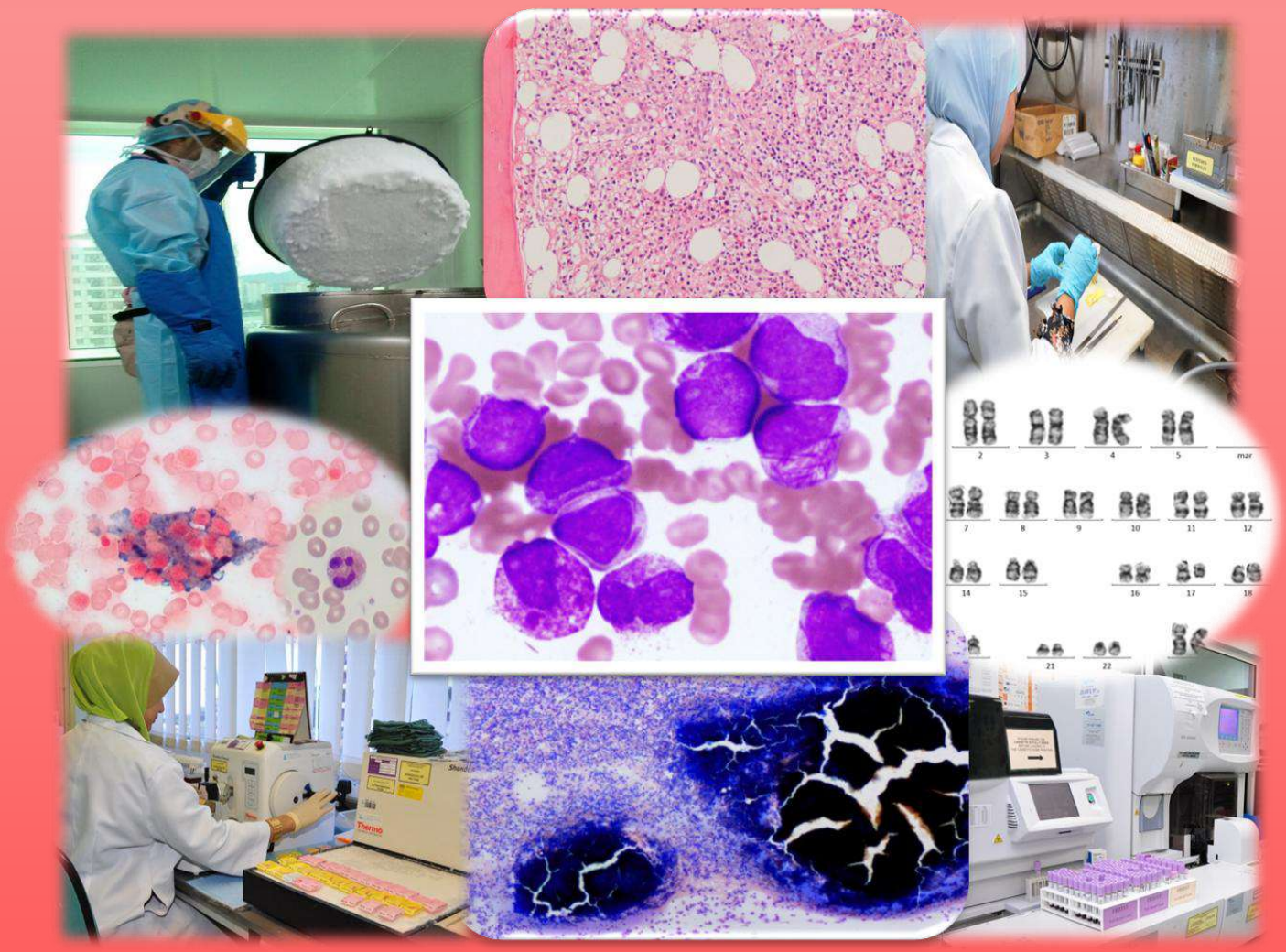
HANDBOOK OF SERVICES IN CLINICAL HAEMATOLOGY REFERRAL LABORATORY



MAKMAL RUJUKAN KLINIKAL HEMATOLOGI
HOSPITAL AMPANG

Department of Haematology
Hospital Ampang
7th Edition
2026

HANDBOOK OF SERVICES IN CLINICAL HAEMATOLOGY REFERRAL LABORATORY

Department of Haematology
Hospital Ampang

FOREWORD

The Clinical Haematology Referral Laboratory, Hospital Ampang, is the National Referral Laboratory in the Ministry of Health for specialised haematology testing. This laboratory is also known as MRKH (Makmal Rujukkan Klinikal Hematologi).

Established in 2006 under the Department of Haematology, the outreach and impact of this laboratory have been significant in the management of patients with haematological diseases. Providing both diagnostic as well as monitoring testing, this laboratory has aided in improving patient outcomes by leaps and bounds throughout the years.

The Department of Haematology's ongoing efforts of reviewing, updating and improving the contents of the laboratory handbook are to ensure that not only accurate and clear information are communicated but also to ensure this laboratory handbook serves as a user friendly guide for all. Given the complexity of the test offered by this laboratory, this Handbook of Services has been compiled to help medical practitioners as well as referring laboratories across the country to be aware of the indications and requirements for testing as well as to guide them make appropriate test choices. This helps to contribute to the optimal use of resources, efficiency and most importantly, improve patient care.

I'm happy to announce that the Clinical Haematology Referral Laboratory was recently awarded with ISO 15189 accreditation. Therefore it is of utmost importance that this Handbook be used as a guide to ensure that the specimens and test are in compliance with the required standards.

Finally, I would like to congratulate the members of the editorial board for their invaluable contributions towards the improvement and revision of this handbook. I sincerely hope that the Department of Haematology will continue to provide accurate, efficient, cost-effective yet high quality services through this laboratory keeping up with their motto "Committed to Standards for Excellence in Laboratory Haematology Services"

Dr Kasuadi Bin Hussin
Director,
Hospital Ampang

PREFACE

Haematology has progressed much since the 17th century after the invention of the microscope which enabled the first person to observe a red blood cell. From morphological observation of cells in the mid-19th century till the mid-20th century where chromosomal abnormalities were observed in leukaemic cells, technological advancement has led to a better understanding of many haematological disorders. Moving forwards, various laboratory methods were then developed to further diagnose, monitor and prognosticate many haematological disorders. Today we are entering a molecular and genomic era where cutting edge technology continues to be the forefront in haematology. All these advances have led to further understanding and characterization of haematological disorders and has been the foundation therapeutic progress.

Hospital Ampang's National Clinical Haematology Referral Laboratory (MRKH) has been set up with the aim of providing laboratory support in the clinical management of haematological disorders. MRKH now consists of seven main laboratories namely the morphology, red cell & hemostasis, cytogenetics, flow cytometry, molecular, histopathology and stem cell laboratories. MRKH is not only serving Hospital Ampang, Selangor but also has expanded its services to other hospitals and institutions nationwide. Therefore, communication and feedback between laboratory and clinicians is paramount to avoid pitfalls which may occur with various laboratory tests and to optimize the management of patients.

The "Handbook of Services in Clinical Haematology Referral Laboratory" aims to provide a comprehensive information of the laboratory's services and assist clinicians in obtaining and utilizing the laboratory's services. This 6th Edition is timely to update the various tests offered and the logistics required for these tests. It is hoped that the laboratory continues to be the forefront of progress in the field of haematology.

Dr Jerome Tan Tsen Chuen
Head and Consultant Haematologist
Department of Haematology
Hospital Ampang Selangor

PREFACE


In the evolving landscape of patient care, the role of the laboratory has never been more critical. Laboratory diagnostics are fundamental to clinical decision-making. It is crucial to ensure patient safety by delivering test results that are precise, reliable, and in keeping with clinical urgency. Achieving this standard requires a seamless integration of meticulous planning, rigorous execution, and comprehensive verification by the entire laboratory team.
This sixth edition of our Handbook of Services is designed to guide clinicians through the complexities of modern haematology testing. It offers a comprehensive overview of test indications, specialized handling requirements, and transportation protocols. By detailing our protocols—from specimen handling and urgent requests to rejection criteria—Hospital Ampang/MRKH aims to standardize excellence across the board.

As we face evolving changes in molecular and cytogenetic testing guidelines, our goal is to foster a centralized network that reduces redundancy and maximizes efficiency. We advocate for a centralized laboratory network to optimize national resources and improve turnaround times.

We are deeply grateful to the Advisory Committee for their support in making this essential update of this 'HANDBOOK OF SERVICES IN CLINICAL HAEMATOLOGY REFERRAL LABORATORY' possible..

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HANDBOOK OF SERVICES IN CLINICAL HAEMATOLOGY REFERRAL LABORATORY

SIXTH EDITION

HAEMATOLOGY DEPARTMENT
HOSPITAL AMPANG

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Our appreciation also goes to:

Head of Pathology Department

All staffs of Clinical Haematology Referral Laboratory & Pathology Department Hospital Ampang who indirectly involved in publication of this handbook.

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1. 0 DEPARTMENT OF HAEMATOLOGY OATH, VISION and MISSION STATEMENTS

1.1 Overview of the organization

The laboratory has adopted a quality management system to effectively and efficiently use its resources. All laboratory staff are committed to the culture of quality. All staff share responsibility for identifying nonconformities and opportunities for improvement, as well as documenting these instances so that corrective or preventive actions can be taken to ensure the laboratory meets the needs of its customers.

The Clinical Haematology Referral Laboratory consists of 7 units [Morphology, Haemostasis and Red cells, Flowcytometry, Molecular diagnostics (Haematology), Cytogenetics (Leukaemia), Bone marrow transplant and Haematopathology providing specialized diagnostic services to various hospitals and clinics. Its function include providing comprehensive diagnostic services at a tertiary level and is the national referral laboratory, training laboratory personnel, medical officers, haematologists, and medical and allied health students.

1.2 Mission statement

i. To provide quality laboratory-based diagnostic and monitoring services responsive to clinical needs and requirements in patient management.
ii. Comprises a team of personnel who are competent, innovative and committed.
iii. Continue the enhancement and promotion of health in partnership with healthcare providers in both the government, private, and society.
iv. Continued education and professional development are needed to cater to growing advancements in the medical field, including continued support for research and development.

1.3 Vision statement

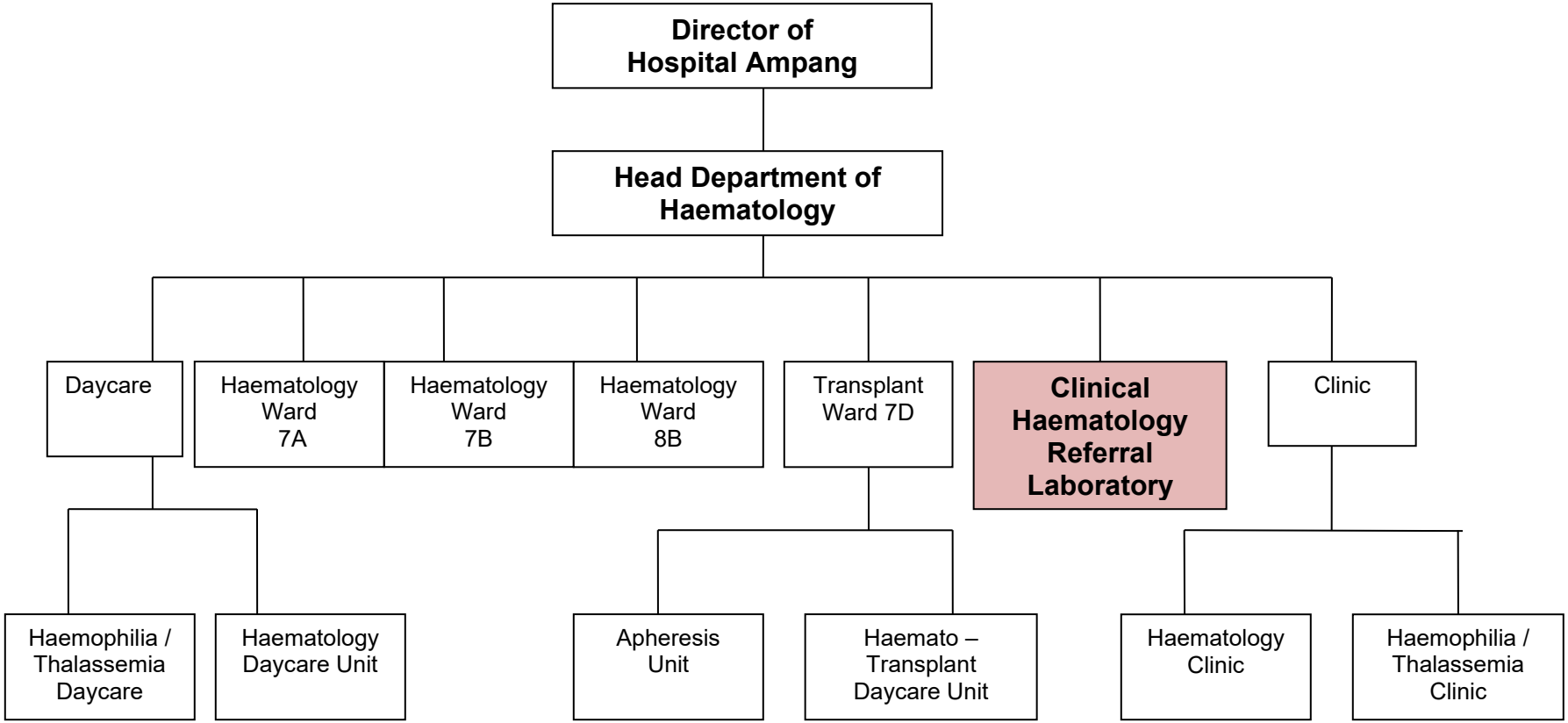
To provide adequate, efficient and prompt services in the field of diagnostic Haematology and surveillance of therapeutic response.

1.4 Objectives

The laboratory objectives are:

i. To provide an effective, efficient, comprehensive, reliable and dedicated diagnostic service.
ii. To produce accurate, reliable and timely analyses and results.
iii. To conduct research and development based on current needs.
iv. Provide training to staff on specialized haematological tests.
v. To achieve and maintain an effective quality management system
vi. To ensure the scope, standard and capability of the laboratory meet clinical needs using appropriate and cost-effective methods.

1.5 DEPARTMENT OF HAEMATOLOGY ORGANISATION CHART



2. 0 GENERAL OPERATING POLICIES, TERM AND SERVICE AGREEMENTS

2.1 Introduction

The aim of this Handbook is to present the Clinical Haematology Referral laboratory in a clear and concise manner. There is a section devoted to each specialised unit with detailed information about available services and how to use them.

Our aim is to provide a wide range of high-quality laboratory services for our users and patients in a timely manner that is consistent with best clinical practice. We welcome any comments or suggestions to improve our services. General comments should be addressed to *Clinical Haematology Referral laboratory, Haematology Department, Hospital Ampang*. For specific queries, please contact the appropriate Head of Unit.

2.2 Quality Assurance

All units aim to provide the highest quality of service with minimum delay. To ensure this, all units participate in External Quality Assurance Programs. All work is subject to internal quality control checks. The individual units are enrolled in the Royal College of Pathologists of Australasia and/or UKNEQAS programs and are currently accredited by MS ISO15189.

2.3 Laboratory Health & Safety Policy

Our laboratory is committed to providing a safe and healthy workplace for all workers and visitors. To assist with compliance, the Clinical Haematology Referral Laboratory has documented policies and terms of reference for the work health and safety as in the Clinical Haematology Referral Laboratory Safety Manual.

