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HOSPITAL KUALA LUMPUR

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PATHOLOGY SERVICES HANDBOOK

HOSPITAL KUALA LUMPUR PATHOLOGY SERVICE HANDBOOK

6TH EDITION, 2026

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The editorial team would like to extend sincere appreciation to all personnel of the Pathology Department, Hospital Kuala Lumpur, for their invaluable support and contributions.

COMPLAINTS AND FEEDBACK

Users are welcome to give any feedback or complaints to help improve the quality of our service. Please scan QR Code or link address.

https://forms.gle/3iyar76WYLcwhMqT6

FOREWORD

I am pleased to announce the publication of this Pathology Handbook, a comprehensive guide developed to support our healthcare professionals in delivering accurate, timely, and high-quality diagnostic services.

Pathology forms the cornerstone of modern medicine. It plays a critical role in disease detection, management, and prevention, directly influencing clinical decisions and patient outcomes. This handbook reflects our institution's commitment to excellence by providing clear guidelines, standardized procedures, and essential reference information for daily practice.

I would like to commend the dedicated team of Pathology Department and contributors who have invested their expertise and effort into compiling this resource. Their commitment ensures that our laboratory services continue to meet the highest standards of quality, safety, and reliability.

As healthcare continues to evolve, so too must our practices. I encourage all staff to utilize this handbook not only as a reference but also as a tool for continuous learning and improvement. Through collaboration, adherence to best practices, and a shared commitment to patient care, we can uphold the highest standards in pathology services.

Thank you for your ongoing dedication and professionalism.

YBhg. Dato' Dr. Harikrishna a/l K.Ragavan Nair
Director
Hospital Kuala Lumpur

FOREWORD

It is a great pleasure to present the latest edition of the Pathology Laboratory Services Handbook for the Department of Pathology, Hospital Kuala Lumpur (HKL).

As the nation's premier referral hospital, HKL's Department of Pathology carries the vital responsibility of providing accurate, timely, and high-quality diagnostic services. Beyond routine testing, our laboratory functions as a National Reference Centre, offering a comprehensive range of specialized and complex test profiles to support clinical needs nationwide.

This publication serves as the primary resource for our clients, both within HKL and from external healthcare facilities regarding:

- Scope of Services: Outlining the expertise of our specialized units, including Anatomical Pathology, the Core Laboratory, Drug and Toxicology, Haematology, Microbiology, the Pathology Specialist Clinic (SCACC), and Special Chemical Pathology.
- Pre-Analytical Requirements: Essential guidelines on specimen collection techniques, container selection, and transportation protocols to ensure sample integrity.
- Specialized Testing: Detailed information on high-level reference tests designed to assist in the diagnosis of rare diseases and conditions requiring advanced technical expertise.

We place the highest priority on quality, in strict alignment with international accreditation standards. By integrating cutting-edge laboratory technology and efficient automation with the dedication of our specialists and technical staff, we ensure that every result contributes meaningfully to patient management.

It is my hope that this handbook will bridge the gap between laboratory and clinical teams, minimizing errors and prioritizing patient safety. We welcome your feedback as we continue to enhance the quality of our services.

Dr Norhayati binti Omar
Head of Pathology Department
Hospital Kuala Lumpur

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GENERAL INFORMATION

LOCATION OF PATHOLOGY LABORATORY

The Department of Pathology is located at Level 1, Main Block of Hospital Kuala Lumpur. The department provides medical laboratory diagnostic and consultation services to the entire clinical services in the hospital and external health facilities.

All samples are received at the *Kaunter Utama Jabatan Patologi* (Common Receiving Area-CRA) except for Histopathology (*Pintu 6*), Cytology (*Pintu 7,* Level 2), Drug & Toxicology services (*Pintu 2*) and Pathology Specialist Complex and Ambulatory Care Centre (SCACC), Level 1 which have a separate receiving counter at respective laboratory.

Drug and Toxicology services was extended to the Level 2 of Institute of Urology & Nephrology (IUN) Block B, Hospital Kuala Lumpur.

LOCATION OF PATHOLOGY LAB

These functional units are located in the following areas:

Name of Functional Unit	Location
Microbiology	Ground floor and level 1 of the main block of HKL
Special Chemical Pathology	Level 1 of the main block of HKL
Core Laboratory	
Haematology	
Drug & Toxicology Laboratory	Level 1, Main Block, HKL (*Pintu* 2)
	Makmal Patologi, Level 2, Block B, Institute of Urology & Nephrology (IUN), HKL
Anatomic Pathology-Histopathology	Level 1 of the main block of HKL
	Makmal Neuromuskular, Level 1 of *Bangunan IKTAR*, HKL
	Makmal Molekular Anatomik Patologi, IMR, Jalan Pahang
Anatomic Pathology-Cytology	Level 2 of the main block of HKL
Pathology SCACC	Level 1 of SCACC , HKL
Quality	Level 2 of the main block of HKL
Pejabat Pentadbiran	Level 1 of the main block of HKL
Finance	Level 1 of the main block of HKL
Integrated Store	Ground floor of the main block of HKL

OPERATING HOURS

Pathology Department provides 24-hour services for the Core Laboratory and Microbiology Laboratory. Other laboratories operate during office hours, from 7:30 a.m. to 5:30 p.m.

For specimen reception and other counter-related matters, please refer to the schedule provided below:

No	Counter	Counter Operating Hours
1	Main counter (Core laboratory)	24 hours
2	Pathology SCACC	7:30 am - 4:30 pm Monday to Friday (including lunch hours except on Friday)
3	a) Drug & Toxicology Laboratory (Main Block) b) Drug & Toxicology Laboratory (IUN Block B)	a) 8:00 am - 4:30 pm Monday to Friday (closed during lunch hour, except Friday) b) 8:00 am - 4:30 pm Monday to Friday (closed during lunch hour)
4	Anatomic Pathology-Histopathology	7:30 am - 4:30 pm Monday to Friday (including lunch hour except on Friday)
5	Anatomic Pathology-Cytology	7:30 am - 4:30 pm Monday to Friday (closed during lunch hour)
6	Haematology	7:30 am - 4:30 pm Monday to Friday (closed during lunch hour)
7	Microbiology	24 hours

SCOPE OF SERVICES

The department provides the following services:

Unit	Scope of Service
Anatomic Pathology - Histopathology	• Histopathological Examination (HPE) • Frozen Section • Histochemistry(Special Stain) • Immunohistochemistry (IHC) • Immunofluorescence microscopy (IF) • Enzyme Histochemistry • Molecular Anatomic Pathology • Clinical Autopsy
Anatomic Pathology - Cytology	• Gynaecology (GYN) • Non-gynaecology (NGY) • Fine Needle Aspiration Cytology (FNAC)
Core Laboratory	• General Chemistry • General Haematology (FBC, Reticulocytes, Coagulation and ESR) • General Endocrine • Anemia Profile • Specific Protein • Tumour marker • Clinical Toxicology and Therapeutic Drug Monitoring (TDM)
Drug & Toxicology	• Drug of Abuse • Clinical Toxicology • Specialised Therapeutic Drug Monitoring
Haematology	• Peripheral Blood and Bone Marrow Morphology • Red Cells Disorders • Molecular Alpha Thalassaemia • Molecular Beta Thalassaemia • Molecular Haemoglobinopathy
Microbiology	• Bacteriology • Virology • Serology • Immunology • Parasitology • Mycology • Molecular
Pathology SCACC	• Phlebotomy services • General Chemistry • General Haematology
Special Chemical Pathology	• Special Endocrine • Special Protein • Dynamic Function Test • Metabolic

LABORATORY DIRECTORY

Staff / Location	Ext. Number
Administratives	
Head of Department	5636
Assistant Office Secretary	5594
General Office	6854
Quality	5634
Integrated Store	5629
Finance	5624
Anatomic Pathology - Histopathology	
Head of Unit	5595
Histopathology Office	5595
Pathologist Pusat Diagnostik Patologi Anatomik (PDPA)	2252, 5619, 5243, 5244, 5704, 5707, 7586
Medical Officer and Scientific Officer Microscopic Room	5603, 6851
Routine Histopathology Laboratory	5605
Neuromuscular Laboratory	6651
Senior Medical Laboratory Technologist	6572
Anatomic Pathology - Cytology	
Head of Laboratory	5623
Anatomic Pathologist	5704
Scientific Officer	5620
Senior Medical Laboratory Technologist	5626
Result Tracing	5599
Sample Reception Counter	6495
Core Laboratory	
Head of Unit	5625
Deputy Head of Unit	6077
Scientific Officer Room	5608
Laboratory - Office Hour	5610, 7569
Laboratory - After Office Hour	5606

LABORATORY DIRECTORY

Staff / Location	Ext. Number
Microbiology	
Head of Unit	5590
Deputy Head of Unit	5613
Bacteriology 1 Laboratory	5615
Bacteriology 2, Parasitology Laboratory & Senior Medical Laboratory Technologist Room	5627
TB Laboratory	6860
Immunoserology Laboratory	7436
Virology Laboratory	6852
Mycology Laboratory	6859
Molecular Virology Laboratory	5632
Bilik Bekalan	6456
Scientific Officer Room 1 (Zon 16)	5614
Scientific Officer Room 2 (Zon 14)	5618
Scientific Officer Room 3	5609
Virology Scientific Officer	5633
Pathology SCACC	
Head of Unit	1100
Scientific Officer	1097
Senior Medical Laboratory Technologist	1099
Laboratory (Diagnostic Section)	1094
Counter 1 (Patient Registration Counter)	1005
Counter 3 (Sample Receiving Counter)	1008

LABORATORY DIRECTORY

Staff / Location	Ext. Number
Haematology	
Head of Unit	5281
Haematologist Room (*Pusat Diagnostik Hematologi*)	5239
Haematologist Room (Laboratory)	6853
Medical Officer (MO) - Urgent FBP (Laboratory)	6374
Medical Officer (MO) (*Pusat Diagnostik Hematologi*)	7514
Senior Medical Laboratory Technologist	5311
Laboratory (Morphology/ Referred section)	6549
Laboratory (Red Cell Disorder section)	6549
Laboratory (Molecular Haematology section)	5746, 5748
Drug & Toxicology	
Head of Unit	7014
Deputy Head of Unit	5631
Record Officer	5631
Scientific Officer	5612
Sample Receiving Counter	6076
Sample Receiving Counter (IUN)	2472, 2473
Scientific Officer (IUN)	2475, 2479
Special Chemical Pathology (SCP)	
Head of Unit	5630
Deputy Head of Unit	5284
Scientific Officer	5609, 5611
Senior Medical Laboratory Technologist	5596
Laboratory	5284

URGENT TEST

Urgent request must be justified by clinical summary, diagnosis and reason for the urgency.

Unit	Test
Anatomic Pathology - Histopathology	• Urgent biopsy • Frozen section (All requests require consultation and approval by Anatomic Pathologist)
Anatomic Pathology - Cytology	• Cerebrospinal fluid (CSF) • Fine Needle Aspiration Cytology (FNAC) - requested as urgent by clinicians • Non-gynaecology - requested as urgent by clinicians • Gynaecology - requested as urgent by clinicians
Core Laboratory	• General chemistry and haematology urgent test requests must include **diagnosis and stamped urgent** on the request form. • Troponin, Amylase, Lactate, Ammonia & Blood Gases • Clinical Toxicology (Urine Paraquat, Acetaminophen, Salicylate, Lithium & Ethanol) • TDM tests • Body Fluids & CSF Chemistry • Tumour marker - BhCG (urgent request require consultation and approval from Medical Officer) General endocrine, anaemia profile, and specific protein tests need consultation and approval from the Medical Officer or Pathologist on-call (weekends and public holidays).
Haematology	All urgent requests require consultation and approval from Medical Officer or Haematologist.
Microbiology	• Gram stain examination for positive blood culture • Cerebrospinal Fluid (CSF) microscopy/ FEME • CSF Cryptococcal Antigen test • Microscopy examination (FEME) for peritoneal fluid and peritoneal dialysis. • Blood Film Malaria Parasite (BFMP) • Needle Stick Injury (New case only) • Pre-Transplant (Cadaveric case)
Special Chemical Pathology	All urgent requests require consultation and approval from Medical Officer or Chemical Pathologist.

PRE-EXAMINATION PROCESS

LIST OF TEST AND LIST OF REFERRED TEST

List of test and list of referred tests can be accessed through the following link:

List of test

List of Referred test

PRE-ANALYTICAL REQUIREMENT

REQUEST FORM

PER.PAT 301 form is used for all tests unless otherwise stated (refer to respective unit). All request forms must be legibly written. The completed forms shall be signed and stamped by a doctor.

The following information must be provided for every request:

- Patient's detail: Name, identity card (IC) number, sex and age.
- Source: Ward, clinic and name of hospital (if relevant).
- Patient's clinical summary: Relevant clinical summary including provisional medical diagnosis and treatment. Abbreviations are discouraged.
- Test details: Request must specify the test required.
- Sample: Date and time of sample collection. Type of samples and anatomical site (if relevant).
- Requestor detail: Doctor's name, signature and official stamp.

Mark (√) at the appropriate box for the tests required. Tests which are not listed in the request form should be stated under the column OTHERS. For Histopathology, Microbiology and Virology the type of sample should be stated under the appropriate column.

The word "**URGENT"** must be written clearly or stamped preferably in red at the top on the right hand corner of the request form.

SAMPLE COLLECTION

- The samples should be properly collected in appropriate containers.
- The containers must be labelled with at least two identifiers (i.e. name of patient and patient's IC number) and the name of test requested.
- The containers should be placed in biohazard plastic bags with the respective request forms stapled outside the bag.

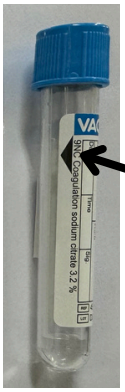
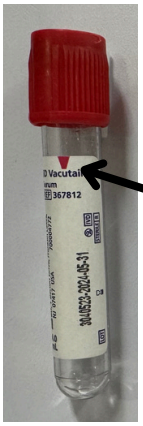
TYPES OF TUBES AND CONTAINERS

Refer to **list of test** for the guidelines and recommendation.

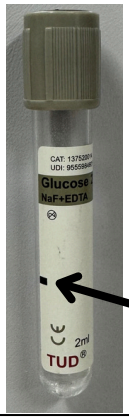
TRANSPORTATION OF SAMPLE

- The sample should be transported to the laboratory in appropriate time frame. Refer to the **list of test**.
- All samples should be sent to the laboratory together with a despatch book/ list and receive acknowledgement from the laboratory staff.
- The time of sample received at the counter should be clocked in by the laboratory user and the sample will subsequently be attended by the laboratory staff for the URGENT tests to be carried out.

TYPE OF TUBES

Blood collection tube	Additives	Mix by inverting	Common Use
 **Correct filling level**	Trisodium Citrate 3.2% Tube	**Note: Adequate sample volume is VERY IMPORTANT.** To be filled up to indicator line. **Invert tube gently 3-4 times** after collection.	**<u>Haematology:</u>** Coagulation test, Bleeding Disorder, Thrombophilia Testing, ADAM TS-13 Profile
 **Appropriate filling level**	Plain tube without gel	**Invert tube gently 6-8 times** after collection.	**<u>Chemical Pathology:</u>** Rheumatoid Factor, Therapeutic Drug Monitoring (TDM) except Immunosuppressant **<u>Microbiology:</u>** Virology **<u>Haematology:</u>** Cryoglobulin Test, Serum Erythropoietin
 **Appropriate filling level**	Plain tube with gel	**Invert tube gently 6-8 times** after collection.	**<u>Chemical Pathology:</u>** General chemistry , Tumour markers, Hormones, Special proteins, Anemia profile, Protein electrophoresis, **<u>Microbiology:</u>** Immunoserology and virology (other than molecular)
 **Appropriate filling level**	Lithium heparin	**Invert tube gently 8-10 times** after collection.	**<u>Chemical Pathology:</u>** General chemistry **<u>Hematology:</u>** Osmotic Fragility Test Cytogenetic (Peripheral Blood Samples)

TYPE OF TUBES

Blood collection tube	Additives	Mix by inverting	Common Use
 Appropriate filling level	Sodium heparin	**Invert tube gently 8-10 times** after collection.	**Hematology:** Cytogenetic (Bone Marrow Aspiration Samples)
 Correct filling level	EDTA	**Note: Adequate sample volume is VERY IMPORTANT.** **Invert tube gently 8-10 times** after collection.	**Chemical Pathology:** ACTH (in ice), HbA1c, Everolimus, MPA, Ammonia, Cyclosporin, Tacrolimus **Haematology:** Haematology test except coagulation **Microbiology:** Molecular test
 Appropriate filling level	Sodium Flouride or Potassium Oxalate	**Invert tube gently 8-10 times** after collection.	**Chemical Pathology:** Glucose, Lactate

