



# OPERATIONAL POLICY IN PATHOLOGY SERVICES

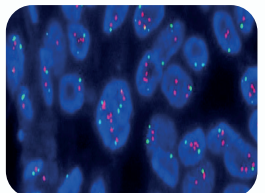
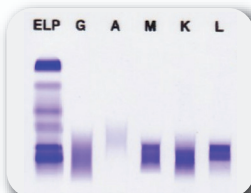
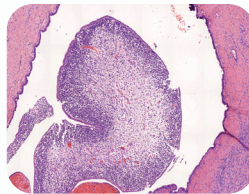
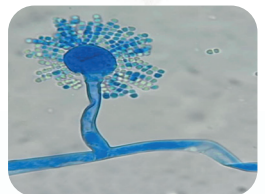
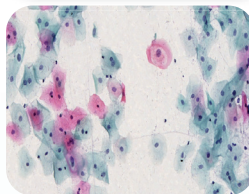
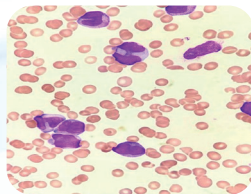
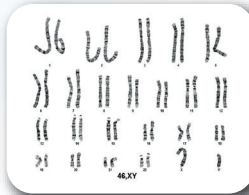
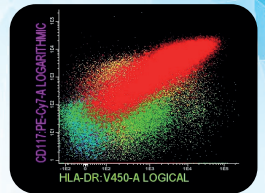
2nd Edition

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OPERATIONAL POLICY  
IN PATHOLOGY SERVICES  
(2nd Edition)

MEDICAL DEVELOPMENT DIVISION  
MINISTRY OF HEALTH MALAYSIA

A catalogue record for this book is available from the library and Resource Unit of the  
Institute of Medical Research, Ministry of Health ;

MOH/P/PAK/463.21(BP)

Also available from the National Library of Malaysia ;

ISBN 978-967-2634-80-5

ISBN 978-967-2634-80-5



Published in October 2021

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Director of the Medical Development Division, Ministry of Health Malaysia

This policy was developed by the Medical Development Division and the Drafting  
Committee of the Operational Policy In Pathology Services(2nd Edition), Ministry of Health  
Malaysia.

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# **FOREWORD**


# FOREWORD

Director General of Health Malaysia



**YBhg. Tan Sri Dato' Seri Dr Noor  
Hisham Abdullah**

**P**athology Services are essential services provided by clinics and hospitals to aid clinicians in disease management, particularly in the diagnosis and prognosis. Advancements in the field of medicine, in tandem with the rapid changes in technologies, necessitate the implementation of standard operational procedures in various disciplines. The arrival of this comprehensive national policy will set forth the appropriate approaches in realizing the Vision and Mission of the Ministry of Health (MOH), Malaysia. With this second edition of Operational Policy in Pathology Services, the previous Departmental Policy of Pathology Services will no longer be valid. The Operational Policy in Pathology Services (2nd Edition) will assist organizations to operate in an orderly manner and optimize service delivery to the general public. It is a comprehensive policy that outlines all service aspects in all the Pathology Department in the MOH facilities. Those involved in the provisions of pathology services may find this policy will assist quality improvement strategies for their clients. I extend my congratulation to the Medical Development Division of the Ministry of Health and the working committee for their commitment to developing this document which sets the standard for laboratory services in the Ministry of Health.



TAN SRI DATO' SERI DR NOOR HISHAM ABDULLAH



## FOREWORD

Deputy Director  
General of Health Malaysia (Medical)



### YBhg. Dato' Asmayani Khalib

**M**edical laboratory services are an integral component of the health system. Efficiency and effectiveness of both clinical and public health functions including surveillance, diagnosis, prevention, treatment, research and health promotion are influenced by reliable laboratory services. The Pathology services require collaboration with multiple disciplines to provide for a complete plan and implementation of care and services. The Operational Policy in Pathology Services (2<sup>nd</sup> Edition) will be able to provide information on the basic and specialised services that are provided at the hospitals. I would like to take this opportunity to congratulate the working committee for initiating and coordinating this effort. I hope that the quality of our medical services will continue to improve in tandem with the Ministry's mission to provide the country with a holistic healthcare system.

A handwritten signature in black ink, appearing to be 'Dato' Dr Asmayani Binti Khalib'.

DATO' DR ASMAYANI BINTI KHALIB

# FOREWORD

## Head of Pathology Services



### YBrs. Dr. Arni Talib

**T**he universal need to convert an expansive mass of laboratory data into accessible, cost effective and clinically usable information has continued to be a matter of increasing significance throughout the medical community. The need for swift and clear information is imperative in the daily practice of clinical pathology and also in diagnostic and management decisions with treating clinicians. Nowadays, laboratory tests guide more than seventy percent of medical decisions. They range from early disease detection and diagnosis confirmation right up to personalised treatment plan.

The discipline has developed from providing basic and routine laboratory services into modern multidisciplinary laboratories providing specialised diagnostic tests, training and research services in Malaysia. Many of our medical laboratories have been accredited by Standards Malaysia, complying to MS ISO15189.

I am thankful and greatly indebted to all my colleagues in various hospitals who shared with me their invaluable time, and experience, gathering their thoughts and ideas for the development of this document. I am very grateful to the Secretariat of the Medical Development Division, Ministry of Health Malaysia, for the insightful advice and dedicated efforts in editing this document and making it wholesome. Lastly, I sincerely hope that the content and information of this new edition of our Operational Policy in Pathology Services(2<sup>nd</sup> Edition) in the Ministry of Health Hospitals serves its purpose.

  
**Dr. Arni Talib**



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# INTRODUCTION

## 1. INTRODUCTION

The Pathology discipline in the Ministry of Health Malaysia (MOH) provides a comprehensive range of services to hospitals and health clinics. Medical laboratory services are essential to healthcare as it contributes to screening, diagnosis, prognosis determination and treatment monitoring of diseases. A laboratory network service is available to meet the needs of all patients and healthcare personnel. As clinical care becomes more complex, pathology involvement becomes crucial in multidisciplinary team management. Advancement in technologies is adopted and aligned to MOH and Operational Policy in Pathology Services.

The Operational Policy in Pathology Services applies to all the pathology laboratory services in MOH hospitals and facilities. The document cuts across all disciplines in pathology, specifically Anatomic Pathology, Chemical Pathology, Genetic Pathology, Haematology, and Medical Microbiology. It is recommended to be used in healthcare planning for service delivery, resource management and training, as well as finance allocation.

This policy covers key areas of laboratory services such as organisation, human resource, equipment and infrastructure requirements. It is intended to guide healthcare providers, hospital managers and policymakers on the requirement, operation and development of laboratory services in the MOH hospitals. The document outlines optimal achievable standards following best practices and guidelines. Necessary steps need to be taken for hospitals and health centres that do not fully meet these standards. The document shall be reviewed and updated every 5 years or as the need arises.

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**SCOPE OF SERVICES**

## 2. SCOPE OF SERVICES

The scope of pathology services includes Anatomic Pathology, Chemical Pathology, Haematology, Medical Microbiology and Genetic Pathology. The service encompasses of;

- a. Consultancy and advisory services.
- b. Outsourcing services for those tests which are not provided by any MOH laboratories.
- c. Provision of External Quality Assurance (EQA) Programme.
- d. Research and Development (R&D) activities.
- e. Routine and urgent tests with specified laboratory turnaround time (LTAT).
- f. Specialised tests in selected MOH laboratories.
- g. Supervision and monitoring of Point of Care Testing (POCT).
- h. Technical evaluation of reagent kits and analysers.
- i. Training for all categories of Pathology staff and individuals from other institutions.
- j. Twenty-four (24) hour service for acute patient management.



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**GENERAL POLICY**

### 3. GENERAL POLICY

- 3.1 Basic and specialised services provided in the hospital laboratories are based on hospital types as classified by MOH i.e. state, major, minor and non-specialist hospitals. (Appendix 1).
- 3.2 Regionalisation or centralisation of service shall be determined by workload, test complexity, technical skill, expertise and cost-effectiveness.
- 3.3 Calculation and collection of pathology laboratory workload data are done in a standardised and coordinated manner across all MOH laboratories according to the latest "Guideline on Standardisation of Workload Data Collection" for Pathology Services.
- 3.4 Referral tests shall be made possible between Ministry of Health (MOH) laboratories and coordinated by respective state pathologists and heads of relevant disciplines.
- 3.5 If the scope of the test is not available within MOH laboratories, outsourcing of service should be arranged with accredited non-MOH laboratories. The laboratory shall be responsible for facilitating the outsourcing process according to a standardised procedure.
- 3.6 There shall be an established agreement for providing medical laboratory services between laboratories regardless of MOH or non-MOH facilities, including private institutions.
- 3.7 New services planned by MOH laboratories shall be coordinated by state pathologists and the Head of Pathology Services, and the relevant pathology discipline.
- 3.8 New programmes to be introduced by MOH shall involve pathology service in the planning and implementation to ensure the sustainability of resources and quality of testing.
- 3.9 Setting up new laboratories within MOH facilities shall engage pathology service in the planning and implementation to meet the expected requirement.
- 3.10 All medical devices, including equipment, reagent, and consumables, shall comply with the Medical Device Act (MDA) 2012.
- 3.11 All laboratory charges shall follow the latest Fees Act.
- 3.12 The pathology service is committed to compliance with Pathology Laboratory Act 2007.



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# **ORGANISATION**

## 4. ORGANISATION

- 4.1 The Medical Development Division is responsible for the overall planning and development of Pathology service in all MOH hospital laboratories in Malaysia. It shall be assisted by the Head of Pathology Services, the Heads of Pathology Disciplines, State Pathologists, Heads of related Allied Health Professions and Coordinators of Pathology Committees. (Appendix 4).
- 4.2 The Head of Pathology Services shall be appointed by the Director-General of Health and is responsible for the planning and development of the Pathology Services.
- 4.3 Heads of Pathology Disciplines are nominated by the respective discipline fraternity and shall be endorsed by the Head of Pathology Services. They are responsible for assisting in the standardisation of practices, monitoring quality performance, proposing resources required and training initiatives in the respective disciplines.
- 4.4 State Pathologists are appointed by the respective State Director of Health with the advice of the Head of Pathology Services. They shall be a senior pathologist and preferably also Head of the State hospital laboratory, responsible for planning and implementation of the service in the State.
- 4.5 Heads of Allied Health Professions which consist of science officers of Biochemistry, Microbiology, Genetic Pathology, Biomedical Science and medical laboratory technologist, are appointed by the Director-General of Health with the advice of the Director of Allied Health Division and Head of Pathology Services. They are responsible for the planning and development of the respective professions.
- 4.6 Coordinators of MOH Pathology Committees shall be appointed by the Head of Pathology Services and are responsible for the respective tasks (Appendix 4).
  - 4.6.1 Asset
  - 4.6.2 Finance
  - 4.6.3 Human Resource
  - 4.6.4 IT and Transportation
  - 4.6.5 Point of Care Testing (POCT)
  - 4.6.6 Procurement
  - 4.6.7 Quality and Accreditation
  - 4.6.8 Research and Development
  - 4.6.9 Sub speciality
  - 4.6.10 Training
  - 4.6.11 Workload
- 4.7 All the appointed personnel mentioned above have a specific Term of Reference (TOR) and hold office for a minimum of 2 years.

- 4.8 Hospital laboratories without pathologists shall be headed by a resident medical officer trained in laboratory services or a senior science officer in compliance with MS ISO 15189. In addition, there shall be regular hospital visits by a pathologist from the respective discipline for professional and technical consultations.



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**PERSONNEL**

## 5. PERSONNEL

- 5.1 Human resources in pathology laboratories shall include but not be limited to pathologists, medical officers, science officers, medical laboratory technologists, clerical staff and healthcare assistants.
- 5.2 Head of Pathology Services shall coordinate with the head of disciplines/profession and state pathologist to post and distribute pathologists, science officers, and medical laboratory technologists to ensure appropriate placement.
- 5.3 The distribution of human resources shall depend on the service needs based on workload, service requirement, subspecialty distribution and geographical location (Appendix 8).
- 5.4 State and major specialist hospitals should have all major disciplines with an adequate and appropriate number of pathologists and allied health personnel (Appendix 5).
- 5.5 Minor specialist and non-specialist hospitals should have at least three major disciplines: Haematology, Chemical Pathology and Medical Microbiology, with an adequate and appropriate number of pathologists and allied health personnel (Appendix 6 and 7).
- 5.6 Where specially trained personnel needed for the service are not available, contract personnel can be appointed full-time or part-time.
- 5.7 All staff involved in technical activities shall be appropriately credentialed and privileged.
- 5.8 Head of Department
  - 5.8.1 The Head of Pathology Department at the state hospital shall be a senior pathologist appointed by the hospital director.
  - 5.8.2 The laboratory in major and minor specialist hospitals shall be headed by a pathologist appointed by the hospital director.
  - 5.8.3 The laboratory in non-specialist hospitals or hospitals without pathologists shall be headed by a trained medical officer in pathology or science officer, under the supervision of a visiting pathologist, as appointed by the hospital director.
- 5.9 Pathologist
  - 5.9.1 A pathologist shall be a medically qualified pathologist who has obtained a post-graduate qualification in Pathology such as a Master in Pathology or its equivalent and completed gazettement in MOH hospital.
  - 5.9.2 A pathologist who has completed at least one (1) year of working experience after the qualification should register with National Specialist Register (NSR).
- 5.10 Quality Manager
  - 5.10.1 An appropriate and trained pathologist, medical officer or science officer shall manage the Quality Management System in the laboratory. There should be a Quality Manager in each department.

### 5.11 Laboratory Manager

5.11.1 An appropriate and trained medical officer, science officer or senior medical laboratory technologist may be appointed to assist the Head of Department in laboratory management.

### 5.12 Medical Officer

5.12.1 There shall be an adequate number of trained medical officers placed on a full-time basis to cover for the disciplines of Pathology at the laboratory in all hospitals including non-specialist hospitals (Appendix 5,6 and 7).

5.12.2 Medical officers shall be assigned to Pathology Departments. Priority shall be given to medical officers inclined to pursue a career in Pathology.

### 5.13 Science Officer

5.13.1 Science officer (SO) shall be placed in all disciplines within the laboratory according to their respective fields of expertise. The number shall follow the norm/ workload. Refer to Minimum Requirements of Science Officer in MOH's Hospitals (Appendix 8).

5.13.2 There shall be at least one (1) senior science officer category C54 post in each discipline in the state hospital.

5.13.3 Science officer shall carry out after hour duty including weekends and public holidays when required.

### 5.14 Medical Laboratory Technologist (MLT)

5.14.1 There shall be at least two (2) senior MLTs (U40) placed in every state to supervise MLTs in hospital and public health laboratories.