2.4 General Information

a) Location

The laboratory is located on Level 2 of the Hospital complex adjoining the Department of Pathology, while the Bone Marrow Transplant (BMT) Unit is located on level 7.

b) Address

Clinical Haematology Referral Laboratory,
Level 2,
Hospital Ampang,
Jalan Pandan Mewah
68000 Ampang, Selangor
Malaysia

c) Contact Numbers
Call the direct line to respective laboratory unit: 03-4289xxxx followed by Extension number (Ext)

UNIT	Extension number (Ext)
Administration	Ext 6219
Morphology	Ext 6532
Haemostasis	Ext 6461
Red Cell	Ext 6217
Flowcytometry	Ext 6218
Haematopathology	Ext 6222
Molecular	Ext 6056
Cytogenetics	Ext 6055
Bone Marrow Transplant	Ext 6390
Medical Officers	Ext 6531/6530/6527

Official email address: mrkhampang@moh.gov.my

d) Operating Hours
7.30am - 5.30pm Monday to Friday (closed on national & Selangor public holidays, and weekends).

e) Customer Services
General comments, complaint or feedback should be addressed to:
Clinical Haematology Referral Laboratory, Haematology Department, Hospital Ampang,

There are 2 methods available:

1. Scan QR code as below. This QR Code is also available at the CHRL (MRKH) Counter.

2. Email to: **aduan.mrkh@gmail.com**
For specific queries, please contact the appropriate Head of Unit.

f) Additional Information

This Handbook of Services in Clinical Haematology Referral laboratory is available at the Hospital Ampang website: https://jknselangor.moh.gov.my/hampg/index.php/informasi/senarai-jabatan-perkhidmatan/klinikal/jabatan-hematologi or scan the QR code below:

2.5 Term and Service Agreements

2.5.1 During the term of this service agreement, Clinical Haematology Referral Laboratory of Haematology Department (CHRL) shall provide the services as set in the section of "List of tests provided by specialized haematology unit".

2.5.2 The parties agree that:

a. Each request accepted by the laboratory for examination shall be considered an agreement. This agreement shall also include request for the examination and the report. The examination processes used were defined in Table 1.1, 2.1, 3.1, 4.1, 5.1, 6.1 & 7.1.
b. The agreement shall specify the information needed on the request to ensure appropriate examination and result interpretation.
c. Clinical staff shall provide signatures and/or initials as indicated on the requisition form.
d. CHRL shall have the right to perform Hematopathology services during the term of this agreement and reserves the right to expand the technical pathology services.
e. CHRL shall have the right to designated to all laboratory personnel and pathologists to perform their laboratory testing at Hospital Ampang facilities, at another location designated by CHRL or partner with any other entity, commercial or otherwise, and its associated professional component for performance by a third party.
f. CHRL from time to time, may engage additional visiting haematopathologists to furnish services under this Agreement.
g. All laboratory personnel shall have the skills, be properly trained, and have the qualified expertise necessary for the performance of the intended examinations.

h. The specified requirements for each testing procedure selected shall be appropriate and relate to the intended use of that examination.
i. Pathologists and any parties agree that they shall not at any time disclose to any others, use, copy or permit to be copied whose confidential information prior written consent except where permitted or required by federal law or state laws and Hospital or Ministry of Health regulations regarding the confidentiality of such information.
j. Changes in service shall be reflected in explanatory information and laboratory reports.
k. Any amendment of service Agreement shall be communicated to all affected parties.
l. Users shall be informed of deviations from the agreement that impact upon the examination results.
m. References shall be made to any work referred by the laboratory to a referral laboratory or consultant.
n. The lab must notify patients when legally required to share confidential information, unless prohibited by law. All patient-related information from external sources shall be kept confidential, and their anonymity shall be ensured unless otherwise agreed.

2.6. Impartiality & confidentiality

CHRL activities shall be carried out with impartiality. CHRL is committed to consistently maintaining impartiality and confidentiality. The CHRL laboratory management is fully dedicated to upholding impartiality and confidentiality in all aspects of our operations.

3.0 GENERAL TEST ORDERING INFORMATION

3.1 Indication for specialised laboratory test

Clinical laboratory test data are important parameter in diagnosis, screening and monitoring. The clinical laboratory is responsible for providing laboratory data to medical doctors with adequate information and correct interpretation of result, thereby supporting the doctors in the decision-making process for patient care. Therefore to ensure clinician request appropriate laboratory testing in our laboratory, it is important to follow the clinical indications stated below and for sample collection as instructed in the laboratory testing table in each unit.

***Remarks*: All cases not fulfilling these clinical indication criteria must consult with the Haematologists before sampling.**

A. Indication Criteria for molecular test:

1. Acute Leukaemia:
    a. Acute Lymphoblastic Leukaemia (ALL)
        i. *BCR*::*ABL1* : For diagnostic and follow up

    b. Acute Myeloid Leukaemia (AML)
        i. *RUNXI*::*RUNXITI*: For diagnostic and follow up
        ii. *CBFB*::*MYH11*: For diagnostic and follow up
        iii. *FLT3*-ITD: For diagnosis and follow up only
        iv. *NPM1*: For diagnosis and follow up only

    c. Acute Promyelocytic Leukaemia (APML)
        i. PML/RARA: For diagnostic and follow up

2. Myeloproliferative Neoplasm (MPN)
    a. *JAK2*
    b. *CALR*
    c. *BCR*::*ABL1*
    d. PDGFRA: for Hypereosinophilia cases

3. Chronic Myeloid Leukaemia (CML)
    a. *BCR*::*ABL1*: For diagnostic and follow up.

B. Indication Criteria for cytogenetic test

a. Leukemias
b. Myeloma / Lymphomas (test must be discussed with haematologist prior to sampling).

Please refer to specialized laboratory test in section 5 Cytogenetic for more details of test requirement.

C. Indication Criteria for flowcytometry test:

1. Acute Leukaemia: For diagnosis and MRD assessment.
2. Lymphoproliferative disorder (LPD): For diagnosis only.
3. Paroxysmal Nocturnal hemoglobinuria (PNH).
4. Cerebrospinal fluid (CSF) and body fluid: For suspected or visceral infiltration.

D. Indication for haemostasis test:

All samples or test *MUST BE discussed with the haematologist prior to sampling. Failing which sample/test might be rejected.*

3.2 Specimen/Request Forms

To ensure that requests are dealt with effectively, it is essential to comply with the following guidelines.

a) Specimens

Specimens should be placed in a securely fastened appropriate container.

Small (38x20mm) pre-printed labels may be attached to the specimen bottles. (Please do not use larger labels as these can obstruct automated equipment and delay result turnaround). Unlabelled and falsely labelled samples will be rejected.
All specimens **must** be labelled with 2 identifiers:

- Full patient name
- Identification Card (IC) number

and should have;

- Date and time of sampling
- Location/Ward
- Contact number of requesting doctor/ person

The container should be sealed and placed in the bag accompanied by a Special Haematology request form, or placed in a clear plastic bag, with the request form in the outside sleeve. Specimens should be transported to the laboratory as soon rapidly as possible to ensure sample integrity.

If a specimen is to be mailed, the packaging must comply with postal regulations. Please refer to storage and transportation for each specialised unit for specific test requirement.

Biohazard samples must be double bagged and **labelled as biohazard**.

b) Request Forms

All laboratory tests are requested through eHIS except:

- When system is down; or
- Request from external agencies

All tests shall be accompanied by a completed HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY requisition form. The latest version of the requisition form can be downloaded at the Hospital Ampang website: https://jknselangor.moh.gov.my/hampg/index.php/informasi/senarai-jabatan-perkhidmatan/klinikal/jabatan-hematologi

It is essential that the correct request form be completed to ensure an efficient flow of work. Please ensure that request forms and specimen Labelling are completed as specified below and that the writing is legible.

A completed request form must accompany each specimen sent to the laboratory. It **must** clearly state the following information and in legible handwriting / labelling.

- Patient surname and forename
- Age and sex
- IC number or Hospital Ampang Registration number
- The requesting location and mailing address
- Relevant clinical history
- Tests being requested
- Type of specimen and date and time collected
- Indication if **HIGH RISK** status (see below)
- Name and mobile phone number of ordering physician. Molecular, flowcytometry and cytogenetic tests can be ordered only by a **Specialist or Consultant**.

Additional information may be required for some investigations, please see unit sections.

"Unknown" patients e.g. those admitted unconscious, unaccompanied or without documentation, should have their specimens identified with the A&E unique number.

Specimens will be discarded if labelling is inadequate, leaving the patient's identification in doubt, if contents have leaked or been contaminated. In these circumstances, every effort will be made to inform the requesting doctor; hence contact of the requesting physician is vital.

c) Clinical Details

When receiving a sample for analysis, it is important that sufficient and relevant, clinical information is provided to determine the type of test required. Certain samples require special techniques and may not be detected in the routine examination of a sample.

Relevant details may include:

- Date of onset of illness
- Recent infections
- Underlying conditions e.g. diabetes, autoimmune disease, malignancy
- Pregnancy
- Foreign travel
- Transfusion & bleeding history

d) High Risk Specimens and Safety

High-risk groups include patients with clinical suspicion of:

- HIV infection
- Hepatitis B
- Hepatitis C
- Mycobacterium tuberculosis (TB)
- I.V. drug-use
- Patients who have had recent foreign travel with unexplained high pyrexia

NB. Specimens and Request Forms **MUST** be labelled “High Risk”. The form must be folded to ensure confidentiality. The specimen must be sealed in a plastic transport bag. The specimen must then be placed in a secondary biohazard plastic bag and sealed.

To protect health care workers, requests for investigations on high risk patients should be minimised as far as possible.

3.3 Sample Collection (Phlebotomy)

i) Venous blood is preferred.
ii) To ensure consistent and accurate results, follow strictly the volume required for the type of test specified or up to the mark on the label (Please refer to volume required on Table 1.1, 2.1, 3.1, 4.1, 5.1, 6.1 and 7.1).
iii) Gently mix the blood collection tubes immediately by inverting several times. Do not mix vigorously.
iv) To prevent haemolysis;
    a. Avoid collecting blood from an area of haematoma.
    b. The site of collection should be allowed to air dry after cleansing with 70% isoprophyl or ethyl alcohol.
    c. Ensure smooth venipuncture and steady blood flow into the syringe.
    d. Do not force blood through needle while transferring blood into collection tube.
v) Sample Collection for Coagulation test. Please refer to Appendix A, Procedure 1.0).

3.4 Receipt of Specimens

All specimens should be delivered to the Clinical Haematology Referral Laboratory reception during working hours. (Monday to Friday: 7.30 am to 5.30 pm). This reception counter is located **at** the main sample receiving area : Counter marked MRKH.

3.5 Specimen Handling

Haematology tests are extremely sensitive to methods of collection and preservation. It is important that sample collection and processing instructions be followed to ensure accurate test results.

3.5.1 Special Handling Requirements

Contact the relevant unit for information regarding special handling requirements.

3.5.2 Unacceptable Samples

Samples which are incorrectly collected, labelled, processed, or transported will not produce accurate results. When a sample is found to be unacceptable, Laboratory will notify the sender / requester via telephone before rejecting the specimen. If you have any question prior to collection or transportation of a sample, please contact the appropriate unit.

(Refer to this handbook at Section of *SPECIMEN REJECTION CRITERIA*)

3.6 Contact Form

For results dispatch and notification of unacceptable samples, provide name and fax number of Contact person. It will be the responsibility of the referring lab to notify us of any change in Contact person.

3.7 Urgent Request

Please contact the relevant unit during working hours to alert staff on samples en-route for urgent processing. Ordering physician should discuss with Lab Specialist before obtaining/sending sample.

3.8 Urgent Testing After Office Hours

It is essential to contact the ***Medical Officer on call*** before sending the specimen. This is only for URGENT FULL BLOOD PICTURE (FBP) and relevant URGENT haemostasis tests.

3.9 Turnaround Time

The turnaround time for each test is stated in the individual test description. For further details or to request expedited testing, please contact the respective laboratory unit.

3.10 Results/Reports

Results needing attention will be notified as soon as possible to the attending clinician. Therefore, it is important for clinicians to leave their contact number in the requisition

form as requested. Any discrepancy noted from previous report/results shall be informed immediately to the relevant personnel.

Any delay in laboratory reports for conditions that might pose a risk to patient due to prolonged test results will be notified immediately to the relevant personnel/treating physician via telephone for external samples. Preliminary reports will be issued in the eHis system for internal samples in the case of delayed reports.

Printed reports
Printed results are dispatched ONLY during down time or system off-line for internal FBC results. Printed reports to external locations are sent via post in the event the requester does not provide an email address to send reports.

Electronic reports
Results are available via the eHIS/LIS Hospital Information System for FBC, FBP, marrow, iron stores, cytospin, trephine, Flow cytometry, Haemostasis, Hb analysis, Erythropoietin, molecular and cytogenetics.

Alpha/Beta DNA analysis results from referral laboratory are transcribed into the eHIS/LIS Hospital Information System. Copies are available in the Red Cell Unit.

Reports to external locations are sent by an email to the email address given by respective hospital (user).

3.11 Confidentiality
All tests and results remain confidential.

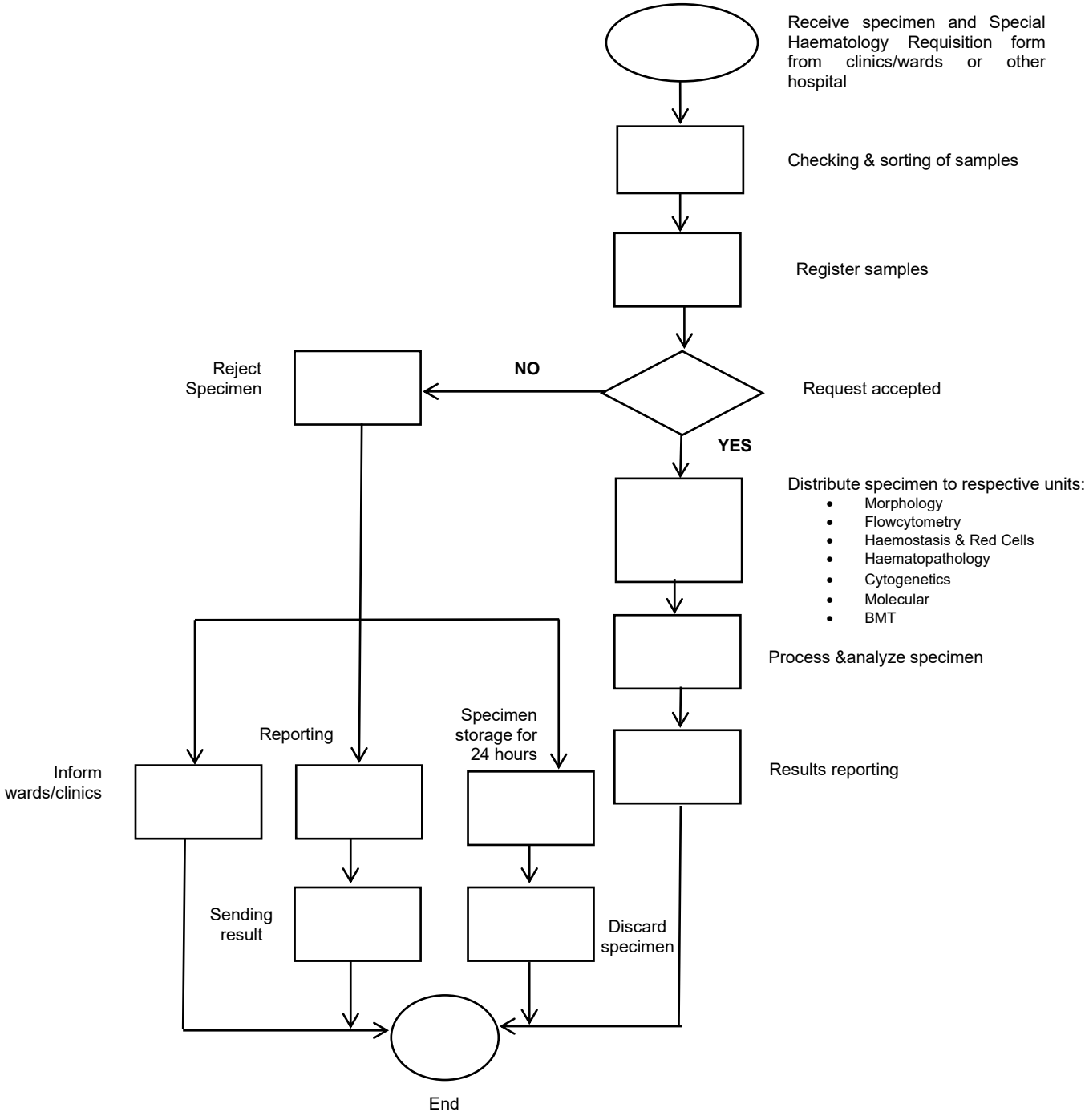
4.0 SPECIMEN STORAGE & DISPOSAL

4.1 Specimen Storage
Specimens are stored under appropriate conditions that permit reliable retrieval in each unit.

4.2 Specimen Disposal
All the specimens are disposed in accordance with the Environmental Quality (Scheduled Waste) Regulation 2005 and other guidelines issued by the Department of Environment (DOE) and/or local authorities. Scheduled wastes are disposed of at prescribed premises for incineration.