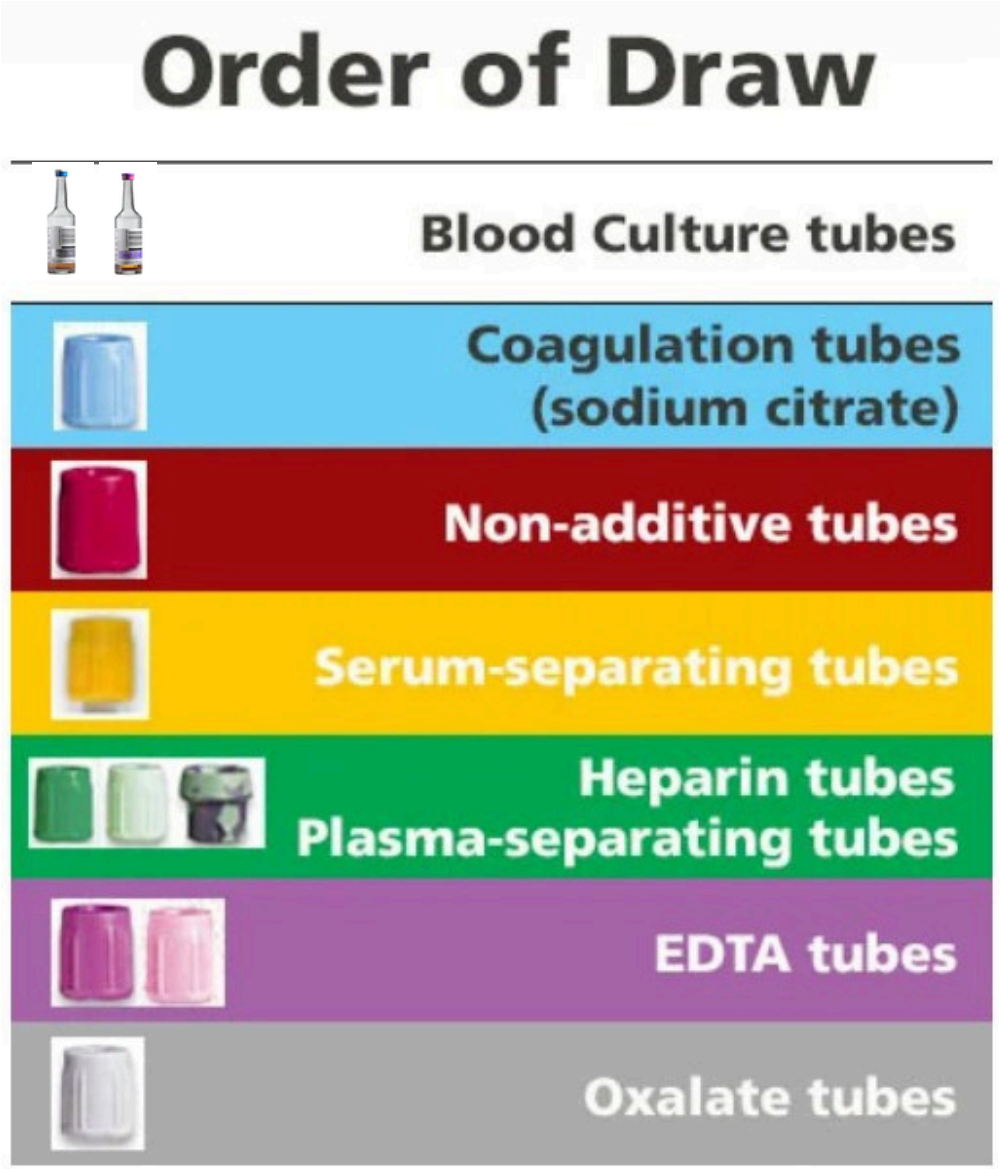
TYPE OF CONTAINERS

Image of container	Container	Sample
	Universal Sterile container	Urine, body fluids, tissue, Bone Marrow Trephine biopsy (with 10% formalin), Urine Hemosiderin
	Stool container	Stool
	Bijou bottle	CSF
	24 hr urine container	24 hr urine collection
	Pre-heparinized syringe	Blood Gases (ABG / VBG)
	Liquid based Cytology	Cervical pap smear
	Slaid mailer	Gynaecology (Convensional Pap smear), Aspirate

- For further detail, please refer to **list of test**

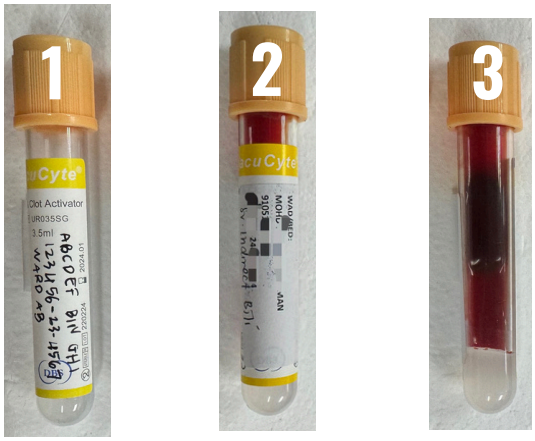
ORDER OF DRAW

- Blood sample must be drawn by phlebotomist in a specific order to avoid cross-contamination of the sample by additives found in different collection tubes.
- Let the vacuum in the tube fill the blood up to its level.
- Do not press the syringe plunger as this will lead to haemolysis.
- Gently invert according to the instruction and be sure that the entire inner surface of the blood collection tube is coated with blood while mixing.



SAMPLE LABELLING

Refer to the details below regarding the proper labelling of the patient's details on the sample tube or container. Non compliance with these instructions may result in delayed or failure in analysis.

Tube	Sample Image
Blood Tubes 1. Patient's details (name & IC) can be written on the blood tubes or using secondary label. 2. If secondary label is used, the label should cover only the primary tube label. 3. This is important so that the sample can be visualised.	
Blood Culture • Do not cover the barcode on the bottle • Do not store in the refrigerator	

REJECTION CRITERIA

- Every sample along with the request form will be scrutinized to make sure it is appropriate for analysis.
- Samples rejection will be carried out if it does not meet the criteria.
- Rejection shall be notified to the requestor.
- Rejection reports can be accessed through the LIS.

1. General Rejection Criteria

NO	REJECTION CRITERIA
	REQUEST FORM
1	No request form
2	Incomplete request form/ No clinical indication
3	Duplicate request/ Duplicate order/ Redundant request
4	Wrong request form
5	Clerical error
6	No prior discussion with specialist
	SAMPLE
7	Blood clotted
8	Hemolysed
9	Insufficient specimen/ sample
10	Analysis could not be performed due to technical issues
11	Test is temporarily suspended/ not available/test not offered
12	Specimen/ sample not suitable for analysis
13	Icteric sample
14	Lipaemic sample
15	Specimen spilled / Leaked/ Broken/Unseal
16	Wrong container
17	No specimen received
18	Specimen not labelled
19	Sample received with needle attached
20	Query on sample result
22	Incorrect preservative used
23	Sample not in ice
24	**OTHER**

REJECTION CRITERIA

2. Rejection Criteria by Specific Unit

Unit	Rejection Reasons
Core Laboratory	1. Blood Gases with needle. 2. The Medicolegal sample is not sealed. 3. Unable to analyze the sample due to high viscosity. 4. Over/underfilling for coagulation tests may lead to an incorrect anticoagulant ratio. 5. Haemodiluted sample. 6. No clinical history and diagnosis for FBP and HBA request. 7. The sample is not suitable for testing because the temperature was not maintained optimally during transportation to the laboratory (blood gases, ammonia & lactate). **Rejection shall be notified to requestor via LIS for internal user and email to the requestor's email address for external user. Effective date : 3rd June 2024 onwards.** **Click here for further information.**
Microbiology	1. Culture sample in formalin 2. Leaking sample 3. Using non-sterile container for culture 4. Dry swab 5. Wrong container
Anatomic Pathology-Cytology	1. Sample leakage with no remain 2. Broken slide received beyond repair 3. Sample sent not suitable for Cytology test.
Anatomic Pathology-Histopathology	1. Unsuitable sample for HPE 2. No sample received (empty container)
Special Chemical Pathology	1. HbA1c request less than 3 months from previous result. 2. History of persistent unreportable result of HbA1c due to persistent abnormal chromatogram. 3. Protein electrophoresis request less than 1 month from previous result. 4. ACTH sample received not on ice.
Drug & Toxicology Laboratory	1. Insufficient urine sample. Minimum urine sample volume is 30 mL. 2. Urine sample container not sealed/not properly sealed/broken sealed. 3. Serial number on urine sample container not tally.

REJECTION CRITERIA

2. Rejection Criteria by Specific Unit

Haematology	**Haemoglobin Analysis** 1. Normal Haemoglobin (Hb), Mean Corpuscular Volume (MCV) and Mean Corpuscular Haemoglobin (MCH) for age, EXCEPT : a) Partner/ family/ cascade screening. b) Mother of cord blood donor. c) For establishment of Juvenile Myelomonocytic Leukemia (JMML) diagnosis. 2. Post-transfusion sample within 3 months. 3. Redundant request with no suggestion/ indication to repeat the test. 4. Form 4 screening : Low haemoglobin level (<13 g/dL) for male/ <12 g/dL for female) EXCEPT post-iron challenge. **DNA Alpha and Beta Thalassaemia** **CLERICAL ERROR** 1. Incorrect request form (DNA Analysis For Thalassaemia Syndromes & Haemoglobinopathies Version 4.1 (DNA Ana for Thal Synd & Hbpathy(s) REQform | Haematology Unit, CaRC IMR| Date of Issue: 21.11.2022 | Version 4.1. 2. No or incomplete consent form. 3. Incomplete patient identification (missing two COMPLETE patient's identifier) on request form, sample, copy of Hb Analysis result and copy of recent Full Blood Count (FBC) result. 4. Patient identification information does not tally between request form and sample. 5. Patient identification information does not tally between FBC/ Hb Analysis report and request form/ sample. 6. No attachment of recent FBC report (<3 months) and the FBC result in the Hb Analysis report is more than 3 months. 7. No attachment of Hb Analysis report. 8. Incomplete Hb Analysis and/ or FBC report. 9. Illegible/ unclear FBC and/ or Hb Analysis report. 10. No requesting doctor's name/ signature/ official stamps on the request form and consent form. 11. Cascade/ family screening request that is not accompanied with cascade's or family member's request form, copy of recent FBC report (<3 months) and Hb Analysis report. **NOT INDICATED** 1. Hb Analysis report with Code D16 and N for Form 4 screening request. 2. Test not offered in Makmal Molekular Hematologi, Jabatan Patologi HKL i.e a) Further testing for alpha and beta globin gene. b)Other type of thalassaemia e.g Delta Beta Thalassaemia or Hereditary Persistence of Fetal Haemoglobin (HPFH). c) Other haemoglobin variant/ haemoglobinopathy (other than Hb E, Hb S and Hb C).

EXAMINATION PROCESSES

The laboratory ensures the clinical accuracy of patient testing by carefully selecting and using validated examination methods. Before any method is introduced, the laboratory verifies its capability to perform the test effectively, ensuring that all required performance specifications whether defined by the manufacturer or the method are consistently met. Should the manufacturer revise a method, the laboratory conducts re-verification as necessary to maintain reliability.

To support result confidence, the laboratory evaluates the measurement uncertainty (MU) of reported values. These evaluations are reviewed regularly.

In addition, the laboratory continuously monitors the validity of examination results through internal quality control (IQC), external quality assessment (EQA), and comparability studies. Any nonconformities identified during these processes are promptly investigated, corrected, documented, and communicated to users where appropriate.

POST-EXAMINATION PROCESSES

The laboratory ensures the clinical accuracy of patient testing by carefully selecting and using validated examination methods. Before any method is introduced, the laboratory verifies its capability to perform the test effectively, ensuring that all required performance specifications whether defined by the manufacturer or the method are consistently met. Should the manufacturer revise a method, the laboratory conducts re-verification as necessary to maintain reliability.

To support result confidence, the laboratory evaluates the measurement uncertainty (MU) of reported values. These evaluations are reviewed regularly.

In addition, the laboratory continuously monitors the validity of examination results through internal quality control (IQC), external quality assessment (EQA), and comparability studies. Any nonconformities identified during these processes are promptly investigated, corrected, documented, and communicated to users where appropriate.

CRITICAL RESULT NOTIFICATION

Critical value results and toxicity levels will be notified to the requestor (doctors or pharmacists) by phone call and/or can be viewed through the LIS system.

Table 1: Critical Limit in General Chemistry

Test	Critical Limit	
	Lower Limit	Upper Limit
Potassium	2.8 mmol/L	6.0 mmol/L
Sodium	125 mmol/L	155 mmol/L
Glucose	2.8 mmol/L	20.0 mmol/L
Calcium	1.5 mmol/L	3.0 mmol/L
Magnesium	0.41 mmol/L	2.0 mmol/L
Phosphate	0.32 mmol/L	2.87 mmol/L
Lactate	-	5.0 mmol/L
Creatinine Kinase	-	5000 U/L
Bilirubin	-	300 umol/L
Serum Osmolality	250 mOsm/kg H2O	350 mOsm/kg H2O
Serum Osmolality (Paeds)	250 mOsm/kg H2O	310 mOsm/kg H2O
Ammonia (Paeds)	-	> 100 umol/L

CRITICAL RESULT NOTIFICATION

Table 2a: Toxicity level in Therapeutic Drug Monitoring

Test	Unit	Toxicity level
Acetaminophen	mg/L	Refer Rumack Matthew Nomogram
Amikacin	mg/L	Trough > 10.00
Carbamazepine	mg/L	> 20.00
Digoxin	µg/L	>2.50
Ethanol	mg/dL	> 400.0
Gentamicin	mg/L	Trough > 2.00
Lithium	mmol/L	> 1.2
Phenobarbital	mg/L	> 60.00
Phenytoin	mg/L	> 25.00
Salicylate	mg/L	> 400.00
Theophylline	mg/L	> 25.00
Valproic Acid	mg/L	> 150.00
Vancomycin	mg/L	Trough > 25.00

Table 2b: Toxicity level in Specialised Therapeutic Drug Monitoring (IUN)

Test	Unit	Toxicity level
Immunosuppressants TDM		
Cyclosporine	ng/mL	> 500.0
Tacrolimus	ng/mL	> 25.0
Antifungals TDM		
Voriconazole	mg/L	> 4
Total Itraconazole (Itraconazole + Hydroxyitraconazole)	mg/L	>5
	mg/L	
Posaconazole	mg/L	>3.75
Flucytosine	mg/L	Trough : No established toxicodynamic threshold. Peak ≥ 100
Isavuconazole	mg/L	>5

Please note that the reference range and unit for Therapeutic Drug Monitoring (TDM)'s tests is in mg/L, with effect from 28 November 2024

CRITICAL RESULT NOTIFICATION

Table 3: Critical Limits in Haematology

Test	Critical Limit	
	Lower Limit	Upper Limit
Haemoglobin	6.0 g/dL	19.0 g/dL
Haematocrit	0.200 L/L	0.600 L/L
Platelet	20 x 10^9 /L	1000 x 10^9 /L
Prothrombin time	-	30.0 sec
International Normalized Ratio (INR)	-	5
Activated Partial Thromboplastin Time (APTT)	-	80.0 sec
Fibrinogen	100 mg/dL	-
D-Dimer	-	20.0 ug/mL FEU
Test	**Qualitative Critical Limit**	
Full Blood Picture	1. Acute Promyelocytic Leukaemia (APML) 2. Microangiopathy Haemolytic Anaemia (MAHA)	

CRITICAL RESULT NOTIFICATION

Critical Result Notification Histopathology

Test	Critical Limit
Histopathological Examination (HPE)	
1. Unexpected or discrepant findings	Unexpected malignancy Wrong organ removed
2. Reports of infections	Bacteria in heartvalves or bone marrow Organism inimmune-compromised patient such as AFB, fungi, viral, protozoa Unusual organisms or organism in unusual sites e.g., Amoeba in the eye
3. Reports on critically ill patients requiring immediate therapy	Crescents in greater than 50% of glomeruli in renal biopsy sample Transplant rejections
4. Cases that have immediate clinical consequences	-Fat in endometrial curettage -Mesothelial cells in a heart biopsy - Fat in snare colon biopsy specimens

Critical Result Notification Cytology

Test	Critical Limit
Test for Cytology examination.	
1. Unexpected or discrepant findings	Unexpected malignancy
2.Reports of infections	-Organism in immune-compromised patient such as AFB, fungi, viral, protozoa -Unusual organisms or organism in unusual sites e.g., Cryptococcus in CSF

CRITICAL RESULT NOTIFICATION

Critical Result Notification (Microbiology)

All critical results shall be notified to respective ward or clinic once the result ready. Refer to list below for the critical results

No.	Sample/Test	Findings
1	Acid Fast Bacilli	Positive smear result (new case)
2	Malaria Parasite	Presence of parasite on blood film

LIST OF REFERRAL/ OUTSOURCE LABORATORIES

- Referral Laboratory: External laboratory to which a sample or data is submitted for examination.
- Outsource Laboratory : External laboratory outside the MOH facilities to which a sample is sent for examination procedure or for second opinion.

No.	Referral Laboratory	Transport Schedule
1	Hospital Tunku Azizah, Jalan Pahang, WP Kuala Lumpur (click here to view HTA Pathology Handbook)	Monday to Friday
2	Hospital Ampang, Selangor	Monday to Friday
3	Hospital Sungai Buloh, Selangor	Tuesday and Friday
4	Hospital Selayang, Selangor	Tuesday and Thursday
5	Hospital Sultan Idris Shah, Serdang, Selangor	Monday to Friday
6	Hospital Putrajaya, WP Putrajaya	Monday and Wednesday
7	Hospital Sultanah Aminah, Johor Bahru	Monday to Friday
8	Hospital Canselor Tuanku Muhriz UKM (HCTM), Cheras, WP Kuala Lumpur	Wednesday
9	Institut Kanser Negara, WP Putrajaya	Monday
10	Institut Perubatan Respiratori, Jalan Pahang, WP Kuala Lumpur	Monday to Friday
11	Institut Penyelidikan Perubatan (IMR), Jalan Pahang, WP Kuala Lumpur	Monday to Friday
12	Institut Penyelidikan Perubatan (IMR), National Health Institute (NIH), Setia Alam, Selangor	Monday to Friday
13	Makmal Kesihatan Awam Kebangsaan, Sungai Buloh, Selangor	Tuesday and Friday
14	Makmal Kesihatan Awam Ipoh, Perak	Monday to Friday
15	Pusat Darah Negara, WP Kuala Lumpur	Monday to Friday
16	Pusat Perubatan Universiti Malaya, Petaling Jaya, Selangor	Monday to Friday
17	Jabatan Kimia Malaysia, Petaling Jaya, Selangor	Wednesday
18	Hospital Sultanah Bahiyah, Alor Setar, Kedah	Monday and Tuesday
19	Hospital Tengku Ampuan Rahimah, Klang , Selangor	Tuesday and Thursday

(For every request for test conducted in private laboratories, please contact the relevant Pathologist in Pathology Department to discuss regarding the request. Request can only be made by specialist).