5.14.2 Hospitals shall have an appropriate number of MLTs following the norms. There shall be various categories of MLTs in hospital laboratories, minimally as follows:

- i. U40 - state and major specialist hospitals
- ii. U36/38 - state/ major specialist hospitals
- iii. U32 - state/ major/ minor and non-specialist hospital
- iv. U29 - the major workforce of all laboratories

5.14.3 MLTs are required to perform after-hours duty including weekends and public holidays.

### 5.15 Healthcare Assistant/ *Pembantu Perawatan Kesehatan (PPK)*

They shall function as personnel for sample receipt, sorting, packaging of specimen/ sample, sorting filing and dispatching of samples, results and any other extended duties with training as determined by the HOD/ HOU.

5.16 Clerical staff

Clerical work involves administrative and daily office duties including data entry, report typing, sorting and filing documents, storekeeping and other non-technical works determined by HOD/HOU.

5.17 IT personnel

All state and major specialist shall have dedicated IT officer(s) to manage Laboratory Information System and other IT system that is related to pathology service

5.18 Autoclave operator

A competent autoclave operator shall provide the autoclave service in the laboratory. They should have the necessary qualification and training.



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**TRAINING**



## 6. TRAINING

### 6.1 General

- 6.1.1 The heads of pathology disciplines, head of department and allied health profession shall plan and identify specialised training needs and nominate suitable personnel.
- 6.1.2 All categories of staff in the Pathology Services should be allowed to attend relevant courses during their service period to maintain efficiency and competency.
- 6.1.3 All personnel shall undergo orientation, training and scheduled educational programmes.
- 6.1.4 Credentialing and privileging of laboratory personnel shall follow the national requirement.
- 6.1.5 All personnel appointed on a contract basis shall be competent to carry out their duties.
- 6.1.6 Training for specialised and subspecialised services shall be in a team approach comprising a pathologist, SO and MLT.
- 6.1.7 Medical officers and technical staff shall undergo supervised training in a specific discipline and be deemed competent.
- 6.1.8 Continuous schedule competency training shall be implemented for all categories of staff to support routine and special tests.

### 6.2 Specific

#### 6.2.1 Pathologist

- 6.2.1.1 The Head of Pathology Services and head of disciplines shall plan and identify the subspecialty training needs and personnel.
- 6.2.1.2 Subspecialty/ area of interest training must be coordinated by the *Jawatankuasa Subkepakaran Perkhidmatan Patologi, KKM*.
- 6.2.1.3 Pre-training exposure in a local institution in the chosen area is encouraged before going for the fellowship training abroad.
- 6.2.1.4 Placement of the trained personnel shall be according to the plan and clinical needs/demands.
- 6.2.1.5 Post-training contribution shall be in the form of service development and establishment /expansion of local training programmes.

#### 6.2.2 Medical Officer

All medical officers posted to a Pathology unit without a resident pathologist should be trained for at least three months in Pathology Department in the state/ major specialist hospital.

6.2.3 Science Officer

6.2.3.1 All newly employed science officers shall undergo training at the state or major specialist hospital for three months before posting to minor or non-specialist hospitals. The training should encompass laboratory management, including techniques, stringent quality control protocols, and budget and equipment procurement.

6.2.3.2 Subject Matter Expert for science officer will be recognized by Public Services Department. Qualified science officer in specific niche area may apply for Subject Matter Expert through processes which will be determined by the Ministry of Health.

6.2.4 Medical Laboratory Technologist

All newly employed medical laboratory technologists to be posted to non-specialist hospitals and Klinik kesihatan shall undergo at least two weeks of training at the nearest hospital with a pathologist and fulfil the logbook requirement.

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**SERVICE DELIVERY**

## 7. SERVICE DELIVERY

Test directory is accessible at [www.patologi.gov.my](http://www.patologi.gov.my) and through the hospital website/handbook.

A system shall be in place to ensure all tests are validated by pathologists or trained and competent personnel (MO/ SO/ MLT).

- 7.1 Automation shall replace manual methods where available.
- 7.2 Standardisation of practices and procedures shall be implemented according to MS ISO 15189.
- 7.3 Pre-analytical
  - 7.3.1 The Department of Pathology is responsible for providing a user manual to guide sample collection, handling and transportation to the laboratory.
  - 7.3.2 The test shall only be requested by registered medical and dental practitioners involved in patient management.
  - 7.3.3 Genetic tests shall only be requested by a specialist/consultant.
  - 7.3.4 The request shall be made in the specified laboratory form, or electronically where available as agreed by the organization. Verbal requests for additional tests are discouraged. However, they should be considered on a situational basis and depend on the sample's stability and adequacy. These requests shall be documented, specifying the person making the request, the date and time, and the reason for the request.
- 7.4 Sample collection
  - 7.4.1 Sample collection shall follow the guidelines provided by the Pathology Department.
  - 7.4.2 MLTs should not perform phlebotomy in hospitals and health facilities.
- 7.5 Sample transportations
  - 7.5.1 Mechanical transportation systems, e.g. pneumatic tubes, shall be made available when there is a requirement for effective sample transport.
  - 7.5.2 The sample transport system shall include the Emergency & Trauma Department and intensive care wards.
  - 7.5.3 The department is responsible for monitoring the transportation condition of samples to the laboratory to ensure the quality of test results is maintained.
  - 7.5.4 Patients are discouraged from bringing their samples to the laboratory.
- 7.6 Reception of sample in the laboratory
  - 7.6.1 The laboratory shall have a dedicated area for sample reception.
  - 7.6.2 The laboratory shall only accept samples from private and university hospital with an established service agreement.

- 7.6.3 Payment shall be made to the *Unit Hasil* of the respective hospital before sample acceptance.
- 7.7 Analytical
  - 7.7.1 All methods shall be validated before use, and all records are kept.
  - 7.7.2 Clinical interpretation of test results/ reports shall only be made by a trained medical officer or pathologist.
  - 7.7.3 Routine diagnostic services that share a common instrument/method platform encompassing Chemical Pathology, Haematology and Microbiology may preferably be integrated into one central laboratory.
  - 7.7.4 The laboratory shall participate in EQA Programme for each test item they offer.
  - 7.7.5 If the EQA programme is unavailable, the laboratory shall consider other methods (e.g. interlaboratory comparison) to determine the acceptability of test results.
- 7.8 Post Analytical
  - 7.8.1 Critical value notification shall be practised according to national guidelines (Improving Notification of Critical Result in MOH Hospitals, 2010) and Malaysia Patient Safety Goal, Guidelines & Implementation 2020).
  - 7.8.2 All test results shall be reported within stipulated LTAT that reflect clinical needs.
  - 7.8.3 Laboratory results should be released to the authorised requestor and not directly to the patients themselves.
  - 7.8.4 All patients' records and samples are to be retained as required by guidelines and regulations.
  - 7.8.5 All referrals for a second opinion shall be arranged through liaising pathologists of both laboratories. Records or specimens shall not be transferred from the primary laboratory without the approval of the pathologist in charge of the laboratory.



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**DISCIPLINES**

## 8. DISCIPLINES

### 8.1 Anatomic Pathology (AP)

- 8.1.1 Anatomic Pathologists should only be posted to the identified AP centres according to the norms based on workload. (Appendix 8).
- 8.1.2 Identified AP centres should have at least two (2) in-house anatomic pathologists.
- 8.1.3 All AP centres shall have at least two SO and adequate numbers of MLT and clerical staff based on the workload at the centre.
- 8.1.4 Frozen section service must be retained in the major specialist hospitals, which have been identified as the AP centres. Requests for frozen section service shall be on an appointment basis and shall be made at least 24 hours before the scheduled procedure except for transplant cases. Facilities for frozen section services shall be made available near the OT set up, complete with an effective communication system.
- 8.1.5 Trained cytotechnologists shall be posted to the designated gynaecological cytology centres.
- 8.1.6 All FNAC procedures can be done either by anatomic pathologists or by trained doctors/clinicians.
- 8.1.7 All clinical autopsies shall be performed with input from a team of doctors, including the pathologist and clinician managing the case.
- 8.1.8 Subspecialty service shall be provided by the regional centres or central referral lab if the speciality is not available in the AP centres.
- 8.1.9 Training shall be geared towards the needs of the service. All sub-specialisation will be developed in phases and numbers following the clinical demand.

### 8.2 Chemical Pathology

- 8.2.1 State hospitals shall be the referral centre for all Chemical Pathology services within the state.
- 8.2.2 The state chemical pathologist will coordinate and arrange with other MOH regional chemical pathology or national centres to ensure appropriate services.
- 8.2.3 Therapeutic Drug Monitoring (TDM) service shall be performed in the chemical pathology laboratory.
- 8.2.4 Endocrine, Tumour markers, TDM tests shall be performed at specialist hospitals.
- 8.2.5 All state hospitals should have at least two (2) chemical pathologists, while major and minor hospitals should have at least one chemical pathologist. In addition, non-specialist hospitals should have at least one science officer with three years of related working experience. Other numbers should be considered with increasing workload.
- 8.2.6 Drug of Abuse (DOA) – Screening and confirmatory tests will be done at centres equipped with Gas Chromatography/Mass Spectrometry (GCMS).

- 8.2.7 Inborn Error of Metabolism (IEM) testing is performed at Hospital Tunku Azizah, Kuala Lumpur and Institute for Medical Research (IMR).
- 8.3 Medical Microbiology
- 8.3.1 State hospitals shall be the referral centre for microbiology services within the state. To ensure the availability of appropriate services, State Medical Microbiologist will coordinate and arrange with other MOH regional microbiology or referral centres.
- 8.3.2 State and major specialist hospitals shall have at least two (2) medical microbiologists. The numbers may be added according to the norms based on workload and the function of the laboratory as a regional or national referral centre (bacteriology, virology, mycology, parasitology or immunology centres). In addition, medical microbiologists may be placed in a minor specialist hospital according to service needs.
- 8.3.3 There shall be at least one trained medical officer placed in state and major specialist hospitals full-time to support diagnostic medical microbiology services.
- 8.3.4 Routine culture and antimicrobial testing shall be performed at all state and major specialist hospitals. It may be performed at a minor specialist hospital if a resident medical microbiologist is available or the transport time to the referral centre is expected to be prolonged (more than 2 hours). A minor hospital providing culture and sensitivity shall have two (2) science officers in the absence of a medical microbiologist. They will be supervised by a medical microbiologist from the nearest hospital.
- 8.3.4 State and major specialist hospital laboratories shall offer 24-hour microbiology services. The minimum test to be offered are as follows:
- i. Blood, cerebrospinal fluid and sterile body fluid culture.
  - ii. Gram stain and cell count for cerebrospinal fluid /sterile body fluid
  - iii. Gram stain for corneal scraping
  - iv. Malaria detection in blood.
  - v. Routine infectious disease screening for cadaveric organ(s) donor and recipient of this organ(s)
- 8.3.6 Result for needle stick injury shall be made available within 24 hours of injury.
- 8.4 Haematology
- 8.4.1 State hospitals shall be the referral centre for Haematology services within the state. To ensure the availability of appropriate services, state haematologists will coordinate and arrange with other MOH regional haematology or referral centres.
- 8.4.2 There shall be at least two (2) haematologists in the state hospitals and one haematologist in major and minor specialist hospitals. Additional haematologists are placed according to the workload and service needs.
- 8.4.3 There shall be at least two (2) science officers in the haematology laboratory in the state hospital and one in major specialist hospitals, preferably biomedical graduates.



- 8.4.4 There shall be adequate MLT placed according to the norms set and specialisation of tests offered.
- 8.4.5 The range of specialised tests to be provided by the state hospital shall include but not be limited to FBP, Haemoglobin analysis, Bone marrow aspirate/trephine smear, Kleihauer test, Osmotic fragility test, Mixing test, Factor VIII and IX assay, Factor inhibitor/Bethesda assay, Lupus anticoagulant test and CD4/8 enumeration.
- 8.4.6 The range of specialised tests provided by the major and minor specialist hospital shall include but not be limited to FBP, bone marrow smear and mixing tests.
- 8.4.7 Subspecialty services shall be provided by the regional centres or central referral lab.
- 8.4.8 A transfusion specialist/s shall manage the laboratory transfusion service in the state hospital. However, haematologists may manage the transfusion service in the major and minor specialist hospitals (in the absence of a transfusionist).
- 8.5 Genetic Pathology
- 8.5.1 Genetic Pathology is an integral part of the pathology discipline as the practice of medicine now has evolved to be personalised, predictive, preventive and participatory.
- 8.5.2 To address this, Genetic Pathology must be directly connected to the strategic planning with the clinical teams. For this purpose, an inherent indirect link with the Medical Development Division (*Cawangan Perkembangan Perkhidmatan Perubatan – Unit Perkhidmatan Obstetrik Ginekologi dan Pediatrik*) is essential. The rationale for these is:
- a. Genetic Pathology needs a powerful, cost-effective, intelligent, digitised, innovative strategy for screening, risk stratification, early detection, monitoring and efficacy of an intervention in prenatal disorders, malignancies, congenital anomalies and rare diseases. A robust genetic diagnostic testing, up-to-date bioinformatics test systems, molecular analysis, artificial intelligence and machine learning is the way forward. Genetic testing is not only applicable in common disorders (i.e. prenatal, paediatrics, neurodegenerative, autism, neuropsychiatric, and endocrine disorders), but it is also an essential diagnostic tool in rare diseases, disorders of sexual differentiation and cancer genetic diagnostics. This is an evolving, state-of-the-art, specialised diagnostic applicable across medical and surgical, paediatrics and adult disciplines.
  - b. In addition, genetic testing is expensive, niche speciality. For this, we need to tap into the budget of other disciplines like Orphan Drug, In-vitro Fertilisation, Disorders of Sexual Differentiation and the National Genetic Committee to ensure intelligent, sustainable patient-centred service delivery.
  - c. The technical platforms used in Genetic Pathology complement each other in the analytical test process, and these Molecular Genetic platforms are applicable in diagnostic work across all disciplines.
- 8.5.3 The Head of Genetic Pathology appointment is based on merits, experience and

fellowship qualification(s) in Genetic Pathology by Head of Pathology Services with endorsement by the Genetic Pathology fraternity.

- 8.5.4 The Head of Genetic Pathology and the Head of Pathology Services shall coordinate all new services planned by any MOH laboratories involving genetic testing. This can be achieved by smart reorganisation and optimisation of human resources, funds and facilities to solve increasing workload issues.
- 8.5.5 A minimum of six (6) in-house genetic pathologists is needed to manage the national genetic referral centre. There shall be adequate numbers of qualified medical officers, subject matter experts (SME), SO, MLT and clerical staff based on technical skills and expertise. Additional numbers of residential genetic pathologists and genetic-based laboratory personnel may be required with increasing workload and test complexity.
- 8.5.6 The Genetic Pathology will pave the way for industrial/specialisation/sub-specialisation training programmes to cater to the expanding national clinical demands and needs.
- 8.5.7 Test duplication shall be avoided at all costs to prevent dilution of budget and wastage as this results in a financial burden to the healthcare system. The operational funding in setting up duplicated tests should be effectively channelled to develop other genetic tests that have not been offered yet. Coalescence of Genetic Pathology testing, including molecular diagnostic, should address common platform use in Genetic Pathology and other disciplines. The country needs a carefully coordinated approach to laboratory testing to ensure the most cost-effective, sustainable and meaningful Genetic Pathology service.



