HANDBOOK OF SERVICES
IN
CLINICAL HAEMATOLOGY REFERRAL LABORATORY

Department of Haematology
Hospital Ampang
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FOREWORD

The Clinical Haematology Referral Laboratory/MRKH (Department of Haematology, Hospital Ampang) is the national referral laboratory in the Ministry of Health for specialized haematology testing. Established in 2006, the outreach and impact of this laboratory have been significant. Given the complexity of these tests, this Handbook of Services has been compiled to help medical practitioners across the country not only to be aware of the indications and requirements for testing but also make appropriate choices. This contributes to optimal use of resources, efficiency and importantly, better patient care.

Dr Ghazi bin Abdul Manaf
Director
Hospital Ampang
Laboratory tests play a very crucial role in the diagnosis and management of patient care. These test results must therefore be precise, accurate and reliable and have to be made available to the clinicians in a timely manner. The generation of high quality results involves a step wise process of meticulous planning, perfect execution and thorough checking of results by the whole team involved.

The third edition of ‘HANDBOOK OF SERVICES IN CLINICAL HAEMATOLOGY - REFERRAL LABORATORY’ is the latest edition to provide the essential core knowledge required before any routine or specialized haematology tests are ordered by hospital users, especially by those involved in haematology patient management.

The Clinical Haematology Referral Laboratory Hospital Ampang/MRKH is expected to play a lead role in haematology testing guidelines, especially in molecular and cytogenetics testing. We have provided a full purview of our laboratory general information, test indications, specimen handling, special handling requirements, urgent requests, storage & transportation and rejection criteria. It is also hoped that over a period of time a network of haematology laboratories can be established to centralise specific tests. This would save enormous time, money and resources.

I would also like to gratefully acknowledge the guidance and support of all experts of the Advisory Committee in preparing this ‘HANDBOOK OF SERVICES IN CLINICAL HAEMATOLOGY REFERRAL LABORATORY’.

Dr Jameela Sathar
Head and Consultant Haematologist
Department of Haematology
Hospital Ampang
HANDBOOK OF SERVICES IN
CLINICAL HAEMATOLOGY REFERRAL LABORATORY

THIRD 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 for the effective and efficient use of its resources. All laboratory staffs are committed to the culture of quality. All staff share responsibility for identifying nonconformities and opportunities for improvement, 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 & 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, medical and allied health student.

1.2 Mission statement
i. To provide quality health care that is responsive to the needs of all including patients and staff.
ii. Comprises of a team of personnel who are competent, innovative and committed.
iii. To partner the individual and society in the promotion of health.
iv. To plan educational and professional development and performing biomedical research.

1.3 Vision statement
To be a national centre of excellence in the field of diagnostic haematology.

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.
iv. To help training of staff specialising in haematology tests.
v. To achieve and maintain an effective quality management system
vi. To ensure the scope, standard and capability of the laboratory meets clinical needs and technology used state of the art, appropriate and cost-effective.
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 and 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 give the highest quality of service with the minimum of 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 preparing for 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 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)

<table>
<thead>
<tr>
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<th>Extension number (Ext)</th>
</tr>
</thead>
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<tr>
<td>Administration</td>
<td>Ext 6219</td>
</tr>
<tr>
<td>Morphology</td>
<td>Ext 6532</td>
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<tr>
<td>Haemostasis</td>
<td>Ext 6461</td>
</tr>
<tr>
<td>Red Cell</td>
<td>Ext 6217</td>
</tr>
<tr>
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<td>Ext 6218</td>
</tr>
<tr>
<td>Haematopathology</td>
<td>Ext 6222</td>
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<tr>
<td>Molecular</td>
<td>Ext 6056</td>
</tr>
<tr>
<td>Cytogenetics</td>
<td>Ext 6055</td>
</tr>
<tr>
<td>Bone Marrow Transplant</td>
<td>Ext 6390</td>
</tr>
<tr>
<td>Medical Officer</td>
<td>Ext 6531/6530/6527</td>
</tr>
</tbody>
</table>

Email: mrkh@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.
Or fax number: 03-42970059
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 Hospital Ampang website; http://hampg.moh.gov.my/ under Haematology Department front page. Please see; [Buku rujukan Makmal Rujukan Klinikal Hematologi, KLIK DI SINI].
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 specialised haematology unit”.

2.5.2 The parties agree that:

a. Each request accepted by laboratory for examination shall be considered an agreement. This agreement shall also include request to the examination and the report. The examination processes to be used was 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, reserves the right to expand the technical pathology services.

e. CHRL shall have the right to designated to all laboratory personnel and pathologist to perform their laboratory testing at Hospital Ampang facilities, at another location as designated by CHRL or partner with any other entity, commercial or otherwise, and its associated professional component for performance by third party.

f. CHRL from time to time may engage additional visiting haematopathologist to furnish services under this Agreement.

g. All laboratory personnel shall have the skills and be properly trained and 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. Customers or 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.

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 plays a role and responsibility in 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 an appropriate laboratory testing in our laboratory, it is important to follow the clinical indications stated below as well as for sample collection as instructed in the laboratory testing table in each unit.

Remarks: All cases that do not fulfill these clinical indication criteria must consult with the Hematologist prior to sampling.

A. Indication Criteria for molecular test:

1. Acute Leukemia:
   a. Acute Lymphoblastic Leukemia (ALL)
      i. BCR/ABL1: For diagnostic and follow up
   
   b. Acute Myeloid Leukemia (AML)
      i. RUNXI/RUNXITI: For diagnostic and follow up
      ii. CBFB/MYHII: For diagnostic and follow up
      iii. FLT3-ITD: For diagnosis only
      iv. NPM1: For diagnosis only
   
   c. Acute Promyelocytic Leukemia (APML)
      i. PML/RARA: For diagnostic and follow up

2. Myeloproliferative Neoplasm (MPN)
   a. JAK2
   b. CALR (If JAK2 not detected)
   c. BCR/ABL1
   d. PDGFRA: for Hypereosinophilia cases.
3. Chronic Myeloid Leukemia (CML)
   a. BCR/ABL1: For diagnostic and follow up.

B. Indication Criteria for cytogenetic test:
Karyotyping: At diagnosis only.
   1. Acute leukemia.
   2. Myelodysplastic syndrome (MDS).
   3. Chronic Myeloid Leukemia (CML).

Fluorescence in situ hybridization (FISH):
   1. PML/RARA (for Acute Promyelocytic Leukemia).
   2. Chimerism X/Y (mismatched donor only)
   3. MLL (as per Hematologist request).
   4. TP53 (as per Hematologist request).

C. Indication Criteria for flowcytometry test:
   2. Lymphoproliferative disorder (LPD): For diagnosis only.
   3. Paroxysmal Nocturnal hemoglobinuria (PNH).

D. Indication for haemostasis test:

   All samples or test must be discussed with the haematologist prior to sampling.

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 identifier:
   - 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.

It is essential that the correct request form be completed to ensure an efficient flow of work. Please ensure that request forms and specimen labeling 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 labeling 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 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 eg 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 labeled “High Risk”. The form must be folded to ensure confidentiality. The specimen must be sealed in the 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 Clinical Haematology Referral Laboratory reception during working hours. This reception counter is located inside the main laboratory adjacent to the morphology lab.

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, labeled, 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 needed attention will be notified to the clinician. Any discrepancy between clinical findings and report/results should be informed immediately to the relevant personnel.
Printed reports
Printed FBC results are dispatched ONLY during down time or system off-line. Reports to external locations are sent via post.

Electronic reports
Results are available via the eHIS/LIS Hospital Information System for FBC, FBP, marrow, iron stores, cytopsin, 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.