5.0 General workflow of Clinical Haematology Referral Laboratory

GENERAL WORKFLOW OF CLINICAL HAEMATOLOGY REFERRAL LABORATORY



LIST OF TESTS PROVIDED BY SPECIALISED HAEMATOLOGY UNIT

1. MORPHOLOGY UNIT

Introduction

The morphology unit provides Full Blood Count (FBC), Full Blood Picture (FBP), Bone Marrow Aspiration (BMA),cytospin for body fluids morphology and as well as iron stain.

List of services

1. Urgent services
    a. For Urgent Full Blood Picture after office hours please contact CHRL medical officer on-call via Hospital operator.
        - Urgent FBP is indicated only to rule out :
            i. Acute Leukaemia/APML
            ii. Microangiopathic Hemolytic Anemia (MAHA) and
            iii. Active Haemolysis

2. Routine services
    a. Full Blood Count (FBC)
    b. Full Blood Picture (FBP)
    c. Bone Marrow Aspiration (Smear)
    d. Staining such as Wright Eosin, May Grunwald Giemsa, Leishman
    e. Body Fluids Morphology

3. Special services
    a. Cytochemistry stains (Iron Stain) run in batches

Instructions for Submitting Samples

A completed HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY requisition form MUST accompany all specimens.

Please note that incomplete or illegible labelling of forms and/or specimens, or use of incorrect specimen tubes, may result in delay or rejection of specimens.

Sample Requirements

a) Sample for morphology tests:

i. Full Blood Count (FBC): 2.0 ml of peripheral blood must be received within 6 hrs of collection. Invert several times to mix blood.
ii. Full Blood Picture (FBP): 2.0 ml of peripheral blood must be received within 6 hrs of collection. Invert several times to mix blood.
iii. Bone marrow aspiration: will be smeared by lab staff
iv. Body fluids for cytospin: minimum 1 ml. CSF/ Body Fluids should be processed as soon as possible, or within 4-6 hours after collection.Samples for cytospin should reach lab by **3pm (Monday-Thursday)** and before **12pm (Friday)**.

b) Sample Labelling

Specimens should be Labelled using a waterproof pen with at least **2 Unique patient identifiers**.

I. Patient's Full Name (Surname, First name)
II. Patient identification number (Patient's Hospital Number /IC / Passport / Military/Police number). Please provide full identification number (e.g IC: 123456-78-9012)

c) The collection date and time, and the origin (source) of the specimen, when applicable. The information on the specimen label should match the information on the lab requisition form; failing which the sample will be rejected.

d) Clinical history, reason for referral, prior therapy and transplant history should be written on the form.

Rejection criteria:

Refer to this handbook at Section of *SPECIMEN REJECTION CRITERIA*

Performing Laboratory

Morphology Unit, Clinical Haematology Referral Laboratory, Department of Haematology, Hospital Ampang. Contact number: 03-42896532

Setup Schedule

Setup: Monday-Friday 7.30 am to 5.30 pm.
After office hours, Weekends, Public Holidays: Urgent FBP requests only.

Samples for cytospin should reach lab by **3 pm (Monday-Thursday)** & before **12 pm (Friday).**

Sample for Full Blood Picture from external Klinik Kesihatan must be received only on **Tuesday** and **Thursday** afternoon every week.

Unless otherwise indicated, all tests are available Monday-Friday 8.00 am to 5.00 pm.

Table 1.1 List of tests offered at Morphology Unit

No	Test name	Method	Specimen type	Container type	Volume required	Department instructions	TAT	Unit*/ Remarks
1	Full Blood Count (FBC) Reticulocyte Count	Flowcytometry/ RF DC Method	Whole Blood	K2/K3 EDTA Tube	2 ml	Sample must be received within 6 hrs of collection Lipaemic/icteric samples can affect the performance of test and may delay results	Urgent: 45 min Non-urgent: 8 hours	Internal cases only.
2	Full Blood Picture (FBP)	Wright Eosin Staining	Whole Blood	K2/K3 EDTA Tube	2 ml	Sample must be received within 6 hrs of collection Sample from external *Klinik Kesihatan* must received only on **Tuesday** and **Thursday** afternoon every week.	Urgent : 1 hour after reception Non-urgent: 7 working days	Internal cases only. External cases only for assigned *Klinik Kesihatan* (PKD under current JKNS instructions). For urgent Full Blood Picture after office hours please contact Haematology lab medical officer on call. No urgent Full Blood Picture for External cases.
3.	Body Fluids Morphology	Cytospin	Body Fluids	Screw Cap Tube	1 ml	Transport to lab immediate after collection	24 hours	Internal haematology cases.

No	Test name	Method	Specimen type	Container type	Volume required	Department instructions	TAT	Unit*/ Remarks
4.	Bone marrow Aspirate for May Grunwald Giemsa Stain	May Grunwald Giemsa Stain	Marrow Aspirate Smear	Minimum 6 slides	NA	Air Dry Transport in slides Holder 6x bone marrow smears for morphology (All slides MUST be Labelled with hospital number, surname and date of sample. (Please note, DOB is not required, date of sample is crucial)	7 working days	Internal cases only. External slide (from other hospitals) for 2nd opinion.
5.	Iron Stain	Perl's Prussian Blue staining	Marrow Aspirate Smear	Minimum 2 slides	NA	Air Dry Transport in slides Holder	14 working days	Internal cases only. External slide (from other hospitals) for 2nd opinion.

Table 1.2 Reference range

Parameter	Range	Unit
Hemoglobin		
Males <60	13.5-17.4	
Males >60	11.8-16.9	g/dl
Females	11.6-15.1	
RBC		
Males <60	4.53-5.95	
Males >60	3.86-5.62	10^{x12}/L
Females	3.87-5.21	
Hematocrit		
Males <60	40.1-50.6	
Males >60	35.7-48.9	%
Females	35.1-44.9	

Parameter	Range	Unit
MCV	80.6-95.5	fL
MCH	26.9-32.3	pg
MCHC	31.9-35.5	g/dl
RDWSD	37.5-48.1	fL
RDW-CV	12-14.8	%
Ret He	30.7-38.9	pg
Retic	0.40-1.6	%
RPI	0.1-1.5	
IRF	0-8.9	%
Platelets		
Males	142-350	10^{x9}/L
Females	171-399	10^{x9}/L
IPF	0-4	%
MPV	8.9-11.9	fL

Parameter	Range	Unit
Total WBC	4.078-11.370	10^{x9}/L
Neutrophils	3.929-7.147	10^{x9}/L
Lymphocytes	1.847-4.807	10^{x9}/L
Monocytes	0.385-1.141	10^{x9}/L
Eosinophils	0-0.827	10^{x9}/L
Basophils	0-0.95	10^{x9}/L

References: (PLoS ONE 9(3): e91968. doi:10.1371/journal.pone.0091968, Haematological Reference Intervals in a Multiethnic Population. Ambayya et al.)

2. FLOW CYTOMETRY

Introduction

The Flow cytometry laboratory provides services to support the investigation and monitoring for patients with various hematological malignancies.
The aim of leukaemia and lymphoma immunophenotyping is to

a) Identify the lineage of the neoplastic cells and level of maturation to aid the classification of leukaemia and lymphoproliferative neoplasms according to WHO classification of Tumours of Haematopoietic and Lymphoid Tissues.
b) Aid in the minimal residual disease monitoring (MRD) of Leukaemia patients undergoing treatment.

In addition, flow cytometry can be used to identify patients with Paroxysmal Nocturnal Haemoglobinuria (PNH) using FLAER.

List of services and Test indication

The flow cytometry for immunophenotyping of Leukaemia and lymphoproliferative neoplasms in MRKH, Hospital Ampang currently cater to the cases **internally** within Hospital Ampang for **adults >12 years old of age.****

External cases for flow cytometry immunophenotyping of Leukaemia and lymphoproliferative neoplasms are REQUIRED to be discussed with the Specialist-in-charge of Flow cytometry unit prior to sending the samples over. Please contact the Flow cytometry lab at 03-4289 6218. Test offer was listed in Table 2.1.

Table 2.1 List of tests offered in Flow Cytometry Unit

Test Name	Sample	Indication	Source
Immunophenotyping of Leukaemia and Lymphoproliferative neoplasms	Blood or Bone Marrow Aspirate (BMA)	Diagnostic • Suspected Leukaemia and Lymphoproliferative neoplasms	Internal cases. ***External cases are REQUIRED to be discussed with Specialist-in-charge of Flow cytometry prior to sending samples.**
	Bone Marrow Aspirate (BMA)	Follow-up for Minimal residual disease (MRD) monitoring • As per Clinical Haematologist request	Internal cases. ***External cases for pre-Bone marrow transplantation assessment.**
Immunophenotyping of Leukaemia and Lymphoproliferative neoplasms	Cerebro spinal fluid (CSF)or Body Fluid	Diagnostic • Suspected infiltration	Internal cases only.
Paroxysmal Nocturnal Haemoglobulinuria (PNH)	Blood	Diagnostic	All external and internal cases.

***Flow cytometry samples for immunophenotyping of Leukaemia/ lymphoproliferative neoplasms for Patients ≤12 years old for within and out of Hospital Ampang (internal & external) are advised to send to Unit Hematologi, Jabatan Patologi, Hospital Tunku Azizah, Kuala Lumpur.*

Instructions for Submitting Samples

For external samples, the requesting Doctor is required to contact the Specialist In-charge of Flow cytometry unit before making arrangements to send flow cytometry samples.

A complete HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY requisition form MUST accompany all specimens with specification of discussion with Specialist In-charge of Flow cytometry unit.

Please note that incomplete or illegible labelling of forms and/or specimens, or use of incorrect specimen tubes, may result in delays or rejection of specimens.

(Refer to the flow charts at the end of this text for a concise overview)

Sample Requirements

a) Samples for Flow Cytometry Immunophenotyping Collection

- Bone Marrow Aspirates/ Peripheral Blood:
  a. Samples must be sent in K2/K3 EDTA tube. Invert several times to mix blood or bone marrow.
  b. Samples for flow cytometry immunophenotyping is encouraged to be the **first draw** of the bone marrow aspirate, especially for MRD samples.
  c. Samples should reach the laboratory within <4 hours of draw internally and within 24 hours of draw for external samples. This is due to the atypical cells are usually highly proliferative and this may lead to premature apoptosis.
  d. However for external samples, there is a time allowance of up to *48 hours for irreplaceable specimens.
     **Note: Suboptimal sample may be indicated in the final report.*

- Cerebrospinal Fluid (CSF) / Body Fluid:
  a. Samples must be sent in special medium which can be obtained from Cytogenetics Laboratory, Clinical Haematology Referral Laboratory, Hospital Ampang.
  b. The amount of sample to be filled in the tube should be equivalent to the amount of transporting medium in the respective tubes (e.g. 1 ml of sample to 1 ml of transporting medium).
  c. However, if the body fluid other than CSF is heavily blood stained, the sample should be collected in K2/K3 EDTA tube.
  - Samples must be sent immediately and reach the lab within < 4 hours of sampling to ensure viability of the cells.
  - Samples should reach lab by **3 pm (Monday-Thursday)** & before **12 pm (Friday).** For delayed samples, contact medical laboratory technologist in flow cytometry unit.

b) Sample Labelling

Specimens should be labelled using a **waterproof pen** with at least **2 unique patient identifiers**.

I. Patient's Full Name (Surname, First name)
II. Patient identification number (Patient's Hospital Number /IC / Passport / Military/Police number). Please provide full identification number (e.g IC: 123456-78-9012).

c) The collection date and time, and the origin (source) of the specimen, when applicable. The information on the specimen label should match the information on the lab requisition form.

d) Clinical history, reason for referral, prior therapy and transplant history should be written on the form.

e) For external cases, please provide referring Doctor's name and contact number for further queries if needed.

Storage and Transportation

All external samples should be transported in 2-8°C to avoid apoptosis. Use cold pack for transport. Ensure cold pack is not in direct contact with specimen during transport. The specimen should arrive at the lab no more than 24 hours after collection.

Rejection Criteria:

Refer to this handbook at Section of *SPECIMEN REJECTION CRITERIA*

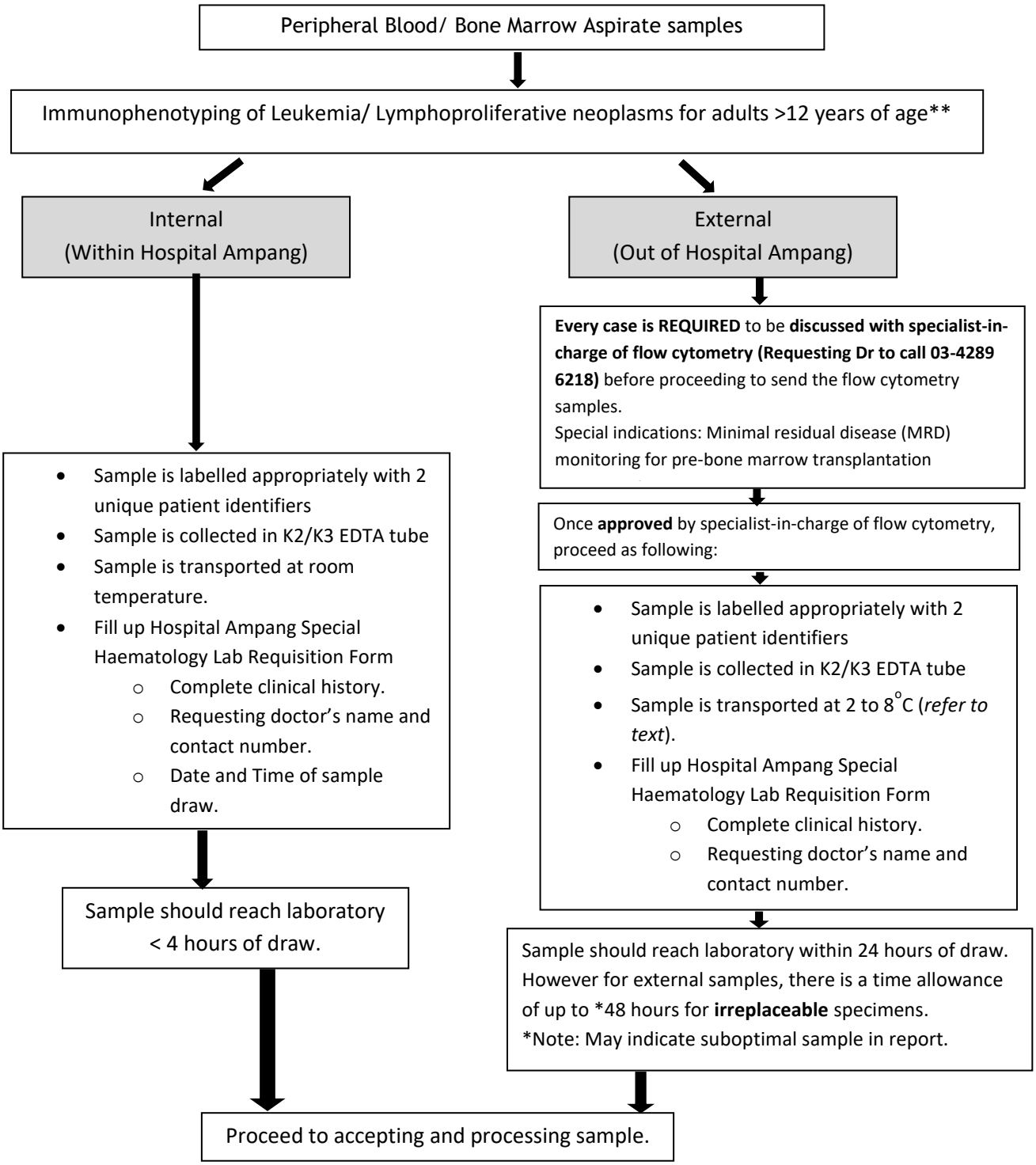
Performing Laboratory

Flow Cytometry Unit, Clinical Haematology Referral Laboratory,
Department of Haematology, Hospital Ampang.
Contact number: 03-4289 6218