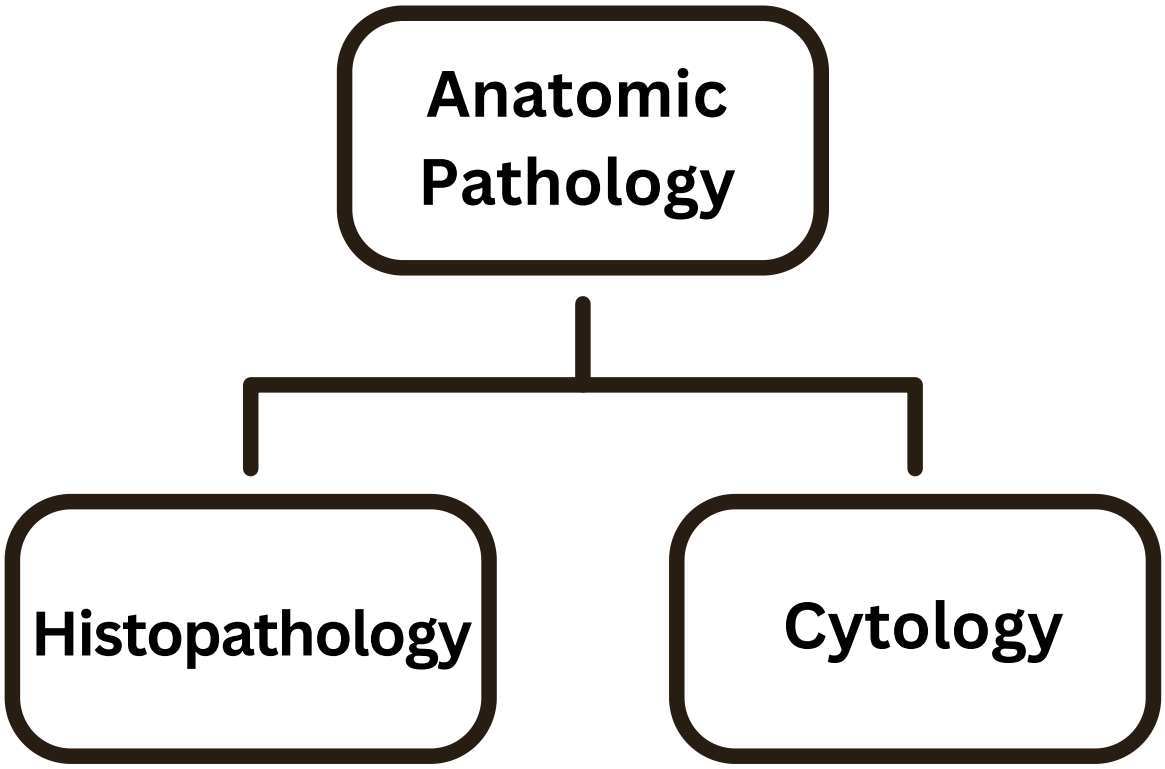
RESULT TRACING

Laboratory	Email Address
Core Laboratory	makmalterashkl@moh.gov.my
Special Chemical Pathology Lab	patologikimiahkl@moh.gov.my
Haematology Lab	hematologihkl@moh.gov.my
Cytology Lab	sitologihkl@moh.gov.my
Microbiology Lab	mikrobiologihkl@moh.gov.my
Histopathology Lab	histopatologihkl@moh.gov.my
Molecular Anatomic Pathology	molpath.histohkl@moh.gov.my
Drug & Toxicology (Main Block)	makmaldadahhkl@moh.gov.my
Drug & Toxicology (IUN, Block B)	iuntdmhkl@moh.gov.my

LABORATORY INFORMATION

ANATOMIC PATHOLOGY

Anatomic pathology unit is broadly divided into Histopathology (Surgical pathology) and Cytology.



ANATOMIC PATHOLOGY - HISTOPATHOLOGY

INTRODUCTION

Histopathology has 4 functional laboratories:
1. Routine Histopathology Laboratory
2. Specialised Laboratory (Special stain, Immunohistochemistry, Immunofluorescence microscopy)
3. Neuromuscular Laboratory
4. Molecular Anatomic Pathology Laboratory

ANATOMIC PATHOLOGIST AND SUBSPECIALTY SERVICE

Pathologist Name	Subspecialty	Email Address	Ext. No
Dr. Norhayati Omar (Head of Department)	Molecular Anatomic Pathology	norhayatiomar@moh.gov.my	5594
Dr. Noraini Mohd Dusa (Head of Anatomic Pathology Unit)	Soft Tissue and Bone Pathology	noraini.mdusa@moh.gov.my	5595
Dr. Mohamad Rafie Md Kaslan	Breast and Endocrine Pathology	mohamadrafie@yahoo.com	5603
Dr. Zuliatul Faizah Baharom (Head of Cytology Laboratory)	Dermatopathology	zuliatul.faizah@moh.gov.my	7586
Dr. Hemlata Kumari Gnanasegaram (Head of Histopathology Laboratory)	Renal Pathology	hemlatakumari@moh.gov.my	2252
Dr. Sellymiah Adzman	Perinatal Pathology	sellymiah@moh.gov.my	2252
Dr. Siah Hui Hui	Paediatric Pathology	siahhuihui@moh.gov.my	5619
Dr. Nor Aizan Ab.llah @ Ariffin	Neuropathology and Neuromuscular Pathology	nor.aizan@moh.gov.my	5619
Dr. Asmawiza Awang	Lymphoreticular Pathology	asmawiza.awang@moh.gov.my	7586

ANATOMIC PATHOLOGY - HISTOPATHOLOGY

Pathologist Name	Subspecialty	Email Address	Ext. No
Dr. Nur Dini Jalaludin	Breast and Endocrine Pathology	nurdini.jalaludin@moh.gov.my	5704
Dr. Sugunah Sallapan	Gastrointestinal and Hepatobiliary Pathology	sugunah@moh.gov.my	5244
Dr. Nurul Akmal Kamarudin	Lung and Thoracic Pathology	akmal.kamarudin@moh.gov.my	5244
Dr. Teoh Pei Yeing	-	teohpeiyeing@moh.gov.my	5243
Dr. Muhammad Afiq Mohamad	-	afiqmohamad@moh.gov.my	5704
Dr. Aniqah Shamimi Jaafar	-	aniqah.shamimi@moh.gov.my	5243
Dr. Nurhazwani Mohd Latif	-	nurhazwani.latif@moh.gov.my	5707

OUT-OF-HOURS SERVICE

- A histopathologist is rostered for oncall to cater for frozen section, transplant and clinical autopsy services as well as surgical pathology consultation. He / she can be contacted through the hospital operator.

- All samples for routine histopathological examination taken after office hours should be fixed in 10% neutral buffered formalin (10% NBF) in the respective ward or OT room and kept at room temperature.

- The sample should then be dispatched to the unit receiving area (URA) at Histopathology Laboratory, during operating working hours.

HOW TO MAKE A REQUEST FOR HISTOPATHOLOGY SERVICE

1. Request form for Histopathology Examination (HPE)

- Use PER-PAT 301 carbonized (3 ply) or printed request form (3 copies) filled in with relevant clinical and radiological information for all histopathological examination requests.
- If HPE report is needed urgently, please write or stamp URGENT clearly at the top centre of the request form.
- One request form (PER-PAT 301 carbonized (3 ply) or printed request form (3 copies) is suffix for one patient including a request of multiple samples.
- Each sample anatomical sites must be written clearly e.g.,
  - 1- Terminal Ileum, 2- Caecum, 3- Ascending Colon, 4- Transverse Colon, 5- Descending Colon, 6- Sigmoid, 7- Rectum,
  - 1 - Wide local excision, 2- Lymph node dissection
  - 1 -Pipelle sampling, 2- Cervical biopsy
- The information on the sample containers and the request form should be identical and clearly written.

2. Frozen Section

- All requests for frozen section examination must be preceded by appointment and discussion with surgical pathologist on call at least 1 day before the operation.
- Fill the request form for the frozen section and submit it to the Histopathology Laboratory at least 1 day before the operation for notification.
- Request form for frozen section (HKL/JP/HI/AK-05-02) is available at the Histopathology Office and website -*Senarai borang Unit Histopatologi.*
- Please inform medical officer at ext. 6851 or 5603 if frozen section examination is postponed or cancelled.
- All cases scheduled for frozen section examination are best placed first in the operating list. So, it can be done during normal working hours.

3. Clinical Autopsy

- Clinical autopsy or post-mortem examination is conducted to ascertain the cause of death in non-medicolegal cases. This service is only provided for patients who died in Hospital Kuala Lumpur, Hospital Tunku Azizah (HTA) and Institut Perubatan Respiratori (IPR).

- The following procedure should be followed:

1. The requesting doctor shall first obtain written consent from the next of kin.

2. Use Borang Keizinan Bedah Siasat Mayat Klinikal (Autopsi Klinikal HKL/JP/AP/PK02-01). Explanatory notes is attached to the consent form. This consent form is available at the mortuary counter of Forensic Department, Hospital Kuala Lumpur and website - *Senarai borang Unit Histopatologi.*

3. In cases where the next of kin is not available, the Hospital Director and one medical specialist will have to give their consent.

4. In case of a foreigner whom the next of kin is not available, consent from their respective embassy official is required.

5. The clinician who requests for clinical autopsy shall communicate directly with the Histopathology Medical Officer or Pathologist on call.

6. Clinical autopsy is usually performed during office hour. However, after office hour clinical autopsy can be requested if necessary.

7. During office hour, the Medical Officer/ Pathologist on call for clinical autopsy can be contacted at extension 6851 or 5603.

8. After office hour, the Histopathology Medical Officer and Pathologist on call can be contacted through telephone. Duty roster of Histopathology Medical Officer /Pathologist on call and their contact numbers are available at the mortuary counter of Institut Forensik Negara (IPFN), HKL (ext. 6695) and hospital operator.

9. A clinical summary together with the case notes and consent form shall be sent to the Histopathology Medical Officer or Pathologist on duty.

10. The requesting specialist from the clinical department is required to be present during clinical autopsy.

11. The requesting specialist of clinical autopsy service may request for report summary of the case. Use Borang Permohonan Laporan Autopsi Klinikal Jabatan Patologi (Autopsi Klinikal HKL/JP/AP/PK02-02). This request form is available at Histopathology Unit Office and website 3b) *Senarai borang Unit Histopatologi.*

4. Subspecialised Histopathology Services / Referrals
Histopathology Subunit provides specialized histopathology services in areas as listed above.

i. For consultation:
The client (pathologist or clinician) should communicate directly with the Pathologist specialised in the respective field.

ii. Referral for second opinion:

a. For patients within HKL

- The requesting doctor (Clinician) is required to communicate directly with the Pathologist specialised in the respective field. A request form as routine cases and diagnostic material (paraffin embedded tissue, stained and/or unstained slides) should be sent to Histopathology Laboratory.
- Paraffin embedded tissue is preferred in case further ancillary studies is required.
- The HPE report can be viewed in LIS.

b. For patients outside HKL

- The Clinician or Pathologist is required to communicate directly with the Pathologist specialised in the respective field.
- A referral letter and diagnostic material (paraffin embedded tissue, stained and/or unstained slides) should be sent to Histopathology Laboratory.
- Paraffin embedded tissue is preferred in case further ancillary studies is required.
- Please include the department's official email address in the letter.
- The request should be directed or addressed to the specialised Pathologist in the respective field.
- The HPE report will be emailed to the respective department's official email address

Note 1: The general referral cases or cases other than the above listed subspecialties will be reported by the pathologist on call on that particular day.

Note 2: If the case has been reported elsewhere, the HPE report should be sent together.

SAMPLE COLLECTION, CONTAINER, TRANSPORTATION AND DISPATCH

A: GENERAL REQUIREMENT

- All samples for routine histological examination are to be fixed in 10% neutral buffered formalin (10% NBF) in a suitable clean leak-proof container. The containers should have wide opening, preferably with screw cap to prevent leakage.
- The volume of formalin used must be at least 10 times the volume of sample to be fixed. Do not put large sample in small containers as this would prevent proper fixation of the tissue and distort the sample.
- All sample containers should have the same identification details as those that is written on the request forms. Multiple small samples such as gastrointestinal biopsies should ideally be mounted on a piece of filter paper and immediately placed in formalin containers.
- Samples from different anatomical sites should be sent in separate containers, properly labelled and must be clearly itemized in the request form.
- For cases that require confirmation of the adequacy of surgical excision, the margins of the sample must be marked or tagged accordingly by sutures or other suitable methods, preferably with diagrammatic representation of the excised sample.
- Samples for routine histopathological examination should be sent to Histopathology Laboratory, Pathology Department (Pintu 6)

B: SPECIFIC REQUIREMENT

1. FROZEN SECTION

- sample for frozen sections should be sent **fresh in an empty universal container without fixative or any solutions.**
- Fresh tissue sample for frozen section should be **sent immediately to Histopathology Laboratory (Pintu 6).**

2. ENZYME HISTOCHEMISTRY (Acetylcholinesterase)

- Sample for enzyme histochemistry (Acetylcholinesterase, AChE) studies is to be sent **fresh immediately without fixative** in a universal container and moistened with normal saline to prevent drying
- Fresh tissue sample for enzyme histochemistry (Acetylcholinesterase, AChE) should be sent immediately to Histopathology Laboratory (Pintu 6).

3. MUSCLE BIOPSY

- All requests for muscle biopsy must have prior arrangement with the pathologist concerned or Medical Laboratory Technologist (MLT) at extension 5605 at least one day before the procedure.
- Important information to be included in the request form are:
  - Relevant clinical history and muscle MRI
  - Family history of similar problems
  - Creatinine kinase level, Muscle Specific Antibody (MSA)
  - Lactate dehydrogenase (LDH)
  - Contact number and official email address of treating clinician

- Usually, the biceps or quadriceps muscle suffice in most cases.
- For open muscle biopsy:
  - Remove at least one good cylinder of muscle measuring 10mm in diameter and 5mm in depth.
  - For optimal processing muscle sample must be wrapped with aluminium foil and sent fresh in a dry, air tight and clean container.
  - If sample cannot be sent immediately, the container containing sample that is wrapped in aluminium foil should be placed in a larger container containing ice/gel ice for transportation.
  - Do not tie the muscle to stretch it.

- The laboratory will accept fresh muscle biopsy sample up to 4-6 hours upon removal but please remember that optimal result requires the sample to be as fresh as possible.
- The sample should be sent directly to Histopathology Laboratory (Pintu 6).

4. RENAL BIOPSY

- Prior arrangement with the Pathologist concerned is preferred for urgent requests.
- Two samples are recommended for each case for proper histopathological evaluation, i.e., formalin fixed tissue for ordinary light microscopy examination (H&E) and fresh tissue for immunofluorescence staining.
- Renal biopsy tissue for immunofluorescence:
  - Take at least a core of fresh tissue measuring 5 mm in length.
  - The fresh tissue should be sent in phosphate buffer and properly packed.
  - Do not place the fresh tissue sample on gauze.
  - If sample cannot be sent immediately, the sample that is in phosphate buffer containing container should be placed in a larger container containing ice/dry ice.

- The sample should be **sent directly to Histopathology Laboratory (Pintu 6).**

5. MOLECULAR TESTING

- Summary of material required *(subjected to changes)*
- For all molecular tests (except DDISH) prior discussion and approved by Pathologist in charge is required

No	Tests	Material required
1.	**CISH (HER2 -DDISH)** Sample requirement : At least ≥ 20% tumour cellularity	• 1 H&E stained slide (recut)* • Original HER2 IHC slide ** • 4 unstained, **positively charged slides**, or equivalent, 3µm thick • No control tissue required
2.	**CISH (EBER ISH)** Sample requirement : At least ≥ 20% tumour cellularity	• 1 H&E stained slide (recut)* • 3 unstained, **positively charged slides**, or equivalent, 3µm thick • No control tissue required
3.	**Fluoresence In situ Hybridization (FISH- 1p19q, ALK, BCL6, CDK4, ETV6, EWSR1, MDM2, MYCN, ROS1, SS18)**	• 1H&E stained slide (recut and circle area of interest)* • 6 unstained, **positively charged slides** or **equivalent per test**, 3µm thick • No tissue control required
4.	**A) Polymerase Chain Reaction (PCR) (KRAS Codon 12/13, BRAF V600, EGFR, IDH1/2)** **B) Pyrosequencing (PSQ) (RAS Extension, MGMT Methylation)** Sample requirement : At least ≥ 20% tumour cellularity or 500-1000 tumour cells in a cytology cell block	• 1 H&E stained slide (recut)* • 10 paraffin rolls, 5-10 µm thick (combined into one or two sterile Eppendorf tube(s) • Additional 4 unstained, **positively charged slides,** or **equivalent**, 3µm thick (BRAF V600 or IDH1/2) **OR** • 1 H&E stained slide (recut)* • 10 unstained (frosted) slides, 5-10 µm thick • Additional 4 unstained, **positively charged slides**, or **equivalent**, 3 µm thick(BRAF V600 or IDH1/2) • Note: If remaining biopsy tissue is scant and limited, cut minimum five (5) sections or five (5) paraffin rolls at 5 m thickness.

*None of the submitted material will be returned upon completion of testing. The laboratory will contact the referring hospital if additional material is required.
**The origional HER2 IHC slide will be returned upon completion of DDISH testing

HISTOPATHOLOGY REPORTS

TURN AROUND TIME (TAT)

Service	TAT
Frozen section	45 minutes per sample
Surgical sample - Urgent biopsy report (not more than 3 containers, and/or not require further levels or ancillary tests)	3 working days
Surgical sample – other than Urgent biopsy	Within 14 days (70%)
Clinical autopsy report	3 months

For further details, please refer to List of tests

- NOTE: Please include the requesting doctor's name and contact number on the request form for further clarification or information of the case.
- Results of frozen section will be immediately communicated to the surgeon via telephone or the doctor who brought the sample to the laboratory.

ACCESS TO HPE REPORTS

- For clinics / wards / departments within HKL, HPE reports can be accessed via laboratory information system (LIS). For requests from outside HKL, the reports will be emailed to the respective departments.

- Request of a second copy for HPE reports prior to the year 2020 shall be made in writing or using the PERMOHONAN MENDAPATKAN SALINAN LAPORAN HPE UNIT HISTOPATOLOGI (HKL/JP/AP/AK-09-BP-04) form. Refer website; *Senarai borang Unit Histopatologi*.

HPE Report	TAT to get second copy of HPE report
Recent report (during offline)	1 working day
Report before Year 2020	7 working day

INTERDEPARTMENTAL CLINICOPATHOLOGY CONFERENCE (CPC) AND MULTIDISCIPLINARY TEAM (MDT) MEETING

- Histopathology Unit participates in CPC and MDT with other clinical departments in Hospital Kuala Lumpur, Hospital Tunku Azizah (HTA) and Institut Perubatan Respiratori (IPR).
- The schedule of CPC for the whole year is issued before every New Year begins.
- The clinical department concerned is required to submit the list of patients to be discussed in CPC / MDT to the Histopathology Office at least one week prior the scheduled date.
- Enquiries about CPC should be communicated directly to the Medical Officer in charge or Pathologist concerned at extension 6851 or 5603.

REQUEST OF BLOCKS/SLIDES FROM HISTOPATHOLOGY UNIT

- All paraffin blocks and slides of the samples are archived in Histopathology Unit for 20 years and 7 years respectively.
- For certain valid reasons, the unit allows clinician to take diagnostic material (paraffin block / slide) from the Unit. The following procedures must be followed:

1. The request to borrow the diagnostic material must be made by a SPECIALIST.
2. The requesting specialist needs to fill up the PERMOHONAN PEMINJAMAN / PENGAMBILAN BAHAN DIAGNOSTIK UNIT HISTOPATOLOGI (HKL/JP/AP/AK-09-BP-01) form that is available at Histopathology office or website - *Senarai borang Unit Histopatologi.*
3. The form should be submitted to Histopathology Office and the material can be taken within 7 working days upon submitting the form to the Histopathology Office.
4. The paraffin block and stained slides must be returned to Histopathology Office as soon as possible after completion of report or test.

Disclaimer: Pathology Department HKL is not responsible to bear any cost on the referral or test performed on this diagnostic material.

REQUEST OF TISSUE/SAMPLE FROM HISTOPATHOLOGY UNIT

o All samples (tissue) sent to and officially received by Histopathology Laboratory will be kept in the unit up to 1 month after the official report is released.
o The Histopathology Unit allows the patient to take back their remaining tissue, organ or limb upon request. Please follow this procedure:

- The patient or next of kin must make a formal request by filling up the PERMOHONAN PENGAMBILAN SPESIMEN/ TISU UNIT HISTOPATOLOGI (HKL/JP/AP/AK-09-BP-02) form.
- This form is available in Histopathology Office and website- *Senarai borang Unit Histopatologi.*
- The completed form should be submitted to Histopathology Office.
- The tissue is released only after the sample has been reported and validated by the Pathologist.