3.11 Confidentiality
All tests and results remain confidential.

4.0 SPECIMEN STORAGE & DISPOSAL

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

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

Receive specimen and Special Haematology Requisition form from clinics/wards or other hospital

Checking & sorting of samples

Register samples

Request accepted

YES

Distribute specimen to respective units:
- Morphology
- Flowcytometry
- Haemostasis & Red Cells
- Haematopathology
- Cytogenetics
- Molecular
- BMT

Process & analyze specimen

RESULTS REPORTING

NO

Reject Specimen

YES

Inform wards/clinics

Sending result

Discard specimen

End

YES

Send result

NO

Specimen storage for 24 hours

Report testing

Inform wards/clinics

Send result
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 Hematology lab 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 labeling 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 12hrs of collection. Invert several times to mix blood.
   ii. Full Blood Picture (FBP): 2.0 ml of peripheral blood must be received within 6hrs 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.
b) Sample Labeling
   Specimens should be labeled 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 8.00am to 5.00pm
After office hours, Weekends, Public Holidays: Urgent FBP requests only
<table>
<thead>
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<th>No</th>
<th>Test name</th>
<th>Method</th>
<th>Specimen type</th>
<th>Container type</th>
<th>Volume required</th>
<th>Department instructions</th>
<th>TAT</th>
<th>Unit* Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Full Blood Count (FBC)</td>
<td>Flowcytometry/RF DC Method</td>
<td>Whole Blood</td>
<td>K2/K3 EDTA Tube</td>
<td>2 ml</td>
<td>Sample must be received within 12 hrs of collection</td>
<td>Urgent: 45 min</td>
<td>Internal cases only.</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td>Lipaemic/icteric samples can affect performance of test and may delay results</td>
<td>Non urgent: 8 hours</td>
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</tr>
<tr>
<td>2</td>
<td>Full Blood Picture (FBP)</td>
<td>Wright Eosin Staining</td>
<td>Whole Blood</td>
<td>K2/K3 EDTA Tube</td>
<td>2 ml</td>
<td>Sample must be received within 6 hrs of collection</td>
<td>Urgent: 1 hr after reception</td>
<td>Internal cases only.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Non urgent: 7 working days</td>
<td>Non urgent: 7 working days</td>
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</tr>
<tr>
<td>3</td>
<td>Body Fluids Morphology</td>
<td>Cytospin</td>
<td>Body Fluids</td>
<td>Bijou Bottle</td>
<td>1 ml</td>
<td>Transport to lab immediate after collection</td>
<td>24 hours</td>
<td>Internal hematology cases.</td>
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<tr>
<td>No</td>
<td>Test name</td>
<td>Method</td>
<td>Specimen type</td>
<td>Container type</td>
<td>Volume required</td>
<td>Department instructions</td>
<td>TAT</td>
<td>Unit*/ Remarks</td>
</tr>
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</tr>
<tr>
<td>4</td>
<td>Bone marrow Aspirate for May Grunwald Giemsa Stain</td>
<td>May Grunwald Giemsa Stain</td>
<td>Marrow Aspirate Smear</td>
<td>Minimum 6 slides</td>
<td>NA</td>
<td>Air Dry Transport in slides Holder&lt;br&gt;6x bone marrow smears for morphology (All slides MUST be labeled with hospital number, surname and date of sample. (Please note, DOB is not required, date of sample is crucial)</td>
<td>7 working days</td>
<td>Internal cases only. External slide (from other hospitals) for 2nd opinion.</td>
</tr>
<tr>
<td>5</td>
<td>Iron Stain</td>
<td>Perl’s Prussian Blue staining</td>
<td>Marrow Aspirate Smear</td>
<td>Minimum 2 slides</td>
<td>NA</td>
<td>Air Dry Transport in slides Holder</td>
<td>7 working days</td>
<td>Internal cases only. External slide (from other hospitals) for 2nd opinion.</td>
</tr>
</tbody>
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### Table 1.2 Reference range

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Unit</th>
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<tr>
<td><strong>Hemoglobin</strong></td>
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<tr>
<td>Males &lt;60</td>
<td>13.5-17.4</td>
<td>g/dl</td>
</tr>
<tr>
<td>Males &gt;60</td>
<td>11.8-16.9</td>
<td>g/dl</td>
</tr>
<tr>
<td>Females</td>
<td>11.6-15.1</td>
<td>g/dl</td>
</tr>
<tr>
<td><strong>RBC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males &lt;60</td>
<td>4.53-5.95</td>
<td>10^12/L</td>
</tr>
<tr>
<td>Males &gt;60</td>
<td>3.86-5.62</td>
<td>10^12/L</td>
</tr>
<tr>
<td>Females</td>
<td>3.87-5.21</td>
<td>10^12/L</td>
</tr>
<tr>
<td><strong>Hematocrit</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males &lt;60</td>
<td>40.1-50.6</td>
<td>%</td>
</tr>
<tr>
<td>Males &gt;60</td>
<td>35.7-48.9</td>
<td>%</td>
</tr>
<tr>
<td>Females</td>
<td>35.1-44.9</td>
<td>%</td>
</tr>
<tr>
<td><strong>MCV</strong></td>
<td>80.6-95.5</td>
<td>fL</td>
</tr>
<tr>
<td><strong>MCH</strong></td>
<td>26.9-32.3</td>
<td>Pg</td>
</tr>
<tr>
<td><strong>MCHC</strong></td>
<td>31.9-35.5</td>
<td></td>
</tr>
<tr>
<td><strong>RDWSD</strong></td>
<td>37.5-48.1</td>
<td></td>
</tr>
<tr>
<td><strong>RDW-CV</strong></td>
<td>12-14.8</td>
<td>%</td>
</tr>
<tr>
<td><strong>Ret He</strong></td>
<td>30.7-38.9</td>
<td>Pg</td>
</tr>
<tr>
<td><strong>Retic</strong></td>
<td>0.40-1.6</td>
<td>%</td>
</tr>
<tr>
<td><strong>RPI</strong></td>
<td>0.1-1.5</td>
<td></td>
</tr>
<tr>
<td><strong>IRF</strong></td>
<td>0-8.9</td>
<td>%</td>
</tr>
<tr>
<td><strong>Platelets</strong></td>
<td>142-350</td>
<td>10^6/L</td>
</tr>
<tr>
<td><strong>IPF</strong></td>
<td>0-4</td>
<td>%</td>
</tr>
<tr>
<td><strong>MPV</strong></td>
<td>8.9-11.9</td>
<td>fL</td>
</tr>
</tbody>
</table>

### Parameter Range

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total WBC</td>
<td>4078-11370</td>
<td>Cells/µl</td>
</tr>
<tr>
<td>Neutrophils</td>
<td>3929-7147</td>
<td>Cells/µl</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>1847-4807</td>
<td>Cells/µl</td>
</tr>
<tr>
<td>Monocytes</td>
<td>385-1141</td>
<td>Cells/µl</td>
</tr>
<tr>
<td>Eosinophils</td>
<td>0-827</td>
<td>Cells/µl</td>
</tr>
<tr>
<td>Basophils</td>
<td>0-95</td>
<td>Cells/µl</td>
</tr>
</tbody>
</table>

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 identify the lineage of the neoplastic cells and level of maturation to aid the classification of leukaemia and lymphoma. Flow cytometry immunophenotyping also aids in the minimal residual disease monitoring (MRD) and Paroxysmal Nocturnal Haemoglobinuria (PNH).

Test Indication
Refer to Indication for specialized laboratory test for flowcytometry test.

Instructions for Submitting Samples
Contact the Specialist In-charge or on-call before making arrangements to send flow cytometry samples. Only Bone Marrow Aspirates/ Peripheral Blood samples are accepted for external cases. Completed HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY requisition form MUST accompany all specimens with specification of discussion with Specialist In-charge or on-call.

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

Sample Requirements
a) Samples for Flow Cytometry Immunophenotyping
   • Bone Marrow Aspirates/ Peripheral Blood: Samples must be sent in K2 EDTA and must reach the laboratory within 24 hours of draw.
   • CSF: Samples must be sent in special medium which can be obtained from Cytogenetics Laboratory, Hospital Ampang. Samples must be sent immediately and reach the lab within 4 hours of sampling to ensure viability of the cells.

b) Sample Labeling
   Specimens should be labeled 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.
**Collection Instructions**
- BMA/Blood in K2 EDTA tube: Invert several times to mix blood or bone marrow.
- CSF should be processed as soon as possible and not more than four hours after collection. CSF should reach the flow cytometry unit before 4.00 pm. For delayed samples (>4.00 pm), contact Specialist In-Charge (only) to ensure the acceptance of the samples, followed by a call to notify the medical laboratory technologist in flow cytometry unit.