Setup Schedule

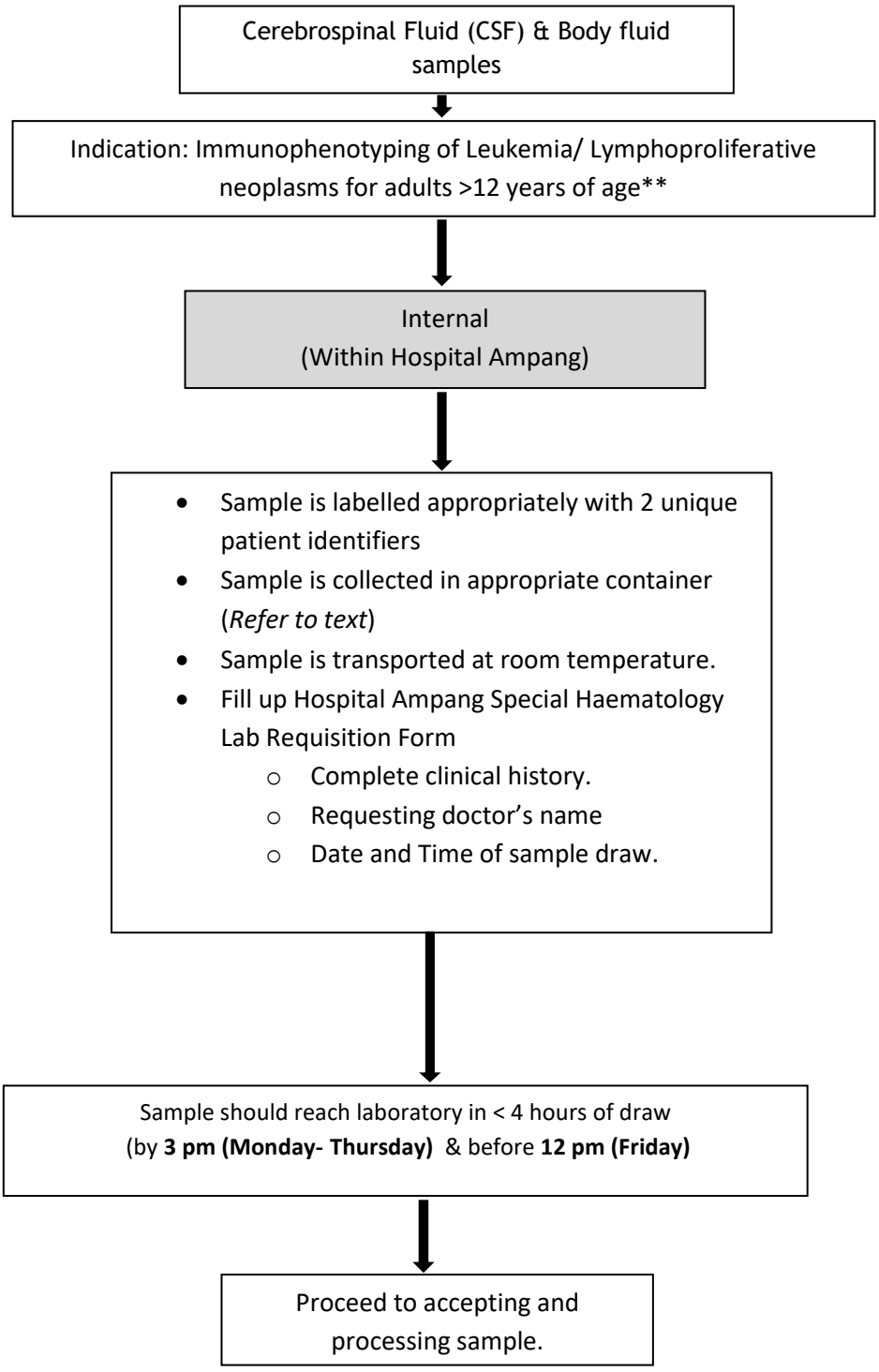
Setup: Monday-Friday
Service time: 8.00am to 5.00pm

FLOW CHART 1: PERIPHERAL BLOOD AND BONE MARROW ASPIRATE SAMPLES RECEPTION FOR FLOW CYTOMETRY IMMUNOPHENOTYPING OF LEUKAEMIA/ LYMPHOPROLIFERATIVE NEOPLASMS FOR ADULTS >12 YEARS OLD



***Flow cytometry samples for immunophenotyping of leukemia/ lymphoproliferative neoplasms for Patients ≤12 years old for within and out of Hospital Ampang (internal & external) are advised to send to Unit Hematologi, Jabatan Patologi, Hospital Tunku Azizah, Kuala Lumpur.*

FLOW CHART 2: CEREBROSPINAL FLUID (CSF) AND BODY FLUID SAMPLES RECEPTION FOR FLOW CYTOMETRY IMMUNOPHENOTYPING OF LEUKAEMIA/ LYMPHOPROLIFERATIVE NEOPLASMS FOR ADULTS >12 YEARS OLD



***Flow cytometry samples for immunophenotyping of leukemia/ lymphoproliferative neoplasms for Patients ≤12 years old for within and out of Hospital Ampang (internal & external) are advised to send to Unit Hematologi, Jabatan Patologi, Hospital Tunku Azizah, Kuala Lumpur.*

FLOW CHART 3: PERIPHERAL BLOOD SAMPLES RECEPTION FOR FLOW CYTOMETRY FOR PNH IMMUNOPHENOTYPING

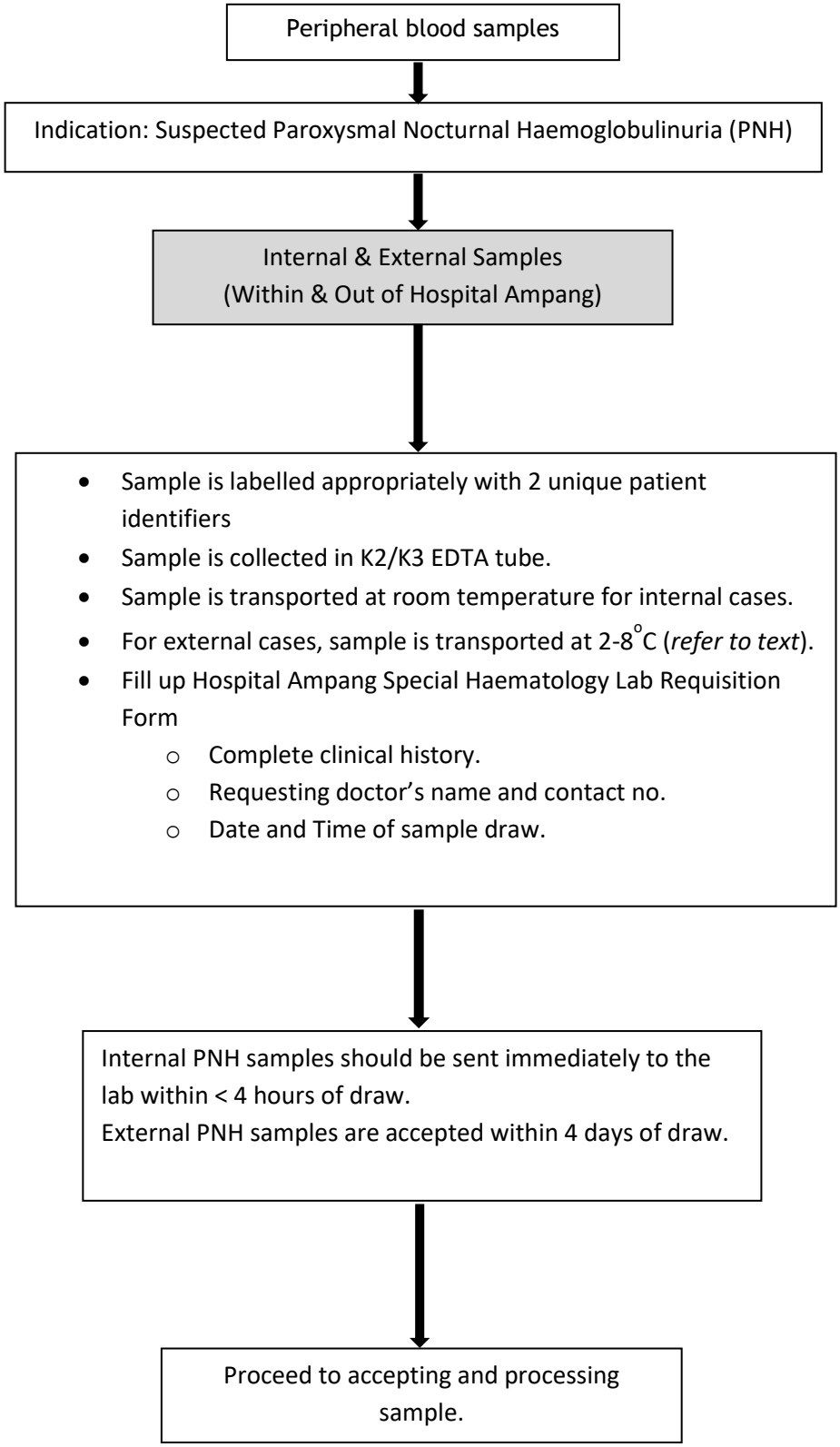


Table 2.2 Summary of tests offered in Flow Cytometry Unit

No	Test name	Method	Specimen Type	Container Type	Volume required	Department Instructions	TAT	Remarks
1	Immunophenotyping of Leukaemia/ Lymphoproliferative Neoplasm	Flow cytometry	Blood or Bone Marrow Aspirate	K2/K3 EDTA tube	4 ml	Bone Marrow Aspirates/ Peripheral Blood: Samples must be sent in K2 EDTA and must reach the laboratory within 24 hours of draw.	Urgent : 1 working day Routine : 7 working days	Internal cases only External cases are REQUIRED to be discussed with specialist-in-charge of flow cytometry prior to sampling
2	Paroxysmal Nocturnal Haemoglobinuria (PNH)	Flow cytometry	Blood	K2/K3 EDTA tube	2 ml	Internal PNH samples must be sent immediately to the lab within 4 hours of draw. External PNH samples are accepted within 4 days of draw.	7 working days	Referral lab for PNH for both internal and external cases.
3	Immunophenotyping of Leukaemia/ Lymphoproliferative Neoplasm – for suspected infiltration	Flow cytometry	CSF or Body Fluid	Transport Medium	Min 1 ml	Samples must be sent in special medium which can be obtained from Cytogenetics or Flowcytometry Unit, Hospital Ampang. Samples must be sent immediately and reach the lab within 4 hours of sampling to ensure viability of the cells.	7 working days	Internal cases only

3. HAEMOSTASIS & RED CELLS UNIT

Introduction

The Haemostasis Laboratory provides a diagnostic service to evaluate bleeding and thrombotic disorders. The laboratory perform routine coagulation test (PT, INR, APTT, Fibrinogen, Thrombin Time, D-Dimer), Factor assays and von Willebrand Factor assays (vWF:Ag, vWF:Act, vWF:Ricof, CBA). The laboratory also does Anti-Xa, Protein C, Protein S, Free Protein S, Antithrombin, Lupus anticoagulant assay and Platelet aggregation test for special situations.

The Red Cell Unit offers Hb Analysis (Capillary electrophoresis and Gel electrophoresis) and DNA analysis for Thalassemia (sent to referral lab- IMR and HKL). The unit also performs serum erythropoietin test.

Test indication

All samples or tests must **consult** with the **Lab Haematologist** prior to sampling.

List of services

A) Haemostasis Unit (refer to Table 3.1 & 3.3)

1. Urgent services
    a) Coagulation screen (examples: PT, INR, APTT, Fibrinogen, TT, D-Dimer) within 1 hour of request.
    b) Factor assays to diagnose haemophilia.

2. Routine services
    a) Coagulation screen (TAT- 90 minutes, LTAT 60 minutes)

3. Special services
    a. Test run in batches – Factor assays, vWF assays, Lupus anticoagulant screen, ADAMTS-13 activity and inhibitor.
    b. Test run by appointment – Platelet aggregation test, Anti-Xa.

B) Red Cells Unit (refer to Table 3.2)

1. Special services
    a. Test run in batches – Hb Analysis, serum erythropoietin (EPO).
    b. Test (refer to referral lab) – DNA analysis for Thalassemia.

Instructions for Submitting Samples

A completed **HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY** requisition form **MUST** accompany all specimens.

Please note that incomplete or illegible Labelling of forms and/or specimens, or use of incorrect specimen tubes, may result in delays or rejection of specimens.

Remarks: Please refer to procedure 1.0 for blood collection for haemostasis test. The sample for haemostasis test from outside of Hospital Ampang **please put in dry ice** but no direct contact with the sample; otherwise it will be rejected.

Sample Requirements

a) Samples for Haemostasis & Red cells as per table 3.1 and 3.2

b) Sample Labelling

Specimens should be labelled using a waterproof pen with at least **2 Unique patient identifiers**.

I. Patient's Full Name (Surname, First name)
II. Patient identification number (Patient's Hospital Number /IC / Passport / Military/Police number). Please provide full identification number (e.g IC: 123456-78-9012).

c) Sample collection date, time and the origin (source) of specimen, when applicable. Information on the specimen label should match information on the lab requisition form.

d) Relevant clinical history should be written on the form. ***Requesting physician contact information*** is required to obtain further history or to inform urgent results.

Sample for Hb Analysis (Hb Electrophoresis):

- Thalassemia screening is indicated in cases with first degree relatives of thalassemia/hemoglobinopathy and cases with low or normal Hb with low MCH < 27 pg.
- In case of iron deficiency, please treat accordingly and repeat FBC after 3 month of treatment. Hb analysis is indicated if MCH is persistently low < 25pg despite adequate iron therapy.
- For family screening, please include the index case particulars (name/IC/diagnosis) in the request form.
- In cases which need DNA analysis for confirmation, please send a new sample together with the DNA ANALYSIS FOR THALLASEMIA SYNDROMES & HAEMOGLOBINOPATHIES form to the laboratory along with Hb analysis report and the latest FBC/FBP. (Alpha DNA analysis will be sent to HKL and Beta DNA analysis to IMR).
- Please complete the request form properly; those with no relevant history will be rejected.