09

**POINT OF CARE  
TESTING (POCT)**

## **9. POINT OF CARE TESTING (POCT)**

- 9.1 POCT services shall be implemented in line with the current National Point of Care Testing Policy and Guidelines.
- 9.2 POCT services shall be coordinated by the POCT Committee at all levels and implemented in consultation with the pathologist or the science officer (in the absence of a resident pathologist).
- 9.3 The POCT Committee shall ensure fast, safe, effective management and use of POCT devices that fit for the intended purpose.



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10

**SATELLITE  
LABORATORY**

## 10. SATELLITE LABORATORY

The hospital shall have a central pathology laboratory to optimise resources. If a satellite laboratory is required, it shall be under the purview of the head of pathology department and hospital director.

- 10.1 Pathology services shall provide technical advice and consultation.
- 10.2 Pathology services also encompass training and research.
- 10.3 All laboratories shall be equipped with Laboratory Information System.
- 10.4 There shall be standardisation of test names, test codes and test methods (where possible).

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11

# **FACILITIES & EQUIPMENT**

## 11. FACILITIES & EQUIPMENT

### 11.1 Facilities

- 11.1.1 Laboratories in MOH Hospitals shall have adequate and conducive functional areas inclusive of storage space.
- 11.1.2 The laboratory shall have adequate space and environment suitable for the task to be undertaken.
- 11.1.3 Laboratory and office facilities include lighting, ventilation, communication system, electrical source, water, waste disposal and air condition.
- 11.1.4 Storage facilities are essentials to ensure the integrity of sample materials, documents, equipment, reagent, records and results.
- 11.1.5 Staff facilities such as washroom, on-call room, prayer room, pantry, locker and the changing room shall be made available.
- 11.1.6 Safety facilities and devices including eyewash station and emergency shower shall be made available.

### 11.2 Equipment

#### 11.2.1 General

- 11.2.1.1 The laboratory shall be equipped with the minimum standard list of equipment based on the level of hospital and workload (Appendix 9).
- 11.2.1.2 All critical equipment shall have a backup unit or at least a contingency plan in the event of a breakdown.

#### 11.2.2 Procurement

- 11.2.2.1 Procurement of equipment utilizing reagent is preferably made through the purchase of reagent with equipment placement.
  - 11.2.2.2 All proposed procurements shall be submitted to the Head of Pathology Services and/or State Director of Health.
  - 11.2.2.3 All equipment procured shall meet the specifications for the standard methodology used.
  - 11.2.2.4 The list of equipment procured is to be maintained by *Jawatankuasa Peralatan Perkhidmatan Patologi Kebangsaan*.
  - 11.2.2.5 Referral shall be made to the state pathologist or head of discipline for any equipment donated for its suitability, usage and location. Acceptance of the donation must follow the current MOH Treasury circular.
- 11.2.3 The performance and verification of its suitability for use shall be determined as part of the commissioning process before it can be used for service.
  - 11.2.4 Proper testing and commissioning of all newly acquired equipment must be conducted in the presence of the end-user, supplier, representative from concession company and related hospital support service personnel, after which the equipment



must be entered into the hospital asset list.

11.2.5 Procurement of equipment and reagents must adhere to *Akta Tatacara Kewangan 1957, Arahan Perbendaharaan (Pindaan 2008)* and *1 Pekeliling Perbendaharaan (1PP)*.

### 11.3 Maintenance

11.3.1 All equipment shall have planned preventive maintenance and shall be following the manufacturer's recommendation.

11.3.2 Certain identified equipment shall be maintained and repaired by qualified personnel.

### 11.4 Training

The vendor shall provide adequate training to ensure the competency of the laboratory staff before the equipment is used.

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12

**LABORATORY  
INFORMATION  
MANAGEMENT AND  
COMMUNICATION  
SYSTEM**

## 12. LABORATORY INFORMATION MANAGEMENT AND COMMUNICATION SYSTEM

### 12.1 General

The laboratory information includes the management of data and information contained in computer and non-computerized systems.

### 12.2 Laboratory Information System (LIS)

All hospital laboratories shall have a Laboratory Information System (LIS) suitable for the scope of their service. The strategic goal is to ensure seamless sharing of complete, up to date, accurate, and protected laboratory data among service providers i.e. national electronic laboratory record. Pathology services should be consulted for any planning and implementation of new LIS.

12.2.1 LIS should be able to interface with other LIS and information system in MOH.

12.2.2 The LIS may be extended to the user locations where viewing or printing of the reports can be done with appropriate security procedure.

12.2.3 The system shall have a provision for efficient data backup with minimum downtime.

12.2.4 The laboratory shall have a contingency plan in the event of downtime. The data integrity shall be verified upon recovery of downtime.

12.2.5 The system shall provide data mining capability as required by laboratory operation.

12.2.6 The relevant LIS and procedure documentation shall be reviewed regularly as required by respective hospital.

12.2.7 There shall be a provision for upgrading the LIS when available.

12.2.8 Data collection, processing, recording, reporting, storage and retrieval shall comply with MS ISO 15189:2014.

12.2.9 Adequate training shall be made available to staff to handle the LIS.

### 12.3 Data security

12.3.1 The LIS programme shall be adequately protected from unauthorized access and safeguarded against tampering or loss.

12.3.2 The HOD shall define the authorized users and their level of access to the LIS programme or its data.

12.3.3 Appropriate security measures shall comply with the relevant data security act. (Malaysian Communications and Multimedia Commission Act 1998 and User Access Control Policy and Guidelines, Dec 2011).



13

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**TRANSPORTATION**

### **13. TRANSPORTATION**

- 13.1 Transportation of clinical samples shall be the responsibility of the pathology service. It shall meet the requirement of MS ISO 15189 and Standard Operating Procedure for Transport of Biological Specimens in Malaysia 1st Edition 2012.
- 13.2 The scope of services shall encompass sample handling after collection, sample packaging, transportation, and laboratory report delivery within MOH facilities and external laboratories.
- 13.3 The choice of transportation mode depends on sample type to ensure biological safety and sample integrity.
- 13.4 The pathology services shall take an active role in training personnel involved in sample collection, packaging, and transportation.



14

**QUALITY  
ASSURANCE AND  
LABORATORY  
ACCREDITATION**

## 14. QUALITY ASSURANCE AND LABORATORY ACCREDITATION

### 14.1 Quality Assurance

- 14.1.1 MOH hospital laboratories shall participate in performance monitoring programmes conducted or coordinated at the national, ministry or state level, which are applicable without exception, such as the Laboratory National Indicator Approach (NIA), Key Performance Indicators and Patient's Safety Goals. The laboratories shall also monitor the indicator achievements and take appropriate corrective actions for shortfalls encountered.
- 14.1.2 The state pathologists shall provide direction and leadership to enhance and strengthen quality assurance activities.
- 14.1.3 The state pathologists shall initiate and implement quality improvement activities for the state.
- 14.1.4 The state pathologists shall ensure participation, monitor performance and coordinate the compilation and submission of quality improvement reports for all laboratories under their supervision.
- 14.1.5 All MOH hospital laboratories shall promote, participate and implement quality improvement activities.

### 14.2 Accreditation

- 14.2.1 All MOH hospital laboratories are to be accredited to the MS ISO15189.
- 14.2.2 All accredited laboratories shall maintain the MS ISO 15189 accreditation status.
- 14.2.3 The state pathologists shall provide leadership, guidance, training and resources to all the hospitals within their state to achieve and maintain the MS ISO 15189 accreditation.
- 14.2.4 All MOH hospital laboratories shall seek MS ISO 15189 accreditation for all tests done in-house unless there is a valid reason for an exception.
- 14.2.5 All MOH hospital laboratories shall continually improve the quality and strengthen the pathology service provided to meet the current demands of patient care and patient safety.
- 14.2.6 Pathologists within a state shall provide supervisory and advisory services to hospitals without such speciality. However, this function can be extended to hospitals in the neighbouring state if required.
- 14.2.7 State pathologists and/or heads of pathology department of supervising hospitals shall ensure
- 14.2.8 Provide professional and technical advisory services to the health clinic laboratories within the State or district under their supervision.

### 14.3 Technical evaluation of reagent kits and analysers.

- 14.3.1 Pathology service in MOH hospitals shall evaluate reagent kits, analysers and POCT

test kits.

- 14.3.2 Technical evaluations can be performed within the purview of the Jawatankuasa Evaluasi Teknikal Perkhidmatan Patologi KKM scope of activity, independently or in collaboration with other institutions/organisations.
  - 14.3.3 All technical evaluations carried out shall be included in the evaluation registry.
  - 14.3.4 All technical evaluations performed shall have detailed, and summary performance reports.
- 14.4 Provision of External Quality Assurance (EQA) programme
- 14.4.1 Currently offered EQA programme shall be maintained and enhanced.
  - 14.4.2 New EQA programme shall be developed according to service needs and capability.
  - 14.4.3 EQA programme provided shall be accredited to MS ISO 17043.
  - 14.4.4 Separate operational budget shall be made available to provide the currently offered and newly developed EQA programme.



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15

**BUDGET  
AND FUND  
MANAGEMENT**

## 15. BUDGET AND FUND MANAGEMENT

- 15.1 Head of Pathology Services, state pathologists and heads of pathology department are responsible for planning and managing allocation of the operational budget at different levels of service.
- 15.2 Budget planning shall include but not be limited to the reagent, consumables, equipment, training, EQA programme subscription, accreditation fees and outsourcing.
- 15.3 Proposal of a new clinical program that requires laboratory support shall include an allocation for pathology service.
- 15.4 All new pathology services to be introduced shall align with clinical speciality requirements and are subject to the detailed proposal, including budget approval.
- 15.5 Extension or expansion of pathology service shall be based on workload and clinical speciality needs.
- 15.6 Sufficient budget allocation, human resources and equipment need to be provided when any pathology services are being taken over from another government centre/institute.
- 15.7 Pooled procurement of reagent or equipment should be implemented where possible.
- 15.8 To achieve the most cost-effective, sustainable and meaningful pathology service, reorganisation and optimisation of resources shall be implemented.

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16

**SAFETY**

## 16. SAFETY

- 16.1 Laboratory Safety Manual shall be made available in all laboratories, and its content shall comply with relevant statutory acts and regulations as follow:
- i. Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations 2000 (USECHH Regulations).
  - ii. Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations).
  - iii. Guidelines on Chemical Management in Healthcare Facilities Ministry of Health 2010.
  - iv. Policies and procedures on infection, prevention and control (3rd Edition. Ministry of Health)
- 16.2 All personnel shall be given adequate training in laboratory safety.
- 16.3 The laboratory shall have a disaster preparedness plan.
- 16.4 The laboratory shall be equipped with an appropriate fire-fighting system.
- 16.5 Measures shall be taken to comply with safety and quality standards as required by MS ISO 15189.

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17

**RESEARCH AND  
DEVELOPMENT**

## **17. RESEARCH AND DEVELOPMENT**

- 17.1 There shall be active participation and support for research and development geared towards service needs and growth.
- 17.2 All research shall comply with relevant legislation, regulations, codes, and guidelines applicable from time to time.
- 17.3 All research conducted in MOH laboratories shall be formally registered to the Institute for Clinical Research and must comply with NIH Guidelines for Conducting Research in Ministry of Health Institutions and Facilities.
- 17.4 Priority in research or project should include studies to improve service delivery and patient safety.
- 17.5 An efficient networking system shall be established between the MOH, universities and private laboratories to ensure equity of intellectual property and accessibility of specialised and sub-specialised Pathology services throughout the country.



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# **APPENDIX**

## APPENDIX 1: LIST OF MOH HOSPITAL BY TYPES

STATE / WILAYAH PERSEKUTUAN	SPECIALIST HOSPITALS & INSTITUTIONS				NON-SPECIALIST HOSPITALS
	STATE HOSPITAL	MAJOR SPECIALIST HOSPITAL	MINOR SPECIALIST HOSPITAL	SPECIAL HOSPITALS / INSTITUTIONS	
<b>TOTAL</b>	14 Target : 49 resident specialties	27 Target: 20 resident specialties	18 Target: 10 resident specialties	11 Specific resident specialties	76
<b>WILAYAH PERSEKUTUAN</b>	Hospital Kuala Lumpur	Hospital Putrajaya	Hospital Labuan	Institut Perubatan Respiratori	
				Hospital Rehabilitasi, Cheras	
				Institut Kanser Negara	
				Hospital Tunku Azizah, Kuala Lumpur	
<b>PERLIS</b>	Hospital Tuanku Fauziah				
<b>KEDAH</b>	Hospital Sultanah Bahiyah, Alor Setar	Hospital Abdul Halim, Sg Petani	Hospital Sultanah Mailha, Langkawi		Hospital Baling
		Hospital Kulim			Hospital Sik
<b>PULAU PINANG</b>	Hospital Pulau Pinang	Hospital Seberang Jaya	Hospital Bukit Mertajam Hospital Kepala Batas		Hospital Yan
					Hospital Sungai Bakap
					Hospital Baik Pulau



STATE / WILAYAH PERSEKUTUAN	SPECIALIST HOSPITALS & INSTITUTIONS				NON-SPECIALIST HOSPITALS	
	STATE HOSPITAL	MAJOR SPECIALIST HOSPITAL	MINOR SPECIALIST HOSPITAL	SPECIAL HOSPITALS / INSTITUTIONS		
	Target : 49 resident specialties	Target : 20 resident specialties	Target : 10 resident specialties	Specific resident specialties		
PERAK	Hospital Raja Permaisuri Bainun, Ipoh	Hospital Taiping	Hospital Slim River	Hospital Bahagia, Hulu Kinta	Hospital Parit Buntar	Hospital Gerik
		Hospital Teluk Intan	Hospital Seri Manjung		Hospital Kuala Kangsar	Hospital Selama
SELANGOR	Hospital Tengku Ampuan Rahimah Klang	Hospital Selayang	Hospital Banting	*Pusat Kawalan Kuasa Negara (PKKN)	Hospital Kuala Kubu Baru	Hospital Tanjung Karang
		Hospital Serdang				
		Hospital Ampang				
		Hospital Sungai Buloh				
		Hospital Kajang				
		Hospital Shah Alam				
NEGERI SEMBILAN	Hospital Tuanku Ja'afar, Seremban	Hospital Tuanku Ampuan Najihah, Kuala Pilah	Hospital Port Dickson		Hospital Tampin	Hospital Jempol
		Hospital Melaka			Hospital Jelebu	Hospital Rembau
MELAKA	Hospital Melaka	Hospital Sultan Ismail			Hospital Alor Gajah	Hospital Jasin
		Hospital Pakar Sultanah Fatimah, Muar	Hospital Enche/ Besar Hajah Kalsom, Kluang		Hospital Kota Tinggi	Hospital Mersing
		Hospital Sultanah Nora Ismail, Batu Pahat		Hospital Pontian	Hospital Tangkak	
		Hospital Segamat		Hospital Temenggung Seri Maharaja Tun Ibrahim, Kulai		
JOHOR	Hospital Sultanah Aminah, Johor Bharu					