REQUEST TO OBTAIN MICROSCOPIC IMAGE FROM HISTOPATHOLOGY UNIT

- Microscopic images are not archived as routine but images can be provided upon request.
- All request shall be made or endorsed by HKL SPECIALIST.

i. For presentation at a meeting:

- The requesting doctor should communicate directly with the Pathologist concerned
- A request shall be made by filling up the PERMOHONAN MENDAPATKAN GAMBAR HISTOPATOLOGI (HKL/JP/AP/AK-09-BP-03) form which is available at the Histopathology Office and website - *Senarai borang Unit Histopatologi*. The completed form should be submitted to the Histopathology Office.

ii. For poster or publication:

- The requesting doctor shall communicate directly with the Pathologist concerned followed by filling up the PERMOHONAN MENDAPATKAN GAMBAR HISTOPATOLOGI (HKL/JP/AP/AK-09-BP-03) form which is available at the Histopathology Office and website - *Senarai borang Unit Histopatologi.* The completed form should be submitted to the Histopathology Office.
- The abstract of the poster or publication should be emailed to the respective Pathologist and the reporting Pathologist should be included as co-author.

Note: All request should be submitted at least 2 weeks ahead of the deadline. Only soft copy of the images is provided.

COLLABORATIVE RESEARCH AND INDUSTRY SPONSORED RESEARCH (ISR)

A: COLLABORATIVE RESEARCH

- The Histopathology Unit welcomes research projects or studies to be done in collaboration
- All collaborative studies or research projects must have approval from the Head of Pathology Department.
- A copy of research proposal, NMRR ID and registration with CRC HKL (AK-02-01 and AK-02-02 forms) must be provided.
- One pathologist from the unit shall be appointed as collaborator or co-researcher.
- The researcher will be assisted by the appointed Pathologist to retrieve the materials required if the research project requires archival material from this unit.
- All archival slides can be borrowed for review in the unit only
- If paraffin blocks are required for further testing, sections should be done at the allocated station in this laboratory.
- No archival material should be taken out from Histopathology Unit.

B: INDUSTRY SPONSORED RESEARCH (ISR)

All industry sponsored research (ISR) should be registered under National Medical Research Register (NMRR) and approved by Medical Research and Ethics Committee (MREC).

I. ISR registered in HKL

- All ISR conducted in HKL should be registered under Clinical Research Centre (CRC), HKL.
- All ISR involving pathology department should obtain approval from the Head of Pathology Department and a liaison pathologist should be appointed.
- All study materials/ sample processing protocol should be overseen by the pathologist in-charge and briefed to the laboratory staffs.

Relevant administrative fees will be charged accordingly invoiced by the pathologist in-charge to the principal investigator, which is to be paid to Unit Hasil, HKL.

II. ISR registered outside HKL

- For ISR conducted outside HKL that requires study materials/ samples, the principal investigator should write a request letter to the Head of Pathology Department for approval
- Once approved by Head of Pathology Department, the instructions will be carried forward to the respective unit.
- All study materials/ sample processing protocol should be overseen by the pathologist in-charge and briefed to the laboratory staffs.
- Relevant administrative fees will be charged accordingly invoiced to the principal investigator, which is to be paid to the Unit Hasil, HKL.

APPENDIX 1: HISTOCHEMISTRY (SPECIAL STAINS)

1. Alcian Blue
2. Bielschowsky's silver
3. Congo Red
4. Cresyl Fast Violet
5. Fouchet (Bile)
6. Giemsa
7. Gomori Trichrome
8. Gram
9. Grocott-Gomori Methenamine Silver (GMS)
10. Hematoxylin and Eosin (H&E)
11. Leder Giemsa
12. Luxol Fast Blue
13. Luxol Fast Blue/H&E
14. Luxol Fast Blue/PAS
15. Martius Scarlet Blue
16. Masson Fontana
17. Masson Trichrome
18. Melanin Bleach
19. Mucicarmine
20. Oil Red O (Fat)
21. Orcein
22. Periodic Acid Silver Stain (PAAG/Jones)
23. Periodic acid–Schiff (PAS)
24. PAS / Alcian Blue
25. PAS + D/ Alcian Blue
26. PAS + D
27. Perl Prussian Blue (Iron)
28. Phosphotungstic Acid Haematoxylin (PTAH)
29. Reticulin (Gordon/Sweet)
30. Rhodanine (Copper stain)
31. Rubeanic acid
32. Schmorl's stain
33. Toluidine blue
34. Von Kossa stain
35. Van Giesonstain
36. Verhoeff Van Gieson (EVG)
37. Wade-Fite
38. Warthin-Starry (Steiner)
39. Ziehl Neelsen

APPENDIX 2: IMMUNOHISTOCHEMISTRY (IHC)

A. IMMUNOHISTOCHEMISTRY:

1. ABCB11 (BSEP)
2. ABCB4 (MDR3)
3. ACTH
4. ADENOVIRUS TYPE 5 E1A
5. AFP
6. ALK 1
7. ALPHA DYSTROGLYCAN
8. ALPHA SARCOGLYCAN
9. AMACR (P504S)
10. AMYLOID A
11. ANNEXIN A1
12. ATRX
13. BCL2
14. BCL6
15. BCOR
16. BER-EP4
17. BETA-CATENIN
18. BETA SARCOGLYCAN
19. BOB-1
20. BRACHYURY/ BRY
21. BRG1
22. C4D
23. C5b-9
24. CA-125
25. CALCITONIN
26. CALDESMON
27. CALRETININ
28. CAMTA1
29. CARBONIC ANHYDRASE IX (CA IX)
30. CCNB3
31. CD10
32. CD117 (C-KIT)
33. CD123/IL3RA
34. CD138/ Syndecan-1
35. CD15
36. CD163
37. CD1A
38. CD2
39. CD20
40. CD21
41. CD23
42. CD3
43. CD30
44. CD31
45. CD34
46. CD4
47. CD43
48. CD5
49. CD56
50. CD61
51. CD68
52. CD7
53. CD79A
54. CD8
55. CDX2
56. CEA
57. CHROMOGRANIN A
58. CK 19
59. CK 20
60. CK 5/6
61. CK 7
62. CK MNF
63. CMV
64. C-MYC
65. COLLAGEN VI
66. CYCLIN D1
67. D2-40 (PODOPLANIN)
68. DESMIN
69. DELTA SARCOGLYCAN
70. DNAJB9
71. DOG 1
72. DYSFERLIN
73. DYSTROPHIN 1
74. DYSTROPHIN 2
75. DYSTROPHIN 3
76. E-CADHERIN
77. EMA
78. ER
79. ERG
80. EZHIP
81. FIBRONECTIN
82. FLI 1
83. FSH
84. GAB1
85. GATA3
86. GAMMA SARCOGLYCAN

87. GFAP
88. GH
89. GLUT 1
90. GLYCOPHORIN A /CD235A
91. GLYPICAN-3
92. HCG
93. HEPATOCYTE
94. HER-2
95.HHV-8
96. HISTONE H3.3 G34R
97. HISTONE H3.3 G34W
98. HISTONE H3 (K27M)
99. HISTONE H3 (TRI METHYL K27)
100. HISTONE H3 K36M
101. HLA-ABC Ag (MHC1)
102. HLA-DR (MHC2)
103. HMB45 (MELANOSOME)
104. HMW CK
105. IDH1
106. IgD
107. IgG
108. IgG4
109. IgM
110. INHIBIN, ALPHA
111. INI-1
112. INSM1
113. KAPPA
114. KI67
115. L1CAM
116. LAMBDA
117. LANGERIN
118. LCA (CD45)
119. LH
120. LYSOZYME
121. MAMMAGLOBIN
122. MDM2
123. MELAN A (MART-1)
124. MEROSIN
125. MIC 2 (CD99)
126. MLH 1
127. MPO
128. MSH 2
129. MSH 6
130. MUC 2
131. MUC 4
132. MUC6
133. MUM 1
134. MX1
135. MYOD1
136. MYOGENIN
137. MYOGLOBIN
138. NAPSIN A
139. NCL-MHCf
140. NCL-MHCs
141. NEU N
142. NEUROFILAMENT
143. NKX2.2
144. NKX3.1
145.NSE
146. NUT1
147. OCT-2
148. OCT-4
149. OLIG2
150. P16
151. P40
152. P53
153. P63
154. P65 NF-KB
155. PAN CK (AE1/AE3)
156. PAX 2
157. PAX 5
158. PAX 8
159. PD1
160. PHOX2B
161. PLA2R
162. PLAP
163. PMS2
164. PR
165. PROLACTIN
166. PSA
167. PTEN
168. RETINOBLASTOMA PROTEIN (RB)
169. S100
170. SALL4
171. SATB2
172. SDHB
173. SF-1
174. SMA
175. SMAD4
176. SOX10
177. SOX11
178. SQSTM1 (P62)

179. SSTR2A
180. SSX (C-TERMINAL)
181. SS18-SSX
182. STAT6
183. SV40
184. SYNAPTOPHYSIN
185. TDT
186. TFE3
187. THYROGLOBULIN
188. TIA-1
189. TLE1
190. TOXOPLASMA GONDII
191. TpIT
192. TSH
193. TTF-1
194. VIMENTIN
195. VS38C
196. WILM'S TUMOUR 1 (NT)
197. YAP1

B. COMPANION DIAGNOSTIC IMMUNOHISTOHISCHEMISTRY

1. ALK D5F3
2. BRAF V600E
3. PanTRK
4. ROS1
5. PD-L1 (SP263)

APPENDIX 3 : IMMUNOFLUORESCENCE AND ENZYME HISTOCHEMISTRY

IMMUNOFLORESCENCE MICROSCOPY

1. IgG
2. IgA
3. IgM
4. C3
5. C1q
6. Fibrinogen
7. Kappa
8. Lambda

ENZYME HISTOCHEMISTRY

A. RECTAL BIOPSY FOR HIRCHSPRUNG'S DISEASE

1. Acetylcholinesterase (AChE)

B. MUSCLE BIOPSY FOR NEUROMUSCULAR DISORDER

1. Acid phosphatase
2. Alkaline phosphatase
3. AT Pase (pH 4.3 to pH 10.9)
4. Cytochrome Oxidase-Succinate dehydrogenase
5. Cytochrome Oxidase
6. NADH-TR
7. Succinate dehydrogenase

APPENDIX 4: MOLECULAR HISTOPATHOLOGY

A. CHROMOGENIC IN SITU HYBRIDIZATION (CISH)

1. EBER ISH
2. HER-2 DDISH

B. FLUORESCENCE IN SITU HYBRIDIZATION (FISH)

1. 1P19Q
2. ETV6
3. EWSR1
4. MDM2
5. NMYC
6. CMYC
7. BCL2
8. BCL6
9. CDK4
10. ALK
11. ROS1

C. POLYMERASE CHAIN REACTION (PCR)

1. BRAF
2. IDH1/2
3. KRAS
4. EGFR PLUS

D. PYROSEQUENCING

1. MGMT metyhlation
2. RAS extension

ANATOMIC PATHOLOGY - CYTOLOGY

INTRODUCTION

- Cytology is a discipline that involves the morphologic study of cells. It is broadly divided into exfoliative cytology and aspiration cytology.

- Exfoliative cytology involves examination of samples that contain cells exfoliated from body cavities and surface. It is further subdivided into gynaecological cytology (Pap/cervical smears) and non-gynaecological cytology (pleural fluid, peritoneal fluid, cerebrospinal fluid, urine, sputum, brushing, etc).

- Aspiration cytology involves examination of cells that are actively obtained by Fine Needle Aspiration (FNA).

LIST OF SERVICE

Exfoliative cytology

1. Gynaecological Cytology
   - Conventional pap smear
   - Fluid-based Cytology

2. Non-gynaecological Cytology
   - Body fluids, CSF, urine, sputum, brushing, etc.

3. Aspiration Cytology
   - Fine Needle Aspiration Cytology

SERVICE AFTER OFFICE HOUR

- No sample for cytological examination is processed after office hour.
- sample collected outside officer hours should be refrigerated at 2°C - 8°C before dispatched to the cytology laboratory the next day. Refrigeration helps preserving the cell.
- **DO NOT FREEZE** the sample.

SAMPLE COLLECTION

Gynaecological Cytology

1. Conventional

a) Label a clean glass slide with patient's name and IC number with pencil on the frosted end.
b) DO NOT use lubricant on the speculum.
c) Place cervical spatula at the external os and rotate through 360 degrees, lightly scraping the squamous – columnar junction.
d) Smear the material onto the labeled glass slide about as thick as a blood film.
e) Fix the slide immediately, either by immersing it in a coplin jar containing 95% alcohol for at least 30 minutes or use a spray fixative.
f) Air-dry the fixed slide.
g) Place the slide in a slide mailer and dispatch to the cytology laboratory.

2. Liquid-based Cytology

a) Label the vial with patient's name and IC number.
b) DO NOT use lubricant on the speculum
c) Obtain an adequate sample from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in clockwise direction five times.
d) Rinse the broom into the vial containing the fixative solution by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.
e) Tighten the cap and send the vial to the cytology laboratory.

Non-gynaecological Cytology

1. **Sputum**

Sample must be collected on three (3) consecutive days
a) Instruct the patient to empty the mouth of all saliva immediately after he wakes up in the morning.
b) The patient should then cough deeply and collect the resulting sputum in the container supplied.
c) The sample must be sent immediately to the cytology laboratory.
d) DO NOT forget to collect a similar sample on the next two days.
e) The sample container should be labeled according to the day the sample is collected.
f) For sputum sample submitted as smears;

- Label two clean glass slides for each patient with name and IC number.
- Prepare smears as thick as blood film and immediately place the slides in 95% alcohol for at least 30 minutes or use spray fixative.
- Air-dry the smears.
- Ensure the slides are not placed face to face in the slide mailer.

2. Urine

The patient should void and discard the first morning urine sample.
• Collect the next voided urine and send immediately to the Cytology laboratory.

3. Body fluid

(Pleural fluid, peritoneal fluid, pericardial fluid, CSF, etc.)

- Samples are collected in clean containers and dispatched immediately to the cytology laboratory.
- CSF sample should be processed within 2-3 hours after sampling to avoid cellular degradation. Please ensure sample taken and send during office hours before 3.30pm.

4. Brushing

(Bronchial brushing, CBD brushing, etc.)
i. Label one (1) to three (3) clean glass slides with patient's name and IC number.
ii. Smear the material about as thick as a blood film.
iii. Immediately place the slides in 95% alcohol for at least 30 minutes or use spray fixative.
iv. Air-dry the smears.
v. If more than one slide is to be placed in the same slide mailer, ensure that they are not placed face to face.

Fine Needle Aspiration Cytology (FNAC)

a) Appointment
The FNAC clinic is conducted twice a week for palpable lesions on appointment basis at the following day, location and time:
i) Monday (9.00am-12.00pm): Non breast/ endocrine cases, at Otolaryngology Clinic, Level 6, SCACC. (Please contact Cytology Laboratory at extension 5599 for appointment)
ii) Thursday (9.00am-12.00pm): Breast/ endocrine cases, at Surgical Outpatient Clinic, Level 2, SCACC. (Please contact Cytology Laboratory at extension 5599 for appointment)

b) FNAC for deep-seated lesions is conducted at Diagnostic & Imaging Department (Angiography and CT scan) and Gastroenterology Unit (Endoscopic). Appointments are by the respective clinic/department.

(c)Request and consent
i) FNAC should be requested by medical officer or specialist.
ii) The request form should be filled legibly, complete with the relevant clinical history and findings. Whenever there is more than one lump or swelling present, the clinician should indicate which lump/s or swelling/s to be aspirated.
iii) A signed consent from the patient must be obtained by the operator.
iv) Urgent FNAC:
For urgent FNAC request, the Pathologist on-call must be contacted.
Please note:
a)Breast and thyroid cyst may be aspirated by the surgeon and material sent for cytology examination.
b)There is no indication for FNAC in multinodular goiter or diffuse goiter.
c)Vascular lesions or those of vascular origin are not suitable for FNAC.

FNAC for deep seated lesions are performed by radiologist under radiological guidance on appointment basis.

ANATOMIC PATHOLOGY - CYTOLOGY

GUIDELINES FOR COLLECTION AND TRANSPORTATION

NO	SITE/TYPE	CONTAINER	VOLUME/ QUANTITY	REMARKS
1	Bronchial brushing	Smear in coplin jar with 96% alcohol or place spray fixed slide in slide mailer/slide tray	1 – 3 Smears	Wet fix immediately either by placing slides in a closed container containing 96% alcohol or spray fixed slide.
2	Bronchial washing	Sterile sample container	Minimum of 20mL up 200mL or as collected depending on storage facility	Despatch immediately for processing. If delay refrigerate at 2°C - 8°C
3	Bronchial alveolar lavage	Sterile sample container	Minimum of 20mL up 200mL or as collected depending on storage facility	Despatch immediately for processing. If delay refrigerate at 2°C - 8°C
4	Cervical Vaginal (PAP) smear a) Conventional b) Liquid-based	a) Fixed smear b) Supplied vial with fixative.	a) 1 smear b) As collected	Wet fix immediately in 96% alcohol or spray fix. Despatch immediately to laboratory for processing.

ANATOMIC PATHOLOGY - CYTOLOGY

NO	SITE/TYPE	CONTAINER	VOLUME/ QUANTITY	REMARKS
5	Cerebrospinal fluid	Sterile bijou bottle/ collecting tube	As collected	Despatch immediately to laboratory for processing.
6	Cyst fluid	Sterile sample container	As collected	Despatch immediately for processing. If delay refrigerate at 2°C - 8°C.
7	Eye fluids/ Eye washing	Sterile bijou bottle/ collecting tube	As Collected	Despatch immediately for processing. If delay refrigerate at 2°C - 8°C.
8	Fine Needle Aspiration of all organ	a) Wet fix smear in coplin jar with 96% alcohol b) Air dried smears c) sample for cell block in 10% Neutral Buffered Formalin	As collected	

ANATOMIC PATHOLOGY - CYTOLOGY

NO	SITE/TYPE	CONTAINER	VOLUME/ QUANTITY	REMARKS
9	Pericardial fluid	Sterile sample container	Minimum of 20 mL up 200 mL or as collected depending on storage facility	Despatch immediately for processing. If delay refrigerate at 2°C - 8°C.
10	Pleural fluid	Sterile sample container	Minimum of 20 mL up 200 mL or as collected depending on storage facility	Despatch immediately for processing. If delay refrigerate at 2°C - 8°C.
11	Peritoneal fluid / Peritoneal washing/ Ascitic fluid	Sterile sample container	Minimum of 20 mL up 200 mL or as collected depending on storage facility	Despatch immediately for processing. If delay refrigerate at 2°C - 8°C.
12	Sputum	Sterile sample container	As collected	Fresh early morning sample produced from a deep cough (minimum of 3 samples over 3 consecutive days). Despatch fresh sample immediately to the laboratory.
13	Urine	Sterile sample container	As collected	2nd morning sample after hydration of patient. Despatch immediately. If delay refrigerate at 2°C - 8°C.