Sample Collection for Coagulation test. Please refer to Apendix A, Procedure 1.0

Rejection criteria:
Refer to this handbook at Section of *SPECIMEN REJECTION CRITERIA*

Performing Laboratory
a) Haemostasis Unit, Clinical Haematology Referral Laboratory, Department of Haematology, Hospital Ampang. Contact number: 03-42896461.
b) Red Cells Unit, Clinical Haematology Referral Laboratory, Department of Haematology, Hospital Ampang. Contact number: 03-42896217

Setup Schedule
Setup: Monday-Friday
Weekend: Depending on the cases (confirmation by Consultant Haematology)
Service time: 7.30 am to 5.30 pm
Service after office hours: 5.30 pm to7.30 am

Reference range
Refer to table 3.1 & 3.2

Note:

1. Thrombophilia test: Indicated for investigation of Purpura Fulminans (in newborn) and upon discussion with Haematologist (for selected case ONLY).

2. Platelet Aggregation test: For control sample, patient needs to bring along a friend or relative of the same gender and age to be tested. ***Appointment should be made at least one (1) month prior to sampling. Test is only done on Tuesday. The requester must confirm the appointment two (2) days before the appointment date. No sample shall be send on public holiday. Sampling is done in the Thalassemia Hospital Hospital Ampang as the samples must be fresh and run immediately.***

3. Lupus Anticoagulant Assay- Result & Interpretation:

DRVVT Screen Ratio = $\frac{\text{dRVVT Screen (Time of patient Sec.)}}{\text{dRVVT Screen (Time of Normal control Sec.)}}$

DRVVT Confirm Ratio = $\frac{\text{dRVVT Confirm (Time of patient Sec.)}}{\text{dRVVT Confirm (Time of Normal control Sec.)}}$

Normalize final ratio = $\frac{\text{dRVVT screen ratio}}{\text{dRVVT confirm ratio}}$

Final result : Ratio > than 2.0 = Strong Positive for Lupus Anticoagulant.
Ratio 1.6-2.0= Moderate Positive for Lupus Anticoagulant.
Ratio 1.2-1.5= Weak Positive for Lupus Anticoagulant.

Reference: Kitchen S, Olson JD, Preston E.Quality in Laboratory Hemostasis and Thrombosis Wiley-Blackwell,2009.

Table 3.1 List of tests offered at Haemostasis Unit

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
Coagulation test								
PT (Prothrombin Time)	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%x1	Collect until indicated mark x 1 tube	Deliver tubes immediately to the laboratory at room temperature.	Routine: 1 day Urgent request: within 1 hour	Routine	Based on lot to lot reference interval. Refer the report released
APTT (activated partial tromboplastin time)	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 1 tube	Deliver tubes immediately to the laboratory at room temperature.	Routine: 1 day Urgent request: within 1 hour	Routine	Based on lot to lot reference interval. Refer the report released
Fibrinogen	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 1 tube	Deliver tubes immediately to the laboratory at room temperature.	Routine: 1 day Urgent request: within 1 hour	Routine	Based on lot to lot reference interval. Refer the report released
D-Dimer	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 1 tube.	Deliver tubes immediately to the laboratory at room temperature.	Routine: 1 day Urgent request: within 1 hour	Routine	Based on lot to lot reference interval. Refer the report released.

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
Thrombin Time	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 1 tube	Deliver tubes immediately to the laboratory at room temperature.	Routine: 1 day Urgent request: within 1 hour	Routine	Based on lot to lot reference interval. Refer the report released
Factor Assay								
Factor II Assay	Mechanical / Photo Optical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	**Known case** - 1 tube (until indicated mark) **Out source**- (New case)Collect until indicated mark x 3 tubes	Deliver tubes immediately to the laboratory at room temperature. OR Separate and alliquot ≥500 µL plasma from cells into secondary tube (e.g polyphyrene tube (PPT)) as soon as possible Store frozen at -40ºC and transport frozen plasma on dried ice	1 day for urgent request 2 weeks for normal request	By appointment	50-150%
Factor V Assay								50-150%
Factor VII Assay								50-150%
Factor VIII Assay								66.9-155.3%
Factor IX Assay								50-150%
Factor X Assay								50-150%
Factor XI Assay								50-150%
Factor XII Assay								50-150%
Factor XIII Assay	Photo Optical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	**Known case**- 1 tube (until indicated mark) **Out source**- (New case) Collect until indicated mark x 3 tubes	Deliver tubes immediately to the laboratory at room temperature. OR Separate and alliquot ≥500 µL plasma from cells into secondary tube (e.g polyphyrene	1 day for urgent request 2 weeks for normal request	By appointment	50-150% * These factor assay normal value does not apply to paediatric age. *Put disclaimer and reference source

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
					tube (PPT)) as soon as possible. Store frozen at -40ºC and transport frozen plasma on dried ice.			
Von Willebrand Factor Assay								
VWF Antigen	Photo Optical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 3 tubes	Deliver tubes immediately to the laboratory at room temperature. OR Separate and alliquot ≥500 µL plasma from cells into secondary tube (e.g polyphyrene tube (PPT)) as soon as possible. Store frozen at -40ºC and transport frozen plasma on dried ice.	1 day for urgent request. 2 weeks for normal request	By appointment	52.9-182.5%
VWF : Ricof								59.8-131.5%

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
CBA (Collagen Binding Assay)	ELISA	Blood (Plasma	Trisodium Citrate 3.2	Collect until indicated mark x 1 tube	Deliver tubes immediately to the laboratory at room temperature OR Separate and alliquot ≥500 µL plasma from cells into secondary tube (e.g polyphyrene tube (PPT)) as soon as possible. Store frozen at -40ºC and transport frozen plasma on dried ice	6 weeks	Batches	Group O: 62-138% Non-Group O: 86-160%
Lupus Anticoagulant Assay								
DRVV Screen	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 4 tubes	Deliver tubes immediately to the laboratory at room temperature. OR Separate plasma from cells as soon as possible (double spin) Platelet count must be <10x10^9/L in plasma prior to freezing. Store frozen at -40ºC and transport frozen plasma on dried ice	2 weeks	Batches	30.8 - 42.8Sec
DRVV Confirm								30.4 - 40.6 Sec
PTT LA								32.3 - 43.9 Sec

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
Thrombophilia Test								
Antithrombin Activity	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 4 tubes	Deliver tubes immediately to the laboratory at room temperature. OR Separate plasma from cells as soon as possible (double spin). Platelet count must be <10x10^9/L in plasma prior to freezing. Store frozen at -40ºC and transport frozen plasma on dried ice.	2 weeks	Batches	70 - 142%
Protein C Activity								70 - 142%
Protein S Activity								55 – 140%
Protein S Free								50 – 150% *To recheck range for thrombophilia test
Therapeutic Monitoring								
Anti Xa	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	<u>Adult:</u> Collect until indicated mark x 1 tube <u>Peads:</u> Collect until indicated mark x 2 paeds tube	Deliver tubes immediately to the laboratory at room temperature. OR Separate plasma from cells as soon as possible, ideally within one hour of specimen collection (double spin) Platelet count must be <10x10^9/L in plasma prior to freezing. Store frozen at -40ºC and transport frozen plasma on dried ice	1 day – Urgent (verbally informed) 2 weeks – Formal report	By appointment	Therapeutic Range: Adult : 0.7 – 1.2 IU/ml (after 4 hrs infusion) Paeds : 0.5 – 1.0 IU/mL

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
Platelet Function Test								
Platelet Aggregation Test	Photo Optical Automated Coagulation Analyzer	Blood (Platelet Rich Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark	Deliver tubes immediately to the laboratory at room temperature (platelets are activated at cold temperature) Do not refrigerated or freeze specimen	2 weeks	By appointment (Case need to be discussed with Haematologist prior testing; Subject and control need to come to Hospital Ampang for blood sampling)	Total aggregation (% @ 5 min) : ADP : 63-89% Arachidonic Acid: 65-90% Collagen : 61-99% Epinephrine : 54-101%
ADAM TS-13								
ADAM TS-13 ACTIVITY	ELISA KIT	Blood (plasma)	Trisodium Citrate 3.2%	Collect until indicated mark.	Deliver tubes immediately to the laboratory at room temperature. OR Separate plasma from cells as soon as possible (double spin) Platelet count must be $<10x10^9$/L in plasma prior to freezing. Store frozen at -40°C and transport frozen plasma on dried ice	6 weeks	Batches	ADAMTS-13 ACTIVITY : 40-130%

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
ADAM TS-13 INHIBITOR								ADAMTS-13 INH : Negative : <12 U/ml Boderline : 12-15 U/ml Positive : >15 U/ml
Anti PF4 Antibody Testing								
HiTT /ViTT	ELISA	Serum	Plain Tube	Collect 2 tubes	Samples must be fresh; and allowed to clot for 30 mins Centrifuge for 10 mins at 3000g Remove serum and store at -20 to -80 degrees Send frozen after informing lab staff	12 - 16 weeks	Batches	Positive : > 1 OD Negative : < 1 OD **subject to change based on kit used**

Table 3.2 List of tests offered at Red Cells Unit

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
Hemoglobin Analysis								
Gel Electrophoresis	Electrophoresis	Whole blood	K2/K3 EDTA tube	Collect until indicated mark x 1 tube	Deliver tubes within 24 hours to the laboratory at room temperature	6 weeks	Batches	Guideline for the range, need to refer the QC pattern from the gel staining
Capillary Electrophoresis	Electrophoresis	Whole blood	K2/K3 EDTA tube	Collect until indicated mark x 1 tube	Deliver tubes within 24 hours to the laboratory at room temperature	6 weeks	Batches	Hb A : 96.8-97.8% Hb A2 : 2.2-3.2%
DNA analysis for Thalassaemia (To referral lab)		Whole blood	K2/K3 EDTA tube	Collect until indicated mark x 1 tube	Deliver tubes within 24 hours to the laboratory at room temperature	HKL - 90 working days IMR – 120 working days	Outsource. MUST use DNA Ana for Thal Synd & Hbpathy(s) REQ & Consent forms Date of issue: Nov 2022 Version 4.1)	Result based on molecular test : (Alpha from HKL, Beta from IMR)

Serum Erythropoietin								
Serum EPO (Erythropoietin)	ELISA	Whole blood Serum	Plain tube	3.5 ml (inpatient) If from outsource, separate serum minimum 1.5 ml .	Internal: Deliver tubes immediately to the laboratory at room temperature. External: Separate serum from cells as soon as possible. Store frozen at -40°C and transport frozen serum on dried ice Must attach FBC result with request form.	MDS: 8 weeks MPN & PRV: 12 weeks	Batches Tests will be only performed after molecular results are available for MPN cases.	3.22 – 31.9 mIU/ml

Table 3.3 Summary of Pre-analytical sampling errors that will affect coagulation test results

Sample Type	Routine Coagulation Tests	Potential Consequences On Factor Assays	Potential Consequences On Other Hemostasis Tests
EDTA plasma	Prolongs PT and APTT, and occasionally TT, Might influence fibrinogen and D-Dimer assays.	False low levels (especially FV and FVIII)	False impression of inhibitors to FV and FVIII, and may show time dependence (enhanced with incubation), false LA feasible.
Serum or fully clotted coagulation sample	No fibrinogen, so no clot in PT, APTT or TT, False impression of afibrinogenemia, D-Dimer assays can be affected especially if testing delayed.	False low levels (especially FII, FV, and FVIII), false high FVII	False impression of factor inhibitors or VWD, false LA feasible.
Partially clotted coagulation sample	Depending on relative extent of platelet activation, haemolysis and loss of fibrinogen might lead to false prolongation of PT, APTT, and TT or false shortening of APTT	False low factor levels or false high factor VII.	Flow obstructions in PFA-100 testing.
Underfilled primary citrate anticoagulant tube	Will typically prolong PT, APTT and TT, may underestimate fibrinogen and D-Dimer.	False low factor levels likely	False low levels of most haemostasis tests likely
Vitamin K-deficient plasma, patient on vitamin K antagonist therapy, liver disease sample	Prolongs PT and APTT (PT raised > APTT raised)	False low factors (especially FII, FVII, FIX, FX)	False low protein C (potentially different effect with clot-based assays vs chromogenic assays), false low protein S, false APCR, false LA feasible
Heparin 'contamination' (either ex-vivo or due to collection tube error)	Prolongs PT, APTT, and TT (usually TT raised > APTT raised > PT raised), false low fibrinogen.	Reduced factors (especially FVIII, FIX, FXI, FXII)	False low Antithrombin, false LA feasible. False impression of factor inhibitors.

Reference: Emmanuel J. Favaloro Dorothy M. (Adcock) Funk Giuseppe Lippi *Laboratory Medicine*, Volume 43, Issue 2, 1 February 2012, Pages 1–10, https://doi.org/10.1309/LM749BQETKYPYPVM

4. HAEMATOPATHOLOGY UNIT

Introduction

The Haematopathology unit provides a wide range of diagnostic services to support the investigation and treatment monitoring for patients with various haematological malignancies. These include tissue processing, haematoxylin and eosin staining, immunohistochemistry tests and special staining.

Tests offered in Haematopathology unit include histopathologic examination of bone marrow trephine, second opinion on previous histopathology findings and requests for H&E, IHC, ISH and special stains.

Test indication

Bone marrow trephine histology examination is indicated for diagnosis, disease staging and therapeutic monitoring of various myeloid and lymphoproliferative disorders. Furthermore, it is also indicated for investigation of cytopenia, anaemia, thrombocytosis, leukocytosis and certain cases of PUOs

Instructions for Submitting Samples for histopathology examination

A completed HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY requisition form MUST accompany all specimens.

Please note that incomplete or illegible Labelling of forms and/or specimens, or use of incorrect specimen tubes, may result in delays or rejection of specimens.

For trephine biopsies, MLT who attend bone marrow aspiration procedure will bring the container filled with 10% neutral buffered formalin.

Sample Requirements

a) Samples for Haematopathology:

- bone marrow trephine

b) Sample Labelling

Specimens should be Labelled using a waterproof pen with at least **2 unique patient identifiers**.

I. Patient's Full Name (Surname, First name)
II. Patient identification number (Patient's Hospital Number /IC / Passport / Military/Police number). Please provide full identification number (e.g IC: 123456-78-9012).

c) The collection date and time, and the specimen anatomical sites. The information on the specimen label should match the information on the lab requisition form.

d) Clinical history, reason for referral, prior therapy and transplant history should be written on the form.

Special Instruction

For trephine biopsies, MLT who attend bone marrow aspiration procedure will bring the container filled with 10% neutral buffered formalin.

Storage and Transportation

Specimen should be fixed using 10% neutral buffered formalin at room temperature.