STATE / WILAYAH PERSEKUTUAN	SPECIALIST HOSPITALS & INSTITUTIONS				NON-SPECIALIST HOSPITALS		
	STATE HOSPITAL	MAJOR SPECIALIST HOSPITAL	MINOR SPECIALIST HOSPITAL	SPECIAL HOSPITALS / INSTITUTIONS			
	Target : 49 resident specialties	Target : 20 resident specialties	Target : 10 resident specialties	Specific resident specialties			
PAHANG	Hospital Tengku Ampuan Afzan, Kuantan	Hospital Sultan Haji Ahmad Shah, Temerloh	Hospital Pekan			Hospital Muadzam Shah	
			Hospital Bentong			Hospital Rompin	
			Hospital Kuala Lipis			Hospital Sultanah Kalsom, Cameron Highland	
TERENGGANU	Hospital Sultanah Nurzahirah, Kuala Terengganu	Hospital Kemaman				Hospital Besut Hospital Hulu Terengganu	
KELANTAN	Hospital Raja Perempuan Zainab II, Kota Bharu	Hospital Sultan Ismail Petra, Kuala Krai				Hospital Machang	
			Hospital Tanah Merah			Hospital Pasir Mas	
			Hospital Queen Elizabeth II, Kota Kinabalu			Hospital Tengku Anis, Pasir Puteh	
SABAH	Hospital Queen Elizabeth, Kota Kinabalu	Hospital Queen Elizabeth II, Kota Kinabalu	Hospital Lahad Datu	Hospital Mesra Bukit Padang		Hospital Beaufort	
			Hospital Duchess of Kent, Sandakan			Hospital Beluran	Hospital Papar
		Hospital Tawau					Hospital Kota Belud
				Hospital Keningau			Hospital Semporna
					Hospital Tambunan		
					Hospital Tenom		
					Hospital Sipitang		
					Hospital Kota Marudu		
						Hospital Kuala Penyu	
						Hospital Pitas	
						Hospital Tuaran	

STATE / WILAYAH PERSEKUTUAN	SPECIALIST HOSPITALS & INSTITUTIONS				NON-SPECIALIST HOSPITALS	
	STATE HOSPITAL	MAJOR SPECIALIST HOSPITAL	MINOR SPECIALIST HOSPITAL	SPECIAL HOSPITALS / INSTITUTIONS		
	Target : 49 resident specialties	Target : 20 resident specialties	Target : 10 resident specialties	Specific resident specialties		
SARAWAK	Hospital Umum Sarawak, Kuching	Hospital Bintulu	Hospital Limbang	Hospital Sentosa	Hospital Serian	
		Hospital Sibul	Hospital Sarikei			Pusat Jantung Sarawak
			Hospital Miri	Hospital Kapit	Hospital Betong	
		Hospital Daro		Hospital Daro	Hospital Rajah Charles Brooke Memorial	
				Hospital Simunjan	Hospital Lawas	
						Hospital Saratok
						Hospital Mukah
						Hospital Kanowit
						Hospital Marudi
						Hospital Dalat
				Hospital Daro		
				Hospital Simunjan		

\*\* PKKN, although not yet officially de-gezzetted as a leprosariorium, is part of Hospital Sungai Buloh for Administrative matters  
Target for resident specialties are based on specialist/subspecialty framework

**APPENDIX 2: LIST OF TESTS ACCORDING TO HEALTHCARE LEVEL****ANATOMIC PATHOLOGY**

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
	<b>A. HISTOPATHOLOGY</b>						
	Routine HPE (surgical pathology)				√	√	√
	Frozen section				√	√	√
	Clinical autopsy				√	√	√
	Ancillary tests						
	Histochemistry method				√	√	√
	Immunohistochemistry method				√	√	√
	Immunofluorescence method				√	√	√
	Enzyme histochemistry method					√	√
	Molecular diagnostic tests						√
	FISH method						√
	PCR method						√
	<b>B. CYTOLOGY</b>						
	<b>GYNAECOLOGICAL</b>						
	PAP smear conventional				√	√	√
	PAP smear liquid based				√	√	√
	<b>NON-GYNAECOLOGICAL</b>						
	Body fluid cytology (include CSF, Pericardial fluid, pleural fluid, peritoneal fluid, synovial fluid etc)				√	√	√
	Brushing cytology (include Bronchial brushing, CBD brushing etc)				√	√	√
	Cyst fluid				√	√	√
	Imprint cytology				√	√	√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
	<b>FINE NEEDLE ASPIRATION</b>						
	Fine needle aspiration cytology				√	√	√
	Radiological guided cytology				√	√	√
	Endoscopic guided cytology				√	√	√

Note:

1. Ancillary tests available in AP centres are according to the need of the centres
2. Some specific tests are only available in referral AP centre

**CHEMICAL PATHOLOGY**

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
	<b>ROUTINE CHEMISTRY</b>						
1	Alanine transaminase	√	√	√	√	√	√
2	Albumin	√	√	√	√	√	√
3	Alkaline phosphatase	√	√	√	√	√	√
4	Ammonia			√	√	√	√
5	Amylase		√	√	√	√	√
6	Aspartate Transaminase	√	√	√	√	√	√
7	Bilirubin Total	√	√	√	√	√	√
8	Bilirubin Direct	√	√	√	√	√	√
9	Blood gases		√	√	√	√	√
10	Calcium		√	√	√	√	√
11	Chloride	√	√	√	√	√	√
12	Cholesterol	√	√	√	√	√	√
13	Creatinine	√	√	√	√	√	√
14	Creatinine Kinase		√	√	√	√	√
15	Creatinine Kinase Isoenzyme (CK-MB)				√	√	√
16	<b>Creatinine clearance</b>		√	√	√	√	√
17	C-Reactive Protein				√	√	√
18	CSF Biochemistry			√	√	√	√
19	Gamma Glutamine Transaminase			√	√	√	√
20	Glucose	√	√	√	√	√	√
21	Glucose Tolerance test	√	√	√	√	√	√
22	High Density Lipoprotein	√	√		√	√	√
23	Lactate			√	√	√	√
24	Lactate Dehydrogenase		√	√	√	√	√
25	Magnesium		√	√	√	√	√
26	Microalbumin (urine) (qualitative)/ quantitative	√ (qualitative)	√ (qualitative)	√ (qualitative)	√ (qualitative)	√ (qualitative)	√ (qualitative)
27	Osmolality					√	√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
28	pH, body fluid				√	√	√
29	Phosphate, Inorganic		√	√	√	√	√
30	Potassium	√	√	√	√	√	√
31	Protein, total	√	√	√	√	√	√
32	Reducing sugar (urine/ stool)					√	√
33	Stool Occult Blood		√	√	√	√	√
34	Sodium	√	√	√	√	√	√
35	Triglyceride	√	√	√	√	√	√
36	Troponin I / Troponin T				√	√	√
37	Urea	√	√	√	√	√	√
38	Uric Acid	√	√	√	√	√	√
39	Urine Biochemistry	√	√	√	√	√	√
40	Urine Microscopy				√	√	√
41	Urine Pregnancy Test (Qualitative)	√	√	√	√	√	√
42	Urine Hemoglobin					√	√
	<b>ENDOCRINE</b>						
43	17-Hydroxy Progesterone (17-OHP)					√	√
44	ACTH					√	√
45	Aldosterone					√	√
46	Anti- Thyroglobulin Antibody					√	√
47	Anti-Thyroid Receptor Antibodies					√	√
48	Anti-Mullerian Hormone					√	√
49	Thyroid Microsomal Antibody/ Thyroid Peroxidase antibody					√	√
50	Catecholamine					√	√
51	Calcitonin					√	√
52	Cortisol (blood)				√	√	√
53	Cortisol (urine)					√	√
54	Cortisol (salivary)					√	√
55	C – Peptide					√	√
56	DHEA – S					√	√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
57	Estradiol				√	√	√
58	Follicular Stimulating Hormone (FSH)				√	√	√
59	Functional Endocrine Tests				√	√	√
60	Growth Hormone					√	√
61	Insulin					√	√
62	Insulin Like Growth Factor 1 (IGF1)					√	√
63	Intact Parathyroid Hormone (PTH)					√	√
64	Luteinising Hormone				√	√	√
65	Macroprolactin					√	√
66	Metanephrine					√	√
67	Progesterone				√	√	√
68	Procalcitonin					√	√
69	Prolactin				√	√	√
70	Renin					√	√
71	SHBP					√	√
72	Testosterone					√	√
73	Thyroglobulin					√	√
74	Thyroxine Free (FT 4)				√	√	√
75	Thyroid Stimulating Hormone				√	√	√
	<b>METABOLIC</b>						
76	Anti-Glutamic acid decarboxylase (GAD)					√	√
77	Anti-islet cells (ICA)					√	√
78	Anti-Insulinoma-Associated Antigen 2 (IA2) /ICA512					√	√
79	Vitamin B 12				√	√	√
80	25-OH-Vit D					√	√
81	Ferritin				√	√	√
82	Folate				√	√	√
83	Fructosamine					√	√
84	HbA1c	√		√	√	√	√



	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
85	Iron			√	√	√	√
86	Iron Binding Capacity, Total (TIBC)			√	√	√	√
87	Transferrin					√	√
	<b>TUMOR MARKERS</b>						
88	Alpha – fetoprotein				√	√	√
89	Beta – HCG				√	√	√
90	CA 125				√	√	√
91	CA 15.3					√	√
92	CA 19.9					√	√
93	Carcinoembryonic Antigen				√	√	√
94	Prostate Specific Antigen (PSA), Total				√	√	√
95	Prostate Specific Antigen (PSA), Free					√	√
	<b>PROTEIN AND PROTEOMICS</b>						
96	Alpha-1 Antitrypsin					√	√
97	Alpha-1 Glycoprotein (Orosomuroids)					√	√
98	Alpha-2 Macroglobulin					√	√
99	Beta-2 Microglobulin					√	√
100	Complement 3 (C3)				√	√	√
101	Complement 4 (C4)				√	√	√
102	Caeruloplasmin					√	√
103	Cryoglobulin (Screening)					√	√
104	Cryoglobulin (Confirmation)						√
105	Free Kappa Light Chain					√	√
106	Free Lambda Light Chain					√	√
108	Haptoglobin					√	√
109	Immunoglobulin A (Ig A)					√	√
110	Immunoglobulin G (Ig G)					√	√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
111	Immunoglobulin M (IgM)					√	√
112	Immunoglobulin E (IgE)					√	√
113	Myoglobin					√	√
114	Protein Electrophoresis					√	√
115	CSF Oligoclonal					√	√
116	Interleukin-6						√
	<b>THERAPEUTIC DRUG MONITORING</b>						
117	Amikacin				√	√	√
118	Carbamezepine				√	√	√
119	Cyclosporine					√	√
120	Digoxin				√	√	√
121	Everolimus					√	√
122	Gentamycin				√	√	√
123	Lithium					√	√
124	Methotrexate					√	√
125	Mycophenolic Acid (MPA)					√	√
126	Phenobarbital				√	√	√
127	Phenytoin				√	√	√
128	Sirolimus					√	
129	Tacrolimus					√	√
130	Theophylline				√	√	√
131	Valporoic Acid				√	√	√
132	Vancomycin				√	√	√
	<b>CLINICAL TOXICOLOGY</b>						√
133	Acetaminophen				√	√	√
134	Alcohol (Ethanol)					√	√
135	Benzodiazepine					√	√
136	Carboxyhemoglobin					√	
137	Cholinesterase				√	√	√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
138	Methanol					√	√
139	Methemoglobin					√	√
140	Paraquat,Urine			√	√	√	√
141	Salicylate				√	√	√
	<b>DRUG OF ABUSE</b>						√
142	Amphetamine				√	√	√
143	Cannabinoids				√	√	√
144	Codeine					√	√
145	Dextromethorphan					√	√
146	Ephedrine					√	√
147	Ketamine					√	√
148	Methadone					√	√
149	Methamphetamine				√	√	√
150	Methylenedioxyethylamphetamine (MDEA)					√	√
151	Methylenedioxymethamphetamine (MDMA)					√	√
152	Monoacetylmorphine					√	√
153	Nimetazepam					√	√
154	Nitrazepam					√	√
155	Norephedrine					√	√
156	Norketamine					√	√
157	Opiate (screening)		√	√	√	√	√
158	Morphine (Confirmatory)				√	√	√
159	Phentermine					√	√
	<b>TRACE ELEMENTS</b>						
160	Cadmium					√	√
161	Chromium					√	√
162	Copper					√	√
163	Iodine					√	√
164.	Lead					√	√
165	Mercury					√	√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
	<b>INBORN ERROR OF METABOLISM</b>						
166	Screening for Inborn Error of				√	√	
167	Screening Serum Amino Acid					√	√
168	Quantitative Serum Amino acid					√	√
169	Quantitative Organic Acid					√	√
170	Carnitine					√	√
171	Orotic acid					√	√
172	Homocysteine					√	√

**HAEMATOLOGY**

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
	<b>GENERAL HAEMATOLOGY</b>						
1	Full Blood Count	√	√	√	√	√	√
2	Reticulocyte Count		√	√	√	√	√
3	ESR	√	√	√	√	√	√
4	Full Blood Picture		√	√	√	√	√
5	PT/INR*	√	√	√	√	√	√
6	APTT*		√	√	√	√	√
7	Fibrinogen *			√	√	√	√
8	D-Dimer*			√	√	√	√
9	Mixing Test **			√	√	√	√
	<b>BONE MARROW ASPIRATE / TREPINE</b>						
10	BMA smear		√	√	√	√	√
11	Routine stains (MGG & Perls')			√	√	√	√
12	Special stains			√	√	√	√
	<b>HAEMOLYTIC ANAEMIA, RED CELLS AND HAEMOGLOBIN DISORDERS</b>						
14	H inclusion test***				√	√	√
15	Sickling test***				√	√	√
16	Kleihauer test				√	√	√
17	Osmotic fragility tests					√	√
18	Molecular diagnosis of Thalassaemia/ Hemoglobinopathy						√
19	G6PD screening		√	√	√	√	√
20	G6PD assay						√
21	Pyruvate kinase assay						OS
22	Other red cell enzyme assays						OS
23	Osmotic fragility test					√	√
	<b>HEMOSTASIS / THROMBOSIS</b>						

