ranges?	5.6.4 SC-28 8.3	•	☐	☐	☐		
- Has the correlation procedure addressed both routine comparison and data review at defined intervals?	5.6.4 SC-28 8.3	•	☐	☐	☐		
- Do the number of samples to be used and the frequency of run commensurate with the performance of the equipment?	5.6.4 SC-28 8.3	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
- Have acceptance criteria of results of comparison been documented?	5.6.4 SC-28 8.3	•	☐	☐	☐		
- Has appropriate statistical analysis been applied for reviewing the comparison results?	5.6.4 SC-28 8.3	•	☐	☐	☐		
Blood Film Examination							
Is there a documented programme to ensure that all technical staff members involved in blood film examination have an opportunity to test external quality assessment programme samples and have their results submitted to the programme provider?	5.6.3.1	•	☐	☐	☐		
When external quality assessment programme results are available, is the performance of individual technical staff reviewed against the expected results?	5.6.3.4	•	☐	☐	☐		
Manual Erythrocyte Sedimentation Rate							
Are internal QC materials tested at least once per day when the assay is performed or every shift if it is a 24-hour service?	5.6.2.2	•	☐	☐	☐		
Post-examination processes	**5.7**						
Are specimens stored under appropriate conditions for the period specified after report issued?	SC-28 Table 1	•	☐	☐	☐		
Are abnormal slides kept and are they readily accessible?	5.7.2	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Are slides and reports for cytochemical studies filed and readily accessible?	5.7.2	•	☐	☐	☐		
Are slides and reports for bone marrow preparations filed and readily accessible?	5.7.2	•	☐	☐	☐		
Are slides and reports for immunocytochemical studies filed and readily accessible?	5.7.2	•	☐	☐	☐		
Reporting of results	**5.8**						
Do haematology reports include the appropriate reference intervals?	5.8.3(j)	•	☐	☐	☐		
Are diagnosis and classification of haematolymphoid malignancies given according to the WHO classification?							
- Bone Marrow Preparations	N/A	•	☐	☐	☐		
- Cytochemical Studies	N/A	•	☐	☐	☐		
- Immunocytochemical studies	N/A	•	☐	☐	☐		
Immunohaematology and blood bank							
Control of records	**4.13**						
Other than interpreted results, are records of original observations retained?	4.13.H(b) SC-28 5.2	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Accommodation and environmental conditions	**5.2**						
Preservation of blood and blood products							
Is emergency power available for each unit of blood storage equipment?	5.2.2	•	☐	☐	☐		
If emergency power is not available for each blood storage equipment, are there written emergency procedures to maintain the proper storage of the donor units?	5.2.2	•	☐	☐	☐		
Is there controlled access to blood stores?	5.2.2	•	☐	☐	☐		
Is the blood storage space adequate for the needs of the facility?	5.2.3	•	☐	☐	☐		
Are there standard operation procedures for handling blood unit outside the blood bank (avoidance of prolonged warming, need for filter)?	5.2.3	•	☐	☐	☐		
Are donor units transferred to suitable storage device promptly after receipt?	5.2.3	•	☐	☐	☐		
Are there documented policies for returning unused blood?	5.2.3	•	☐	☐	☐		
Are donor units segregated in the blood storage device so as to avoid confusion regarding the following?							
- blood group	5.2.6	•	☐	☐	☐		
- blood under quarantine	5.2.6	•	☐	☐	☐		
- blood suitable for crossmatch	5.2.6	•	☐	☐	☐		