Rejection criteria:

Refer to this handbook at Section of *SPECIMEN REJECTION CRITERIA*

Performing Laboratory

Haematopathology Unit, Clinical Haematology Referral Laboratory, Department of Haematology, Hospital Ampang. Contact number: 03-42896222

Setup Schedule

Setup: Monday-Friday
Service time: 7.30 am to 4.30 pm

Table 4.1 List of tests offered at Haematopathology Unit

	Name of test	Method	Volume required	Special instructions	Collection instruction	Storage and transportation	TAT	Remarks
1	Bone marrow trephine biopsy	Hematoxylin & Eosin (H&E) Staining, immunohistochemistry (IHC) staining, special stain, in-situ hybridization (ISH) staining	Trephine biopsy in 20-30ml of 10% neutral buffered formalin (Max level of sterile container used / provided by lab).	None	Immerse trephine biopsy in formalin immediately	Room temperature	14 working days for non complicated cases	Internal cases only
2	Second opinion on histopathologic examination / requests of staining	Hematoxylin & Eosin (H&E) Staining, immunohistochemistry (IHC) staining, special stain, in-situ hybridization (ISH) staining	None	Polylysine coated unstained slides required.	None	Room temperature	14 working days for non complicated cases	

5. CYTOGENETICS (LEUKAEMIA) UNIT

A. INTRODUCTIONS

Cytogenetic studies help diagnose neoplastic disorders by identifying numerical or structural changes in chromosomes. Such abnormalities can confirm a clonal disease, guide diagnosis and prognosis, monitor remission, and indicate targeted treatments. Cytogenetic analysis (karyotyping) examines metaphase and interphase cells using light or fluorescence microscopy to detect chromosome abnormalities. The cytogenetic analysis involves culturing cells to produce metaphase chromosomes, which are then visualized individually.. The cytogenetic technique requires fresh material and will only yield information on dividing cells. Samples should be as fresh as possible to ensure optimal results with viable disease cells. The cells are processed and stained using banding techniques to produce a karyotype. Abnormalities are identified and described according to the International System for Human Cytogenomic Nomenclature (ISCN).

B. TEST AVAILABLE

Haemato-Oncology (acquired)

- Chromosome analysis (Blood and Marrow)
- Fluorescence in situ Hybridization (FISH)

C. REQUEST INDICATION:

The reason for referral is crucial for determining the appropriate culture types, tests to perform, cell counts to analyse, and sample prioritization. All relevant clinical and hematological information, including the likely diagnosis, should be included. Successful cytogenetic studies depend on a clear indication for testing or a presumptive diagnosis. Cultures are set up based on the involvement of myeloid or lymphoid cells and the presence of blast cells, with different approaches for acute and chronic disease states to enhance the detection of acquired abnormal cells. The type of specimen received also influences the potential number of abnormal cells. Providing comprehensive clinical information at the time of specimen collection is essential for optimal laboratory results.

D. TEST OFFERING FOR CASES:

We offer testing for the following cancers:

- Leukemias
- Myeloma / Lymphomas (test must be discussed with haematologist prior to sampling)

All cases that do not fulfil these clinical indication criteria must consult with the Haematologists prior to sampling. If you need help for cytogenetic (including

Fluoresence in situ hybridization, FISH) testing, Please contact Cytogenetic Lab (603) 4289 6055. Please refer to Table 5.1 for the test offer for cytogenetic.

Fluorescence in situ hybridization (FISH):

1. RARA break-apart (for Acute Promyelocytic Leukaemia).
2. *PDGFRA* for Hypereosinophilia cases (as per Haematologist request)
3. *BCR*::*ABL1* for variant
4. TP53 (as per Haematologist request).
5. CCND1 (as per Haematologist request)
6. Chimerism X/Y (mismatched donor only)

Please refer to Table 5.1: List of tests offered at Cytogenetics (Leukaemia) Unit

E. SAMPLE TYPES ACCEPTED

Bone Marrow is the tissue of choice to investigate patients suspected with leukaemia or related haematological neoplasms. Bone marrow aspirate specimens are routinely received, but a peripheral blood specimen may be used if the marrow is fibrotic or otherwise difficult to aspirate.

Peripheral blood can be used if the marrow is fibrotic or difficult to aspirate, provided that disease cells are present in sufficient numbers (at least 10% abnormal cells) to enable cell culture and/or FISH studies. For chronic lymphocytic leukaemia (CLL), blood is suitable for cytogenetic and FISH studies if there is peripheral blood lymphocytosis. Peripheral blood is acceptable for plasma cell leukemia but not for multiple myeloma.

F. SAMPLE REQUIREMENTS AND REFERRING SAMPLES

It is the responsibility of the referring clinician to request a laboratory test and to ensure that all samples are labelled appropriately and accompanied by a fully completed request form. Samples at high risk of being infected with hazardous biological agents must be labeled. Samples are generally referred by hospital consultants, but exceptions are made for general clinician (non-hematologist specialists) for karyotyping or FISH in hemato-oncology, provided they consult with a consultant beforehand.

G. REQUESTS FOR ADDITIONAL TESTS (ADD-ONS)

Requests for additional tests on a sample, provided they fall within the scope of the original request (such as cytogenetic analysis or FISH), are considered part of the routine work-up and can be submitted by telephone (include verbal request) or email by the referring consultant or other clinician involved in the patient's care. A new hard-copy written request for each additional test is not necessary. However, the name of the requester and the time and date of the request will be recorded in the request form (initial) by laboratory. The handling scientist or clinical hematologist will review the

relevance of the additional test and the suitability of the remaining specimen. If needed, they will discuss these aspects with the requester. Any new tests will be prioritized according to when the sample was first received by the laboratory.

1. Clinical history, reason for referral, prior therapy and transplant history should be written on the form.

H. SAMPLE LABELLING AND REQUEST FORMS

- Samples must be labeled using a waterproof pen with least **2 Unique patient identifiers**, including
    - Full patient name (Surname, First name)
    - IC number
    - Date of collection

  The information on the specimen label should match the information on the lab requisition form.

- A fully completed request form should accompany each sample. Please note that incomplete or illegible Labelling of forms and/or specimens, or use of incorrect specimen tubes, may result in delays or rejection of specimens. Please provide information on the request form, including:
    - Patient's full name, NRIC number/Passport number, sex, age, date of birth
    - Clinical diagnosis, relevant clinical information
    - Specimen type
    - Name of referring doctor, clinic, telephone / fax number
    - Date and time the specimen was taken from the patient

- Clinical indications being essential
  Clinical history/reasons for referral are required with test order. Prior therapy and transplant history (e.g: donor gender) should be provided with test order. Clinical indications are needed to determine test protocols and interpret cytogenetic findings.

I. SPECIFIC SAMPLE REQUIREMENTS

Bone Marrow Aspirate / Blood - karyotyping and FISH (general information)

i. Collect fresh samples in sterile bone marrow transport medium (**provided by the laboratory):** Bone marrow transport medium is available upon request.please contact us for further advice.

ii. If Bone marrow transport medium unavailable, use a heparinized tube, preferably sodium heparinized.

iii. All samples for cytogenetics studies should be collected under sterile conditions.

iv. One tube is adequate if both tests are ordered (chromosome study and FISH analysis).

v. Keep the sample at room temperature or in the refrigerator, and ensure it arrives within 24 hours of collection.

Collection instruction

1. **Bone marrow**: Collect 1-2 ml in a sterile bone marrow transport medium or in a heparin tube (preferably sodium heparin tube).
2. **Leukemic Blood**: Collect 10 ml of blood (at least 10% blasts) in a sterile bone marrow transport medium or a heparin tube (preferably a sodium heparin tube).

   *****Myelodysplastic neoplasms (MDS) with a low blast of at least 5% (bone marrow) or 2% in peripheral blood.
3. Gently invert sample for 6 times to mix.
4. Samples should be sent directly to the laboratory and ensure it arrive within 24 hours of collection, e.g., by hospital transport, post, courier service, etc.

   (Delays can result in the loss of malignant cells. **Samples subject to possible reject** when Blood sample arriving after 48 hours and Marrow sample after 72 hours).
5. Samples can be stored overnight at +4°C but **DO NOT FREEZE** if there is an unavoidable delay between collection and dispatch.
6. When sending samples by post or courier:
   - Samples **MUST NOT** be frozen.
   - Avoid dry ice and direct contact with a cool / ice pack (a cool / ice pack may be used to ensure that the samples are not exposed to temperatures in excess of 37ºC) for transportation.

J. IN ABEYANCE

A state of temporary inactivity in which all samples with an uncertain diagnosis (e.g., query of myeloma, lymphoma, CLL case, etc) will be placed on hold until further information is provided. Please contact the laboratory to activate a case following diagnosis. This procedure is necessary because the diagnosis may not be clear during the biopsy, and chromosome analysis may not be required after examining bone marrow morphology. Consultants are asked to cooperate fully with this policy to avoid unnecessary and labour-intensive analytical work, helping the laboratory manage its

large workload and minimize costs. Please contact the laboratory to activate a case following diagnosis.

K. REJECTION CRITERIA

The following samples will not be proceed for testing by the Cytogenetics Laboratory:

- Unlabeled, frozen, or grossly contaminated
- Gross clotted blood samples
- Collected into the wrong tube
- Inadequately labeled samples - when it has not been possible to confirm the patient of origin
- Inadequately packaged samples, including damaged or leaking samples.
- Incorrect specimen type
- Exposed to extreme temperatures.
- Received in the laboratory after an extended period (Blood 48 hours and Bone marrow sample after 72 hours or more).

Unacceptable Specimen Samples

When a sample is found unacceptable, Laboratory will notify via telephone. If you have any question prior to collection or transportation of a sample, please contact the appropriate Laboratory unit.

Exceptionally Accepted:

- Test requested by general practitioner, provided they consult with a consultant beforehand
- Samples collected in a lithium heparinized tube
- Samples collected in EDTA tubes for FISH tests only
- Samples with minute, not visible clotting
- Clotted samples (e.g., marrow specimens) for suspected APL cases, for FISH testing only (depend on sample quality). Handling as case by case basis.
- Clotted samples (e.g., marrow specimens) for suspected Philadelphia positive acute leukemia, for FISH testing only (depend on sample quality). Handling as case by case basis.

Turnaround Time

Average turnaround time is 45 days. For further details or to request expedited testing, please contact the respective Laboratory unit.

Urgent Request

Please contact laboratory during working hours to alert laboratory staff for urgent processing.

Contact

For results dispatch and notification of unacceptable samples, provide name and fax number of Contact person. It will be responsibility of the referring lab to notify us any change in contact person.

Performing Laboratory

Cytogenetics (Leukaemia) Unit. Clinical Haematology Referral Laboratory for Department of Haematology Hospital Ampang. Contact number: 03-4289 6055

Setup Schedule

Setup: Monday-Friday
Service Hours: Regular hours of operation (excluding national & Selangor public holidays and weekends): 7.30am – 5.00pm Monday to Friday.

Table 5.1 List of tests offered at Cytogenetics (Leukaemia) Unit

No	Test Name	Method	Specimen Type	Volume Required	Container Type	Specimen Transport Guidelines	TAT
1	Bone Marrow Chromosome study	Karyotyping. A minimum of 20 G-banded metaphases studied	Bone marrow aspirate (BMA)	Minimum 1-2.0ml	Sterile transport medium with heparin is always preferred (available from lab) If transport medium not available, collect sample in sterile-**heparinize** tube (preferable: sodium heparin)	Transport samples without delay at room temperature. **DO NOT** freeze specimens	45 days
2	Leukaemia (Neoplasia) Blood Chromosome analysis	Karyotyping. A minimum of 20 G-banded metaphases studied	Peripheral Blood (PB)	10.0 ml		Transport samples without delay at room temperature. **DO NOT** freeze specimens.	45 days
3	Leukaemia FISH analysis (only)	FISH interphase analysis	BMA	Minimum 1 -2.0 ml	Sterile transport medium with heparin is always preferred (available from lab). If transport medium not available, collect sample in sterile—**heparinize** tube (preferable: sodium heparin)	Transport samples without delay at room temperature. **DO NOT** freeze specimens.	18 days
			Peripheral Blood (PB)	10.0 ml			
4	Bone Marrow or blood (neoplasia) Chromosome study &	Karyotyping & FISH Interphase analysis	BMA	Minimum 1-2.0ml	Sterile transport medium with heparin is always preferred (available from	Transport samples without delay at	45 days (Karyo-

No	Test Name	Method	Specimen Type	Volume Required	Container Type	Specimen Transport Guidelines	TAT
	Leukaemia FISH analysis	If ordering both tests (Chromosome study and FISH analysis), **one** tube is adequate (refer to specimen type collection	Peripheral Blood (PB)	10.0mL	lab). If transport medium not available, collect sample in sterile **heparinize** tube (preferable: sodium heparin)	room temperature. **DO NOT** freeze specimens.	typing) 18 days (FISH)

6. MOLECULAR (HAEMATOLOGY) UNIT

Introduction

Molecular haematology laboratory plays a key role in diagnosing and managing various haematologic malignancies. This laboratory also provides critical information regarding the clinical management of bone marrow transplant patients. The Molecular Diagnostics (Haematology) unit offers molecular testing for acquired haematological disorders. We are a referral laboratory for other hospitals (MOH) nationwide.

Test indication

Refer to Indication for a specialized laboratory test for molecular test.

LIST OF SERVICE

Haematological malignancies cases:

i. *BCR::ABL1*, Major (p210), Quantitative
ii. *BCR::ABL1*, Minor (p190), Quantitative
iii. *PML::RARA,* Quantitative
iv. *JAK2* (Janus Kinase 2) V617F Mutation Detection
v. Calreticulin mutation
vi. *FLT3*-ITD detection
vii. *NPM1* mutation detection
viii. Fusion translocation screening
ix. *RUNX1*::*RUNX1 T1*
x. *CBFβ*::*MYH11A*

Instructions for Submitting Samples

A completed HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY requisition form MUST accompany all specimens.

Please note that incomplete or illegible Labelling of forms and/or specimens, or use of incorrect specimen tubes, may result in delays or rejection of specimens.

Sample Requirements

a) Sample for molecular tests:

- MPN cases – refer to table 6.1
- Acute leukaemia- refer to table 6.1

b) Sample Labelling

Specimens should be Labelled using a waterproof pen with at least **2 Unique patient identifiers**.

i. Patient's Full Name (Surname, First name)
ii. Patient identification number (Patient's Hospital Number /IC/ Passport / Military/Police number). Please provide full identification number (e.g IC: 123456-78-9012).

c) The collection date and time, and sample type. The information on the specimen label should match the information on the lab requisition form.

d) Clinical history, reason for referral, prior therapy and transplant history should be written on the form.

Collection Instructions:

1. Invert several times to mix blood or bone marrow.
2. A copy of the requisition must be sent with the specimen.

Storage and Transportation

Samples should never be frozen. Use cold pack but not dry ice for transport, making sure cold pack is not in direct contact with specimen. Transport sample to the laboratory at room temperature within 24 hours. The specimen must arrive to the laboratory no later than 24 hours after collection.

Specimens should be delivered to the laboratory as soon as possible after they are taken to ensure the quality of the specimen and the success of the results. Any specimens which have been delayed in transit may not be suitable for processing and may therefore not be accepted by the Laboratory.

Rejection Criteria

Refer to this handbook at Section of *SPECIMEN REJECTION CRITERIA*

Performing Laboratory

Molecular Diagnostics (Haematology) Unit. Clinical Haematology Referral Laboratory for Department of Haematology, Hospital Ampang. Contact number: 03-4289 6056

Setup Schedule

Setup: Monday-Friday
Service time: 7.30am to 4.30pm (excluding national & Selangor public holidays and weekends)

Table 6.1 List of tests offered at Molecular (Haematology) Unit

No	Test Name	Method	Specimen Type	Volume Required	Container Type	Special Instruction	TAT
1.	*BCR*::*ABL1* (*for suspected CML case only)	Qualitative PCR	PB, before starting therapy BM, acceptable	PB, Minimum 10 ml BMA, 1-2ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	4 weeks
2.	*BCR*::*ABL1* (*CML AND Ph+ve ALL/AML case)	Quantitative RT-PCR	**Follow-up:** BMA (Ph+ ALL/AML case)	Minimum 1-2ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	12 weeks
			PB preferred in CML case	Minimum 10 ml			
3.	Minor *BCR::ABL1*	Quantitative RT-PCR	**Follow-up**: BMA	Minimum 1-2 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	6 weeks
4.	JAK2 / CALR Calreticulin (	Qualitative PCR	BMA or PB	Minimum 1-2 ml Minimum 10 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	8 weeks
5.	*FLT3* ITD (AML: Diagnosis and follow-up)	Qualitative PCR	BMA or PB	Minimum 1-2 ml Minimum 10 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens	4 weeks
6.	*NPM1* (AML: Diagnosis and follow-up)	Qualitative PCR	BMA or PB	Minimum 1-2ml Minimum 10 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DONOT** freeze specimens.	4 weeks
7.	*PML*::*RARA* (bcr1, bcr2 & bcr3) [Monitoring]	Quantitative RT-PCR	**Initial / Follow-up:** BMA	Minimum 1-2 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	6 weeks

No	Test Name	Method	Specimen Type	Volume Required	Container Type	Special Instruction	TAT
8.	*RUNX1*::*RUNX1 T1* [Monitoring]	Quantitative RT-PCR	**Follow-up:** BMA	Minimum 1-2 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	6 weeks
9.	*CBFβ*::*MYH11A* [Monitoring]	Quantitative RT-PCR	**Follow-up:** BMA	Minimum 1-2 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	6 weeks

7. BONE MARROW TRANSPLANT UNIT

Introduction

The bone marrow transplant unit provides a diagnostic service to support the investigation and treatment monitoring of patients who undergo transplants. These include processing of stem cells such as cryopreservation of Peripheral Blood Stem Cell (PBSC), bone marrow and cord blood and storage of stem cells for transplantation.