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
24	Factor VIII & IX assays					√	√
25	Factors Inhibitor assay					√	√
26	Other Coagulation Factor assays						√
27	Reptilase Time						√
28	Antiphospholipid test: LA assay					√	√
29	Antiphospholipid test: ACL & β2GP1 Antibodies						√
30	VWF Profile						√
31	Platelet aggregation test						√
32	APC Resistance						√
33	Anti-thrombin III antigen / activity						√
34	Protein C antigen / activity						√
35	Protein S antigen / activity						√
36	Molecular diagnosis of bleeding and thrombotic disorder						√
	<b>IMMUNOPHENOTYPING</b>						
37	Immunophenotyping (IPT) for leukaemia/ lymphoma					√	√
38	T-lymphocytes subset enumeration (CD4/ CD8)					√	√
39	CD20 quantitation						√
40	Double Negative T Cell						√
41	PNH Immunophenotyping						√
42	Platelets Glycoproteins Immunophenotyping						√
43	Lymphocyte subsets analysis for immune disorders (CD3/CD4/ CD8/ CD19/NK)						√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
	<b>MOLECULAR HEMATOLOGY NON- MALIGNANT</b>						
44	G6PD						OS
45	Haemophilia						√
46	Thrombophilia						√
	<b>MOLECULAR HEMATOLOGY NON- MALIGNANT</b>						
47	Thalassaemia/ Haemoglobinopathy $\alpha$ globin gene						√
48	Thalassaemia/ Haemoglobinopathy $\beta$ globin gene						√
	<b>MOLECULAR HAEMATO-ONCOLOGY</b>						
49	Mutation/translocation detection in leukaemia						√
50	BCR-ABL1 Qualitative						√
51	Molecular quantitative BCR-ABL1 P190						√
52	Molecular quantitative BCR-ABL1 P210					√	√
53	Molecular quantitative PML-RARA						√
54	<b>AML Mutation Study</b>						√
55	Myeloproliferative neoplasm mutation study						√
56	Chronic myeloid leukaemia mutation study (T3151 gene)						√
57	Minimal residual disease (MRD) for acute leukaemia						√
58	BCR-ABL1 Kinase Domain Mutation Analysis						√
59	Chimerism						√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
60	Molecular tests for lymphomas						Offered in Molecular Histopathology
	<b>HAEMOPOIETIC STEM CELL TRANSPLANTATION</b>						
61	Stem cell processing & manipulation						√
62	Cryopreservation (HSC and T cells)						√
63.	CD34 enumeration						√
64	Buffy coat enrichment						√
65	RBC depletion						√
66	Plasma depletion						√
67	TCRαβ/B cell depletion						√
68	CD34 Selection						√

**Notes:**

1. OS-outsourcing
2. Basic coagulation tests (PT/INR and APTT) are available in all hospitals. Extended basic coagulation tests (DIVC screening) are offered in specialist hospitals \*
3. Interpretative test requiring clinical correlation must be reported by resident Pathologist or competent medical officers or referred to Haematologist at nearest specialist or cluster hospital (e.g.mixing test) \*\*
4. Hb Analysis is offered at State hospitals and selected Major specialist hospitals depending on workload. Supplementary tests e.g. H-Inclusion and Sickling tests are recommended to be made available in the laboratory\*\*\*



**MICROBIOLOGY**

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
<b>A</b>	<b>BACTERIOLOGY</b>						
1	Air sampling culture				√	√	
2	Biological indicator-Attest/ Spordi			√	√	√	
3	Cell count – body fluid, CSF			√	√	√	
4	Culture & Sensitivity			√*	√	√	
5	Gram stain	√	√	√	√	√	
6	Isolate for identification & sensitivity confirmation					√	√
	<b>Mycobacteriology</b>						
7	AFB direct smear	√	√	√	√	√	
8	MTB Culture					√*	√
9	MTB Sensitivity						√
10	MTB identification						√
11	Interferon gamma release assay						√
12	MTB PCR						√
13	PCR Multiplex for TB resistant gene						√
14	MTB rapid PCR for resistant gene					√	
15	MDR TB Line Probe Assays						√
16	M. leprae microscopic examination of Slit Skin Smear	√	√	√	√	√	
17	M. leprae Culture & Sensitivity						√
18	M. leprae PCR						√
19	<b>Molecular detection of multidrug resistance organisms</b>						√
20	<b>Serotyping for surveillance</b>						√
	<b>Bacteriology - Antigen detection/ Serology</b>						
21	Anti-Streptolysin O titre (ASOT)			√	√	√	

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
22	Bartonella antibody (Cat Scratch Disease)						√
23	Borrelia Antibody						√
24	Brucella Antibody						√
25	Chlamydia antigen detection					√	
26	<i>Clostridium difficile</i> toxin assay				√	√	
27	Coxiella Antibody						√
28	CSF VDRL						√
29	<i>Legionella pneumophila</i> Antigen				√	√	
30	Leptospira Antibody		√	√	√	√	√
31	Leptospira Antibody - MAT						√
32	<i>Melioidosis</i> Antibody						√
33	<i>Mycoplasma pneumoniae</i> Antibody				√	√	
34	Treponema pallidum Particle Agglutination (TPPA)				√	√	
35	Rapid Plasma Reagin (RPR)	√	√	√	√	√	
36	Rickettsia Indirect Immunoperoxidase (IIP)						√
	<b>Bacteriology - Molecular</b>						
37	Bacterial meningitis panel PCR						√
38	<i>Bordetella pertussis</i> PCR						√
39	Brucella PCR						√
41	<i>C. diphtheria</i> toxin PCR						√
42	Leptospira PCR						√
43	Multilocus sequence typing (MLST)						√
44	Pulse field gel electrophoresis (PFGE)						√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
45	Respiratory infection panel PCR						√
46	<i>Salmonella typhi</i> PCR						√
47	Sexually transmitted infection panel PCR						√
48	16s RNA sequencing						
<b>B</b>	<b>MYCOLOGY</b>						
49	Direct microscopy (KOH)			√	√	√	
50	Indian ink			√	√	√	
51	Cryptococcal Ag (CSF)				√	√	√
52	Cryptococcal Ag (Serum)				√	√	√
53	Aspergillus Galactomannan Ag						√
54	Fungal PCR						√
55	Pneumocystis jirovecii PCR/IF						√
<b>C</b>	<b>PARASITOLOGY</b>						
56	Blood film for filarial parasites	√	√	√	√	√	
57	Blood film for malaria parasites (BFMP)	√	√	√	√	√	
58	Macroscopic examination for helminth				√	√	
59	Microscopic examination for Acanthamoeba/ Naegleria				√	√	
60	Microscopic examination for Leishmaniasis						√
61	Microscopic examination for Trypanosomiasis						√
62	Stool microscopic examination for <i>Cryptosporidium</i> spp, <i>Isospora belli</i> , <i>Coccidia</i> , <i>Microsporidium</i> spp						√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
63	Stool microscopic examination for Ova & Cyst	√	√	√	√	√	
64	Helminth culture						√
65	Amoebiasis Antibody						√
66	<i>Echinococcus</i> / Hydatid disease Antibody						√
67	Filariasis Antibody						√
68	Leishmaniasis Antibody						√
69	Malaria Antibody						√
70	Schistosomiasis Antibody						√
71	Taeniasis/ Cysticercosis Antibody						√
72	Toxocariasis Antibody						√
73	Toxoplasma Antibody					√	√
74	Trichinellosis Antibody						√
75	<i>Acanthamoeba</i> / Naegleria PCR						√
76	Amoebiasis PCR						√
77	Filariasis PCR						√
78	Leishmaniasis PCR						√
79	Malaria PCR						√
80	Trypanosomiasis PCR						√
<b>D</b>	<b>IMMUNOLOGY</b>						
	<b>Autoimmunity</b>						
81	Acetylcholine - receptor Antibody						√
82	ANA					√*	
83	cANCA - pANCA						√
84	Anti - Aquaporin 4 (Anti-Aq4)						√
85	Anti - Beta 2 glycoprotein 1 IgG/IgM						√
86	Anti - Cardiolipin IgG/IgM						√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
87	Anti - Cyclic Citrullinated Protein (CCP/ACPA)						√
88	Anti - Deamidated-Gliadin Antibody IgA/ IgG						√
89	Anti - dsDNA					√	
90	Anti - gastric parietal cell						√
91	Anti - Glomerular Basement Membrane (GBM)						√
92	Anti - leucine rich glioma inactivated protein 1 (Anti LCI1)						√
93	Anti - Liver-Kidney Microsome (LKM)						√
94	Anti - Mitochondrial Antibody (AMA)						√
95	Anti - N-Methyl-D-Aspartate Receptor (NMDAR)						√
96	Anti - Smooth Muscle Antibody (ASMA)						√
97	Contactin-associated protein 2 Antibody (Anti-CASPR2)						√
98	Coeliac Antibodies						√
99	Extractable Nuclear Antigen					√*	
100	Gamma-aminobutyric acid-b Receptor (GABA) Antibody						√
101	Gangliosides Antibodies						√
102	Intrinsic factor						√
103	Specific Liver autoantibodies - Anti-AMA-M2, M2-3E/BPO, Sp100, PML, gp210, LKM1, LC-1, SLA/LP, Ro-52						√
104	Phospholipase A2 Receptor (PLA2R)						√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
105	PNS Antibodies - Anti-Hu, Anti-Ri, Anti-Ma, Anti-Yo, Amphiphysin, CV2						√
106	Panel reactive Antibody (PRA)						√
107	Rheumatoid factor						√
108	Skin Antibodies - Anti BP 180, Anti BP 230						√
109	Skin Antibodies - Anti - desmoglein 1, Anti - desmoglein 3						√
	<b>Allergy</b>						
110	Eosinophilic Cationic Protein						√
111	IgE specific allergen (RAST)						√
112	IgE total, serum						√
113	IgE, drug						√
114	Tryptase						√
	<b>Primary and Secondary Immunodeficiency</b>						
115	Dihydrorhodamine assay (DHR)						√
116	Leukocytes Adhesion Deficiency Type 1						√
117	Lymphocytes Proliferation test						√
118	Phagocytic function test						√
119	T & B Lymphocyte Subset Enumeration Test (TBNK)						√
120	Bruton's tyrosine kinase (BTK)						√
	<b>Transplantation Immunology</b>						
121	HLA Antibody Test Panel Reactive Antibody (PRA)/Donor Specific Antibody (DSA)						√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
122	Human Leukocyte Antigens (HLA) Crossmatch (Complement Dependent Cytotoxicity)						√
123	Human Leukocyte Antigens (HLA) Crossmatch (Flow Cytometry)						√
124	Human Leukocyte Antigens (HLA) Typing Class I (Loci A, B and C) - Low/medium resolution (SSO/SSP-PCR)						√
125	Human Leukocyte Antigens (HLA) Typing Class II (Loci DR, DQ) - Low/medium resolution (SSO/SSP-PCR)						√
126	Human Leukocyte Antigens (HLA) Typing Class I and II (Loci A, B and DR) - Medium/High Resolution (SSO-PCR)						√
127	Human Leukocyte Antigens (HLA) Typing Class I and II (Loci A, B, C, DR and DQ) - high resolution (SSO-PCR) per loci						√
128	Human Leukocyte Antigens (HLA) Typing for Disease Association per loci						√
129	Human Leukocyte Antigens (HLA) Typing Class I and II (Loci A, B, C, DR and DQ) - low resolution (PCR)						√
<b>E</b>	<b>VIROLOGY</b>						
130	Electron microscopy						√
	<b>Virology - Antigen detection</b>						
131	COVID-19 Antigen	√	√	√	√	√	

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
132	Coxsackie virus Antigen						√
133	Dengue NS1 Antigen				√	√	√
134	Enteroviruses Antigen						√
135	Rabies virus Antigen			√	√	√	√
136	Respiratory virus antigen				√	√	
137	Stool for Adenovirus and Rotavirus Antigen			√	√	√	√
	<b>Virology - Serology</b>						
138	Chikungunya Antibody					√	
139	CMV Antibody					√	
140	COVID-19 Antibody					√	
141	Dengue Serology Antibody				√	√	√
142	Dengue Antibody Rapid	√	√	√	√	√	
143	EBV Antibody					√	
144	Hantavirus Antibody						√
145	HAV Antibody					√	
146	HBc Antibody - HBc IgM					√	
147	HBc Antibody - HBc Total Antibody					√	
148	HBe Antibody					√	
149	HBe Antigen					√	
150	HBsAg				√*	√	
151	HBs Ab				√*	√	
152	HCV Ab				√*	√	
153	HCV Antigen					√*	
154	HHV6 serology						√
155	HIV Ag/Ab EIA				√*	√	√
156	HIV Antibody PA				√*	√	√
157	HSV Antibody					√	√
158	HTLV Antibody						√
159	Japanese encephalitis Antibody						√
160	Measles virus Antibody						√



	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
161	Mumps virus Antibody						√
162	Nipah virus Antibody						√
163	Parvovirus B19 Antibody						√
164	Rubella virus Antibody				√	√	√
165	Varicella Zoster virus Antibody						√
	<b>Virology - Molecular</b>						
166	Adenovirus						√
167	Avian influenza Viruses (H5, H7, H9)						√
168	BK virus						√
169	Chikungunya virus						√
170	Cytomegalovirus						√
171	Coronavirus						√
172	Coxsackie virus A16, A24						√
173	Coxsackie B virus						√
174	Crimerian Congo haemorrhagic fever						√
175	Dengue virus						√
176	Dengue virus serotyping						√
177	Ebola virus						√
178	Enterovirus 71						√
179	Enterovirus multiplex						√
180	Epstein-Barr virus						√
181	Flavivirus						√
182	Filovirus						√
183	FluA/Flu B					√	
184	Hantavirus						√
185	Hepatitis B virus DNA quantitative						√
186	Hepatitis C virus RNA qualitative						√
187	Hepatitis C virus RNA quantitative						√
188	Hepatitis C virus genotyping						√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
189	HIV – Drug resistant testing						√
190	HIV Genotyping – assay sequencing						√
191	HIV RNA qualitative						√
192	HIV RNA quantitative						√
193	HIV-2 PCR						√
194	Herpes simplex virus multiplex						√
195	Human herpes virus 6 (HHV6)						√
196	Human papilloma virus						√
197	Japanese Encephalitis virus						√
198	JC Virus						√
199	Lassa Virus						√
200	Marburg virus						√
201	Measles virus						√
202	Meningitis panel						√
203	MERS Corona Virus					√	
204	Mumps virus						√
205	Nipah virus						√
206	Norovirus						√
207	PanEnterovirus						√
208	Parvovirus						√
209	Rabies virus						√
210	Respiratory viruses						√
211	Rift valley nucleic acid – Rift valley fever						√
212	Rubella virus						√
213	Sapovirus						√
214	SARS Coronavirus					√	
215	SARS-COV-2 RT-PCR					√	
216	SARS-COV-2 Rapid molecular					√	
217	St Louis Encephalitis virus						√
218	Varicella zoster Virus						√

	Test	Primary Care	Non-Specialist Hospital	Minor Specialist Hospital	Major Specialist Hospital	State Hospital	Regional /Referral Centre
219	West Nile virus						√
220	Yellow fever virus						√
221	Zika virus					√	√
222	Virology - Isolation						
223	Adenovirus						√
224	Avian influenza Viruses (H5, H7, H9)						√
225	Chikungunya						√
226	Cytomegalovirus						√
227	Coronavirus						√
228	Coxsackie virus						√
229	Dengue virus						√
230	Enteroviruses						√
231	Herpes Simplex Virus						√
232	Japanese Encephalitis						√
233	Measles						√
234	Mumps						√
235	Non-Poliavirus Virus						√
236	Paramyxovirus						√
237	Poliovirus Viral isolation						√
238	Poliovirus Environmental Surveillance						√
239	Rabies						√
240	Rubella						√
241	SARS Coronavirus						√
242	Respiratory viruses						√
243	Unknown viruses						√

**Notes:**

\*Test available in selected hospitals only.