ANATOMIC PATHOLOGY - CYTOLOGY

LAB TURN AROUND TIME (LTAT)

NO	TEST	LTAT	
		URGENT	ROUTINE
1	PAP SMEAR	14 WORKING DAYS	30 CALENDER DAYS
2	NON-GYNAE	3 WORKING DAYS	14 CALENDER DAYS
3	FINE NEEDLE ASPIRATION CYTOLOGY (FNAC)	3 WORKING DAYS	14 CALENDER DAYS

*The cases with additional test (cell block, IHC, molecular) shall be excluded from the stated LTAT

COLLECTION OF REPORT

- The cytology reports are accessible to the clinics and wards via HKL Department of Pathology's Laboratory Information System (LIS).
- Clinics and wards from Institut Perubatan Respiratori (IPR) and Hospital Tunku Azizah (HTA) can view the results through their hospitals' Laboratory Information System (LIS).
- The reports will be emailed to other clinics or hospitals than the above mentioned.

CORE LABORATORY

INTRODUCTION

Core Laboratory unit provides screening, diagnostic and also consultation services to Hospital Kuala Lumpur and also serves as referral center for hospitals and clinics in Malaysia.

The tests offered are:

- General Chemistry
- General Haematology (FBC, Reticulocytes, Coagulation and ESR)
- General Endocrine
- Anemia Profile
- Specific Protein
- Tumour marker
- Clinical Toxicology and Therapeutic Drug Monitoring (TDM)

Other services offered are:

- Handle all diagnostic samples received via postal service from government and private hospitals or institutions.
- Managing the delivery of samples to other reference laboratories and government institutions.
- The Information Counter provides customers with inquiries regarding services provided in the Pathology Department, HKL.

REQUEST FORMS

- **PER PAT 301 Form**
  This form is used for all laboratory test requests except TDM.

- **Therapeutic Drug Monitoring (TDM) request form**
  TDM form should be used for all TDM and toxicology request.

SAMPLE COLLECTION

Proper collection is essential to provide accurate results for patient care and management.
The quality of the sample provided will determine the quality, reliability and accuracy of the test results. The table below shows common factors that can interfere with testing.

Factors	Significance and Precautions
Haemolysis	Potassium, folate, bilirubin, AST, ALT, LDH, CK, Mg, phosphate, certain FBC parameters, and coagulation tests are markedly affected by haemolysis. To minimize haemolysis: • When performing a venipuncture, allow the alcohol used to sanitize the skin **dry completely**. • Do not forcefully push blood into the vacutainer. • After collection, the sample should be **gently** and thoroughly mixed. Vigorous shaking may cause red cells to rupture. • Avoid extreme temperatures. Never place a blood sample (blood gases, ammonia, and lactate) directly on ice, as this may cause haemolysis.
Contamination	Contamination of a blood sample may lead to an incorrect result. • Avoid taking blood from the site where an IV infusion has been set up. It can cause a dilution effect for most analytes. Depending on the type of IV infusion, may lead to increase in glucose, sodium, chloride, and potassium levels. • Avoid decanting blood from one sample tube to another, even if the tubes contain the same anticoagulant. Follow the recommended '**order of draw**' to avoid contamination. Example: K+EDTA contamination may lead to: • Falsely prolonged PT/APTT or low fibrinogen results in coagulation tests. • Severely affect potassium, calcium, and ALP in chemistry tests (serum separator tubes, SST).
Venous Constriction	Vigorous constriction can severely affect calcium, lactate, electrolytes, and proteins. • Avoid prolonged tourniquet application
Delay in transporting of samples (>4hrs)	May affect these analytes (potassium and coagulation testing), as it causes degradation of platelets, RBC, and WBC. • Suggest sending samples as soon as possible to the laboratory.
Inadequate filling of blood collection tubes	Incorrect ratio of blood to anticoagulant which causes falsely prolonged PT and APTT. • To fill the tube up to minimum level as indicated on the tube.

Factors	Significance and Precautions
Icterus	May affect these analytes (creatinine, cholesterol, ammonia, triglycerides, D Dimer, FBC test (Hemoglobin, MCH, MCHC) and coagulation tests). • Results should be interpreted with caution.
Lipemic	May affect these analytes (sodium, ammonia, ALT, AST, salicylate, D Dimer, FBC test (Hemoglobin, MCH, MCHC) and coagulation tests). • Results should be interpreted with caution.
Hematocrit level ≥ 55%	Incorrect ratio of blood to anticoagulant which causes falsely prolonged PT and APTT. • To contact lab for further information.

REPORTING OF RESULTS

- All results will be validated by pathologists, medical officers, scientific officers, and medical laboratory technologists (MLT). Auto-validation is applied for most of the tests.
- Reports can be viewed through the LIS system for internal test requests or via email for external test requests.
- All critical results and toxicity levels of TDM results will be notified to the requestor (e.g., medical officer or pharmacist) by phone call and/or can be viewed through the LIS system.
- Reference ranges are provided for all results that are available in the report. These may be subject to variation (age and sex).

DRUG AND TOXICOLOGY LABORATORY

1. INTRODUCTION

The Drug and Toxicology Laboratory, **established in January 1992**, comprises **three (3) core services:** Drug of Abuse (DOA), Clinical Toxicology, and Specialised Therapeutic Drug Monitoring (sTDM).

The Drug of Abuse (DOA) section serves a critical national role as the **National Referral Centre for drug-of-abuse testing under the Ministry of Health Malaysia (MOH)**, providing comprehensive screening and confirmatory testing services to support enforcement and regulatory agencies.
The laboratory has continuously expanded its scope of services. Most recently, in 2025, specialised therapeutic drug monitoring (sTDM) services for immunosuppressants and antifungal agents were introduced, further strengthening its capacity to support clinical decision-making and patient management.

Beyond diagnostic services, the laboratory provides consultation, training, and collaborative support to government healthcare facilities and external agencies. It also plays an active role in on-site drug testing programmes and research initiatives, contributing to national capacity building and the continuous advancement of toxicology practice.

2. LOCATION

Service	Location / Receiving Counter	Operating Hours	Ext Number
Drug of Abuse	Drug & Toxicology Laboratory, Level 1, Main Block, Hospital Kuala Lumpur (HKL) **(*Pintu 2*)**	8:00 am – 4:30 pm	6076 / 5612 / 5631
Clinical Toxicology	Common Receiving Area (CRA), Pathology Department	24 hours	
Specialised Therapeutic Drug Monitoring (sTDM)	*Makmal Patologi*, Level 2, Block B, Institute of Urology & Nephrology (IUN), Hospital Kuala Lumpur (HKL). ***Please send the sample to CRA after office hours, and during weekends and public holidays**.	8:00 am - 4:30 pm	2472 / 2473 / 2479

3. OVERVIEW OF SERVICE

3.1 DRUG OF ABUSE (DOA)

The Drug of Abuse (DOA) section provides comprehensive drug screening and confirmatory testing services to support key enforcement and regulatory agencies, including the National Anti-Drugs Agency (AADK), Royal Malaysia Police (PDRM), and the Malaysian Armed Forces (ATM), as well as medico-legal cases. Medical check-ups are limited to cases referred by the Unit Keselamatan & Kesihatan Pekerjaan (OSH), HKL.

All samples must be collected and handled in strict accordance with established Chain-of-Custody (COC) procedures to ensure sample integrity, traceability, and legal defensibility.

Urine testing for drugs of abuse is regulated under the **Dangerous Drugs Act 1952** and the **Poisons Act 1952**.

3.1.1 Chain-of-Custody (COC) Requirements

- Collection must be conducted under direct supervision.
- The toilet facility must be free of soap, dispensers, and any cleaning agents.
- The minimum required urine volume is **30mL**.
- The sample container must be sealed with a tamper-evident seal in the presence of the donor.
- The sample container must be properly labelled with the following:

1. **Donor's name**
2. **Identification (IC) number**
3. **Date and time of collection**
4. **Donor's signature**
5. **Requested drug test panel**

Table 1: Pre-Examination Requirements for Drugs of Abuse (DOA) Analysis

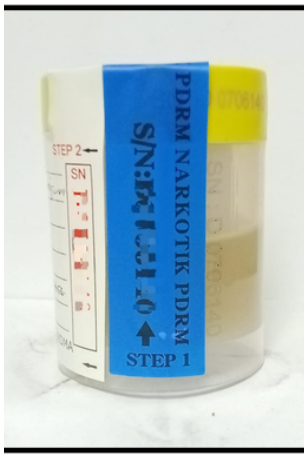
Test	Sample Type	Container type	Request form	Comment
Drug of Abuse (DOA)	Urine (Minimum urine volume: 30 mL)	Urine Container	Borang Permintaan Ujian Pengesanan Dadah Dalam Air Kencing (UPD-1) (3 copies)  	Ensure the container is properly sealed to prevent leakage and maintain chain of custody (COC).

Table 2: List of Drugs of Abuse (DOA), Screening and Confirmatory Methods

Drug Class	Analytes	Screening Method	Confirmation Method
Amphetamine- Type Stimulants (ATS)	1. Amphetamine 2. Methamphetamine 3. MDA 4. MDMA	Immunoassay	GCMS / LCMS/MS
Opiate	Morphine		
Ketamine	Ketamine	Urine Ketamine Strip	
Cannabinoid	Delta-9-THC-COOH	Immunoassay	TLC
Benzodiazepines	1. Nimetazepam 2. Flunitrazepam	-	LCMS/MS
***Mitragynine**	***Mitragynine**	-	LCMS/MS

- **MDA** (Methylenedioxyamphetamine); **MDMA** (3,4-Methylenedioxymethamphetamine); GCMS (Gas Chromatography-Mass Spectrometry); **LCMS/MS** (Liquid Chromatography-Tandem Mass Spectrometry), **TLC** (Thin Layer Chromatography)
- **Medical check-up cases will be tested for opiates, cannabinoids, and amphetamine-type stimulants.**
- ***Mitragynine is classified under Akta Penagih & Penyalah Guna Dadah & Bahan (Rawatan & Pemulihan) 1983 (Akta 283).**

3.2 CLINICAL TOXICOLOGY

The Clinical Toxicology section is responsible for receiving patient samples from hospitals nationwide and providing essential analytical services to support the diagnosis and management of drug exposure and therapeutic compliance, particularly in complex and high-risk clinical scenarios. Analyses are performed using Liquid Chromatography–Tandem Mass Spectrometry (LCMS/MS), except for cannabinoids, which are screened using immunoassay and confirmed by Thin Layer Chromatography (TLC).

Table 1: Pre-Examination Requirements for Clinical Toxicology Analysis

Test	Sample Type	Container type	Request form	Comment
Clinical Toxicology	Urine (Minimum urine volume required: 30 mL)	Universal sterile urine container 	*Borang Permintaan Ujian* PER PAT 301	Ensure the container is properly sealed to prevent leakage.

Table 2: List of Drug Classes and Analytes for Clinical Toxicology Analysis

Drug Class	Analytes	
Amphetamine-Type Stimulants (ATS)	1. Amphetamine 2. Methamphetamine 3. MDA 4. MDMA	5. 3,4 Methylenedioxy ethyl amphetamine (MDEA) 6. Ephedrine 7. Phentermine
Opioids	1. Morphine 2. Codeine 3. Methadone 4. EDDP 5. Fentanyl 6. 6-Acetylmorphine (6-AM) 7. Buprenorphine	8. Dextromethorphan 9. Hydrocodone 10. Hydromorphone 11. Oxycodone 12. Oxymorphone 13. Tramadol
Benzodiazepines	1. Alprazolam 2. Alpha-Hydroxyalprazolam 3. Alpha-Hydroxytriazolam 4. 7-Aminoclonazepam 5. 7-Aminoflunitrazepam 6. 7-Aminonitrazepam 7. 7-Aminonimetazepam 8. Clonazepam 9. Diazepam	10. Flurazepam 11. Flunitrazepam 12. Lorazepam 13. Midazolam 14. Nimetazepam 15. Nitrazepam 16. Nordiazepam 17. Oxazepam 18. Temazepam
Ketamine	1. Ketamine 2. Norketamine	3. Dehydronorketamine
Cathinones	1. Cathinone	2. Mephedrone (synthetic)
Mitragynine	1. Mitragynine	2. 7-Hydroxymitragynine
Cannabinoids	Delta-9-THC-COOH	

- **Clinical toxicology analysis is performed using a panel-based approach, covering all analytes specified above**

3.3 SPECIALISED THERAPEUTIC DRUG MONITORING (sTDM)

The Specialised Therapeutic Drug Monitoring (sTDM) section performs analytical testing for **antifungal** and **immunosuppressant** therapeutic drug monitoring (TDM). It is responsible for receiving patient samples from hospitals nationwide and providing essential analytical services to support the diagnosis and management of therapeutic drug monitoring and its compliance.

Table 1: List of Tests for Antifungal Therapeutic Drug Monitoring

Test	Sample Tube / Type	Testing Day	Method	Request Form
1. Voriconazole 2. Itraconazole 3. Posanazole 4. Flucytosine 5. Isavuconazole ***Fluconazole testing is performed upon request via telephone approval from the Chemical Pathologist in charge.** ***Please refer to the form for steady-state and sampling time.**	(Sample type: Serum)  	Tuesday & Thursday	LCMS/MS	Borang Permintaan Ujian Antifungal Therapeutic Drug Monitoring (TDM) *The test shall only be requested by **Infectious Disease Physicians, Haematologists,Intensivists, and Anaesthesiologist.**

Table 2: List of Tests for Immunosuppressant Therapeutic Drug Monitoring

Test	Sample Tube / Type	Testing Day	Method	Request Form
1. Tacrolimus 2. Everolimus 3. Cyclosporine	EDTA Tube (Sample type: Whole Blood) 	Monday - Friday	LCMS/MS	Borang *Therapeutic Drug Monitoring (TDM)*
4. Mycophenolic acid (MPA) ***Please refer to the form for steady-state and sampling time.**	EDTA Tube (Sample type: Plasma) 	Friday	Immunoassay	

4. LABORATORY TURNAROUND TIME (LTAT)

1. Drug of Abuse (DOA)

- All results are certified by a **Biochemist** before release. Drug test reports are treated as confidential.
- Every URGENT request must be accompanied by a written **URGENT** justification letter and clearly marked "URGENT" on the request form.

Test	LTAT	Reports
Screening result: NEGATIVE	7 days	Reports shall be collected from the counter at the Drug & Toxicology Laboratory, Level 1, Main Block, Hospital Kuala Lumpur (HKL) (Pintu 2).
Confirmation		
1. Cannabinoid 2. Opiate	10 days	
1. Amphetamine Type Stimulants (ATS) 2. Ketamine 3. Benzodiazepine 4. Mitragynine	60 days **(Urgent ATS - 14 days)**	

2. Clinical Toxicology

All results are certified by a **Chemical Pathologist** before release. Drug test reports are treated as confidential.

Test	LTAT	Reports
All analytes as listed in the **'List of Drug Classes and Analytes for Clinical Toxicology Analysis'**	6 weeks	Reports for **internal** cases within Hospital Kuala Lumpur (HKL) will be physically delivered to wards and clinics. For **external** clients and referring institutions (Ministry of Health hospitals outside HKL), reports will be sent via post through the Pathology Department. *__University hospital__ reports shall be collected from the counter at the Drug & Toxicology Laboratory, Level 1, Main Block, Hospital Kuala Lumpur (HKL) (Pintu 2).

3. Specialised Therapeutic Drug Monitoring (sTDM)

Test	LTAT	Reports
Antifungal TDM	3 working days	Reports can be accessed through the **Laboratory Information System (LIS)** for internal test requests, or via **email** for external clients. **Critical Value Notification (CVNC)** will be inform via phone call to respective pharmacy or requesting laboratory / doctor.
Immunosuppressant TDM	Internal patient: 24 hours External Patient: 48 hours	
Mycophenolic acid (MPA)	6 working days	

HAEMATOLOGY

INTRODUCTION

The Haematology Unit, Department of Pathology, HKL provides tertiary diagnostic and consultative haematology services to all government hospitals, clinics in Malaysia as well as private sectors. In Malaysia, it also serves as a training centre in laboratory haematology for undergraduates from local colleges and universities. The unit is also a recognized training centre for doctors majoring in haematology under the Masters in Pathology Program (MPATH) conducted by Universiti Malaya, Universiti Kebangsaan Malaysia, Universiti Sains Malaysia, Universiti Putra Malaysia and Universiti Teknologi Mara.

SCOPE OF SERVICE

The laboratory caters three major specialized diagnostic haematology services, which are bone marrow and peripheral blood morphology, red cell disorders and molecular thalassaemia.
Refer List of Test available

For tests which are not available at Haematology Unit, we provide referral service to other hospital/ institution in Ministry of Health (MOH) that offers the services.
Refer List of Referred Test available

HAEMATOLOGY

Request Form

1. For in-house test, all samples must be accompanied with PER-PAT 301 form.

2. Forms must be filled LEGIBLY and COMPLETELY with the following informations :
   - Patient's details: Name, IC number, sex, age and ward/ hospital name.
   - Patient's clinical and test details : relevant clinical history, diagnosis, tests required, type of sample, time and date of sampling.
   - Requesting doctor's details : name, stamp and signature.

3. For Molecular Alpha Thalassaemia and Molecular Beta Thalassaemia testing, please fill in the DNA Analysis For Thalassaemia Syndromes request form and consent form.

4. Incompletely filled forms may result in sample being rejected for testing.

Sample Collection

For special haematology test :

1. Bone Marrow Aspirate (BMA)

- Please call ext 6549 to arrange for an appointment.
- On the appointment date, Medical Laboratory Technologist (MLT) will be at the procedure room to prepare smears from bone marrow sample obtained by ward doctor. The ward staff has to ensure that all necessary preparation is ready prior to commencement of the procedure, to avoid unnecessary waiting of the MLT.
- Waiting time more than 15 minutes may result in the procedure been postponed.
- MLT in charge will bring a tray full of clean slides for BMA smear and universal container containing 10% formalin for trephine biopsy on the day of the procedure. Other containers for other tests such as EDTA for Immunophenotyping and Molecular study, Lithium Heparin (for peripheral blood samples) and sodium heparin (for bone marrow aspiration samples) both intended Cytogenetics study and blood culture bottles for marrow culture must be provided by ward staff if required.
- The BMA smear will be taken to the Haematology Laboratory by the MLT for subsequent staining and further reporting Haematologist on duty.