Test indication

Stem cell transplant is an established form of treatment for a variety of disease such as haematological malignancies, severe inherited hemoglobin disorders, bone marrow failures and severe immune deficiency states.

Instructions for Submitting Samples

A completed HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY requisition form MUST accompany all specimens.

Please note that incomplete or illegible Labelling of forms and/or specimens, or use of incorrect specimen tubes, may result in delays or rejection of specimens.

Sample Requirements

a) Sample of Peripheral Blood Stem Cell (PBSC), bone marrow and cord blood for processing of stem cells and storage of stem cells for transplantation.

b) Sample Labelling

Specimens should be labelled using a waterproof pen with at least **2 Unique patient identifiers**.

1. Patient's Full Name (Surname, First name)
2. Patient identification number (Patient's Hospital Number /IC / Passport / Military/Police number). Please provide full identification number (e.g IC: 123456-78-9012).

c) The collection date and time, and the origin (source) of the specimen, when applicable. The information on the specimen label should match the information on the lab requisition form.

d) Clinical history, reason for referral, prior therapy and transplant history should be written on the form.

e) Type of samples

Please mention peripheral blood, bone marrow or cord blood.

Special instruction:

Test offered to inpatient or cases referred to Hospital Ampang with Approval from Consultant Haematologist Hospital Ampang. Any enquiries / arrangement for donor or patient stem cell collections please call wad 7D at 03-42896194.

Storage and Transportation
Specimen for pre CD34 Enumeration should be received by 7.00 am on the day of enumeration and result will be release by 9.30 am. For Post CD34 Enumeration result will be release in 24 hours.

Rejection criteria:
Refer to this handbook at Section of *SPECIMEN REJECTION CRITERIA*

Performing Laboratory
Bone Marrow Transplant Unit, Clinical Haematology Referral Laboratory, Department of Haematology, Hospital Ampang. Contact number: 03-42896390

Setup Schedule
Setup: Monday-Friday
Weekend: Depending on the cases
Service time: 7.00am to 5.00pm

Table 7.1 List of tests offered at Stem Cell Transplant Laboratory

No	Test name	Method	Specimen type	Container type	Volume required	Specimen Transport	TAT
1	Stem Cell Cryopreservation • CD34 Enumeration • CD3 Enumeration • Viability Assays	CD34/CD3 enumeration protocol and 7AAD stem cell viability protocol	PBSC/ Bone Marrow/ Cord Blood	1. PBSC in EDTA tube (For CD34 enumeration prior collection) 2. Stem cells collection in apheresis bag / marrow harvesting bag in Hospital Ampang 3. Cryopreserved vial / segment (from N2 gas tank in BMT Lab / cord blood bank prior infusion)	2 ml	1. Room Temperature (Fresh collected stem cell) 2. Cryo-thermos (cryopreserved segment)	24 hour
2	Stem cell derived services include: • Volume Reduction • Red Cell Depletion	CD34/CD3 enumeration protocol and 7AAD stem cell viability protocol	PBSC/ Bone Marrow/ Cord Blood	Stem cells collection in apheresis bag / marrow harvesting bag in Hospital Ampang	2 ml	1. Room Temperature (Fresh collected stem cell) 2. Cryo-thermos (cryopreserved segment	24 hour
3	Full Blood Count	FBC Protocol	Whole Blood / PBSC / Bone Marrow/ Cord Blood	EDTA Tube	2 ml	Room Temperature	1 hour
4	Stem Cell Selection	Selection Protocol using CliniMacs	PBSC	ACDA (in collection bag)	> 100ml	Room Temperature	24 hour

LIST OF TEST OFFER TO OTHER HOSPITALS (MOH)

Table 8.2 List of tests offered to Hospital (MOH) outside Hospital Ampang

1. Full blood picture FBP *(District clinic in Klang Valley only)*

No	Test name	Method	Specimen type	Container type	Volume required	Department instructions	TAT	Unit* / Remarks
1.	Full Blood Picture (FBP)	Wright Eosin Staining	Whole Blood	K2/K3 EDTA Tube	2 ml	Sample must be received within 6 hrs of collection	Non urgent : 7 days	Test offer outside Hospital Ampang **(Klinik Kesihatan)** For Urgent Full Blood Picture after office hours please contact Haematology lab medical officer on call Please take note : Urgent FBP is only indicated for cases to rule out : **Acute Leukaemia/APML, Microangiopathic Hemolytic Anemia (MAHA)& active Hemolysis**

2. PNH (Flowcytometry Unit)

No	Test name	Method	Specimen Type	Container Type	Volume required	Department Instructions	TAT	Remarks
1	Paroxysmal Nocturnal Haemoglobinuria (PNH)	Flowcytometry	Blood	K2 EDTA tube	3 ml	Internal PNH samples must be sent immediately to the lab within 4 hours of draw. External PNH samples are accepted within 4 days of draw.	7 working days	Referral lab for PNH for both internal and external cases.

3. Molecular test (Molecular Unit)

No	Test Name	Method	Specimen Type	Volume Required	Container Type	Special Instruction	TAT
1.	BCR-ABL1 (*for suspected CML case only)	Qualitative PCR	PB, before starting therapy BM, acceptable	PB, Minimum 5.0 ml BMA, 1-2ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	4 weeks
2.	BCR-ABL1 (*CML AND Ph+ve ALL/AML case)	Quantitative RT-PCR	**Follow-up:** BMA (Ph+ ALL/AML)	Minimum 1-2ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	6 weeks
			PB preferred in CML case	Minimum 10 ml			
3.	Minor *BCR-ABL1*	Quantitative RT-PCR	**Follow-up**: BMA	Minimum 1-2 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	6 weeks
4.	JAK2 / CALR Calreticulin (this test only carry out if JAK2V617F mutation negative)	Qualitative PCR	BMA or PB	Minimum 1-2 ml Minimum 5.0 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	8 weeks
5.	FLT3-ITD (AML: Diagnosis and follow-up)	Qualitative PCR	BMA or PB	Minimum 1-2 ml Minimum 5.0 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens	4 weeks
6.	NPM1 (AML: Diagnosis and follow-up)	Qualitative PCR	BMA or PB	Minimum 1-2ml Minimum 5.0 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DONOT** freeze specimens.	4 weeks
7.	PML-RARA (bcr1, bcr2 & bcr3) **[Monitoring]**	Quantitative RT-PCR	**Initial / Follow-up:** BMA	Minimum 1-2 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	6 weeks
8.	RUNX1-RUNX1 T1 **[Monitoring]**	Quantitative RT-PCR	**Follow-up:** BMA	Minimum 1-2 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	6 weeks

No	Test Name	Method	Specimen Type	Volume Required	Container Type	Special Instruction	TAT
9.	CBFβ-MYH11A **[Monitoring]**	Quantitative RT-PCR	**Follow-up:** BMA	Minimum 1-2 ml	K2/K3 EDTA tube	Transport samples without delay preferably within 24 hours at room temperature. **DO NOT** freeze specimens.	6 weeks

4. Hemoglobin Analysis (red cell & Hemostasis Unit)

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
Hemoglobin Analysis								
Gel Electrophoresis	Electrophoresis	Whole blood	K2/K3 EDTA tube	Collect until indicated mark x 1 tube	Deliver tubes within 24 hours to the laboratory at room temperature	6 weeks	Batches	Guideline for the range, need to refer the QC pattern from the gel staining
Capillary Electrophoresis	Electrophoresis	Whole blood	K2/K3 EDTA tube	Collect until indicated mark x 1 tube	Deliver tubes within 24 hours to the laboratory at room temperature	6 weeks	Batches	Hb A : 96.8-97.8% Hb A2 : 2.2-3.2%
Serum Erythropoietin								
Serum EPO (Erythropoietin)	ELISA	Whole blood Serum	Plain tube	3.5 ml (in patient) If from outsource, separate serum minimum 1.5 ml	Deliver tubes immediately to the laboratory at room temperature. OR Separate serum from cells as soon as possible. Store frozen at -40°C and transport frozen serum on dried ice	MDS: 6-8 weeks MPN & PRV: 12 weeks	Batches Tests will be only performed after molecular results available for MPN cases	3.7- 40.7 mIU/ml

5. Coagulation test (red cell & Haemostasis Unit)

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
Factor Assay								
Factor II Assay	Mechanical / Photo Optical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	**Known case** - 1 tube (until indicated mark) **Out source**- (New case) Collect until indicated mark x 3 tubes	Deliver tubes immediately to the laboratory at room temperature OR Separate and alliquot ≥500 µL plasma from cells into secondary tube (e.g polyphyrene tube (PPT)) as soon as possible Store frozen at -40ºC and transport frozen plasma on dried ice	1 day for urgent request 5 working days for normal request	By appointment	50-150%
Factor V Assay								50-150%
Factor VII Assay								50-150%
Factor VIII Assay								66.9-155.3%
Factor IX Assay								50-150%
Factor X Assay								50-150%
Factor XI Assay								50-150%
Factor XII Assay								50-150%
Factor XIII Assay	Photo Optical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	**Known case**- 1 tube (until indicated mark) **Out source**- (New case) Collect until indicated mark x 3 tubes	Deliver tubes immediately to the laboratory at room temperature OR Separate and alliquot ≥500 µL plasma from cells into secondary tube (e.g polyphyrene tube (PPT)) as soon as possible Store frozen at -40ºC and transport frozen plasma on dried ice	1 day for urgent request 5 working days for normal request	By appointment	50-150% * These factor assay normal value does not apply to paediatric age.
Von Willebrand Factor Assay								
VWF Antigen	Photo Optical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 3 tubes	Deliver tubes immediately to the laboratory at room temperature OR Separate and alliquot ≥500 µL plasma from cells into secondary tube (e.g polyphyrene tube (PPT)) as soon as possible Store frozen at -40ºC and transport frozen plasma on dried ice	1 day for urgent request. 2 weeks for normal request	By appointment	52.9-182.5%
VWF : Ricof								59.8-131.5%

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
CBA (Collagen Binding Assay)	ELISA ~~KIT~~	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 1 tube	Deliver tubes immediately to the laboratory at room temperature OR Separate and alliquot ≥500 µL plasma from cells into secondary tube (e.g polyphyrene tube (PPT)) as soon as possible Store frozen at -40ºC and transport frozen plasma on dried ice	~~4~~-6 weeks	Batches	Group O: 62-138% Non-Group O: 86-160%
Lupus Anticoagulant Assay								
DRVV Screen	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 4 tubes	Deliver tubes immediately to the laboratory at room temperature **OR** Separate plasma from cells as soon as possible (double spin) Platelet count must be <10x10^9/L in plasma prior to freezing Store frozen at -40ºC and transport frozen plasma on dried ice	2 weeks	Batches	30.8-42.8Sec
DRVV Confirm								30.4 - 40.6 Sec
PTT LA								32.3 – 43.9 Sec
Thrombophilia Test								
Antithrombin Activity	Mechanical Automated Coagulation Analyzer	Blood (Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 4 tubes	Deliver tubes immediately to the laboratory at room temperature **OR** Separate plasma from cells as soon as possible (double spin) Platelet count must be <10x10^9/L in plasma prior to freezing Store frozen at -40ºC and transport frozen plasma on dried ice	2 weeks	Batches	70 - 142%
Protein C Activity								70 - 142%
Protein S Activity								55 – 140%
Free Protein S								50 – 150%

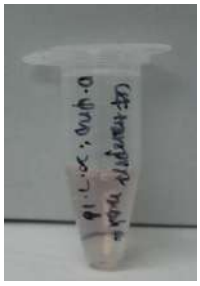
Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
Therapeutic Monitoring								
Anti Xa		Blood (Plasma)	Trisodium Citrate 3.2%	Adult: Collect until indicated mark x 1 tube Peads: Collect until indicated mark x 2 paeds tube	Deliver tubes immediately to the laboratory at room temperature **OR** Separate plasma from cells as soon as possible, ideally within one hour of specimen collection (double spin) Platelet count must be $<10x10^9$/L in plasma prior to freezing Store frozen at -40ºC and transport frozen plasma on dried ice	1 day – Urgent (verbally informed) 2 weeks – Formal report	By appointment	Therapeutic Range: Adult : 0.7 – 1.2 IU/ml (after 4 hrs infusion) Paeds : 0.5 – 1.0 IU/mL
Platelet Function Test								
Platelet Aggregation Test	Photo Optical Automated Coagulation Analyzer	Blood (Platelet Rich Plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x ~~4~~ 6 tubes	Deliver tubes immediately to the laboratory at room temperature (platelets are activated at cold temperature) Do not refrigerated or freeze specimen	2 weeks	By appointment (Case need to be discussed with Haematologist prior testing) (Patient and control need to come to Hospital Ampang for blood sampling)	Total aggregation (% @ 5 min) : ADP : 63-89% Arachidonic Acid: 65-90% Collagen : 61-99% Epinephrine : 54-101%
ADAM TS-13								

Test Name	Method	Specimen Type	Container Type	Volume Required	Department Instructions	TAT	Remarks	Normal Range
ADAM TS-13 ACTIVITY	ELISA	Blood (plasma)	Trisodium Citrate 3.2%	Collect until indicated mark x 1 tube	Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible (double spin) Platelet count must be <10x10^9/L in plasma prior to freezing Store frozen at -40°C and transport frozen plasma on dried ice	4-6 weeks	Batches	ADAMTS-13 ACTIVITY : 40-130%
ADAM TS-13 INHIBITOR								ADAMTS-13 INH : Negative : <12 U/ml Boderline : 12-15 U/ml Positive : >15 U/ml
HITT / VITT								
Anti PF4 Antibody Testing	ELISA	Blood (plasma)	Plain Tube	Collect 2 tubes	Samples must be fresh allowed to clot for 30 minutes Centrifuge for 10 minutes at 3000g Remove serum and store at -20 to -80 degrees Send frozen after informing lab staff	12-16 weeks (prevous 6-8 weeks)	Batches	Positive : >1OD Negative : < 1OD **subject to changes based on kit used**

LIST OF SPECIMEN CONTAINER & TUBES

LIST OF SPECIMEN CONTAINER/TUBES

Unit/Test	Container /Tube	Specimen volume	Rejected Sample Tube
MORPHOLOGY FBC FBP Reticulocyte Count	 K2/K3 EDTA Tube (Purple cap)	Peripheral blood: 2 ml	 Lysed sample
	 Neonate EDTA Tube (Purple cap**)**	Peripheral blood: 250-500ul	
Cytospin	 Screw Cap Tube	CSF/Body fluids: Minimum 1 ml	 Blood in CSF tube
FLOW CYTOMETRY	 K2 EDTA Tube (Purple cap)	Peripheral blood/BMA: 3 ml	