**Storage and Transportation**
Samples should be transported in 4°C to avoid apoptosis. Use cold pack for transport. Ensure cold pack is not in direct contact with specimen during transport. The specimen must arrive at the lab no more than 24 hours after collection.

*ONLY Bone Marrow Aspirates/ Peripheral Blood samples are accepted for external cases.

**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: 7.30am to 5.00pm
### Table 2.1 List of tests offered in Flow Cytometry Unit

<table>
<thead>
<tr>
<th>No</th>
<th>Test name</th>
<th>Method</th>
<th>Specimen Type</th>
<th>Container Type</th>
<th>Volume required</th>
<th>Department Instructions</th>
<th>TAT</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Immunophenotyping of Leukaemia/ Lymphoproliferative Neoplasm</td>
<td>Flowcytometry</td>
<td>Blood or Bone Marrow Aspirate</td>
<td>K2 EDTA tube</td>
<td>3 ml</td>
<td>Bone Marrow Aspirates/ Peripheral Blood: Samples must be sent in K2 EDTA and must reach the laboratory within 24 hours of draw.</td>
<td>Urgent: 1 working day; Routine: 7 working days</td>
<td>Internal cases only</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Paroxysmal Nocturnal Haemoglobinuria (PNH)</td>
<td>Flowcytometry</td>
<td>Blood</td>
<td>K2 EDTA tube</td>
<td>3 ml</td>
<td>Internal PNH samples must be sent immediately to the lab within 4 hours of draw.</td>
<td>7 working days</td>
<td>Referral lab for PNH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>External PNH samples are accepted within 7 days of draw.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Immunophenotyping of Leukaemia/ Lymphoproliferative Neoplasm – for suspected CNS infiltration</td>
<td>Flowcytometry</td>
<td>CSF</td>
<td>Transport Medium</td>
<td>Min 1 ml</td>
<td>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.</td>
<td>1 working day</td>
<td>Internal cases only</td>
</tr>
</tbody>
</table>
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 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 osmotic fragility test and serum erythropoietin.

Test indication
All sample or tests must consult with the Hematologist 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
   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 labeling 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 Labeling
   Specimens should be labeled 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) Relevant clinical history should be written on the form.

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 PER PAT 301 form to the laboratory along with Hb analysis report and latest FBC/FBP. (Alpha DNA analysis will be sent to HKL and Beta DNA analysis will be sent to IMR).
- Please fill the request form properly as 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

**Email:** redcellhemostasisampang@gmail.com

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

**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 hematologist (for selected case ONLY).

2. Platelet Aggregation test: For control sample, patient needs to bring along a friend or relative with same gender & age to be tested.

3. Lupus Anticoagulant Assay- Result & Interpretation:

| DRVVT Screen Ratio | = | DRVVT Screen (Time of patient Sec.)  
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>DRVVT Screen (Time of Normal control Sec.)</td>
</tr>
</tbody>
</table>

| DRVVT Confirm Ratio | = | DRVVT Confirm (Time of patient Sec.)  
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>DRVVT Confirm (Time of Normal control Sec.)</td>
</tr>
</tbody>
</table>

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.

Table 3.1 List of tests offered at Haemostasis Unit

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Method</th>
<th>Specimen Type</th>
<th>Container Type</th>
<th>Volume Required</th>
<th>Department Instructions</th>
<th>TAT</th>
<th>Remarks</th>
<th>Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coagulation test</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT (Prothrombin Time)</td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2% x 1</td>
<td>Collect until indicated mark x 1 tube</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>Routine: 1 day</td>
<td>Routine</td>
<td>Based on lot to lot reference interval. Refer the report released</td>
</tr>
<tr>
<td>APTT (activated partial tromboplastin time)</td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 1 tube</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>Routine: 1 day</td>
<td>Routine</td>
<td>Based on lot to lot reference interval. Refer the report released</td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 1 tube</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>Routine: 1 day</td>
<td>Routine</td>
<td>Based on lot to lot reference interval. Refer the report released</td>
</tr>
<tr>
<td>D-Dimer</td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 1 tube</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>Routine: 1 day</td>
<td>Routine</td>
<td>Based on lot to lot reference interval. Refer the report released</td>
</tr>
<tr>
<td>Test</td>
<td>Instrument</td>
<td>Sample</td>
<td>Additive</td>
<td>Collection</td>
<td>Storage</td>
<td>Temperature</td>
<td>Delivery</td>
<td>Request Time</td>
</tr>
<tr>
<td>------</td>
<td>------------</td>
<td>--------</td>
<td>----------</td>
<td>------------</td>
<td>---------</td>
<td>-------------</td>
<td>----------</td>
<td>--------------</td>
</tr>
<tr>
<td>Thrombin Time</td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 1 tube</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>Routine: 1 day</td>
<td>Urgent request: within 1 hour</td>
<td>Routine</td>
</tr>
<tr>
<td>Factor Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
<tr>
<td>Factor II Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
<tr>
<td>Factor V Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
<tr>
<td>Factor VII Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
<tr>
<td>Factor VIII Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
<tr>
<td>Factor IX Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
<tr>
<td>Factor X Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
<tr>
<td>Factor XI Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
<tr>
<td>Factor XII Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
<tr>
<td>Factor XIII Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
<td>1 day for urgent request</td>
<td>2 weeks for normal request</td>
<td>By appointment</td>
</tr>
</tbody>
</table>
| * These factor assay normal value does not apply to paediatric age.
### Von Willebrand Factor Assay

<table>
<thead>
<tr>
<th>VWF Antigen</th>
<th>VWF Activity</th>
<th>VWF : Ricof</th>
<th>CBA (Collagen Binding Assay)-ELISA</th>
<th>Lupus Anticoagulant Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>ELISA KIT</td>
<td>Blood (Plasma)</td>
</tr>
<tr>
<td>Collect until indicated mark x 3 tubes</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible Store frozen at -40°C and transport frozen plasma on dried ice</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible Store frozen at -40°C and transport frozen plasma on dried ice</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible Store frozen at -40°C and transport frozen plasma on dried ice</td>
<td></td>
</tr>
<tr>
<td>1 day for urgent request by appointment</td>
<td>2 weeks for normal request</td>
<td>6 weeks</td>
<td>Batches</td>
<td></td>
</tr>
<tr>
<td>52.9-182.5%</td>
<td>63.5-140.7%</td>
<td>59.8-131.5%</td>
<td>Group O: 62-138% Non-Group O: 86-160%</td>
<td>30.8 - 42.8Sec</td>
</tr>
<tr>
<td>Test</td>
<td>Sample Type</td>
<td>Anticoagulant</td>
<td>Collect until</td>
<td>Deliver</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------</td>
<td>---------------</td>
<td>---------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Thrombophilia Test</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antithrombin Activity</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>indicated mark x 1 tube</td>
<td></td>
</tr>
<tr>
<td>Protein C Activity</td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein S Activity</td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td></td>
</tr>
<tr>
<td>Protein S Free</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti Xa</td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td></td>
</tr>
</tbody>
</table>

Platelet count must be <10x10⁹/L in plasma prior to freezing

Store frozen at -40°C and transport frozen plasma on dried ice

2 weeks

Days

By appointment
| Platelet Aggregation Test | Photo Optical Automated Coagulation Analyzer | Blood (Platelet Rich Plasma) | Trisodium Citrate 3.2% x 4-6 tubes and EDTA x 1 tube | Collect until indicated mark x 4-6 tubes | Platelet count must be <10x10⁶/L in plasma prior to freezing  
Store frozen at -40°C and transport frozen plasma on dried ice  
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) | Total aggregation (% @ 5 min):  
ADP : 63-89%  
Arachidonic Acid: 65-90%  
Collagen : 61-99%  
Epinephrine : 54-101% |

| ADAM TS-13 ACTIVITY | 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 plasma from cells as soon as possible (double spin)  
Platelet count must be <10x10⁶/L in plasma prior to freezing | 6 weeks | Batches | ADAMTS-13 ACTIVITY : 40-130% |
| ADAM TS-13 INHIBITOR ELISA KIT | Blood (plasma) | Trisodium Citrate 3.2% | Collect until indicated mark x 1 tube | Store frozen at -40°C and transport frozen plasma on dried ice | Deliver tubes immediately to the laboratory at room temperature | OR Separate plasma from cells as soon as possible (double spin) | Platelet count must be <10x10⁹/L in plasma prior to freezing | Store frozen at -40°C and transport frozen plasma on dried ice | 6 weeks | Batches | ADAMTS-13 INH : Negative : <12 U/ml | Boderline : 12-15 U/ml | Positive : >15 U/ml |
### Table 3.2 List of tests offered at Red Cells Unit