**GENETIC PATHOLOGY**

	Test	Primary Care	Non-Specialist Hospitals	Minor Specialist Hospitals	Major Specialist Hospitals	State / Regional Centre
A.	<b>CYTOGENETICS</b>					
1.	Blood Cytogenetics					√
2.	Bone Marrow Cytogenetics					√
3.	Skin Fibroblast Cytogenetics					√
B.	<b>MOLECULAR CYTOGENETICS</b>					
4.	FISH for Microdeletion Syndromes, Ambiguous Genitalia and Complex Chromosomal Abnormalities					√
5.	FISH for Hematological Malignancies					√
6.	FISH for Lung Cancer					√
C.	<b>MOLECULAR GENETICS</b>					
7.	Congenital Anomalies					√
8.	Cancer Genetics (Inherited) - Breast - Ovarian - Colorectal					√
9.	Cancer Genetics (Somatic) - Lung - Breast - Brain - Colorectal					√
D.	<b>BIOCHEMICAL GENETICS</b>					
10.	Amino Acidopathies					√
11.	Organic Acidurias					√
11.	Purine & Pyrimidine Disorders					√
12.	Cystine & Homocystine					√
13.	IEM Screening					√

### APPENDIX 3: LIST OF URGENT TESTS ACCORDING TO HEALTHCARE LEVEL

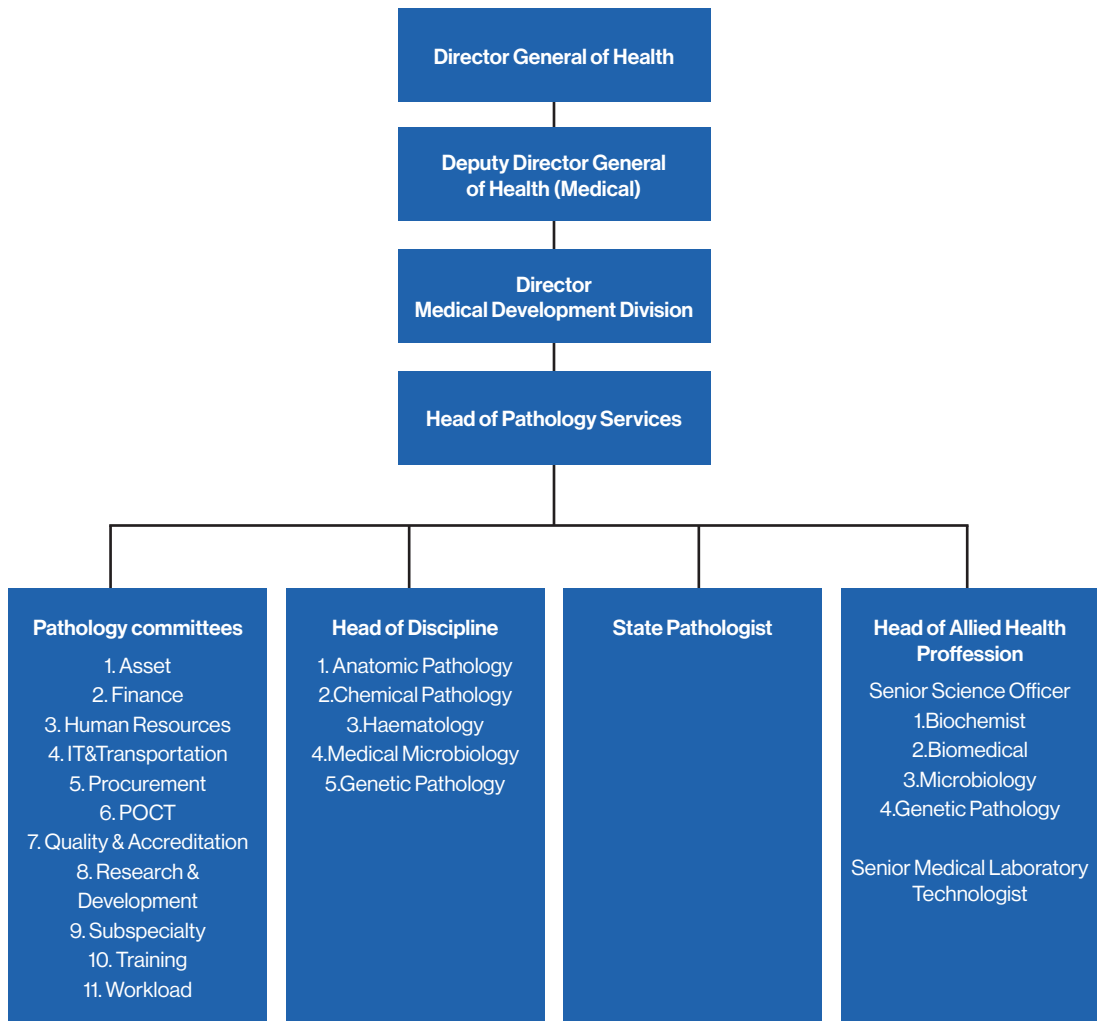
	SERVICES	NON-SPECIALIST	SPECIALIST	STATE / REGIONAL CENTRE
	<b>CHEMICAL PATHOLOGY</b>			
1.	BUSE	√	√	√
2.	RBS	√	√	√
3.	Serum Salicylate	√	√	√
5.	Urine Paraquat	√	√	√
6.	Creatinine Kinase	√	√	√
7.	Bilirubin total	√	√	√
8.	UPT	√	√	√
9.	Urine Biochemistry	√	√	√
10.	ABG	√	√	√
11.	AST		√	√
12.	Urine ketone		√	√
13.	ALT		√	√
14.	S. Calcium		√	√
15.	S. Amylase	√	√	√
16.	S. Paracetamol		√	√
	<b>HAEMATOLOGY/TRANSFUSION</b>			
17	FBP	√ (Resident MO to report/ refer to Pathologist)	√	√
18	Prothrombin Time / INR	√	√	√
19	APTT	√	√	√
20	Fibrinogen		√	√
21	D-Dimer/FDP		√	√
22	Mixing test / Coagulation Factor assay / Coagulation Factor Inhibitor Assay			√
23	Antibody Screening		√	√
24	Antibody Identification		√	√
25	Bone Marrow Aspirate		√	√
26	Leukaemia Immunophenotyping			√

	SERVICES	NON-SPECIALIST	SPECIALIST	STATE / REGIONAL CENTRE
	<b>HAEMATOLOGY</b>			
27.	Group and cross match	√	√	√
28	Full Blood Count	√	√	√
	<b>MEDICAL MICROBIOLOGY</b>			
29	CSF cell count, gram stain		√	
30	Blood, CSF, sterile body fluid culture		√	
31.	Sterile body fluid gram stain		√	
32	Throat swab microscopy for diphtheria		√	
33	Eye swab microscopy for N. gonorrhoea in neonate	√	√	
34	Corneal scraping microscopy		√	

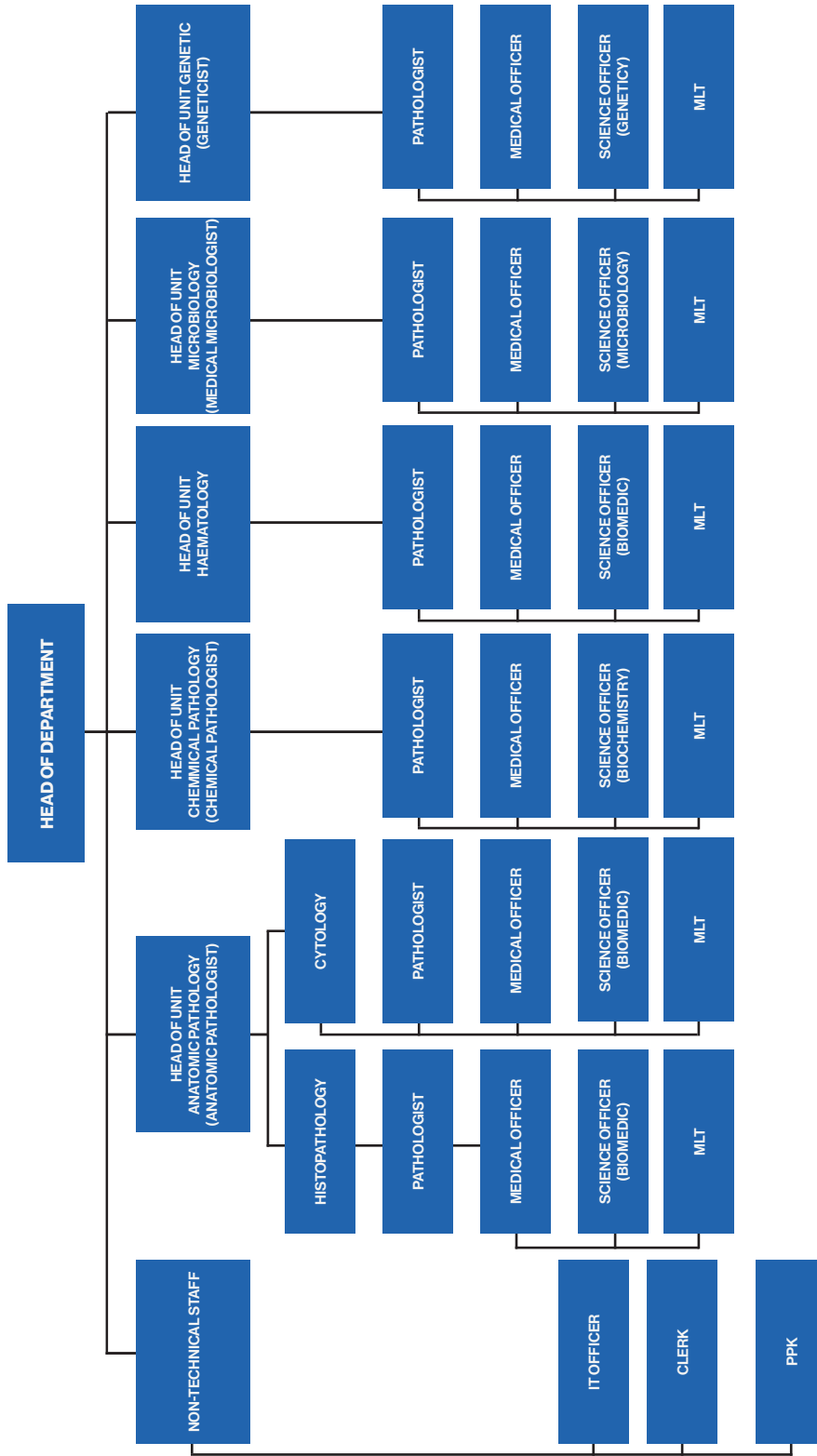
**Notes:**

1. All test offered by level shall be made available depending on workload and subjected to approval by state pathologist
2. All urgent test offered shall be made available depending on justification by head of Department/Unit of Pathology
3. All tests performed manually or automated method offered in Health Clinics shall be enrolled in External Quality Assurance programmes OR Inter-laboratory Comparison (ILC) as recommended in MS 2702 for primary healthcare laboratories.

**APPENDIX 4: ORGANISATIONAL STRUCTURE OF PATHOLOGY SERVICE  
MINISTRY OF HEALTH**



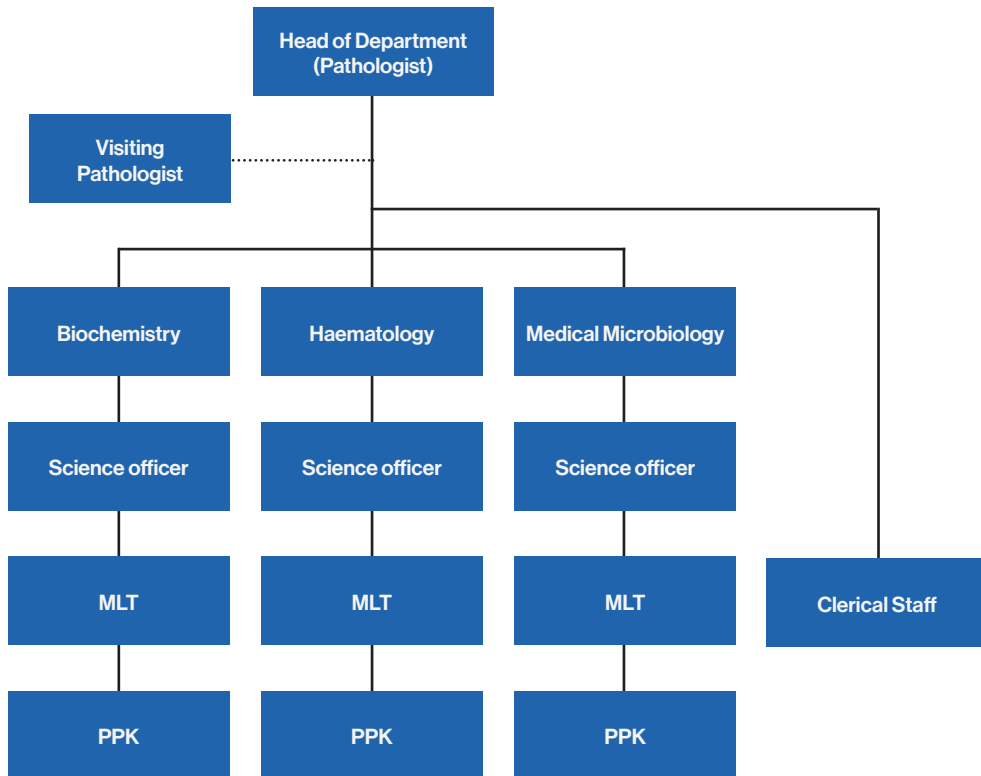
**APPENDIX 5: PATHOLOGY DEPARTMENT ORGANISATIONAL CHART (STATE HOSPITAL / MAJOR SPECIALIST HOSPITAL / SPECIAL INSTITUTION)**



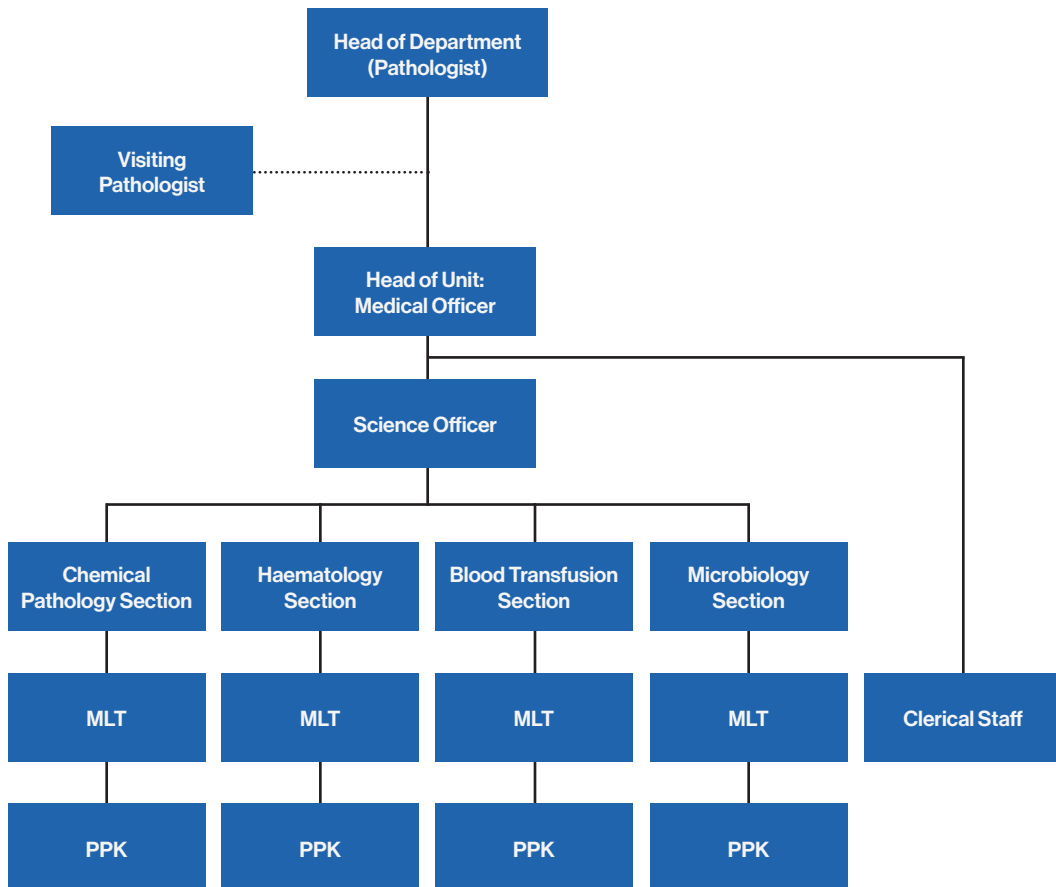
**Notes:**

1. Anatomic pathology service is not available at all major specialist hospitals.
2. Some hospitals have integrated laboratory that run routine tests for Haematology, Chemical Pathology and Serology.
3. Genetic Pathology service is only available in Hospital Tunku Azizah Kuala Lumpur (HTAKL).