	 Bone Marrow Transport Media  CSF Transport Media	Body fluids (Peritoneal/ Pleural fluids) : Minimum 1ml CSF: Minimum 1ml	
HAEMOSTASIS PT, aPTT INR D-Dimer Fibrinogen DIVC screening Factor Assay ADAMTS-13 All coagulation testing	 Sodium Citrate 3.2% tube (Blue cap)	Peripheral blood: up to indicated mark Number of bottles depend on the test requested; Please refer to Table 3.1	 Overfilled sample  Underfilled sample  Lysed sample

PF4 Antibody	 Plain Tube	Peripheral blood (in patient): 3.5 ml If from outsource, spin & separate the serum; minimum 1.5 ml	
RED CELLS Hb analysis	 K2/K3 EDTA Tube (Purple cap)	Peripheral blood: 2 ml	 Lysed sample
	 Neonate EDTA Tube	Peripheral blood: 250-500ul	
EPO level	 Plain Tube	Peripheral blood (in patient): 3.5 ml If from outsource, spin & separate the serum; minimum 1.5 ml	Not send together with dry ice ~~pack~~ (from outsource)

HAEMATO-PATHOLOGY	 Universal container (Trephine)	Recommended trephine length: 2-4 cm	 Volume of formalin < 20X size of trephine
CYTOGENETICS Karyotype FISH	 Bone Marrow Transport Media (in patient)  SodiumHeparintube (Green cap) (Outsource)	BMA : Minimum 1-2 ml CLL case: 5 ml Peripheral blood: 5 ml CLL case: 10 ml Peripheral blood/BMA: Please refer to Table 5.1	 EDTA tube
MOLECULAR		BMA: Minimum 1-2ml Peripheral blood: Minimum 5.0 ml	

	K2/K3 EDTA Tube (Purple cap)		Lysed sample
BONE MARROW TRANSPLANT	 K2/K3 EDTA Tube (Purple cap)  Apheresis bag/Marrow harvesting bag	Peripheral blood/BMA: 2 ml	

SPECIMEN REJECTION CRITERIA

SPECIMEN REJECTION CRITERIA

A. GENERAL

1. General specimen requirement for testing can be referred in "**Handbook of services in clinical haematology referral laboratory"**
2. In order to ensure the quality of results produced and to comply to MS ISO15189:2014, the requirement need to be followed by clients were listed below:

i) Sample Labelling: Specimens shall be Labelled with at least **TWO Unique patient identifiers**. **(i)** Patient's Full Name (Surname, First name) **(ii)** Patient identification number (Patient's Hospital Number /IC/ Passport / Military / Police number). Please provide full identification number (e.g IC: 123456-78-9012).

ii) Request forms shall be filled up completely (Including the details of clinical staff, the collection date and time, and sample type. The information on the specimen label should match the information on the lab requisition form. Clinical history, reason for referral, prior therapy and transplant history shall be written on the form.

B. REJECTION CRITERIA

The below criteria outline when specimens which are deemed unacceptable and should be rejected specific by laboratory.

- Specimen reception staff will notify the client of unacceptable specimens and test cancellations; if a recollection not done, a comment will be made on the report saying that the specimen was received unlabelled or wrongly labelled once the requisitions clinical staff / nurses / phlebotomists accept the responsibility.

- Staff in unit will inform the respective requisitions clinical staff; test cancel once the requisitions clinical staff / nurses / phlebotomists accept the responsibility.

i) **GENERAL HAEMATOLOGY REJECTION CRITERIA**

ii) **Clotted Specimens**

Clotted specimens, where appropriate should be discarded and a recollection performed.

iii) **Insufficient Specimen**

EDTA tube - less than 1ml

Insufficient specimen quantity

iv) **Mislabelled / Unlabelled Specimen**

- Specimens which do not have any patient details or the wrong patient details written on the tube.

- The identification on the requisition and specimen do not match unLabelled or misLabelled or inadequately labelled specimens (will not be processed under any circumstances).

v) **Incomplete / unsigned request form**

- Unsigned of requesting doctor
- Incomplete information on the test request form (clinical history is not provided, incomplete IC no, no specimen date and time collection, specimen site is not stated, name of requesting doctor is not stated).
- Specimen unaccompanied by form (outside Hospital Ampang)

vi) **Haemolysed Samples**

Grossly haemolysed samples giving inaccurate results or unreadable blood films should be rejected and a recollection performed.

vii) **Aged Specimens OR Deteriorated specimen**

Generally EDTA samples up to 24 hours old are acceptable. However if old samples due to delayed in transportation or collection are received and there is significant morphological changes in the white cells or red cells the specimen should be discarded and a recollection performed.

viii)**Other Unsuitable specimens are:**

- Incorrect specimen collection container
- Transported incorrectly
- Inadequate fixative
- Specimen too large for container
- Incorrect anticoagulant
- Leaking specimens / Broken container
- No specimen received Wrong sample
- Test not offered
- Duplicate order
- Test requested is not stated
- Specimen stability compromised (i.e. age of specimen, temperature stored).

1. SPECIFIC REJECTION CRITERIA

1) COAGULATION SPECIMEN REJECTION CRITERIA

i) **Incorrect Ratio Of Blood And Anticoagulant** (underfill or overfill)

Citrate tubes – less or more than 10% of stated tube volume (up to the mark)

ii) Delayed Sample

- Delayed sample received (PT and APTT- tested within 4 hours from the time of specimen collection.)

- **For external requests from outside of Hospital Ampang**
- Specimen MUST be less than 4 hours of collection upon receipt by the external laboratory.
- Immediately, centrifuge the specimen at 3500 rpm for 15 minutes, separate and aliquot ≥500 µL plasma into a secondary tube (eg: PPT tube) and freeze the plasma immediately. All aliquot plasma must be appropriately labelled and ensure tally with the request form.
- The sample is to be sent to CHRL (MRKH) with dry ice. Please refer to the procedure for packaging specimens from external sources for coagulation/serum EPO test at Appendix A.
- A thawed sample will be rejected.

2) RED CELL SPECIMEN REJECTION CRITERIA

a) Hb analysis

- Normal FBC result.

b) DNA analysis

- Refer to HKL / IMR DNA for Thalassemia analysis rejection criteria
- Wrong request form and no signed consent form attached
- No Hb analysis result

3) IMMUNOPHENOTYPING SPECIMEN REJECTION CRITERIA

- External CSF/ Body Fluid samples
- Fixed or frozen specimens
- Clotted specimen
- Insufficient blood / bone marrow samples
- Specimens in anticoagulants other than K2 EDTA tube
- Delayed samples

4) CYTOGENETICS SPECIMEN REJECTION CRITERIA

- Refer to Specialised haematology tests in Section 5. Cytogenetic number (L): Rejection criteria

5) MOLECULAR DIAGNOSTICS SPECIMEN REJECTION CRITERIA

- Frozen specimens (Specimen shall not have direct contact with ice-cool pack or dry ice)
- Clotted specimen
- Specimen exposed to extreme temperature
- Haemolysed specimen
- Delayed sending specimen
- Delay in transport
- Wrong anti-coagulant (Only EDTA tube accepted for molecular analysis)
- Duplicated ordered i.e sample sent previously and still awaiting results.
- Samples which do not fulfil monitoring time-line (Pre determined) will be rejected.

6) HAEMATOPATHOLOGY SPECIMEN REJECTION CRITERIA

- Unlabelled specimen / incomplete information
- No patient identification on request form and /or specimen container/slides
- No request form (only sample received)
- No sample (only request form received)
- Leaking sample (compromising fixation of sample) / sample not in formalin
- Conflict between the patient's identification on specimen and on the Request Form
- Unsuitable specimen to be processed in Haematopathology Lab

NOTE:

i) Specimen container should be labelled with two identifications, the name of the patient and the anatomical site of the specimen. If the histology specimen container is received without site of the specimen, specimen reception staff should note this down on the request form. The pathologist will notify the doctor concerned in the form of a report where by in the macroscopic description, it will be mentioned that the nature of specimen was not designated on the specimen container.

ii) If there is a dispute between specimen received and nature of specimen noted in the request form the haematopathologist concerned will communicate with the requesting Doctor.

REJECTION CONSEQUENCES:

- Communication will be provided to the ordering clinical doctor. Requesting Doctors will be notified the reason for specimen rejection.
- Specimens which can be recollected (eg. blood) will be discarded and the test cancelled.
- Specimens which cannot be recollected (eg. CSF, bone marrow, tissue, etc.), collection personnel will be contacted to correct the Labelling error. Contacted clinical staff stated accepting full responsibility for the non-identification of the specimen. Record name, date and time of statement in request from. Test proceeding with the analysis and the final report should indicate a note referring to this.
- In the event where the specimen is non-sufficient, a physician or clinical consult may be required to determine the order of priority for testing where applicable.

EXCEPTION OF ACCEPTANCE SAMPLE FOR TEST

	Unit Laboratoty	Criteria
1	Cytogenetics	i. Test requested by general practitioner, provided they consult with a consultant beforehand ii. Samples collected in a lithium heparinized tube iii. Samples collected in EDTA tubes for FISH tests only iv. Samples with minute, not visible clotting v. Clotted samples (e.g., marrow specimens) for suspected APL cases, for FISH testing only (depend on sample quality). Case by case basis. vi. Clotted samples (e.g., marrow specimens) for suspected Philadelphia positive acute leukemia, for FISH testing only (depend on sample quality).

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APPENDIX A

PROCEDURE 1.0

Sample Collection for Coagulation Testing

1.General

- The specimen of choice for coagulation testing is plasma.
- Before sample collection ensure that the patient is not on any anticoagulants or tPA therapy; if on please state the type of anticoagulant therapy, patient weight,dose and time of ingestion/administration in relation to sampling on the request form.
- Venous blood is drawn into a 3.2% buffered sodium citrate tube (blue top tube), yielding a whole blood sample with a 9:1 blood to anticoagulant ratio; please ensure that the blood sample is collected up to the indicated mark on the sodium citrate tube (*Inadequate filling of the collection tube will affect this ratio, and may result in erroneous test results*)

- **When drawing the specimen:**
  a) Avoid contaminating the sample with tissue thromboplastin as this may affect results
  b) Venipuncture must be clean with no trauma, and the application of the tourniquet should be limited to 1 minute.
  c) If possible sample should be collected from a large vein (preferrably the vein at the bend of the elbow) using a 21 guage needle for adults and 22 or 23 gauge for infant
  d) If a winged blood collection set is used in drawing a specimen for coagulation testing, a discard tube should be drawn first. The discard tube must be used to fill the blood collection tubing dead space to assure that the proper anticoagulant/blood ratio is maintained, but the discard tube does not need to be completely filled. The discard tube should be a nonadditive or a coagulation tube.
  e) Avoid blood collection for coagulation testing from an indwelling catheter. However, if a blood specimen for coagulation testing must be collected from an indwelling line that may contain heparin, the line should be flushed with 5 mL of saline, and the first 5 mL of blood or 6-times the line volume (dead space volume of the catheter) be drawn off and discarded before the coagulation tube is filled.
  f) If multiple blood test are carried out for a patient, a blue top tube used for coagulation testing should be filled before any other tubes containing additives. This includes tubes containing other anticoagulants and/or plastic serum tubes containing clot activators. A serum tube that does not contain an additive can be collected before the blue top tube.

- If a patient has a hematocrit > 55% or < 25% please call and inform the coagulation lab for further advise on how to sample the patient **OR** the anticoagulant volume may be computed by using this below formula

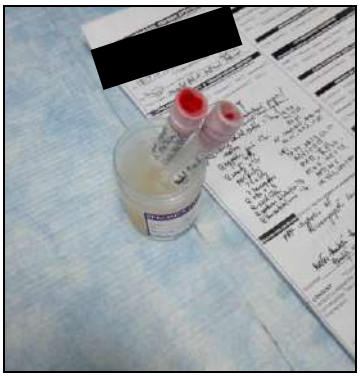
X = Anticoagulant volume required per 1 mL blood
H = Hematocrit
V = Total volume of anticoagulated blood

$$X \text{ mL sodium citrate} = \frac{100 - H}{595 - H} \times V$$

- This is because the plasma to anticoagulant ratio will not be accurate and further adjustments needs to be carried out to ensure accurate diagnosis / reading of coagulation testing.
- Mix gently by inverting the tube end over end 5 to 6 times. Avoid vigorous mixing or additional inversion. Observe for the presence of clots. Specimens containing fibrin clots will, in most cases, be rejected.
- Transport the sample IMMEDIATELY at ambient temperature to the processing site or facility, and maintain at ambient temperature until processed.
- Sample processing ideally should take place within 1 hour of collection; however it must be completed within 4 hours of collection.

1. Collecting specimens for coagulation from laboratories / outside Hospital Ampang

- If sample can be sent to Haemostasis lab at Hospital Ampang within 4 hours of collection, sample can be sent without processing at ambient temperature.
- However if delay is anticipated, the sample has to be processed and sent frozen to the lab ~~in~~ with DRY ICE.
- Methods on sample process the sample will depend on the special coagulation test required.
- Please DO NOT freeze the samples together with water in bags or urine container (direct contact between sample and ice) (examples in pictures below) as this does not follow the correct SOP and will not ensure adequate results.



- Samples sent not in accordance to the guidelines mentioned will be rejected and rejection will be informed to the sender via telephone initially and followed by a rejection memo.

Centrifugation:

1. Platelet Poor Plasma (PPP) for Coagulation/Factor Assay/VWF Assay:

This method of processing is used for most tests of coagulation and is prepared as follows:

a) Blood sample should be centrifuged at a minimum of 3500rpm for at least 15 mins at room temperature not more than 25 degree celcius.

2. Platelet-poor Plasma (PPP) Collection for Lupus Anticoagulant Testing/Thrombophilia/Anti-Xa/ADAMTS-13

For these test, PPP samples should be collected by double centrifugation. PPP should have a platelet count < 10 x 10^9/L

PPP samples should be collected by *double centrifugation*.

1. Centrifuge at 3500 rpm for 15 minutes, and carefully remove two-thirds of the plasma using a plastic transfer pipette.

2. Pool the plasma to a polypyrene tube (PPT), cap, and recentrifuged for 15 minutes.

3. Use a second plastic pipette to remove the plasma, staying clear of the platelets at the bottom of the tube.

4. Transfer plasma using a plastic pipette into another PPT tube with screw cap. Label each tube with patient's name and identity card number.

Shipping specimens for coagulation

1. **In-house patient**
   Should be sent to the lab IMMEDIATELY (within 1 hour of sampling) at ambient temperature.

2. **From laboratories / outside Hospital Ampang**
   Please ensure that all frozen samples are sent with **DRY ICE ONLY.**

PROCEDURE FOR PACKAGING SPECIMENS FROM OUTSIDE SOURCES FOR COAGULATION TESTING AT AMPANG HSOPITAL. (Recommendation)

Disclaimer: This procedure should be followed after the sample has been centrifuged / double-centrifuged.

1. Equipment:
   a) Labeled Micro tube / Eppendorf tube
   b) Urine container / Secondary packaging
   c) Gel / Dry ice
   d) Tissues
   e) Biohazard plastic

2. Procedure:
   a) Label the tubes and urine container.
   b) Transfer the 500-1000 uL plasma into the micro tube, dividing it into 2 to 3 tubes.
   c) Cover the tubes with tissues and place it inside the urine container as a secondary packaging . (Refer picture below)

   d) Prepare biohazard plastic and place appropriate amounts of thawed gel ice inside.
   e) Wrap the urine container with biohazard plastic nicely and place it inside the gel. (Refer picture below).

   f) Freeze it overnight at least.
   g) Double pack it properly and sent the frozen sample to Ampang hospital using dry ice.

3. Below is example of samples that should be received at Ampang Hospital.