Special requirements for other test :

1. Cryoglobulin Test & Osmotic Fragility Test

- Please refer to the list of test available for further information.
  Refer List of Test available

DNA Analysis For Thalassaemia Syndromes & Haemoglobinopathies Request Guide

1. Fill in the latest version of DNA Analysis request form **COMPLETELY** :

- DNA Analysis ForThalassaemia Syndromes & Haemoglobinopathies Version 4.1 (DNA Ana for Thal Synd & Hbpathy(s) REQform | Haematology Unit, CaRC IMR | Date of Issue: 21.11.2022 | Version 4.1

2. Fill in the consent form for DNA Analysis For Thalassaemia Syndromes & Haemoglobinopathies **COMPLETELY** :

- All DNA Analysis requests for thalassaemia and haemoglobinopathies must obtain written consent from the patient/ parents/ legal guardian. The informed consent form for DNA testing is available in both English and Malay on the second page of the request form and must be duly signed.

- Must be provided with details of requesting doctor and signed.

3. Select the designated referral laboratory for DNA Analysis based on the respective region/state

Hospital Kuala Lumpur :

- DNA Analysis Alpha Thalassaemia (Offered for all state **EXCEPT** Kedah, Perlis, Pulau Pinang and Northern Perak).

- DNA Analysis Beta Thalassaemia and Confirmation for haemoglobinopathy (Hb E, Hb S and Hb C only) : Offered for all state **EXCEPT** Kedah, Pulau Pinang, Sabah, Wilayah Persekutuan Labuan and Hospital Ampang.

Institute for Medical Research, National Institutes of Health :

- DNA Analysis Beta Thalassaemia & hemoglobinopathy : Offered to Kedah, Pulau Pinang, Sabah, Wilayah Persekutuan Labuan and Hospital Ampang only.

- Further testing for alpha globin gene, beta globin gene and confirmation for haemoglobinopathy (apart from Hb E, Hb S and Hb C following recommendation and suggestion by Hb Analysis or initial DNA analysis reports).

4. Sample and other

- Sample type :
  - Peripheral blood in EDTA tube : Adult 2.0-2.5 mL, Paeds 0.5 mL.
  - The blood sample must arrive at the reference laboratory within 2 weeks of blood collection.
  - Please ensure the name and identity card/ Mykid/ passport number labeled on the EDTA tube and on the request form are correct and tally.

- If the sample cannot not reach the reference laboratory on the same day, it should be stored in a refrigerator at 4-8°C until transportation is confirmed.

- A copy of Hb Analysis result of the patient.

- A copy of the latest result of Full Blood Count (FBC) (within 3 months) of the patient.
  • Please ensure the name and identity card/ Mykid/ passport number are legible and written completely on the attached FBC results.

- Please ensure that the copy of Hb Analysis and FBC results attached are legible.

- All paediatric samples (≤ 12 years old) referred to IMR must be accompanied by FBC and Hb Analysis results from both parents.

5. Additional requirements for cascade screening cases
- Full details of the index cases and a copy of the DNA Analysis are required for this screening.

6. Any pending Hb analysis report must be informed by the referring hospital/ clinic if the DNA test is requested to prevent the delay of reporting/ rejection of the test.

7. All requests for DNA analysis tests must be SCREENED at the clinic/ hospital/ collection center
Please ensure the above guidelines are followed before sending samples to the reference laborato laboratory. Hb Analysis cases coded as N or D16 for Form 4 alpha thalassaemia screening program are exempt from DNA Analysis and do not need to be referred.

Reference : Surat Pengendalian Permohonan Ujian *Haemoglobin (Hb) Analysis* Dan *DNA Analysis* Bagi Kes Pesakit *Thalassaemia* Di Fasiliti Kementerian Kesihatan Malaysia dengan nombor rujukan HKL/PAT/98/180/1-3 (35) bertarikh 20 Januari 2023.

Reporting Of Result

1. Result will be reported and validated within the laboratory test's turnaround time (LTAT) by a competent Pathologist and/or Medical Officer in Laboratory Information System (LIS). LTAT test are available at List of Test. Reference range are available for test, which contain parameter with numerical value.
2. For urgent results, verbal report will be informed to ward/attending clinician by phone. Final and validated result will be released into LIS once completed.
3. The formal reports for HKL patients (in-patient and out-patient) can be accessed via laboratory information system (LIS).
4. For cases from outside HKL, the results will be emailed to the respective collection centre.

MICROBIOLOGY

INTRODUCTION

Microbiology Unit provides diagnostic and consultative medical microbiology services, training, research and development to support screening, diagnosis and treatment monitoring of infectious diseases caused by bacteria, fungi, parasites and viruses. Services are also provided to support non-infectious diseases such as autoimmune disease, allergy and immunodeficiency. Comprehensive services are provided either in house or referred to other facilities within government agencies or outsourced to other non-Ministry of Health or private laboratories both locally and internationally.

The Microbiology Unit works in close collaboration with Infection Control Unit, Infectious Disease Physician and Pharmacist for the prevention, control and management of hospital acquired infection and antimicrobial resistance. For activities related to prevention and control of vaccine preventable diseases and other communicable infectious diseases, collaboration is with other relevant department and units such as Medical Department, Occupational and Safety Unit and Public Health Unit.

LIST OF SERVICES

Microbiology Unit provides the following services:

Diagnostic microbiological services provided by various laboratories namely bacteriology, mycology, parasitology, bacterial serology, immunology and virology.

Microbiology Laboratory Diagnostic Services offered are as follows:

- Direct detection of bacteria, viruses and fungi in clinical samples by microscopic examination of stained or unstained smears
- Isolation, identification and sensitivity testing of significant isolates of bacteria and fungi
- Utilization of immunological methods for antibody or antigen detection
- Viral genome detection and/or viral load determination using nucleic acid testing such polymerase chain reaction (PCR) both manual and automated.

Participation in hospital wide infection and antibiotic stewardship activities related to surveillance, control and prevention of healthcare-associated infections

Provision of microbiology studies of the hospital environment and sterility testing for prevention and control of infection.

Consultative services to clinicians and other health care providers, contribution to development of relevant policy, clinical care guidelines and hospital infection and antibiotic control related documentation or activity.

Training for technical, scientific, undergraduate and post graduate medical personnel.

LABORATORY CONSULTATION

In addition to overseeing the diagnostic tests the Clinical Microbiologist, Medical Officer and Scientific Officer also provide consultative services to clinicians to determine the most appropriate tests, samples and timing of collection to meet particular diagnostic needs.

The choice of most appropriate test(s) and interpretation of result(s) will require a certain amount of clinical information to be provided on the request form, thus, clinicians should consider consultation when:

- The laboratory frequently requests either more clinical information or additional samples or both
- It is unclear whether routine procedures can provide the information desired
- It is not known whether any specific viral infections are associated with an unusual syndrome.
- It is a medicolegal case
- If the test result are repeatedly unsatisfactory for whatever reason or not in tandem with the patient's clinical state.

SAMPLE COLLECTION AND HANDLING

General guidelines

- The quality of laboratory results depends greatly on the proper collection and handling of the sample as well as obtaining satisfactory material for examination
- The clinical sample must be material from the actual infection site and must be collected with minimum contamination from adjacent tissues, organs or secretions.
- A sufficient quantity of sample must be obtained in order to perform the examination required
- Appropriate collection devices, sample containers and culture media must be used to ensure optimal recovery of microorganisms. Please refer to the list of tests for further details.
- Ideally the sample must be collected before the commencement of antimicrobial therapy
- The sample container must be properly labelled, placed in a biohazard plastic bag and accompanied by a completed laboratory request form
- samples are best transported immediately to the laboratory.

Specific collection guidelines

Bacteriology

Autopsy material

A) Blood

i) Aspirate 10ml of the right heart blood either through skin and chest wall or (through unopened heart) from right ventricle after removal of sternum into a set of blood culture broths or sterile tube.
ii) Avoid contamination with bacteria from the water faucet and with the enteric bacteria. A block of splenic tissue may be submitted in lieu of a blood culture.

B) Tissue

i) Best collected before the body is being handled at an earlier stage. Decontaminate the skin or sear surface of heart or other organ before inserting needle or cutting out tissue block.

ii) Collect the tissue and placed in sterile container. Large piece is preferred (because aseptic collection is difficult). In the laboratory, 1 cm cube will be aseptically cut from the suspicious area including some normal tissue for processing.

Blood cultures and bone marrow aspirate

An automated blood culture system with different types of bottles according to age and tests is available:

- Adults : Aerobic and anaerobic culture bottle, volume : 5 – 10 mL into each bottle
- Pediatric : Paediatric blood culture bottle, volume : 2 -3 mls
- Fungal C&S : Myco-F lytic bottle (To be incubated for 14 days). Fungal blood culture and sensitivity can also be done using aerobic blood culture bottle.
- TB Blood Culture: Use Myco F Lytic bottle (request from Microbiology Laboratory).
- Bone marrow aspirate, 1-2 ml of aspirate is required and to be inoculated directly into the appropriate culture bottles.

Collection and Labelling Blood Culture Bottle:

1. Disinfect the culture bottle with 70% isopropyl alcohol.
2. Palpate for the vein first.
3. Before venepuncture, the skin must be carefully disinfect with 70% alcohol.
4. Swab concentrically starting at the centre with skin disinfectant. Allow the skin disinfectant to dry before blood collection (do not palpate vein at this point). Collect the blood.
5. After venepuncture remove disinfectant from the skin with alcohol
6. Ensure labels that contain patient info stick on proper area. DO NOT COVER THE BOTTLE BARCODES, as this is used by the instrument to process the sample.
7. Transport to the laboratory within 2 hours. Do not refrigerate the bottles

Note:

Endocarditis : 3 sets at 3 intervals at least 30 minutes apart

In the suspicion of catheter related bacteraemia, blood must be drawn from both the line and peripheral vein and submitted concurrently.

Blood Film for Malarial Parasite (BFMP)

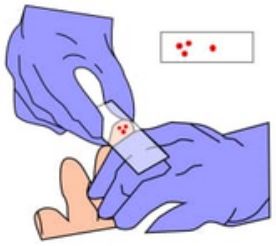
i) Clean new glass slides with absolute alcohol
ii) Select the third finger from the thumb (big toe can be used for infants). Clean the finger with 70% alcohol swab. Dry the finger with cotton towel.

iii) With a sterile lancet, puncture the ball of the finger using quick rolling action.

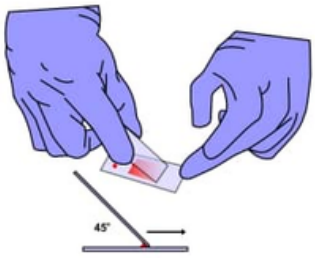
iv) By applying gentle pressure to the finger, express the first drop of blood and wipe it away with dry cotton wool.

How to prepare thin blood film

i) Label the slide with patient's name and ID number with soft lead pencil / sticker
ii) Apply gentle pressure to the finger and collect one (1) small drop of blood (approximately 2 mm in diameter) on the middle of the surface of a clean slide

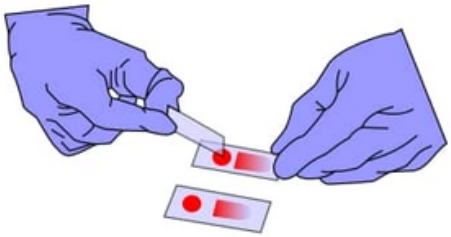


iii) Rest the blood slide on a firm, flat surface. Use another slide as a spreader. Touch the drop of blood with a spreader and allow the blood to run along its edge. Keep the spreader at an angle of 45˚ and in steady movement, firmly push the spreader forward to prepare a thin smear.



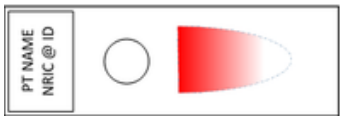
How to prepare thick blood film

i) If thin and thick smear prepared on different slide, label each slide with patient's name and ID number with soft lead pencil / sticker label.
ii) Apply gentle pressure to the finger and collect 3 small drops of blood on the surface of clean slide.

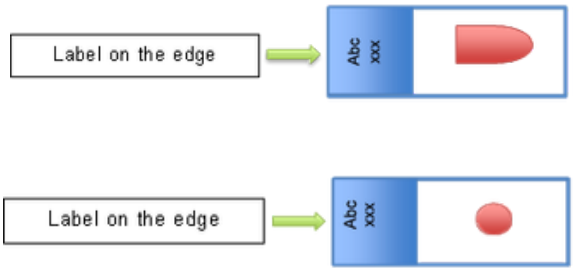


iii) Using the corner of another glass slide as a spreader, quickly spread the blood to make an even, thick film. The blood is spread in a circular motion with 3 – 6 movements, and spread over 1.0 cm diameter.
iv) Place the blood film in a slide tray to air dry at room temperature before send to laboratory. Do not heat-dry.

Option 1
(WHO recommendation)
Thick and thin smear in same slide

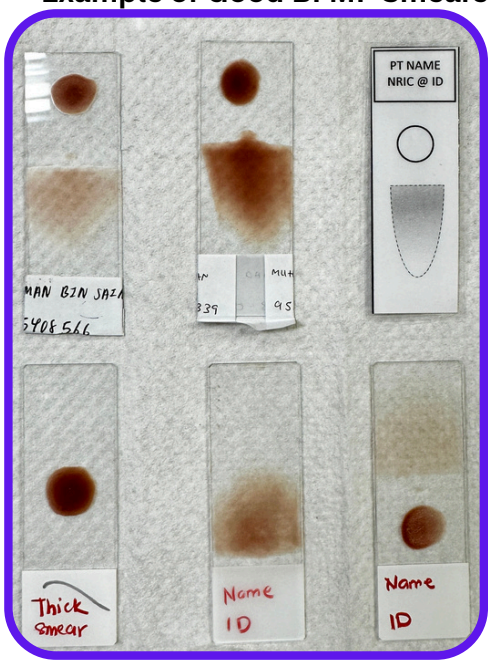


Option 2
Thick and thin smear in different slide



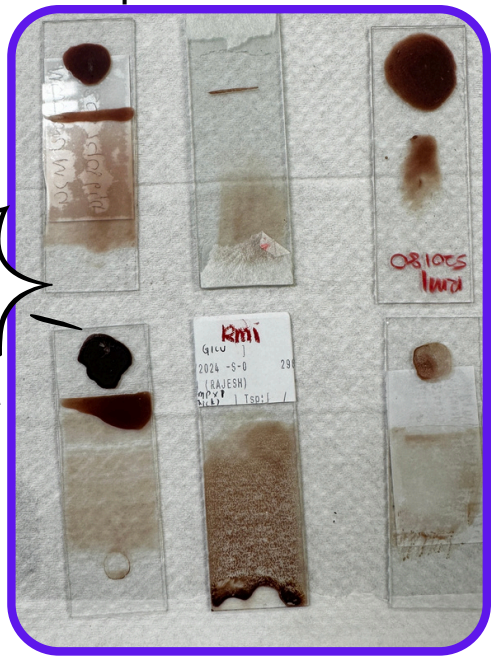
Example of Good BFMP Smears

Good smears, but should label patient info above thick smear



Example of Poor BFMP Smears

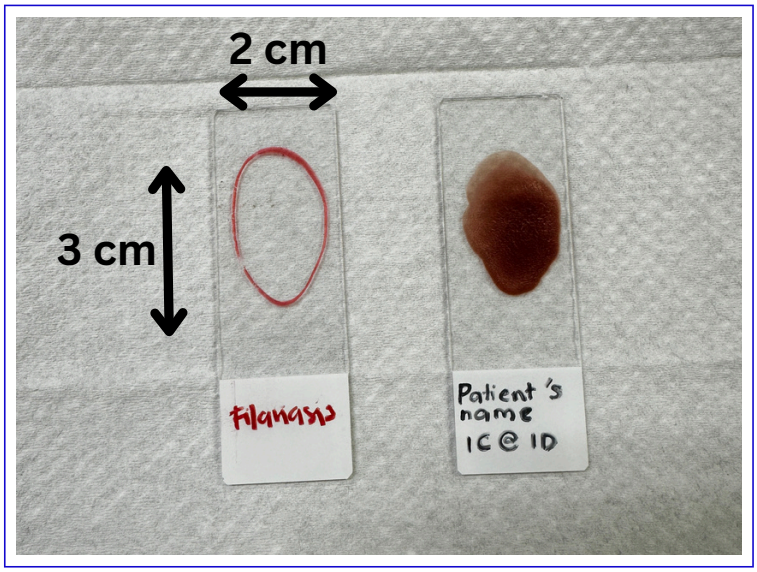
Do not label under the smear!



Blood Film for Microfilaria Parasite (BFMF)

Preparation of smear

i) Collect a big drop of blood (60 ul) by finger-pricked. Blood collection must be done after 9.00 pm (Refer pathologist on-call for preferred time).
ii) Make an **oval and thick** blood film (Approximately 3 x 2 cm) on a clean glass slide.
iii) Dry it in a horizontal position, taking care to protect it from dust and pests.
iv) Wait until the smear is completely dried off and send to the laboratory.



Note:
Smear Quality and Drug Resistance

- A good smear allows visibility of hands of a watch or reading newsprint through it.
- Assess every positive smear for parasitemia due to potential Plasmodium drug resistance, especially P. falciparum.
- For hospitalized patients, repeat BFMP at 24, 48, and 72 hours after starting therapy.

Cerebrospinal Fluid (CSF)

A. Lumbar puncture
1. Disinfect site with 2% iodine tincture.
2. Insert needle with a stylet at L3 – L4, L4 – L5 or L5 – S1 interspace. Upon reaching the subarachnoid space, remove the stylet and collect 1 – 2 ml of fluid into sterile bijou bottle.

Note : always send the most turbid tube to the lab.

B. Ommaya reservoir fluid
1. Clean the Ommaya reservoir site with antiseptic solution and alcohol
2. Remove Ommaya fluid via the Ommaya reservoir unit and place into bijou bottle

C. Brain abscess and CNS biopsy sample
1. Aspirate material or biopsy sample collected from lesions must be placed in a sterile bottle or syringe and send immediately to the laboratory for anaerobic culture.
2. Do not add formalin

Note: CSF for microscopic examination, cell count, bacterial antigen test can be collected into a single screw capped sterile container.

Genital Samples

A. Endocervical swab
i) This is the best sample for the diagnosis of gonorrhoea and puerperal sepsis
ii) Under direct vision, gently compress cervix with blades of the speculum and use rotating motion with swab, obtain exudates from the endocervical canal iii) Inoculate the swab into Amies transport media.

B. Urethral discharge
i) Wipe the urethral with a sterile gauze or swab.
ii) Collect the exudate with a sterile swab and inoculate into Amies transport media. If discharge cannot be obtained by 'milking' the urethra, use a sterile swab to collect material from about 2 cm inside the urethra
iii) Place the swab into Amies transport media.