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Method</th>
<th>Specimen Type</th>
<th>Container Type</th>
<th>Volume Required</th>
<th>Department Instructions</th>
<th>TAT</th>
<th>Remarks</th>
<th>Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hemoglobin Analysis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gel Electrophoresis</td>
<td>Electrophoresis</td>
<td>Whole blood</td>
<td>K2/K3 EDTA tube</td>
<td>Collect until</td>
<td>Deliver tubes within 24 hours to the laboratory at room temperature</td>
<td>6 weeks</td>
<td>Batches</td>
<td>Guideline for the range, need to refer the QC pattern from the gel staining</td>
</tr>
</tbody>
</table>
| Capillary Electrophoresis                      | Electrophoresis       | Whole blood    | K2/K3 EDTA tube | Collect until    | 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    | Deliver tubes within 24 hours to the laboratory at room temperature | 90 working days | Outsource.  
  (MUST use DNA IMR/CaRC/HA EM/22/2203/03 (1)/REQForm and consent form) | Result based on molecular test :  
  (Alpha from HKL, Beta from IMR) |
| Serum EPO (Erythropoietin)-ELISA | ELISA KIT | 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: 8 weeks  
MPN & PRV: 12 weeks | Batches | 3.7-40.7 mIU/ml |
### Table 3.3 Summary of Pre-analytical sampling errors that will affect coagulation test results

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

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, soft tissue biopsies (haematology related) and second opinion on previous histopathology findings.

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 labeling of forms and/or specimens, or use of incorrect specimen tubes, may result in delays or rejection of specimens.

For biopsies done in Hospital Ampang, respective units/ departments are encouraged to obtain formalin from Haematopathology Lab – Level 2, before doing the procedure, so as to assist in maintaining quality in pre-analytical stage of processing of specimen.

Sample Requirements
a) Samples for Haematopathology:
   • bone marrow trephine
   • soft tissue biopsies (haematology related)

b) Sample Labeling
   Specimens should be labeled 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**
Please collect 10% buffered formalin from Haematopathology Laboratory prior to tissue biopsy procedure.

**Storage and Transportation**
Specimen should be fixed using 10% 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: 7.30am to 4.30pm
<table>
<thead>
<tr>
<th>Name of test</th>
<th>Method</th>
<th>Volume required</th>
<th>Special instructions</th>
<th>Collection instruction</th>
<th>Storage and transportation</th>
<th>TAT</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Bone marrow trephine biopsy</td>
<td>Hematoxylin &amp; Eosin (H&amp;E) Staining, immunohistochemistry (IHC) staining, special stain, in-situ hybridization (ISH) staining</td>
<td>10% neutral buffered formalin must be 20 X of the size of tissue biopsy</td>
<td>None</td>
<td>Immerse trephine biopsy in formalin immediately</td>
<td>Room temperature</td>
<td>14 working days for non complicated cases</td>
<td>Internal cases only</td>
</tr>
<tr>
<td>2 Histopathologic examination on tissue biopsy</td>
<td>Hematoxylin &amp; Eosin (H&amp;E) Staining, immunohistochemistry (IHC) staining, special stain, in-situ hybridization (ISH) staining</td>
<td>10% neutral buffered formalin must be 20 X of the size of tissue biopsy</td>
<td>Please collect formalin solution from Haematopathology Laboratory prior to biopsy procedure</td>
<td>Immerse tissue biopsy in formalin immediately</td>
<td>Room temperature</td>
<td>14 working days for non complicated cases</td>
<td>Internal cases only</td>
</tr>
<tr>
<td>3 Second opinion on histopathologic examination</td>
<td>Hematoxylin &amp; Eosin (H&amp;E) Staining, immunohistochemistry (IHC) staining, special stain, in-situ hybridization (ISH) staining</td>
<td>None</td>
<td>Polyllysine coated unstained slides required. Minimum of 10; if T cell malignancy suspected-15 will do.</td>
<td>None</td>
<td>Room temperature</td>
<td>14 working days for non complicated cases</td>
<td>Internal cases only</td>
</tr>
</tbody>
</table>
5. CYTOGENETICS (LEUKAEMIA) UNIT

Introductions
The Cytogenetics (Leukaemia) for Clinical Haematology Referral Laboratory provides cancer cytogenetics services, including routine chromosome diagnostics and advanced molecular cytogenetics (FISH) tests.

Bone marrow cytogenetic evaluation is considered appropriate for patients with neoplastic haematological disorders. Supply 1-2 ml of bone marrow aspirate in sodium heparin vacutainer or bone marrow transport medium.

Cytogenetic evaluation of unstimulated blood samples is appropriate in patients with acquired hematologic malignancy where sufficient neoplastic or with circulating blast cells more than 20%. If the neoplasm is of lymphoid origin then stimulation is needed for B-cells or T-cells. If the blast count or mitotic index is low in the blood, chromosome analysis may be infeasible and interphase FISH could be an alternative (depending on disease type e.g: CLL). Supply 10 ml of peripheral blood in sodium heparin vacutainer or in bone marrow transport medium. Please supply clinical indication (longer turnaround time for B/T-cell malignancies if mitogen stimulation is indicated).

Test Indication
Refer to Indication for specialized laboratory test for cytogenetic test. We currently only offer cytogenetic analysis for acute leukemias and myelodysplastic syndrome. FISH analysis is done for CLL and myelomas and other hematological malignancies on a case to case basis. Cases that do not fulfill this indication will not be done and the requesting physician will be contacted to inform the reason. Please do call the cytogenetic lab prior to sending sample if the indication is not as stated above.

i) Clinical indications being essential
Clinical indications are needed to determine test protocols and interpret cytogenetic findings. 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. Cytogenetic specimen will not be processed without clinical indications. If you need help for cytogenetic testing, please contact Cytogenetic Lab (603) 4289 6055.

ii) Clinical indication for haematologic studies
Refer to Indication for specialized laboratory test for cytogenetic test.

Instruction for submitting sample
A completed HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY requisition form MUST accompany all specimens.

Please note that incomplete or illegible labeling of forms and/or specimens, or use of incorrect specimen tubes, may result in delays or rejection of specimens.
Sample Requirements
a) Sample for Cytogenetics; Chromosome analysis (Karyotyping) and/or Fluorescence in situ hybridization (FISH).
   • **Transport medium is always preferred; however, sodium heparin tube can be used when transport medium is not available.**
   • Bone marrow: Place sample (minimum 1-2 ml) in bone marrow transport medium or sodium heparin tube. Bone marrow transport medium is available upon request.
   • **Peripheral blood 5 ml**. If sodium heparin tube is used send two tubes of 5ml blood.
   • For CLL case: 10 ml peripheral blood in bone marrow transport medium or sodium heparin tube.

b) Sample Labeling
Specimens should be labeled 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.

Specimen Handling
Laboratory test results are dependent on the quality of the specimen submitted. Cytogenetics tests are extremely sensitive to methods of collection and preservation. It is important that the sample collection and processing instructions be followed to ensure accurate test results.

Collection Instructions:
1. Invert several times to mix.
2. If ordering both test Karyotyping & FISH (leukemia) analysis, **ONE** tube is adequate.
3. Other anticoagulants (EDTA, Lithium Heparin) are not recommended as they affect viability of the cells.
   • Bone marrow transport medium is available upon request. Clinical history / reason for referral are required with test order. Prior therapy and transplant history (e.g: donor gender) should be provided with test order.

Storage and Transportation
Samples should never be frozen or refrigerated, and ideally kept at room temperature prior to arrival at the laboratory. Use cold pack but not dry ice for transport and ensure cold pack is not in direct contact with specimen. The specimen must arrive at the lab no later than 24 hours after collection.

**Unacceptable Specimen Samples**
Samples which are incorrectly collected, labeled, processed, or transported will not produce accurate results. When a sample is found to be 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.