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
- crossmatched blood	5.2.6	•	☐	☐	☐		
- rejected blood	5.2.6	•	☐	☐	☐		
- autologous blood	5.2.6	•	☐	☐	☐		
- expired blood	5.2.6	•	☐	☐	☐		
Is blood storage equipment free of materials other than blood products?	5.2.6	•	☐	☐	☐		
Are blood inventory control procedures conducted daily to ensure efficient use of the blood held?	5.2.6	•	☐	☐	☐		
Laboratory equipment, reagents and consumables	**5.3**						
Is every shipment or new lot of each grouping serum checked for avidity (for slide test or where applicable), potency and specificity, according to international guidelines or manufacturer's specification upon receipt?	5.3.2.3	•	☐	☐	☐		
Are known positive and negative control cells used to check the reactivity of all grouping sera?	5.3.2.3	•	☐	☐	☐		
Is there periodic check on the speed and timing of each serologic centrifuge so as to ensure that the supernatant is clear and the cells are not overpacked?	5.3.1.2	•	☐	☐	☐		
Blood bank alarm							

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HOKLAS Requirement	Clause (HOKLAS 015, 5th edition and relevant SC)	*[1]	Y	N	NA	Lab's Document Reference or Remarks[2]	Assessment Team's remarks / questions to be asked at the laboratory
Is a visual alarm system installed?	5.3.1.2 SC-28 4.1.1	•	☐	☐	☐		
Is an audible alarm system installed?	5.3.1.2 SC-28 4.1.1	•	☐	☐	☐		
Is the alarm system continuously monitored at all times (either in or away from laboratory)?	5.3.1.2 SC-28 4.1.1	•	☐	☐	☐		
Is checking of recording and alarm systems performed at least weekly?	5.3.1.2 SC-28 4.1.1	•	☐	☐	☐		
Are the alarms set to trigger outside the preset range?	5.3.1.2 SC-28 4.1.1	•	☐	☐	☐		
Does the alarm system operate independently of main electricity supply?	5.3.1.2 SC-28 4.1.1	•	☐	☐	☐		
Is functional check of alarm performed at scheduled interval and after maintenance of equipment breakdown?	5.3.1.2 5.3.1.5	•	☐	☐	☐		
Are there standard operation procedures to follow if temperature limits are exceeded?	5.3.1.5	•	☐	☐	☐		
Pre-examination processes	**5.4**						
Blood sample requirement							
Are procedures available for positive identification of the intended recipient and verification between the information on the request form and the patient's wristband?	5.4.3	•	☐	☐	☐		

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Is blood sample tube labelled with the patient's unique identification information and the date of collection?	5.4.4.3(e) SC-28 6.4	•	☐	☐	☐		
Blood sample reception procedure							
Has a qualified blood bank staff confirmed that all identification information on the request form agree with that on the sample tube label prior to pre-transfusion testing?	5.4.4.1 5.4.6(a)	•	☐	☐	☐		
Examination processes	**5.5**						
Blood Grouping							
Does the routine procedure include:							
- anti-A (forward grouping)?	5.5.1.1	•	☐	☐	☐		
- anti-B (forward grouping)?	5.5.1.1	•	☐	☐	☐		
- anti-D?	5.5.1.1	•	☐	☐	☐		
- A1 cells (reverse grouping)?	5.5.1.1	•	☐	☐	☐		
- B cells (reverse grouping)?	5.5.1.1	•	☐	☐	☐		
Is a defined haemagglutination grading/scoring system used?	5.5.3	•	☐	☐	☐		
Is there any mechanism to ensure that rare blood groups can be detected?	5.5.1.1	•	☐	☐	☐		
Compatibility Testing							
Does the pre-transfusion procedure include:							