Helicobacter pylori culture

Sample : Gastric biopsy
i) Place biopsy material in a sterile, bullet container with approximately 1 ml of sterile normal saline
ii) Transport immediately to the laboratory. Sample must be processed within 2 hours of collection.

Indwelling devices

The acceptable devices are : IV catheters for semi-Quantitative culture (Maki method) : central, CVP, Hickman,s, Broviac, peripheral, arterial, umbilical, hyperalimentation, Swan-ganz. The sample should be accompanied by blood drawn from peripheral vein.

***Foley's tube is not acceptable for culture
i. Cleanse the skin around the catheter site with alcohol.
ii. Aseptically remove catheter and clip 5 cm of the distal tip of the catheter directly into a sterile screw-cap container
iii. Transport directly to the lab to prevent drying

Mycobacterium : Acid – fast bacilli stains and culture

Acceptable samples:

A. Respiratory secretions, urine, CSF, body fluids, whole blood and tissue biopsies.
***Swab samples are not acceptable.
i) Collect respiratory secretion, urine and tissue biopsies in sterile Falcon tube (available from the general distribution counter)
ii) Collect a minimum of 3 early morning sputum or urine samples in successive 24 hours period
iii) Place whole blood, body fluids and CSF into a commercial TB blood culture bottle (available from the laboratory on request)

B. Sterile body fluid C&S (excluding CSF, urine and blood)
i) Clean needle puncture site with skin disinfectant solution
ii) Aseptically perform percutaneous aspiration to obtain pleural, pericardial, peritoneal or synovial fluid.
iii) Collect fluid into a sterile screw-cap container.
iv) For anaerobic culture send sample immediately in the syringe.

C. Pus / swab / tissue
i) Send pus if available, in a sterile screw-cap container or syringe
ii) Swab is an inferior substitute and should be avoided, if sent, in an Amies Transport Medium.
iii) Send all tissues for culture in sterile screw-cap container. Do not add formalin to the sample.

Note :
i) A dry swab may fail to yield organisms in smear and culture
ii) Surface swabs of deeply infected lesions (eg ; sinus tracts from osteomylitis, pressure sores) usually grow surface contaminants like coliforms and pseudomonads.

Respiratory Samples

Upper Respiratory

A) Nasal swab
Submitted primarily for detection of MRSA carriers
i) Wet a sterile swab in sterile Normal Saline and insert the swab into the the nasal cavity until resistance is met at the level of turbinates (approximately 1 inch into the nose)
ii) Gently rotate the swab against the nasal mucosa
iii) Repeat the process on the other side with the same swab

B) Throat swab

Submitted primarily for the detection of Group A Streptococci, Arcanobacterium sp., (Corynebacterium diphtheriae and Neisseria gonorrhea - upon request)

i) Depress tongue gently with tongue depressor.

ii) Extend sterile swab between the tonsillar pillars and behind the uvula (avoid touching the cheeks, tongue, uvula, or lips.

iii) Sweep the swab back and forth across the posterior pharynx, tonsillar areas, and any inflamed or ulcerated areas to obtain sample.

Lower respiratory tract

A) Sputum

i) Collect early morning sample after rinsing the mouth and gargling with water

ii) Instruct the patient to cough deeply and expectorate sputum only and not saliva into the sterile screw-cap container

B) Tracheal aspirate/ bronchial washing / broncho alveolar lavage / lung aspirate /lung biopsy

Tracheostomy is followed by colonization within 24 hours of insertion of the tube. Results must be correlated with clinical findings such as fever or infiltrate on chest x-ray.

Stool

A) Stool Culture and Sensitivity / Clostridium difficile C&S / C. difficile toxin

1. Collect faeces into a sterile / clean wide-mouth screw-capped plastic container
2. If the faeces is liquid, the container maybe filled to one-third full (excessive amount will result in spillage when opened)

Note:

1.Rectal swab is poor second best alternative to faeces. If it is not possible to obtain faeces, collect a sample by inserting a cotton swab into the rectum and send in a suitable transport medium.

2.For stool clearance culture in cases of typhoid and cholera, stool should be sent upon completion of therapy

3.Clostridium difficile toxin test

·If 2 or more samples are collected on the same day, only one will be tested and reported.

·Collect at least 3 to 5 ml of faeces. Faeces should be loose/watery to conform to the shape of the container. Formed faeces will be rejected unless the requisition indicates the patient may have pseudomembranous colitis.

·Rectal swabs are not an acceptable alternative and will not be tested for toxin.

B) Stool Ova and Cysts/ Cryptosporidium and Isospora / E. histolytica
i) Collect faeces into a clean wide-mouth container with a tight fit lid to prevent accidental spillage and maintain moisture.
ii) The sample should not be contaminated with water and urine.
iii) Place in the plastic bag, label properly, accompanied by a request form and send immediately.

Note:
Stool samples containing barium and antibiotics are not acceptable. sample should be collected 5 – 10 days after these substances are given to the patient. For patients treated with mineral oil, bismuth, anti-malarial agents and non- absorbable anti-diarrhoeal preparation, sample collection should be delayed at least for 2 weeks.
It is recommended that normal examination for stool parasites before therapy include three samples submitted on separate days. Collect the sample every other day or the series of 3 samples within no more than 10 days.

Urine

A) Midstream urine
Male
i) Cleanse the glands and penis with soap and water.
ii) Rinse area with wet gauze pads
iii) While holding the foreskin retracted, begin voiding.
iv) After several millilitres has passed, collect a midstream portion without stopping the flow of urine.

Female
i) Thoroughly cleanse the urethral area with soap and water.
ii) Rinse area with wet gauze.
iii) While holding the labia apart, begin voiding.
iv) After several millilitres has passed, collect a midstream portion without stopping the flow of urine.

B) Suprapubic aspirate (SPA)
SPA is useful in determining urinary infection in adults in which the results from routine procedures are equivocal but the diagnosis is critical. Also useful for paediatric patients when clean-catch urine is difficult to obtain.
i) Before SPA, the patient should force fluids until bladder is full.
ii) Shave and disinfect the suprapubic skin overlying the urinary bladder.
iii) Aspirate urine from the bladder by using a needle aspiration technique.

C) Catheter urine
Catheters are placed in patients who are unable to pass urine
i) Clean the catheter collection port with 70% alcohol wipe
ii) Using sterile technique, puncture the collection port with a needle attached to a syringe. Do not collect the urine from the bag.
iii) Aspirate urine and place it in sterile container.
iv) Send sample immediately to the laboratory

Mycology

A) Skin, nails and hair
Clean cutaneous and scalp lesions with 70% alcohol prior to sampling as this will improve the chances of detecting fungus on microscopic examination, as well as reducing the likelihood of bacterial contamination of cultures. Prior cleaning is essential if ointments, creams or powders have been applied to the lesion.

Skin, nails and hairs samples should be collected into folded squares of paper or directly onto agar plate.

B) Skin
Material should be collected from cutaneous lesions by scraping outwards from the margin of the lesions with the edge of a glass microscope slide or a blunt scalpel.

C) Hair
i) Sample from the scalp should include hair roots, the contents of plugged follicles and skin scales
ii) Hairs should be plucked from the scalp with forceps or the scalp is brushed with a plastic hairbrush and collected onto an agar plate.

D) Nail
i) Nail samples should be taken from any discoloured, dystrophic or brittle parts of the nail.
ii) sample should be cut as far back as possible from the edge of the nail and should include the full thickness of the nail.

E) Mouth and vagina
i) Swabs from the buccal mucosa should be moistened with sterile water prior to taking the sample and sent in Amies transport media
ii) For vaginal infections, swabs should be taken from discharge in the vagina and from the lateral vaginal walls. Swabs to be sent to the laboratory in Amies transport media.

F) Ear
Scrapings of material from the ear canal are to be preferred, although swabs can also be used.

G) Ocular samples
i) Material from patients with suspected fungal infection of the cornea (Keratomycosis) should be collected by scraping the ulcer. The entire base of the ulcer, as well as the edges should be scrape. Swabs are not suitable for sampling corneal lesions
ii) The material is collected directly onto agar plates for culture and to glass slide for microscopic examination.

H) Blood
Blood culture for fungal is collected aseptically as in culture for aerobic bacterial culture but using the available commercial fungal bottle.

The request for fungal culture should be indicated clearly on the request form and a total of two weeks incubation will be carried out.

I) Cerebrospinal fluid
CSF samples (3-5mls) should be collected in a sterile container for microscopy and culture.

J) Bone marrow
This sample is helpful for making the diagnosis in a number of deep fungal infection, including histoplasmosis and cryptococcosis.
3 – 5 ml of aspirated material should be collected and transferred into the commercial fungal culture bottle.

K) Pus
i) Pus from undrained subcutaneous abscesses or sinus tract should be collected with a sterile needle and syringe
ii) If grains are visible in the pus (as in mycetoma), these must be collected. In mycetoma, if the crusts at the opening of the sinus tracts are lifted, grains can often be found in the pus underneath.

L) Tissue
i) If possible, material should be obtained from both the middle and edge of the lesions
ii) Small cutaneous, subcutaneous of mucosal lesions can often be excised completely
iii) Tissue samples should be placed in a sterile container without formalin.

Samples for serological tests

These comprise tests in bacteriology, virology, parasitology and immunology. Method of blood collection:
i) Draw 3 – 5 ml of blood into a plain tube without anticoagulants
ii) Clot at ambient temperature
iii) Despatch to the laboratory within 4 hours of collection for serum separation by centrifugation.
iv) If delays in delivery of more than 4 hours is anticipated, centrifuge blood at 3,000 rpm for 10 min, pack serum properly with dry ice/ wet ice and send to lab via courier service.
Note:
Haemolysed, icteric or lipaemic samples invalidate certain tests. If such samples are received, the samples will be rejected to ensure that results are of clinical value. If the samples was sent from laboratories, please reject at your own laboratories.

Sample for molecular test in virology lab

Viral Genome Detection (PCR)

A) Blood
i) Collect 3-5ml of blood into EDTA tube for HCV genotyping, HCV RNA, HBV DNA, BK virus quantitation, CMV DNA and HIV RNA quantitation. Do not exceed the marked blood level on the EDTA container.
ii) Send directly to Virology Lab within 4 hours after collection in ice-box containing wet ice.

B) CSF
Collect a minimum of 1 ml of CSF into a sterile screw capped container.

C) Respiratory Sample
i) Collect lower respiratory tract samples (deep cough sputum, bronchoalveolar lavage, tracheal aspirate, pleural fluid) into screw capped sterile container.
ii) ONLY if lower respiratory tract samples is not possible, upper respiratory tract samples (URTSs) may be taken:

Note:
❖ COMBINED nasopharyngeal and oropharyngeal swabs (NP/OP swabs), nasopharyngeal aspirate/wash collected in viral transport media (VTM).
Send the samples in ice to the laboratory ASAP. If delay is anticipated, keep samples at 4°C.
DO NOT FREEZE.
❖ Ensure triple packaging if the suspected pathogen is a risk group 3 pathogen and transport in ice

Click here for Annex 4c: Specimen Collection, Transport and Storage MOH 20 September 2022

Medicolegal cases

Specific guidelines
i) Samples should be sealed and send directly to the microbiology laboratory
ii) Samples should be sent to the laboratory by a designated personnel
iii) Chain of custody should be maintained at all times and record book should accompany the sample(s).

Sample collection of various tests should follow the guidelines as of normal microbiological requirements and the specific headings are referred.

SERVICES AFTER OFFICE HOUR

A) Blood for Malaria Parasite and Culture for bacteria and fungi is available 24 hours and 7 days a week.

B) Blood samples from needle stick injury and transplant will be available after office hours and public holidays. Some of routine test in virology services also available during public holidays on a need basis such as in the case of an outbreak.

C) Sample for routine virology tests received during after office hours and on public holidays will be kept in the pre-analytical unit refrigerator and will be processed on the next available working day.

MICROBIOLOGY

LIST OF REQUEST FORMS

FORM NAME	FORM DETAIL	REFERRAL CENTRE
Bacteriology		
Bacteriology Request Form	IMR/BACT/FORM/SMIS/01	IMR
Ricekettsiosis Lab Request Form	IMR/BACT/FORMS/RICK/02	IMR
Bartonellosis Laboratory Request Form	IMR/BACT/FORMS/BART/01	IMR
Brucellosis Laboratory Request Form	IMR/BACT/FORM/BRUCE/02	IMR
Virologi		
HIV PCR Request Form (Baby)	IMR/Viro/HIV/2	IMR
HIV Genotyping Resistance Testing	IMR/Viro/HIV/24	IMR
Dengue and Flavivirus Request Form	MKAK-BPU-D02 (rev_Nov_2015)	MKAK
Measles Request Form	MSLF:02/Rev2024	MKAK
Borang Pengurusan Ujian Makmal (sample Clinical) (eg. Viral identification)	MKAK-BPU-U01/Rev2018	MKAK
Virology Test Request Form	IMR/VIRO/ADMIN/53	IMR

PATHOLOGY SCACC

INTRODUCTION

The Specialist Clinic and Ambulatory Care Centre (SCACC) Pathology Laboratory is located at the Level 1 of SCACC building. Currently, the laboratory offers services as follows:

1. Collection centre for all samples from Specialist Clinics in SCACC with exception of Histopathology samples, Dynamic Tests, and Quantiferon TB Test.
2. Routine Laboratory Services:
    - Full Blood Count
    - Blood Gases
    - Routine Biochemistry
    - Urine Pregnancy Test
    - Urine Biochemistry
3. The laboratory offers phlebotomy (blood taking) service to all patients from Specialist Clinics in SCACC.
4. Histopathology sample from respective Specialist Clinics in SCACC shall be sent by directly to Histopathology Unit, Department of Pathology in the HKL Main Building. Blood for Dynamic Tests and Quantiferon TB will be taken by the respective Specialist Clinics.

NOTES ON PHLEBOTOMY SERVICE

1. All patients shall be given appointment DATE and TIME by Specialist Clinics through the Laboratory Information System (LIS). All test requests shall be registered in the LIS. Phlebotomy request without prior appointment will be rejected.
2. The phlebotomy appointment DATE and TIME shall be written clearly in the patient's appointment request form.
3. **Patients are required to be present at the scheduled DATE and TIME with appropriate completed Laboratory Request Form.**
4. Patients will be given registration ticket for phlebotomy according to the appointment.
5. Patients shall contact the respective Specialist Clinics for rescheduling of the appointment if needed.
6. All sample container such as for urine, sputum and stool will be provided by **Specialist Clinics.**
7. Foreigners are required to make payment at the respective Specialist Clinics and show the payment slip at the laboratory counter during registration.

SPECIAL CHEMICAL PATHOLOGY

INTRODUCTION

The Special Chemical Pathology Unit provides specialised Chemical Pathology testing services for Hospital Kuala Lumpur and serves as a key referral laboratory for Malaysia. The laboratory delivers both diagnostic and consultative services to Hospital Kuala Lumpur as well as other government laboratories nationwide.

SCOPE OF SERVICE

The scope of services includes the analysis and clinical interpretation of specialised Chemical Pathology tests for disease screening, diagnosis, and patient monitoring. The tests cover the analysis of specialised endocrine, metabolic, and protein assays.

Refer List of test

In addition, for Hospital Kuala Lumpur patients the Special Chemical Pathology Laboratory also coordinates the outsourcing of Chemical Pathology tests that are not available within laboratories under the Ministry of Health to accredited private laboratories.

Refer List of referred test

TEST REQUEST

General Requirement

All test requests shall be accompanied by the PER-PAT 301 Form, which is the standard form used for all laboratory test requests.

Specific Requirement

Certain tests have specific requirements, as outlined below:

Test	Details
HbA1c	The minimum retesting interval for HbA1c is three months. Requests submitted within less than three months of the previous test shall not be accepted.
Thyroglobulin and Anti-Thyroglobulin	These tests are indicated primarily for the monitoring of differentiated thyroid cancer (papillary and follicular thyroid carcinoma) and both samples shall be sent together for this purpose.
Thyroid Stimulating Hormone (TSH) Receptor Antibody	Clinical indication must be documented on the request form. Only indicated requests will be processed. To ensure this, the request for the test shall be made by specialist, preferably endocrinologist.
Protein Electrophoresis	Detailed clinical information shall be provided on the request form, as this is essential for accurate result interpretation. The minimum retesting interval is one month. Requests submitted within less than one month of a previous test shall not be accepted.
Diabetes Autoantibodies	Test offered include a panel diabetes antibodies (comprise of anti-GAD, anti-ICA, anti-IA2) and Insulin autoantibodies (anti-IAA). Clinical indication must be documented on the request form. Only indicated requests will be processed. To ensure this, the request for the test shall be made by specialist, preferably endocrinologist.
Anti-Mullerian Hormone (AMH)	Clinical indication must be documented on the request form. Only indicated requests will be processed. To ensure this, the request for the test shall be made by O&G Specialist or Paediatrician.

Test	Details
24-hour Urine Metanephrines	Require 24-hour urine collection (minimum of 1 litre volume for adult patient). Collected in 24 hour urine container with preservatives (6M hydrochloric acid) to achieved urine pH of 4 to 5. Only indicated request will be processed. To ensure this, the request shall be made by specialist preferably endocrinologist. This test could be influenced/interfere by certain drugs: • Levopar, Madopar, Restex • Tricyclic antidepressants, antipsychotics, adrenergic receptor blockers • Salsolinol, Tyramine and antiarrhythmic drug procainamide and its metabolite N-acetylprocainamide (acecainide). Avoid due to possible interference. The optimal duration for discontinuation varies depending on pharmacokinetics; where clinically feasible, should be withheld for at least one week prior to testing.
Intraoperative PTH	Arrangements for test requests shall be made with the Medical Officer/Chemical Pathologist in the Special Chemical Pathology Unit prior to the operating day.

Test	Details
Dynamic Function Test	Request forms shall be filled with patient's details, relevant clinical information, and the type of dynamic test performed. Accurate sample labelling is critical for the correct analysis and interpretation of dynamic tests. Each sample shall be **APPROPRIATELY LABELLED** with: • Patient identifiers (name and identification number) • time of sample collection (e.g 0 minutes, 30 minutes etc.) • site of sample collection (if applicable) Laboratory turnaround time (LTAT) for the dynamic tests is 10 working days. **Dynamic Tests** • Growth Hormone Suppression Test Growth hormone and glucose samples taken at 0 minute, and then at 30, 60, 90 and 120 minutes after glucose load. • Glucagon Stimulation Test Growth hormone and glucose samples taken at 0 minute, and then at 60, 90, 120, 150, 180, 210 and 240-minutes following glucagon administration. • Insulin Tolerance Test Growth hormone, cortisol and glucose samples taken at 0 minute, and then at 30, 45, 60, 90 and 120-minutes following insulin administration.