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

**Turnaround Time**
Average turnaround time is 30 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

<table>
<thead>
<tr>
<th>No</th>
<th>Test Name</th>
<th>Method</th>
<th>Specimen Type</th>
<th>Volume Required</th>
<th>Container Type</th>
<th>Specimen Transport Guidelines</th>
<th>TAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bone Marrow Chromosome study</td>
<td>Karyotyping. A minimum of 20 G-banded metaphases studied</td>
<td>Bone marrow aspirate (BMA)</td>
<td>Minimum 1-2.0ml</td>
<td>Sterile transport medium with heparin is always preferred (available from lab)</td>
<td>Transport samples without delay at room temperature. <strong>DO NOT</strong> freeze specimens</td>
<td>30 days</td>
</tr>
<tr>
<td>2</td>
<td>Leukaemia (Neoplasia) Blood Chromosome analysis</td>
<td>Karyotyping. A minimum of 20 G-banded metaphases studied</td>
<td>Peripheral Blood (PB)</td>
<td>Minimum 5.0 ml</td>
<td>Two (2) tubes of transport medium with heparin are required for blood collection (2.5mL in each tube). If transport medium not available, collect sample in sterile <strong>sodium heparin</strong> tube.</td>
<td>Transport samples without delay at room temperature. <strong>DO NOT</strong> freeze specimens.</td>
<td>30 days</td>
</tr>
<tr>
<td>3</td>
<td>Leukaemia FISH analysis (only)</td>
<td>FISH interphase analysis</td>
<td>BMA</td>
<td>Minimum 1 -2.0 ml</td>
<td>Sterile transport medium with heparin is always preferred (available from lab). Two (2) tubes of transport medium with heparin are required for blood collection (2.5mL in each tube). If transport medium not available collect sample in sterile <strong>sodium heparin</strong> tube.</td>
<td>Transport samples without delay at room temperature. <strong>DO NOT</strong> freeze specimens.</td>
<td>18 days</td>
</tr>
<tr>
<td><strong>Bone Marrow or blood (neoplasia)</strong></td>
<td><strong>Chromosome study &amp; Leukaemia FISH analysis</strong></td>
<td><strong>Karyotyping &amp; FISH Interphase analysis</strong></td>
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<td>-------------------------------------</td>
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</tr>
<tr>
<td>If ordering both tests (Chromosome study and FISH analysis), <strong>one</strong> tube is adequate (refer to specimen type collection)</td>
<td><strong>BMA</strong></td>
<td>Minimum 1-2.0ml</td>
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<tr>
<td></td>
<td></td>
<td>Minimum 5.0 ml (with circulating blasts &gt; 20%)</td>
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<tr>
<td></td>
<td></td>
<td><strong>Peripheral Blood (PB)</strong></td>
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<tr>
<td></td>
<td></td>
<td><strong>and CLL disease:</strong> Minimum 10.0 ml</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Sterile transport medium with heparin is always preferred (available from lab).</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Two (2) tubes of transport medium with heparin are required for blood collection (2.5mL in each tube).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If transport medium not available collect sample in sterile sodium heparin tube.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Transport samples without delay at room temperature. <strong>DO NOT freeze specimens.</strong></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>30 days (Karyotyping)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>FISH (18 days)</td>
<td></td>
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</tbody>
</table>
6. MOLECULAR (HAEMATOLOGY) UNIT

Introduction
Molecular haematology laboratory plays a key role in the diagnosis and management of 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) throughout the country.

Test indication
Refer to Indication for 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 (will do if JAK2 negative)
   vi. FLT3 ITD detection
   vii. NPM1 mutation detection
   viii. Fusion translocation screening

Instructions for Submitting Samples
A completed HOSPITAL AMPANG SPECIAL LAB HAEMATOLOGY requisition form MUST accompany all specimens.

Sample Requirements
a) Sample for molecular tests:
   • MPN cases – refer to table 6.1
   • Acute leukaemia- refer to table 6.1

b) Sample Labeling
   Specimens should be labeled 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>
<thead>
<tr>
<th>No</th>
<th>Test Name</th>
<th>Method</th>
<th>Specimen Type</th>
<th>Volume Required</th>
<th>Container Type</th>
<th>Special Instruction</th>
<th>TAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>BCR-ABL1 (*for suspected CML case only)</td>
<td>Qualitative PCR</td>
<td>PB, before starting therapy BM, acceptable</td>
<td>PB, Minimum 5.0 ml BMA, 1-2ml</td>
<td>K2/K3 EDTA tube</td>
<td>Transport samples without delay preferably within 24 hours at room temperature. DO NOT freeze specimens.</td>
<td>4 weeks</td>
</tr>
<tr>
<td>2.</td>
<td>BCR-ABL1 (*CML AND Ph+ve ALL/AML case )</td>
<td>Quantitative RT-PCR</td>
<td>Follow-up: BMA (Ph+ ALL/AML case)</td>
<td>Minimum 1-2ml</td>
<td>K2/K3 EDTA tube</td>
<td>Transport samples without delay preferably within 24 hours at room temperature. DO NOT freeze specimens.</td>
<td>6 weeks</td>
</tr>
<tr>
<td>3.</td>
<td>Minor BCR-ABL1</td>
<td>Quantitative RT-PCR</td>
<td>Follow-up: BMA</td>
<td>Minimum 1-2 ml</td>
<td>K2/K3 EDTA tube</td>
<td>Transport samples without delay preferably within 24 hours at room temperature. DO NOT freeze specimens.</td>
<td>6 weeks</td>
</tr>
<tr>
<td>4.</td>
<td>JAK2 / CALR Calreticulin (this test only carry out if JAK2V617F mutation negative)</td>
<td>Qualitative PCR</td>
<td>BMA or PB</td>
<td>Minimum 1-2 ml Minimum 5.0 ml</td>
<td>K2/K3 EDTA tube</td>
<td>Transport samples without delay preferably within 24 hours at room temperature. DO NOT freeze specimens.</td>
<td>8 weeks</td>
</tr>
<tr>
<td>5.</td>
<td>FLT3-ITD (AML: Diagnosis and follow-up)</td>
<td>Qualitative PCR</td>
<td>BMA or PB</td>
<td>Minimum 1-2 ml Minimum 5.0 ml</td>
<td>K2/K3 EDTA tube</td>
<td>Transport samples without delay preferably within 24 hours at room temperature. DO NOT freeze specimens.</td>
<td>4 weeks</td>
</tr>
<tr>
<td>6.</td>
<td>NPM1 (AML: Diagnosis and follow-up)</td>
<td>Qualitative PCR</td>
<td>BMA or PB</td>
<td>Minimum 1-2ml Minimum 5.0 ml</td>
<td>K2/K3 EDTA tube</td>
<td>Transport samples without delay preferably within 24 hours at room temperature. DONOT freeze specimens.</td>
<td>4 weeks</td>
</tr>
<tr>
<td>7.</td>
<td>PML-RARA (bcr1, bcr2 &amp; bcr3) [Monitoring]</td>
<td>Quantitative RT-PCR</td>
<td>Initial / Follow-up: BMA</td>
<td>Minimum 1-2 ml</td>
<td>K2/K3 EDTA tube</td>
<td>Transport samples without delay preferably within 24 hours at room temperature. DO NOT freeze specimens.</td>
<td>6 weeks</td>
</tr>
<tr>
<td>No</td>
<td>Test Name</td>
<td>Method</td>
<td>Specimen Type</td>
<td>Volume Required</td>
<td>Container Type</td>
<td>Special Instruction</td>
<td>TAT</td>
</tr>
<tr>
<td>----</td>
<td>---------------------------------</td>
<td>----------------</td>
<td>---------------</td>
<td>-----------------</td>
<td>------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>8.</td>
<td>RUNX1-RUNX1 T1 [Monitoring]</td>
<td>Quantitative RT-PCR</td>
<td>Follow-up: BMA</td>
<td>Minimum 1-2 ml</td>
<td>K2/K3 EDTA tube</td>
<td>Transport samples without delay preferably within 24 hours at room temperature. DO NOT freeze specimens.</td>
<td>6 weeks</td>
</tr>
<tr>
<td>9.</td>
<td>CBFβ-MYH11A [Monitoring]</td>
<td>Quantitative RT-PCR</td>
<td>Follow-up: BMA</td>
<td>Minimum 1-2 ml</td>
<td>K2/K3 EDTA tube</td>
<td>Transport samples without delay preferably within 24 hours at room temperature. DO NOT freeze specimens.</td>
<td>6 weeks</td>
</tr>
</tbody>
</table>
7. BONE MARROW TRANSPLANT UNIT