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- an investigation of cases in which patient's ABO and Rh(D) typing disagree with the historical record?	5.5.1.1	•	☐	☐	☐		
- confirmation of ABO group on all donor units and Rh(D) type on all Rh(D)-negative donor units for Rh(D)-negative recipients (testing for weak D is not required), using a sample from an attached segment?	5.5.1.1	•	☐	☐	☐		
- a policy concerning the maximum interval during which a sample may be employed for testing before obtaining a new sample?	5.5.1.1 SC-28 6.3	•	☐	☐	☐		
- test of each patient's blood sample with anti-A, anti-B, anti-D, A1 and B red cells?	5.5.1.1	•	☐	☐	☐		
- demonstration of compatibility between the recipient and the donor units issued?	5.5.1.1	•	☐	☐	☐		
- performance of tests which can demonstrate ABO incompatibility and clinically significant red cell antibodies?	5.5.1.1	•	☐	☐	☐		
- an antiglobulin or equivalent test in antibody detection tests?	5.5.1.1	•	☐	☐	☐		
- consideration of previous findings in recipient's transfusion record during interpretation of current test results?	5.5.1.1	•	☐	☐	☐		
If investigation reveals no clinically significant antibody, and there is no historical record of such antibodies, has abbreviated crossmatch or computer crossmatch been performed to ensure ABO compatibility?	5.5.1.1	•	☐	☐	☐		

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(i) Abbreviated Crossmatch							
Is abbreviated crossmatch performed by immediate spin test with patient's serum and donor's red cells?	5.5.1.1	•	☐	☐	☐		
(ii) Computer Crossmatch							
Has validation of the computer system been performed on site to prevent the release of ABO incompatible blood?	5.5.1.1	•	☐	☐	☐		
Before the release of compatible blood, does the system check that:							
- There is no history of clinically significant red cell antibodies?	5.5.1.1	•	☐	☐	☐		
- The test result of antibody screening is valid?	5.5.1.1	•	☐	☐	☐		
- There are two concordant determinations of the recipient's ABO group: one by testing a current sample and the second by testing on the same or a second current sample, or by matching with previous records?	5.5.1.1	•	☐	☐	☐		
If a patient is receiving repeated transfusions:							
Is a fresh specimen taken immediately before blood is required if the previous specimen has elapsed the maximum interval for pre-transfusion testing?	5.5.1.1	•	☐	☐	☐		
Is grouping performed on the new specimen?	5.5.1.1	•	☐	☐	☐		
Is the new specimen screened for atypical antibodies and/or employed in subsequent crossmatch?	5.5.1.1	•	☐	☐	☐		

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Are there procedures for emergency release of blood prior to completion of compatibility testing?	SC-28 7.1	•	☐	☐	☐		
Do the procedures include documenting a request for uncrossmatched blood by attending clinicians and collection of a pre-transfusion blood sample from the recipient for subsequent testing?	SC-28 7.1	•	☐	☐	☐		
Transfusion reactions							
Are all transfusion incidents or reactions reported immediately to the blood bank?	5.5.1.1	•	☐	☐	☐		
Are remnants of all packs administered immediately before or during the reaction retained for examination?	5.5.1.1	•	☐	☐	☐		
Does the investigation include:							
- double check that all packs have been given to the intended recipient?	5.5.1.1	•	☐	☐	☐		
- examination for possible error in all clerical work?	5.5.1.1	•	☐	☐	☐		
- repeated blood grouping and antibody screen on recipient's pre-and post-transfusion blood samples?	5.5.1.1	•	☐	☐	☐		
- direct antiglobulin test on recipient's pre-and post-transfusion blood samples?	5.5.1.1	•	☐	☐	☐		
- repeated crossmatch on residual blood in all available donor packs administered before or during the reaction with recipient's pre-and post-transfusion blood samples?	5.5.1.1	•	☐	☐	☐		

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- repeated blood grouping on residual blood in all available donor packs administered before or during the reaction?	5.5.1.1	•	☐	☐	☐		
- check for microbiological contamination of residual blood in all available donor packs?	5.5.1.1	•	☐	☐	☐		
Is there a protocol detailing laboratory tests to be conducted on the recipient so as to determine the nature and extent of the recipient's transfusion reaction?	5.5.1.1	•	☐	☐	☐		
Ensuring quality of examination results	**5.6**						
Transfusion procedure							
Are there documented policies available including:							
- indications for transfusion of blood and blood components?	5.6.2.1	•	☐	☐	☐		
- maximum blood ordering schedule?	5.6.2.1	•	☐	☐	☐		
- standard operation procedures for issuing blood and blood components?	5.6.2.1	•	☐	☐	☐		
Are there instructions to require a compatibility label identifying the intended recipient being applied to each allocated donor unit?	5.6.2.1	•	☐	☐	☐		
Is each unit of blood checked immediately for appearance and expiry date prior to allocation?	5.6.2.1	•	☐	☐	☐		