SAMPLE COLLECTION

Blood

Most Chemical Pathology tests require serum samples collected in plain tubes. However, certain tests have specific sample requirements, as outlined below:

- HbA1c: Requires a whole blood sample collected in an EDTA tube.
- Adrenocorticotropic hormone (ACTH): Requires a whole blood sample collected in an EDTA tube and transported on ice immediately to the laboratory.

Haemolysis may interfere with the measurement of certain labile analytes, including insulin, parathyroid hormone (PTH), ACTH, and growth hormone. This is due to proteolytic enzymes released from erythrocytes, which degrade these peptide hormones and may result in falsely decreased concentrations.

For ACTH, C-Peptide, Insulin and PTH), sample must be send immediately to the laboratory due to short sample stability (Refer List of test for details of sample requirement).

Urine

24-hour urine collection is required for certain test e.g., 24-hour Urine Metanephrines due to its pulsatile release.

The procedure of collection:

Discard the first voided urine and note the start time and date

↓

Collect all urine voided for 24-hour duration and mixed well every time urine is added into the container

! Do not void urine directly into the 24-hour urine container. Please use another clean urine container for urine collection to avoid spillage or acid injury.

↓

Keep the closed urine container in cool and dry place

↓

Add the last voided urine into the container and note the finishing time and date

REPORTING OF RESULTS

Results are reported in accordance with the laboratory turnaround time. Results are released either by auto or manually validation. Auto-validated results are generated based on algorithms approved by a Chemical Pathologist. Manual validation is performed by a Chemical Pathologist, Medical Officer, or Scientific Officer, depending on the complexity of the test.

Reference ranges are provided and may vary according to age and sex, where applicable. For internal requests, reports can be accessed via the Laboratory Information System (LIS). For external requests, reports are issued via official email.

ATTACHMENT/NOTICES/ANNEXES

PEMAKLUMAN PENOLAKAN PERMOHONAN UJIAN KLINIKAL DI UNIT MAKMAL TERAS JAB PATOLOGI HKL

JABATAN PATOLOGI
HOSPITAL KUALA LUMPUR
Jalan Pahang
50586 Kuala Lumpur

Tel: 03-26155555 Ext. 6854
E-Mail: patologi.hkl@moh.gov.my

Ruj. Kami : HKL/PAT/98/180/2-8 (9) Jld. 2
Tarikh : 24 Mei 2024

DATO' DR. HAMRISHNA K.N. NAIR
(MMC 34755)
DMU S.J.S.KMN
Pengarah
Hospital Kuala Lumpur

DR. HAJAH SHAHRUM BINTI ISMAIL
(MPM 30520)
TIMBALAN PENGARAH (PERUBATAN I)
B.P PENGARAH
HOSPITAL KUALA LUMPUR

SEPERTI SENARAI EDARAN

Melalui: Pengarah
Hospital Kuala Lumpur

YBhg. Datuk/Dato'/Datin/Tuan/Puan,

PEMAKLUMAN PENOLAKAN PERMOHONAN UJIAN KLINIKAL DI UNIT MAKMAL TERAS, JABATAN PATOLOGI, HOSPITAL KUALA LUMPUR

Dengan segala hormatnya merujuk kepada perkara di atas.

2. Untuk makluman pihak YBhg. Datuk/Dato'/Datin/Tuan/Puan, hasil pemantauan data-data penolakan sampel sepanjang bulan Januari hingga April 2024, didapati sebanyak 5229 sampel klinikal telah dijalankan proses penolakan sampel. Penolakan sampel dilakukan berdasarkan kepada kriteria penolakan sampel seperti yang dinyatakan dalam **Buku Perkhidmatan Patologi 2024** di laman sesawang Hospital Kuala Lumpur (sila rujuk pautan https://hkl.moh.gov.my/index.php/en-us/mengenai-kami/jabatan/sokongan-klinikal/patologi).

3. Mengikut tatacara penolakan sampel di Unit Makmal Teras, setiap penolakan yang dilakukan akan dimaklumkan kepada pemohon melalui panggilan telefon dan ada masanya panggilan tidak dijawab. Banyak masa dan tenaga kerja dihabiskan untuk tujuan ini. Oleh yang demikian, pihak pengurusan Unit Makmal Teras telah mengambil keputusan untuk memuatnaik Laporan Penolakan Sampel melalui e-mel sahaja. Pihak pemohon boleh merujuk status permohonan ujian melalui e-mel **berkuatkuasa pada 3 Jun 2024**.

4. Sehubungan dengan itu, pihak YBhg. Datuk/Dato'/Datin/Tuan/Puan adalah dipohon untuk menyampaikan maklumat ini kepada semua hospital-hospital atau klinik-klinik kesihatan di bawah seliaan supaya mematuhi kriteria pengambilan yang ditetapkan dalam ***Pre-Analytical Requirements*** **(m/s 11)** dalam Buku Perkhidmatan Patologi 2024, Jabatan Patologi, HKL. Sebarang kemusykilan, sila berhubung dengan Dr. Ng Lai Yee, Pegawai Perubatan UD52, Unit Makmal Teras di sambungan 5610.

5. Kerjasama dan perhatian daripada pihak YBhg. Datuk/Dato'/Datin/Tuan/Puan dalam perkara ini amatlah dihargai dan didahului dengan ucapan terima kasih.

Sekian.

"MALAYSIA MADANI"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

Back to Rejection Criteria

.....
(DR. ZANARIAH BINTI ALIAS)
NO. MMC: 30657
Pakar Perunding Patologi dan
Ketua Jabatan Patologi
Hospital Kuala Lumpur

KUMARI/MT/200524

ANNEX 4C: SPECIMEN COLLECTION, TRANSPORT AND STORAGE ; MOH 20 SEPTEMBER 2022

Annex 4c

SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE

1. Samples of nasopharyngeal and oropharyngeal swabs

1.1 Personnel taking the samples

- The personnel taking the must be a registered medical practitioner who has attended training and has a certificate of attendance for Sample Taking and Handling Training for COVID-19 for General Practitioners and Paramedics from Private Health Facilities issued by the Family Health Development Division, MOH or State / Federal Health Department.
- Sampling can only be done by the Private Healthcare Facilities and Services registered or licensed under Act 586 at the premises or elsewhere that has been approved for the facilities by the Medical Practice Division, Ministry of Health Malaysia.

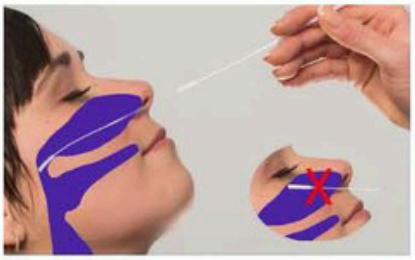
1.2 Personnel conducting the tests

- The personnel conducting the test procedure shall have a minimum Diploma in Medical Laboratory Technology .of at least 3 months.
- Adequate Training and competency in nucleic acid testing methods shall also be documented (etc logbook and competency assessment).
- The laboratory shall have qualified, skilled and experienced signatory (ies) to validate data and troubleshoot problems.
- Approved signatory (ies) shall have a degree or higher in medicine or basic science),trained and competent in the nucleic acid method , with at least one year or more laboratory working experience and 3 months experience in molecular testing.
- Personnel that can validate results are as following :
  - Pathologist
  - Medical Officer
  - Scientific Officer
  - Research Officer
- The lab should have at least one personnel that have qualifications in microbiology.

2. Technique For Specimen Taking

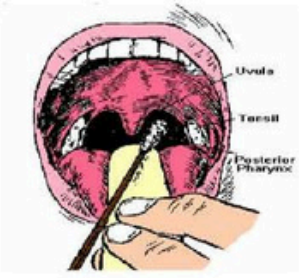
2.1 Technique for specimen taking Nasopharyngeal Swab (NPS)

1. Explain the procedure to patient
2. Bend the patient´s head backward.
3. Swiftly insert the swab into the nostril. The depth of insertion is around 4-8 cm for children and 8-12 cm for adults.
4. Rotate the swab (3 to 5 times at 1 nostril) against the nasopharyngeal mucosa and remove the swab.



2.2 Technique for specimen taking Oropharyngeal Swab (OPS)

1. Ask the subject to open his or her mouth
2. Depress the tongue
3. Swab the posterior pharynx behind the tonsils
4. Avoid the tonsils



2.3 Technique for specimen taking Nasal Swab

1. Carefully insert the swab into patient's nostril. The swab tip should be inserted up to an inch from the edge of the nostril.
2. Dap along the lining of the nostril to ensure that both mucus and cells are collected. Turn the swab several times and remove the swab.
3. Repeat at the other nostril using the same swab tip.

2.4 Technique for Deep Throat Saliva, Oral fluid/ Saliva collection

a) Deep Throat Saliva collection

Patient must not eat or drink, smoke, chew tobacco/betel leaves, brush teeth or gargle with mouth freshener for at least 2 hours prior to the sample collection. Let the patient sit comfortably, in a well-ventilated space.

Methods of deep throat saliva collection

i. Instruct patient to drain mucus from the back of the nose and throat at least 3 times
ii. Ask patient to forcefully breath in 3 times, with head tilt slightly up and cough out the deep throat saliva with mucus.
iii. If patient find difficulty with earlier method, they can be asked to collect the saliva in mouth and bring at deep throat then gargle it for >30sec.
iv. Ask patient to lift specimen collection cup close to his/her mouth and take a deep breath in and cough out or spit out the deep throat saliva into the collection cup.
v. A minimum of 2 ml of deep throat saliva sample is required.

b) For saliva/ oral fluid collection for rapid test kit antigen (RTK Ag), please refer to Instruction for Use (IFU) in the product insert intended.

2.5 Technique for sputum collection

a) Collect early morning specimen after rinsing the mouth and gargling with water
b) Instruct the patient to cough deeply and expectorate only sputum and not saliva into the sterile screw-cap container

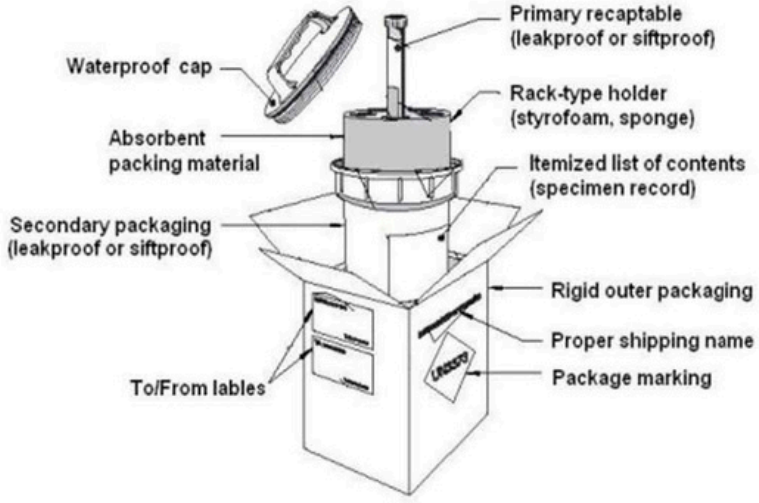
ANNEX 4C: SPECIMEN COLLECTION, TRANSPORT AND STORAGE ; MOH 20 SEPTEMBER 2022

3. SPECIMEN CONTAINER, STORAGE AND TRANSPORTATION

Specimen	Container/ Transport Media		Storage
OPS NPS	For RT-PCR, combine NPS and OPS swab in 1 Viral Transport Media (VTM) As for RTK Ag place the swabs in dry container.		➢ To send the samples immediately laboratory at 2-8°C -If transportation of samples is within 72 hours, store at 2- 8°C and transport in ice
Nasal / NPS	As for RTK Ag place the swabs in container provided		
Sputum/BAL Saliva/ Oral fluid	Sterile Container		
Tissue	VTM or sterile container with few drops of normal saline	 	

Blood (Serology testing)	Plain Tube with gel		If delay in sending blood specimen, centrifuge and store at at 2-8°C

4. TRIPLE LAYER PACKAGING



SOP for Transport of Biological Specimens in Malaysia 2012: category B

- Leakproof primary container
- Secondary packaging- leakproof and watertight container with absorbent material
- Tertiary/ outer shipping box, rigid to protect specimens during shipment

NOTE:

1. **Please avoid excessive packaging that is difficult to unpack.**
2. **Do not use any rubber band or sealed the gauze too tight. (This could cause hazard to laboratory staff when unpack the specimen using sharp material)**

This picture above is an example for land transportation.

- **For airline shipment, please follow SOP for Transport of Biological Specimens in Malaysia 2012: category B**

4.1 Packaging for bigger quantity of samples.

- Place 1 sample per 1 biohazard plastic bag (secondary packaging).
- Secondary packaging can be grouped into 1 bigger plastic bag, not more than 20 samples each.
- The big packaging must be coded according to the name list to facilitate identification of the samples.
- Put the forms into plastic bag/envelope and it **MUST** be put it **OUTSIDE** the polystyrene box for biosafety purpose.

5. SPECIMEN SHIPPING AND TRANSPORTATION BY AIR

For transporting patient specimens cultures or isolates, **especially by air**, personnel must be trained in the proper safety, packing, and shipping regulations in accordance with the current edition of the Division 6.2, UN 3373 Biological Substance, Category B International Air Transport Association (IATA) Dangerous Goods Regulations (DGR) and SOP for Transport of Biological Specimens in Malaysia 2012.

ANNEX 4C: SPECIMEN COLLECTION, TRANSPORT AND STORAGE ; MOH 20 SEPTEMBER 2022

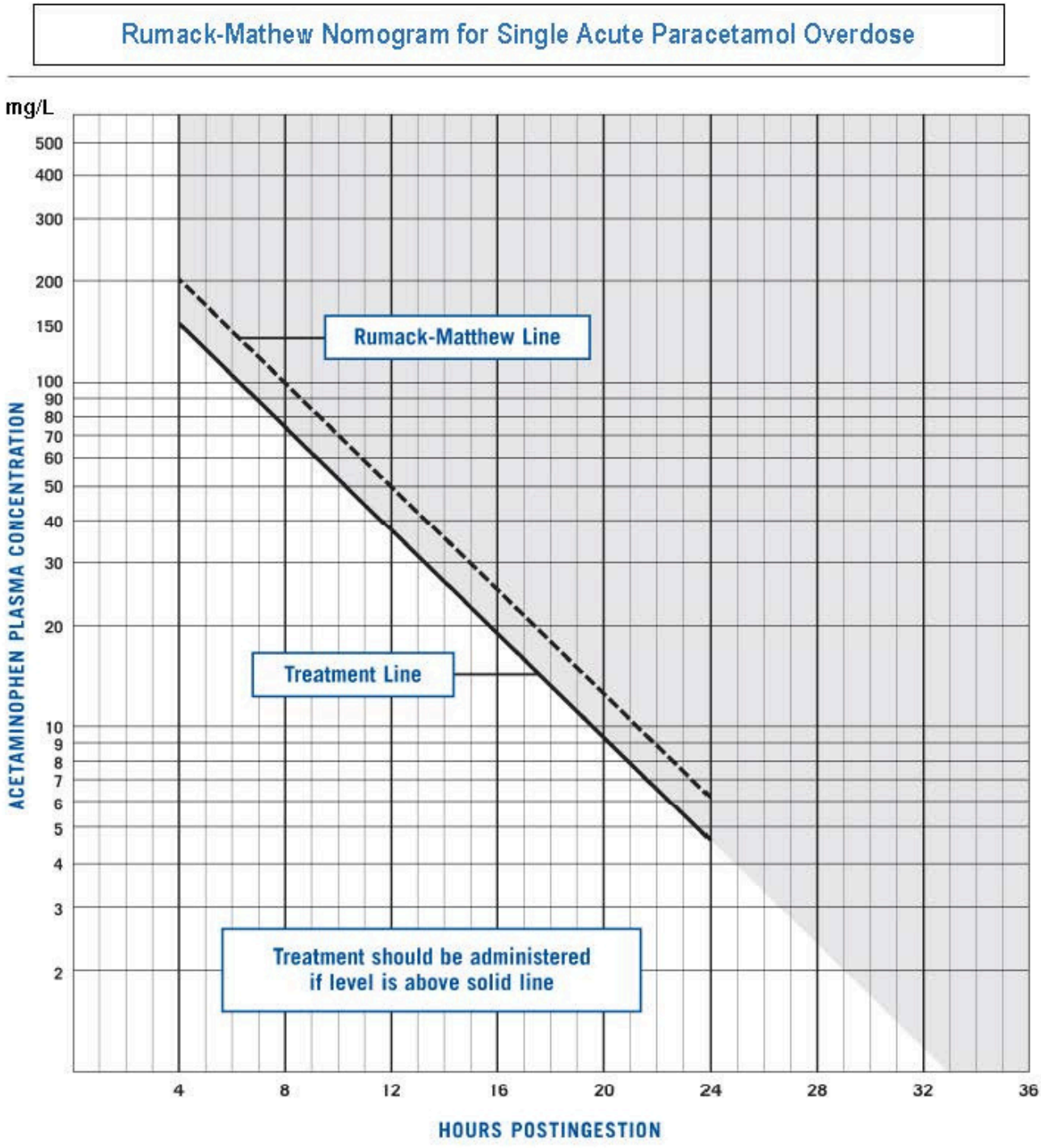
Specimens should be shipped **at 2-8°C** with ice packs. The primary receptacle and the secondary packaging should maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost. Packages containing dry ice should be designed and constructed so as to prevent the build-up of pressure and to allow the release of gas that could rupture the packaging.

Ensure the outer package has been properly marked and labelled with the following:

a) Hazard labelled with UN Identification Number already on label – UN 3373
b) Biological Substance, Category B
c) Shipper's name, address, and phone number
d) Receiver's name, address, and phone number
e) Name and phone number of a responsible person is optional if it is on the airway bill

Back to Microbiology

RUMMACK MATTHEW NOMOGRAM



Nomogram: acetaminophen plasma concentration vs time after acetaminophen ingestion (adapted with permission from Rumack and Matthew. *Pediatrics*. 1975;55:871-876). The nomogram has been developed to estimate the probability of whether a plasma acetaminophen concentration in relation to the interval postingestion will result in hepatotoxicity and, therefore, whether acetylcysteine therapy should be administered.

CAUTIONS FOR USE OF THIS CHART:

1. Time coordinates refer to time postingestion.
2. Graph relates only to plasma concentrations following a single, acute overdose ingestion.
3. The Treatment Line is plotted 25% below the Rumack-Matthew Line to allow for potential errors in plasma acetaminophen assays and estimated time from ingestion of an overdose (Rumack et al. *Arch Intern Med*. 1981;141(suppl):380-385).

OTHER POINTS:

1. This nomogram is applicable for PCM serum levels taken within 24 hours post-ingestion only.
2. NAC can be started empirically if PCM dose ingested >150mg/kg. Efficacy is best if NAC is started within 8 hours post-ingestion & reduced gradually after 24 hours.

[Back to Table 2: Toxicity level in TDM]

DEPARTMENT OF PATHOLOGY
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WILAYAH PERSEKUTUAN KUALA LUMPUR.