**Introduction**
The Bone marrow transplant unit provides a diagnostic service to support the investigation and treatment monitoring for patients in transplant. 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 labeling 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 Labeling
Specimens should be labeled 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 7.00pm
<table>
<thead>
<tr>
<th>No</th>
<th>Test name</th>
<th>Method</th>
<th>Specimen type</th>
<th>Container type</th>
<th>Volume required</th>
<th>Specimen Transport</th>
<th>TAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Stem Cell Cryopreservation</td>
<td>CD34/CD3 enumeration protocol and 7AAD stem cell viability protocol</td>
<td>PBSC/ Bone Marrow/ Cord Blood</td>
<td>1. PBSC in EDTA tube (For CD34 enumeration prior collection)</td>
<td>2 ml</td>
<td>1. Room Temperature (Fresh collected stem cell)</td>
<td>24 hour</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2. Stem cells collection in apheresis bag / marrow harvesting bag in Hospital Ampang</td>
<td></td>
<td>2. Cryo-thermos (cryopreserved segment)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td>3. Cryopreserved vial / segment (from N2 gas tank in BMT Lab / cord blood bank prior infusion)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Stem cell derived services include:</td>
<td>CD34/CD3 enumeration protocol and 7AAD stem cell viability protocol</td>
<td>PBSC/ Bone Marrow/ Cord Blood</td>
<td>Stem cells collection in apheresis bag / marrow harvesting bag in Hospital Ampang</td>
<td>2 ml</td>
<td>1. Room Temperature (Fresh collected stem cell)</td>
<td>24 hour</td>
</tr>
<tr>
<td></td>
<td>Volume Reduction</td>
<td></td>
<td></td>
<td>2. Cryo-thermos (cryopreserved segment)</td>
<td></td>
<td>2. Cryo-thermos (cryopreserved segment)</td>
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</tr>
<tr>
<td></td>
<td>Red Cell Depletion</td>
<td></td>
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</tr>
<tr>
<td>3</td>
<td>Full Blood Count</td>
<td>FBC Protocol</td>
<td>Whole Blood / PBSC / Bone Marrow / Cord Blood</td>
<td>EDTA Tube</td>
<td>2 ml</td>
<td>Room Temperature</td>
<td>1 hour</td>
</tr>
<tr>
<td>4</td>
<td>Stem Cell Selection</td>
<td>Selection Protocol using CliniMacs</td>
<td>PBSC</td>
<td>ACDA (in collection bag)</td>
<td>&gt; 100 ml</td>
<td>Room Temperature</td>
<td>24 hour</td>
</tr>
<tr>
<td>5</td>
<td>TBNK</td>
<td>TBNK Protocol</td>
<td>Whole Blood / PBSC</td>
<td>EDTA Tube</td>
<td>2 ml</td>
<td>Room Temperature</td>
<td>24 hour</td>
</tr>
</tbody>
</table>

Table 7.1 List of tests offered at Stem Cell Transplant Laboratory
LIST OF
TEST OFFER TO
OTHER HOSPITAL (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*)

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

2. PNH (Flowcytometry Unit)

<table>
<thead>
<tr>
<th>No</th>
<th>Test name</th>
<th>Method</th>
<th>Specimen Type</th>
<th>Container Type</th>
<th>Volume required</th>
<th>Department Instructions</th>
<th>TAT</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Paroxysmal Nocturnal Haemoglobinuria (PNH)</td>
<td>Flowcytometry</td>
<td>Blood</td>
<td>K2 EDTA tube</td>
<td>3 ml</td>
<td>Internal PNH samples must be sent immediately to the lab within 4 hours of draw. External PNH samples are accepted within 7 days of draw.</td>
<td>7 working days</td>
<td>Referral lab for PNH</td>
</tr>
</tbody>
</table>
### 3. Molecular test (Molecular Unit)

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

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Method</th>
<th>Specimen Type</th>
<th>Container Type</th>
<th>Volume Required</th>
<th>Department Instructions</th>
<th>TAT</th>
<th>Remarks</th>
<th>Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hemoglobin Analysis</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Gel Electrophoresis</td>
<td>Electrophoresis</td>
<td>Whole blood</td>
<td>K2/K3 EDTA tube</td>
<td>Collect until 1 tube indicated mark</td>
<td>Deliver tubes within 24 hours to the laboratory at room temperature</td>
<td>1 month</td>
<td>Batches</td>
<td>Guideline for the range, need to refer the QC pattern from the gel staining</td>
</tr>
<tr>
<td>Capillary Electrophoresis</td>
<td>Electrophoresis</td>
<td>Whole blood</td>
<td>K2/K3 EDTA tube</td>
<td>Collect until 1 tube indicated mark</td>
<td>Deliver tubes within 24 hours to the laboratory at room temperature</td>
<td>1 month</td>
<td>Batches</td>
<td>Hb A : 96.8-97.8% Hb A2 : 2.2-3.2%</td>
</tr>
<tr>
<td>Serum EPO (Erythropoietin)-ELISA</td>
<td>ELISA KIT</td>
<td>Whole blood</td>
<td>Plain tube</td>
<td>3.5 ml (in patient)</td>
<td>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</td>
<td>MDS: 6-8 weeks MPN &amp; PRV: 12 weeks</td>
<td>Batches</td>
<td>3.7-40.7 mIU/ml</td>
</tr>
</tbody>
</table>
## 5. Coagulation test (red cell & Haemostasis Unit)

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Method</th>
<th>Specimen Type</th>
<th>Container Type</th>
<th>Volume Required</th>
<th>Department Instructions</th>
<th>TAT</th>
<th>Remarks</th>
<th>Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Factor Assay</strong></td>
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<tr>
<td>Factor II Assay</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible Store frozen at -40°C and transport frozen plasma on dried ice</td>
<td>1 day for urgent request 5 working days for normal request</td>
<td>By appointment</td>
<td>50-150%</td>
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<tr>
<td>Factor V Assay</td>
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<tr>
<td>Factor VII Assay</td>
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<td>Factor VIII Assay</td>
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<td>Factor IX Assay</td>
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<tr>
<td>Factor X Assay</td>
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<tr>
<td>Factor XI Assay</td>
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<tr>
<td>Factor XII Assay</td>
<td></td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Known case - 1 tube (until indicated mark)</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible Store frozen at -40°C and transport frozen plasma on dried ice</td>
<td>1 day for urgent request 5 working days for normal request</td>
<td>By appointment</td>
<td>50-150%</td>
</tr>
<tr>
<td><strong>Von Willebrand Factor Assay</strong></td>
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<tr>
<td>VWF Antigen</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 3 tubes</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible Store frozen at -40°C and transport frozen plasma on dried ice</td>
<td>1 day for urgent request 5 working days for normal request</td>
<td>By appointment</td>
<td>52.9-182.5%</td>
</tr>
<tr>
<td>VWF Activity</td>
<td></td>
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<td>63.5-140.7%</td>
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<tr>
<td>VWF : Ricof</td>
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<td>59.8-131.5%</td>
</tr>
<tr>
<td>CBA (Collagen Binding Assay) - ELISA</td>
<td>ELISA KIT</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 1 tube</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible</td>
<td>4-6 weeks</td>
<td>Batches</td>
<td>Group O: 62-138%</td>
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<td>Non-Group O: 86-160%</td>
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<tr>
<td>Lupus Anticoagulant Assay</td>
<td></td>
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<td>Store frozen at -40°C and transport frozen plasma on dried ice</td>
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<tr>
<td><strong>DRVV Screen</strong></td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 4-6 tubes</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible (double spin) Platelet count must be &lt;10x10⁹/L in plasma prior to freezing</td>
<td>2 weeks</td>
<td>Batches</td>
<td>30.8-42.8 Sec 30.4 - 40.6 Sec 32.3 – 43.9 Sec</td>
</tr>
<tr>
<td><strong>DRVV Confirm</strong></td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 4-6 tubes</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible (double spin) Platelet count must be &lt;10x10⁹/L in plasma prior to freezing</td>
<td>2 weeks</td>
<td>Batches</td>
<td>30.8-42.8 Sec 30.4 - 40.6 Sec 32.3 – 43.9 Sec</td>
</tr>
<tr>
<td><strong>PTT LA</strong></td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 4-6 tubes</td>
<td>Deliver tubes immediately to the laboratory at room temperature OR Separate plasma from cells as soon as possible (double spin) Platelet count must be &lt;10x10⁹/L in plasma prior to freezing</td>
<td>2 weeks</td>
<td>Batches</td>
<td>30.8-42.8 Sec 30.4 - 40.6 Sec 32.3 – 43.9 Sec</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Thrombophilia Test</th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Antithrombin Activity</strong></td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
</tr>
<tr>
<td><strong>Protein C Activity</strong></td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
</tr>
<tr>
<td><strong>Protein S Activity</strong></td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
</tr>
<tr>
<td><strong>Free Protein S</strong></td>
<td>Mechanical Automated Coagulation Analyzer</td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
</tr>
<tr>
<td><strong>Anti Xa</strong></td>
<td>Blood (Plasma)</td>
<td>Trisodium Citrate 3.2%</td>
<td>Collect until indicated mark x 1 tube</td>
</tr>
<tr>
<td>Test</td>
<td>Reagents</td>
<td>Collection Procedure</td>
<td>Results</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-----------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Platelet Aggregation Test</td>
<td>Photo Optical Automated Coagulation Analyzer</td>
<td>Blood (Platelet Rich Plasma) Trisodium Citrate 3.2% x 4-6 tubes and EDTA x 1 tube</td>
<td>Collect until indicated mark x 4-6 tubes</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
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</tr>
<tr>
<td>ADAM TS-13 Activity</td>
<td>ELISA KIT</td>
<td>Blood (plasma) Trisodium Citrate 3.2% x 1 tube</td>
<td>Collect until indicated mark x 1 tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
</tr>
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</tr>
<tr>
<td>ADAM TS-13 Inhibitor</td>
<td>ELISA KIT</td>
<td>Blood (plasma) Trisodium Citrate 3.2% x 1 tube</td>
<td>Collect until indicated mark x 1 tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Deliver tubes immediately to the laboratory at room temperature</td>
</tr>
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</tr>
</tbody>
</table>
Store frozen at -40°C and transport frozen plasma on dried ice
LIST OF
SPECIMEN CONTAINER & TUBES
# LIST OF SPECIMEN CONTAINER/TUBES