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Before giving blood transfusion, do qualified staff (doctors or nurses):							
- check blood label for 'Blood group', 'Product type' and 'Expiry date'?	5.6.2.1	•	☐	☐	☐		
- verify patient's identity on blood unit with that on patient's wristband?	5.6.2.1	•	☐	☐	☐		
- check ABO/Rh(D) group on donor units against Blood Transfusion Record?	5.6.2.1	•	☐	☐	☐		
- check patient's identity on donor units against Blood Transfusion Record?	5.6.2.1	•	☐	☐	☐		
Post-examination processes	**5.7**						
Are blood specimens kept for at least 7 days after testing?	5.7.2 SC-28 Table 1	•	☐	☐	☐		
Are the following laboratory records (electronic and/or hardcopy format) retained for appropriate time interval pursuant to the professional, statutory, legislative and HOKLAS requirements?	SC-28 Table 1						
- donor units received and issued by the blood bank		•	☐	☐	☐		
- results of grouping procedures, crossmatch and antibody studies		•	☐	☐	☐		

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- transfusion requests		•	☐	☐	☐		
- transfusion reaction or incident reports		•	☐	☐	☐		
Laboratory information management	**5.10**						
Has the laboratory defined the areas that should be covered in the validation of the blood bank laboratory information system (LIS) after downtime or version upgrade?	5.10.3 (a)	•	☐	☐	☐		
Immunophenotyping							
Examination processes	**5.5**						
Is there a procedure to adjust cell concentration to allow optimal antibody staining?	5.5.1.1	•	☐	☐	☐		
Are gating procedures of acquisition signals verified or validated and in line with those published in peer-reviewed journals or international guidelines?	5.5.1.2 5.5.1.3	•	☐	☐	☐		
Are controls regularly used to validate reagents, preparation methods and staining procedures?	5.6.2.2	•	☐	☐	☐		
For lymphocyte subset analysis:							
- Are lymphocytes gated for analysis?	5.5.1.1	•	☐	☐	☐		

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- Are results of analysis of lymphocyte subset corrected for gating purity?	5.5.1.1	•	☐	☐	☐		
- Are markers set to distinguish fluorescence-negative and positive cell populations?	5.5.1.1	•	☐	☐	☐		
- Is an age- and sex-specific reference interval established for cell subsets?	5.5.1.1	•	☐	☐	☐		
For leukaemia and lymphoma immunophenotyping:							
- Is the panel of monoclonal antibodies sufficiently comprehensive to determine lineage of differentiation of abnormal cells?	5.5.1.1	•	☐	☐	☐		
- Are methods available to distinguish cytoplasmic and surface immunoglobulin staining?	5.5.1.1	•	☐	☐	☐		
- Is a method available to confirm nuclear staining, e.g. TdT?	5.5.1.1	•	☐	☐	☐		
For cells of interest in rare occurrence:							
- Is the mode (e.g., single-platform or dual-platform) of analysis stated in the report?	5.5.1.1	•	☐	☐	☐		
- Are there procedures to distinguish fluorescence-negative and positive cell populations?	5.5.1.1	•	☐	☐	☐		

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Reporting of results	**5.8**						
Does the immunophenotyping report contain:							
- description of specimen / tissue studied?	5.8.3(g)	•	☐	☐	☐		
- interpretation (such as the immunophenotype of abnormal cellular population) and clinical significance?	5.8.3(k)	•	☐	☐	☐		
- diagnosis and classification of haematolymphoid malignancies according to the WHO classification?	SC-28 10.3	•	☐	☐	☐		

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