<table>
<thead>
<tr>
<th>Unit/Test</th>
<th>Container /Tube</th>
<th>Specimen volume</th>
<th>Rejected Sample Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MORPHOLOGY</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBC</td>
<td>K2/K3 EDTA Tube (Purple cap)</td>
<td>Peripheral blood: 2 ml</td>
<td>Lysed sample</td>
</tr>
<tr>
<td>FBP</td>
<td>Neonate EDTA Tube (Purple cap)</td>
<td>Peripheral blood: 250-500ul</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bijou bottle</td>
<td>CSF/Body fluids: Minimum 1 ml</td>
<td>Blood in CSF tube</td>
</tr>
<tr>
<td><strong>FLOW CYTOMETRY</strong></td>
<td></td>
<td>Peripheral blood/BMA: 3 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>K2 EDTA Tube</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HAEMOSTASIS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>--</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT, aPTT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D-Dimer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrinogen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIVC screening</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factor Assay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADAMTS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Citrate 3.2% tube (Blue cap)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral blood: up to indicated mark</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of bottles depend on the test requested; Please refer to Table 3.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| (Purple cap) |  |
| Body fluids (Peritoneal/Pleural fluids): Minimum 1ml |  |
| CSF Transport Media |  |
| CSF: Minimum 1ml |  |

|  |  |
| Overfilled sample |  |
| Underfilled sample |  |
## RED CELLS

<table>
<thead>
<tr>
<th>RED CELLS</th>
<th>K2/K3 EDTA Tube (Purple cap)</th>
<th>Neonate EDTA Tube</th>
<th>Plain Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb analysis G6PD</td>
<td>Peripheral blood: 2 ml</td>
<td>Peripheral blood: 250-500ul</td>
<td>Not together with dry ice pack (from outsource)</td>
</tr>
</tbody>
</table>

**Peripheral blood:**
- 2 ml
- 250-500ul
- 3.5 ml
- If from outsource, spin & separate the serum; minimum 1.5 ml

If from outsource, spin & separate the serum; minimum 1.5 ml.
<table>
<thead>
<tr>
<th>Osmotic Fragility Test</th>
<th>Peripheral blood: 4 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium Heparin tube</td>
<td></td>
</tr>
</tbody>
</table>

**HAEMATO-PATHOLOGY**

<table>
<thead>
<tr>
<th>Universal container (Trephine)</th>
<th>Recommended trephine length: 2-4 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile Specimen container (Soft Tissue)</td>
<td>Volume of formalin &lt; 20X size of trephine</td>
</tr>
</tbody>
</table>

**CYTOGENETICS**

<table>
<thead>
<tr>
<th>Karyotype FISH</th>
<th>BMA : Minimum 1-2 ml CLL case: 5 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Marrow Transport Media (in patient)</td>
<td>Peripheral blood: 5 ml CLL case: 10 ml</td>
</tr>
<tr>
<td>EDTA tube</td>
<td></td>
</tr>
<tr>
<td>Sodium Heparin Tube (Green cap) (Outsource)</td>
<td>Peripheral blood/BMA: Please refer to Table 5.1</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MOLECULAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>K2/K3 EDTA Tube (Purple cap)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BONE MARROW TRANSPLANT</th>
</tr>
</thead>
<tbody>
<tr>
<td>K2/K3 EDTA Tube (Purple cap)</td>
</tr>
<tr>
<td>Apheresis bag/Marrow harvesting bag</td>
</tr>
</tbody>
</table>

**Table 5.1**
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 Labeling: Specimens shall be labeled 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.

1. GENERAL HAEMATOLOGY REJECTION CRITERIA

   i) Clotted Specimens

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

   ii) Insufficient Specimen

      EDTA tube - less than 1ml

      Insufficient specimen quantity

   iii) 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 unlabeled or mislabeled or inadequately labelled specimens (will not be processed under any circumstances).

iv) **Incomplete / unsigned request form**
• Unsigned of requesting doctor
• Incomplete information on the test request form (clinical history is not provided, incomplete IC no, specimen site is not stated, name of requesting doctor is not stated).
• Specimen unaccompanied by form (outside Hospital Ampang)

v) **Haemolysed Samples**
Grossly haemolysed samples giving inaccurate results or unreadable blood films should be rejected and a recollection performed.

vi) **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.

vii) **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).
2. SPECIFIC REJECTION CRITERIA

1) COAGULATION SPECIMEN REJECTION CRITERIA
   i) Insufficient Specimen (under fill or over fill)
      Citrate tubes - less than 10% of stated tube volume (up to the mark)

   ii) Lipaemic Samples
      Grossly lipaemic samples giving inaccurate results even after plasma
      replacement should be recollected.

   iii) Haemostasis Test
      • Delayed sample received (PT and APTT- tested within 4 hours from
         time of specimen collection.)

   iv) Special note for citrate specimen: For requesting test out-side Hospital
       Ampang
      • Specimen MUST be less than 4 hours of collection upon received. The
        sample should delivery to lab in dried ice.
      • Or split plasma immediately, centrifuge specimen at 3000rpm for 15
        minutes, separate and freeze the plasma immediately. The split plasma
        must be labelled with patient’s name and lab number and send to lab in
        dried ice.

2) RED CELL SPECIMEN REJECTION CRITERIA
   a) Hb analysis
      ▪ Normal FBC result.
      ▪ Insufficient sample
      ▪ Poorly haemolysed sample

   b) DNA analysis
      • Wrong request form and no 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
   • Insufficient number of cells (hypocellular)
   • Blast cells less than 20%
   • Specimen exposed to extreme temperature
   • Fixed sample (formalin or alcohol)
   • Specimens in anticoagulants other than sodium heparin.
   • Clotted (massive) samples
   • Contaminated specimens (e.g: bacteria or fungus growth)

5) MOLECULAR DIAGNOSTICS SPECIMEN REJECTION CRITERIA
   • Frozen specimens (Specimen shall not direct contact with ice-cool pack or dry ice)
   • Clotted specimen
   • Specimen exposed to extreme temperature
   • Delayed sending specimen
   • Delay in transport
   • Wrong anti-coagulant (Only EDTA tube accepted for molecular analysis)

6) HISTOPATHOLOGY SPECIMEN REJECTION CRITERIA
   • Poly-lysine coated unstained slides are not provided.
   • Conflict between name of patient on specimen and name on Request Form
   • Unlabelled specimen
   • No patient identification on Requisition Form and /or specimen container/slides
   • Specimen obviously not properly preserved (no / less in formalin)
   • No test or source / side indicated on Request Form.

NOTE:
   i) Specimens from different anatomical sites should be sent in separate containers and must be itemised in the same request form. The other site of specimens sent for testing, it should be itemised in the request from. The containers of such samples must similarly be itemised and labelled with patient’s identification such that they can be cross–referenced to the patient and the anatomic site of origin of the sample.

   ii) 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.
iii) If there is a dispute between specimen received and nature of specimen noted in the request form the pathologist 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 labeling 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.
HOSPITAL AMPANG
SPECIAL HAEMATOLOGY LAB
REQUISITION FORM
### HOSPITAL AMPANG SPECIAL HAEMATOLOGY REQUISITION FORM
Clinical Haematology Referral Laboratory, Level 2, Hospital Ampang, 68000 Ampang, Selangor

**03-42896219  03-42970059**

#### PATIENT

- **Name:**
- **I/C:**
- **Age:**
- **Male / Female:**
- **Ward, Hospital:**

#### CLINICAL, THERAPY & TRANSFUSION HISTORY
Incomplete clinical history will compromise test interpretation

#### SAMPLE

- **Lab no.:**
- **Date of sampling:**
- **Marrow**
- **Blood**
- **CSF**
- **Lymph Node**
- **Trophine**
- **Other:**

#### MORPHOLOGY 03-42896532

- **FBP**
- **Retic**
- **IPF**
- **Bone Marrow**
- **Iron Stain**
- **Aspirate**
- **Cytospin**

#### CYTOGENETICS 03-42896055
(Transport medium preferred; Na Heparin acceptable)

- **FISH:**
- **Y** Chimerism (Donor)
- **Male**
- **Female**
- **Hyppereosinophilia**
- **KARYOTYPE**

#### FLOW CYTOMETRY (EDTA) 03-42896218

- **Leukemia/ Lymphoma**
- **MRD**
- **PNH**

#### MOLECULAR (EDTA) 03-42896056

- **JAK2 V617F**
- **PML-RARa**
- **RUNX1-RUNX1 T1**
- **BCR-ABL1**
- **CBFβ-MYH11**
- **FLT3-ITD / NPM1**
- **CALRETICULIN**

#### HEMOSTASIS (TRISODIUM CITRATE 3.2%) 03-42896461

- **Coagulation Profile**
- **Inhibitor Screen**
- **Protein C**
- **Factor Assay**
- **Inhibitor Titer**
- **Protein S**
- **Anti XA [LMWH]**
- **VWD screen**
- **Anti-thrombin**
- **D-Dimer**
- **Lupus Anticoagulant**
- **ADAMTS-13 activity**
- **Others**

#### RED CELL 03-42896217

- **Hb Analysis (EDTA)**
- **sEPO (Plain tube)**
- **H Inclusion**
- **Heinz Bodies**
- **Kleihauer**

#### HAEMATOPOATHOLOGY 03-42896222

- **Site of biopsy:**
- **Biopsy Trucut / Excision**
- **Block No.:**
- **Slides No.:**
- **Unstained / Stained**
- **External**

#### OTHERS

**Guidelines on reverse:** [Hem-RQ18 Version 2]

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Version 3.  Amended No. 3.
Date: 24-March-2020  MRKH Handbook  
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Bone Marrow Procedure Documentation – Lab Use Only

Date & Time of Marrow ____________________________ FBP ○
Dr. ____________________________ Nurse ____________________________ MLT ____________________________

Site of Marrow PSIS Right Left Condition of Sample Good Clotted Dry Tab
Aspirate ○ Trephine ○ Trephine Roll ○ Number of smears ____ Cytogenetics ○ Flow ○ Molecular ○

MGG Date ____ / ____ / ____ Time ____ ____ MLT ____________________________

GUIDELINES FOR SAMPLING

General
Any questions/urgent requests please call lab and/or Lab Haematology MO on-call (contactable via Hospital operator; 03-42896000) prior to obtaining sample, especially if sampling on Friday or eve of Public Holidays.
Invert tube several times to ensure adequate mixing. Transport samples without delay at room temperature (unless otherwise indicated). Body fluids CSF should reach lab within 1 (ONE) hour of sampling. Unless otherwise indicated, all tests are available Monday-Friday 8am to 5pm.

Bone marrow sample for morphology
Bone marrow sample for morphology should be accompanied a sample for FBP if there has been none in previous 2 days.
To avoid aspiration artefact ALWAYs obtain trephine sample at a site of different from aspiration.

FLOW CYTOMETRY (EDTA) 03-42896218
EDTA Marrow 2ml; Blood 5ml
Body fluids use special medium obtained from cytogenetic lab if the sample is clear. If the sample is bloody, use a K2 EDTA tube for transportation.
CSF use microtube filled with special medium obtained from cytogenetic lab. All samples for flow should reach lab by 4 pm. Call and inform the lab.

CYTOGENETICS (Karyotyping & FISH) 03-42896055
If ordering both tests, one tube is adequate.
Transport medium is always preferred (available from the lab); however, Na Heparin [do not use Li Heparin] can be used if transport medium is not available.
Marrow 2ml, Blood 5ml in sterile transport medium; if Na Heparin is used, send 2 tubes of 5ml blood.

MOLECULAR (EDTA) 03-42896056; amranglab@gmail.com
EDTA tube Marrow ~2ml; Blood 5ml
For BCRABL1 monitoring of CML only: send 15ml of blood.

HEMOSTASIS (TRISODIUM CITRATE 3.2%) 03-42896461
Please discuss with haematologist prior to obtaining sample to avoid rejection.
3.2% Trisodium Citrate of 3ml plasma is required for:
Factor assay (3 tubes), Lupus anticoagulant (4 tubes) [double spin], ADAMTS-13 (2 tube) [double spin]. Anti-Xa [double spin].
Centrifuge sample, aliquot plasma into a new plain tube, freeze immediately at -80°C. Transport frozen in dry ice.
Anti-Xa [LMWH] - Through level, please discuss with haematologist.
- Peak level, 4 hours after dose.

RED CELL 03-42896217
sEPG, plain tube – Separate plasma into a new plain tube, freeze immediately at -80°C. Transport frozen.

SERVICE AGREEMENT

Change in service shall be reflected in explanatory information and laboratory reports. Customers or users shall be informed of deviations from the agreement that impact upon the examination results.
REFERENCES


APENDIX A

PROCEDURE 1.0

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 (preferably 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 as 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.

2) 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 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 (examples in pictures below under rejection criteria) 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):
   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 1700g for at least 10 mins at room temperature not more then 25degree celcius.
   b) If room temperature exceeds 25 degrees a refrigerated (4degrees) centrifuge should be used.

2. Platelet-poor Plasma (PPP) Collection for Lupus Anticoagulant Testing
   Lupus anticoagulants (LA) are nonspecific antibodies that extend clot-based coagulation assays as the result of their interaction with phospholipid in the reaction mixture. Platelets
in plasma samples can act as a source of phospholipid and mask the effects of LA. For this reason, it is important to prepare platelet-poor plasma (PPP) for LA testing. PPP should have a platelet count <10,000/μL.

PPP samples should be collected by double centrifugation.

1. Centrifuge for 10 minutes, and carefully remove two-thirds of the plasma using a plastic transfer pipette, being careful not to disturb the cells.
2. Deliver plasma to a plastic transport tube, cap, and recentrifuge for 10 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 a xxxx tube with screw cap. Label each tube "plasma, citrate."

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 in DRY ICE ONLY