**APPENDIX 6: PATHOLOGY DEPARTMENT ORGANISATIONAL CHART  
(MINOR SPECIALIST HOSPITAL)**

## APPENDIX 7: PATHOLOGY UNIT ORGANISATION CHART (NON-SPECIALIST HOSPITAL)



## APPENDIX 8: RATIO WORKLOAD TO VARIOUS CATEGORIES OF LABORATORY PERSONNEL

CATEGORIES OF PERSONNEL	CHEMICAL PATHOLOGY (test/year)	HAEMATOLOGY (sample/ year)	ANATOMIC PATHOLOGY (sample /year)	MEDICAL MICROBIOLOGY (sample/ year)	GENETIC PATHOLOGY (sample/year)
<b>PATHOLOGIST</b>	1: 1,000,000 (Routine) 1: 150,000 (Specialised) 1 in every subspecialty	1: 100,000 (Routine) 1: 10,000 (Specialised) 1 in every subspecialty	1: 4,000 (without sub specialty)  1: 3,000 (with sub specialty)	1: 35,000 (Routine)  1: 10,000 (Specialised)	1: 500 (specialised)  1 in every subspecialty
<b>SCIENCE OFFICER</b>	1: 250,000 (Routine) 1: 25,000 (Specialised) 1: 15,000 (Complex specialised) 1 in every subspecialty	1: 250,000 (Routine) 1: 15,000 (Specialised)  1 in every subspecialty	1: 8,000 (Histology) 1: 7,000 (Cytology)	1: 13,000 (Routine) 1: 8,000 (Specialised)	1: 250 (specialised)  1 in every subspecialty
<b>MEDICAL LABORATORY TECHNOLOGIST</b>	1: 150,000 (Routine) 1: 20,000 (Specialised) 1: 10,000 (Complex specialised) 2 in every subspecialty	1: 35,000 (Routine) 1: 3,000 (Specialised)  2 in every subspecialty	1: 2,000 (Histopathology without subspecialty) 1: 1,000 (Histopathology with subspecialty)  1: 2,000 (Cytology)	1: 5,000 (Routine)  1: 3,000 (Specialised)	1: 250 (Specialised)

**Note:** Number are based on minimum requirement of staff for each category of hospital.

## APPENDIX 9: MINIMUM STANDARD REQUIREMENT OF EQUIPMENT ACCORDING TO HEALTHCARE LEVEL

HISTOPATHOLOGY							
EQUIPMENT	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE HOSPITALS	REGIONAL CENTRE	
Grossing Station	Nil	Nil	Nil	-1 unit	-2 units	-3 units	
Cassette labeller	Nil	Nil	Nil	-1 unit	-2 units	-3 units	
Automated Tissue Processor	Nil	Nil	Nil	medium capacity (100-200 cassetts) -2 unit	high capacity (at least 300 cassetts) - 2 units	high capacity (at least 300 cassetts) - 3 units	
Embedding station	Nil	Nil	Nil	2 units	2 units	3 units	
Cold plate	Nil	Nil	Nil	2 units	2 units	3 units	
Microtome	Nil	Nil	Nil	2 units	4 units	6 units	
Tissue Float bath	Nil	Nil	Nil	2 units	4 units	6 units	
H&E Autostainer	Nil	Nil	Nil	2 units	2 units	3 units	
Automated Cover slipper	Nil	Nil	Nil	2 units	4 units	6 units	
Automated Immunohistochemistry stainer	Nil	Nil	Nil	1 unit	2 units	3 units	
Autostainer for histochemistry	Nil	Nil	Nil	1 unit	2 units	2 units	
Fume cabinet	Nil	Nil	Nil	2 units	2 units	2 units	
Biosafety cabinet Class II	Nil	Nil	Nil	2 units	2 units	2 units	
Hot air Oven	Nil	Nil	Nil	2 units	2 units	2 units	
Cryostat	Nil	Nil	Nil	2 units	2 units	3 units	
Medical Lab Fridge (2-8°C) (100L)	Nil	Nil	Nil	2 units	4 units	6 units	
Laboratory Freezer (-20°C)	Nil	Nil	Nil	2 units	4 units	6 units	
Laboratory Freezer (-80°C)	Nil	Nil	Nil	Nil	Nil	2 units (muscular pathology)	

EQUIPMENT	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE HOSPITALS	REGIONAL CENTRE
Microscope single viewer Pathologist grade	Nil	Nil	Nil	10 units	15 units	20 units
Microscope single viewer Technologist grade	Nil	Nil	Nil	2 units	4 units	6 units
Microscope double viewers pathologist grade	Nil	Nil	Nil	1 unit	4 units	6 units
Microscope pathologist grade with image capture system	Nil	Nil	Nil	1 unit	2 units	2 unit
Microscope pathologist grade 5 viewers -multithreader	Nil	Nil	Nil	1 unit	2 units	3 units
Brights field Immunofluorescence microscope with image capture system	Nil	Nil	Nil	1 unit	1 unit	2 units
Digital pathology system including slide scanner, server and other accessories	Nil	Nil	Nil	1 unit medium throughput)	1 unit medium throughput	1 unit high throughput

CYTOLOGY							
EQUIPMENT	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE HOSPITALS	REGIONAL CENTRE	
Cytospin	Nil	Nil	Nil	1 unit	1 unit	1 unit	
Centrifuge	Nil	Nil	Nil	1 unit	2 units	2 units	
Laboratory Freezer (-20°C)	Nil	Nil	Nil	1 unit	2 units	4 units	
PAP stain Autostainer	Nil	Nil	Nil	1 unit	1 unit	1 unit	
MGG stain Autostainer	Nil	Nil	Nil	1 unit	1 unit	1 unit	
Liquid based cytology processing system	Nil	Nil	Nil	1 unit (low throughput)	1 unit (high throughput)	1 unit (high throughput)	
Fume cabinet	Nil	Nil	Nil	1 unit	2 units	2 units	
Biosafety cabinet (Class II)	Nil	Nil	Nil	1 unit	2 units	2 units	
Microscope single viewer pathologist grade	Nil	Nil	Nil	4 units	8 units	12 units	
Microscope double viewers pathologist grade	Nil	Nil	Nil	1 unit	2 units	2 units	
Microscope single viewer technologist grade	Nil	Nil	Nil	2 units	2 units	2 units	
Microscope pathologist grade with image capture system	Nil	Nil	Nil	1 unit	1 unit	1 unit	
Microscope pathologist grade 5 viewers	Nil	Nil	Nil	1 unit	2 units	2 units	

DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE / REGIONAL CENTRE
<b>PRE-ANALYTICAL UNIT</b>					
PRE-ANALYTICAL	Centrifuge (24 tubes) – 1 unit	Centrifuge (24 tubes) – 2 units	Centrifuge (24 tubes) – 2 units	Centrifuge (24 tubes) – 3 units	Centrifuge (24 tubes) – 3 units
PRE-ANALYTICAL	-	-	-	Refrigerated centrifuge - 1 unit	Refrigerated centrifuge - 1 unit
PRE-ANALYTICAL	Medical Lab fridge (2-8°C) (600L) – 1 unit	Medical Lab fridge (2-8°C) (600L) – 1 unit	Medical Lab fridge (2-8°C) (600L) – 1 unit	Medical Lab fridge (2-8°C) (1000L) – 1 unit	Medical Lab fridge (2-8°C) (1000L) – 1 unit
PRE-ANALYTICAL	-	-	Medical Lab Freezer (-20°C) (400L) – 1 unit	Medical Lab Freezer (-20°C) (400L) – 1 unit	Medical Lab Freezer (-20°C) (400L) – 1 unit
<b>CHEMICAL PATHOLOGY</b>					
CHEMICAL PATHOLOGY	Automated Clinical Chemistry Analyser (700 Tests/Hr) – 2 unit*#	Automated Clinical Chemistry Analyser (700 Tests/Hr) – 2 units*#	Workload less than 100,000 tests/year shall be equipped with 2 units of Automated Clinical Chemistry Analyser @ ISE with throughput at least 200 Tests/Hr)*#	Workload of 100,000 to 400,000 tests/year shall be equipped with at least 2 units of Automated Clinical Chemistry Analyser @ ISE with throughput at least 800 Tests/Hr)*#	Workload of more than 400,000 tests/year shall be equipped with at least 2 Automated Clinical Chemistry Analyser @ ISE with throughput at least 1200 Tests/Hr)*#
CHEMICAL PATHOLOGY	-	-	Workload of less than 100,000 tests/year shall be equipped with at least 1 unit of Automated Immunochemistry Analyser with throughput at least (200T/Hr)*#	Workload of less than 100,000 tests/year shall be equipped with at least 2 units of Automated Immunochemistry Analyser with throughput at least 150 T/Hr) –*#	Workload of more than 100,000 tests/year shall be equipped with at least 2 units Automated Immunochemistry Analyser with throughput at least 200 Tests/Hr)*#
CHEMICAL PATHOLOGY	Semi-Automated Urine Biochemistry Analyser – 1 unit#	Semi-Automated Urine Biochemistry Analyser – 1 unit#	Semi-Automated Urine Biochemistry Analyser – 1 unit#	Integrated Automated Urine Biochemistry (220 Tests/Hr) & Microscopy Analyser (100T/Hr) – 1 unit#	Integrated Automated Urine Biochemistry (220 Tests/Hr) & Microscopy Analyser (100T/Hr) – 1 unit#
CHEMICAL PATHOLOGY	-	-	Drug Testing Analyser (150T/Hr) – 1 unit #	Drug Testing Analyser (400T/Hr) – 1 unit #	Drug Screening Analyser (400 Tests/Hr) – 1 unit #
CHEMICAL PATHOLOGY	-	-	TDM Analyser (200T/Hr) – 1 unit #	TDM Analyser (200T/Hr) – 1 unit#	TDM Analyser (200 Tests/Hr) – 1unit#

DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE / REGIONAL CENTRE
CHEMICAL PATHOLOGY	-	Blood Gas Analyser (80T/hr) - 1 units*#	Blood Gas Analyser (80T/hr) - 1 units*#	Blood Gas Analyser (80T/hr) - 2 units*#	Blood Gas Analyser (80Tests/hr) - 2 units*#
CHEMICAL PATHOLOGY	-	-	-	Electrolyte (ISE) Analyser (Lithium) - 1unit*#	Electrolyte (ISE) Analyser (Lithium) - 1unit*#
CHEMICAL PATHOLOGY	HbA1c Analyser/POCT	HbA1c analyser#	HbA1c Analyser#	HbA1c Analyser#	Automated HbA1c Analyser #
CHEMICAL PATHOLOGY	-	-	Osmometer-1Unit*#	Osmometer - 1unit*#	Osmometer - 2 units*#
CHEMICAL PATHOLOGY	Horizontal shaker - 1 unit	Horizontal shaker - 1 unit	Horizontal shaker - 1unit	Horizontal shaker - 2 units	Horizontal shaker - 2 units
CHEMICAL PATHOLOGY	-	-	-	pH Meter - 1 unit	pH Meter - 1 unit
CHEMICAL PATHOLOGY	-	-	-	Centrifuge (48-60 tubes) - 2 units	Centrifuge (48-60 tubes) - 3 units
CHEMICAL PATHOLOGY	-	Centrifuge (24 tubes) - 2 units	Centrifuge (24 tubes) - 2 units	Centrifuge (24 tubes) - 2 units	Centrifuge (24 tubes) - 3 units
CHEMICAL PATHOLOGY	-	Micro-centrifuge - 2 units	Micro-centrifuge - 2 units	Micro-centrifuge - 3 units	Micro-centrifuge - 3 units
CHEMICAL PATHOLOGY	-	-	-	Refrigerated centrifuge - 1 unit	Refrigerated centrifuge - 1 unit
CHEMICAL PATHOLOGY	-	-	-	Centrifuge (8-12 cm tubes @ drug testing) - 2 units	Centrifuge (8-12 cm tubes @ drug testing) - 2 units
CHEMICAL PATHOLOGY	Medical Lab fridge (1400L) - 2 units	Medical Lab fridge (1000L) - 2 units	Medical Lab fridge (1000L) - 3 units	Medical Lab fridge (1400L) - 3 units	Medical Lab fridge (2-80C) (1400L) - 4 units
CHEMICAL PATHOLOGY	Medical Lab Freezer (-30°C), (700L) - 1 unit	Medical Lab Freezer (-20°C) (700L) - 1 unit	Medical Lab Freezer (-20°C) (700L) - 1 units	Medical Lab Freezer (-20°C) (700L) - 2 units	Medical Lab Freezer (-20°C) (700L) - 2 units
CHEMICAL PATHOLOGY	-	-	-	Medical Lab Freezer (-80°C) (700L) - 1 units	Medical Lab Freezer (-80°C) (700L) - 2 units



DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE / REGIONAL CENTRE
CHEMICAL PATHOLOGY	-	Hot air Oven (400L)-1 unit	Hot air Oven (400L) - 1 unit	Hot air Oven (400L)- 1 unit	Hot air Oven (400L)-1 unit
CHEMICAL PATHOLOGY	Bio Safety Cabinet (Class II)	-	Bio Safety Cabinet (Class II) - 1 unit	Bio Safety Cabinet (Class II) - 2 units	Bio Safety Cabinet (Class II) - 3 units
CHEMICAL PATHOLOGY	Fume Hood -1 unit	Fume Hood -1 unit	Fume Hood -1 unit	Fume Hood -2 units	Fume Hood -2 units
CHEMICAL PATHOLOGY	Roller mixer -1 units	Vortex mixer -2 units	Vortex mixer -2 units	Vortex mixer -2 units	Vortex mixer -4 units
CHEMICAL PATHOLOGY	-	Hot plate @ stirrer -1 unit	Hot plate @ stirrer -1 units	Hot plate @ stirrer -2 units	Hot plate @ stirrer -2 units
CHEMICAL PATHOLOGY	Deioniser / RO Water purification system- 1unit	Deioniser / RO Water purification system - 1 unit	Deioniser / RO Water purification system - 1 unit	Deioniser / RO Water purification system - 1 unit	Deioniser / RO Water purification system -1 unit
CHEMICAL PATHOLOGY	-	Electronic analytical balance -1 unit	Electronic analytical balance -1 unit	Electronic analytical balance -1 unit	Electronic analytical balance -1 unit
CHEMICAL PATHOLOGY	Micro-pipette (10-100µL) - 1unit	Micro-pipette (20-200µL) -3 units	Micro-pipette (20-200µL) -3 units	Micro-pipette (20-200µL) -4 units	Micro-pipette (20-200µL) -5 units
CHEMICAL PATHOLOGY	Micro-pipette (100-1000µL) -1 unit	Micro-pipette (100-1000µL) -3 units	Micro-pipette (100-1000µL) -3 units	Micro-pipette (100-1000µL) -4 units	Micro-pipette (100-1000µL) -5 units
CHEMICAL PATHOLOGY	Micro pipette (0.5-10)µl - 1 unit	Micro-pipette (1ml-10ml) - 2 units	Micro-pipette (1ml-10ml) - 2 units	Micro-pipette (1ml-10ml) - 4 units	Micro-pipette (1ml-10ml) -5 units

DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE HOSPITALS/ HKL
<b>GENERAL HAEMATOLOGY (FBC/FBP, ESR, NAP Score, G6PD Screening) &amp; BMA (including cytochemical stains) and Trepiline biopsy reporting</b>					
HAEMATOLOGY	Automated haemoglobin analyser - 1 unit OR/AND haematology analyser (BASED ON WORKLOAD) - Medium range (Minimum 18 parameters with 5 parts differentials. Capacity CBC 60-99 samples/Hr) - 1 unit OR - Medium range - 1 unit AND - Low range 1 unit (12-18 parameters with 3 - 5 part differentials. Capacity CBC 40-60/Hr) - 1 unit	Automated haematology Analyser (BASED ON WORKLOAD) - Medium range (Min. 18 parameters with 5 parts differentials. Capacity CBC :60-99 samples/Hr) -Min: 2 units OR - Medium range - 1 unit AND - Low range 1 unit (12-18 parameters with 3 - 5 part differentials. Capacity CBC 40-60/Hr) - 1 unit	Automated haematology Analyser (BASED ON WORKLOAD) - Medium range - Parameters: Min. 18 parts differentials -Capacity: 60-99 samples/Hr -Min. number: 2 units	Automated haematology Analyser (BASED ON WORKLOAD) - High range - Parameters: Min. 22 parts differentials with reticulocytes count and nucleated RBC -Capacity: CBC >100 samples /Hr - Min. number: 2 units OR - High range - 1 unit AND - Medium range - Parameters: Min. 18 parameters, 5 parts differentials -Capacity: 60-99 samples/Hr - Min. number: 1 unit	*Automated haematology Analyser (**integrated with slide maker & stainer) - High range - Parameters: Min. 22 parts differentials with reticulocytes count and nucleated RBC - Capacity: CBC >100 samples /Hr - Min. number: 2 units (2nd unit would be based on workload especially in smaller State hospitals)
HAEMATOLOGY					*Automated slide maker and stainer (**integrated to main haematology analyser) - 1 unit
HAEMATOLOGY					# Automated haematology Analyser - High range. Min. 22 parameters, 5 parts differentials with reticulocytes count and nucleated RBC. Capacity - CBC >100 samples /Hr) - 1 unit

DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE HOSPITALS/ HKL
HAEMATOLOGY	-	Automated haematology stainer - 1 unit (depending on work load)	Automated haematology stainer - 1 unit	Automated haematology stainer - 1 unit	# Automated slide maker and stainer integrated to the main haematology analyser in Hematology lab (depending on the workload) - 1 unit
HAEMATOLOGY	-	-	-	-	# Microscope with digital imaging system – 1 unit (for referral hospital)
HAEMATOLOGY	-	-	-	Microscope. Dual headed - 1 unit	# Microscope. Dual headed - 1 unit
HAEMATOLOGY	-	-	-	-	# Microscope. Multithreaded - 1 unit
HAEMATOLOGY	-	High grade microscope for visiting pathologist - 1 unit	High grade microscope (for Pathologist)	High grade microscope (for Pathologist)	High grade microscopes (for Pathologist)
HAEMATOLOGY	-	Medium grade microscope (Medical officer)-1 unit	Microscope (Medical officer)	Microscope (for Medical officer)	Microscopes (for Medical officer)
HAEMATOLOGY	-	Low grade microscope (MLT) - For slide review and quality check - 1 unit	Microscope (MLT) - For slide review and quality check - 1 unit	Microscope (MLT) - For slide review and quality check - 2 unit	* Microscope (MLT). For slide review screeners - 2 unit # Microscope (JTMP). For quality and morphology check - 2 unit
HAEMATOLOGY	-	White cell differential counter - 2 units	White cell differential counter	White cell differential counter	* # White cell differential counter
HAEMATOLOGY	Automated ESR analyser with ESR mixer - 1 unit OR Manual ESR (Westergren method) – 1 unit	Automated ESR analyser with ESR mixer - 1 unit	Automated ESR analyser with ESR mixer - 2 unit	Automated ESR analyser with ESR mixer - 2 unit	* Automated ESR analyser with ESR mixer - 2 unit

DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE HOSPITALS/ HKL
HAEMATOLOGY	-	G6PD - UV Fluorescent box - 1 unit	G6PD deficiency - UV Fluorescent box - 1 unit	G6PD deficiency - UV Fluorescent box - 1 unit	G6PD deficiency - UV Fluorescent box - 1 unit
HAEMATOLOGY	-	-	Incubator. Temp 36.4°C - 37.6 °C ; 200L (G6PD) - 1 unit	Incubator. Temp 36.4°C - 37.6°C;200L (G6PD) - 1 unit	Incubator. Temp 36.4°C - 37.6°C;200L (G6PD) - 1 unit
HAEMATOLOGY	-	Rotator (G6PD) - 1 unit	Rotator (G6PD) - 1 unit	Rotator (G6PD) - 1 unit	Rotator (G6PD) - 1 unit
HAEMATOLOGY	-	Micropipette. Adjustable air displacement, 10-100 µL - 2 units	Micropipette. Adjustable air displacement, 10-100 µL - 2 unit	Micropipette. Adjustable air displacement, 10-100 µL - 2 unit	Micropipette. Adjustable air displacement, 10-100 µL - 3 unit
HAEMATOLOGY	-	-	-	Micropipette. Adjustable air displacement, 100-1000 µL - 1 unit	Micropipette. Adjustable air displacement, 100-1000µL - 1 unit
HAEMATOLOGY	Medical laboratory refrigerator. 2-8°C, 450 - 600L - Min 1 unit each for storage of sample and storage of reagent (Capacity depending on daily sample workload and reagent)	Medical laboratory refrigerator. 2-8oC, 600L - 1 unit	Medical laboratory refrigerator. 2-8°C, 600L - 1 unit	Medical laboratory refrigerator. 2-8oC, 1000L - 1 unit	* Medical laboratory refrigerator. 2-8oC, 1000L - 1 unit
HAEMATOLOGY		Medical laboratory refrigerator. 2-8°C, 450L - 2 units	Medical laboratory refrigerator. 22-8°C, 450L - 2 unit	Medical laboratory refrigerator. 2-8°C, 450L - 2 unit	* Medical laboratory refrigerator. 2-8°C, 450L - 2 unit
HAEMATOLOGY			Hair Dryer - 1 unit (For manual staining)	Hair Dryer - 1 unit (For manual staining)	* # Hair Dryer - 1 unit (For manual staining)

DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE HOSPITALS/ HKL
<b>BASIC HAEMOSTASIS &amp; THROMBOSIS</b>					
HAEMATOLOGY	PT/INR POCT for Warfarin Clinic	Automated Coagulation analyser Capacity: Medium Throughput (60-100 PTs/Hr) - 1 unit  AND  Semi-automated Coagulation analyser. Benchtop Capacity: Operator dependant - 1 unit	Automated Coagulation analyser Capacity: Medium Throughput (60-100 PTs/Hr) - 1 unit  AND  Semi-automated Coagulation analyser. Benchtop Capacity: Operator dependant - 1 unit	Automated Coagulation analyser Capacity: High Throughput (100-200 PTs/Hr) - 1 unit  AND  Automated Coagulation analyser: Capacity depending on workload e.g. Medium Throughput (60-100 PTs/Hr) - 1 unit	* Automated Coagulation analyser Capacity: High Throughput (100-200 PTs/Hr) Min number: 1 unit  (2nd unit may be placed in Core lab or Haematology Unit to cater for specialised coagulation tests provided by the State hospital)
HAEMATOLOGY	-	Rotator (For manual D-dimer test) - 1 unit	Rotator (For manual D-dimer test) - 1 unit	Rotator (For manual D-dimer test) - 1 unit	-
HAEMATOLOGY	-	Water bath. Temp: Up to 100°C. 20L - 1 unit	Water bath. Temp: Up to 100°C. 20L - 1 unit	Water bath. Temp: Up to 100°C. 20L - 1 unit	* Water bath. Temp: Up to 100°C. 20L - 1 unit
HAEMATOLOGY	-	Centrifuge. Multipurpose, Rack capacity 32-64 tubes. - 1 unit	Centrifuge. Multipurpose, Rack capacity 32-64 tubes. - 2 unit	Centrifuge. Multipurpose, Rack capacity 32-64 tubes. - 2 unit	* Centrifuge. Multipurpose, Rack capacity 32-64 tubes. - 2 unit
HAEMATOLOGY	-	-	-	-	* Micro centrifuge - 1 unit
HAEMATOLOGY	-	Medical Laboratory refrigerator Temp: 2-8°C; Capacity 600L - 1 unit	Medical Laboratory refrigerator Temp: 2-8°C; Capacity 600L - 2 unit	Medical Laboratory refrigerator Temp: 2-8°C; Capacity 1000L - 2 unit	* Medical Laboratory refrigerator. Temp: 2-8°C; Capacity 1000L - 2 unit
HAEMATOLOGY	-	Laboratory Freezer. Temp: - 20°C; Capacity 400L - 1 unit	Laboratory Freezer. Temp: - 20°C; Capacity 400L - 1 unit	Laboratory Freezer. Temp: - 20°C; Capacity 400L - 1 unit	* Laboratory Freezer. Temp: - 20°C; Capacity 400L - 1 unit
HAEMATOLOGY	-	-	-	-	Laboratory Freezer. Temp: - 80°C; Capacity 400L - 1 unit

**LEGEND:**

\* To cater for 24-hour automated haematology service (FBC, ESR, Basic coagulation) in State Hospital / HKL and preferably integrated in CORE LAB with of her automated 24 hours services

# To be provided from Specialized Haematology lab (operating during office hours only) in State Hospital/ HKL

**Comments:**

1. Regarding haematology tests and analysers in laboratory service in Health Clinics:
  - i. Provision of the tests in the laboratory will be based on type of Health Clinics.
  - ii. All tests provided shall be enrolled in External Quality Assurance programmes whether the tests are performed manually e.g. ESR by Westergren Method or automated method including POCT devices, otherwise the samples shall be referred to the nearest MOH referral lab at Health Clinics or hospital.
  - iii. Tests performed as POCT in Health Clinics shall be supervised by haematologists from the nearest MOH hospital.
2. Grade of microscopes for Pathologist is BX40 series and above and for technologist are of grade CX series or equivalent

MICROBIOLOGY					
DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE / REGIONAL CENTRE
MICROBIOLOGY – MEDIA PREPARATION	-	-	-	Laminar flow workstation -1 unit	Laminar flow workstation -1 unit
MICROBIOLOGY – MEDIA PREPARATION	-	-	-	Waterbath -1 unit	Waterbath -1 unit
MICROBIOLOGY – MEDIA PREPARATION	-	-	-	Automated media dispenser -1 unit	Automated media dispenser -1 Unit
MICROBIOLOGY – MEDIA PREPARATION	-	-	-	Automated media preparation system -1 unit	Automated media preparation system -1 unit
MICROBIOLOGY – MEDIA PREPARATION	-	-	-	Autoclave standing -1 unit	Autoclave standing -2 units
MICROBIOLOGY – MEDIA PREPARATION	-	-	-	Electronic analytical balance -1 unit	Electronic analytical balance -1 unit
MICROBIOLOGY – MEDIA PREPARATION	-	-	-	Hot plate with stirrer -1 unit	Hot plate with stirrer -1 unit
MICROBIOLOGY – MEDIA PREPARATION	-	-	-	pH Meter - 1 unit	pH Meter - 1 unit
MICROBIOLOGY – MEDIA PREPARATION	-	-	-	-	Medical Lab Fridge 1400 L, 2-8°C - 5 units (if no cold room)
MICROBIOLOGY – MEDIA PREPARATION	-	Automated blood culture system - 1 unit	Automated blood culture system - 2 units	Automated blood culture system - 6 units	Automated blood culture system - 8 - 10 units
MICROBIOLOGY – MEDIA PREPARATION	-	-	Automated bacteriology identification & susceptibility -1 Unit	Automated bacteriology identification & susceptibility -1 unit	Automated bacteriology identification & susceptibility -1 unit
MICROBIOLOGY- BACTERIOLOGY	-	-	Automated Antibiotic reader -1 Unit	Automated Antibiotic reader -1 unit	Automated Antibiotic reader -2 units

MICROBIOLOGY					
DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE / REGIONAL CENTRE
MICROBIOLOGY-BACTERIOLOGY	-	-	Automated urine microscopy - 1 unit	Automated urine microscopy - 1 unit	Automated urine microscopy - 1 unit
MICROBIOLOGY-BACTERIOLOGY	-	-	-	Automated slide stainer - 1 unit	Automated slide stainer - 2 units
MICROBIOLOGY-BACTERIOLOGY	-	Freezer 700 L-10°C to -30°C - 2 unit	Freezer 700 L-10°C to -30°C - units	Freezer -10°C to -30°C - 2 units	Freezer -10°C to -30°C - 2 units
MICROBIOLOGY-BACTERIOLOGY	Medical Lab Fridge and freezer 600 L - 1 unit	Medical Lab Fridge 600 L, 2-8°C - 2 units	Medical Lab Fridge 1000 L, 2-8°C - 2 units	Medical Lab Fridge 1400 L, 2-8°C - 4 units	Medical Lab Fridge 1400 L, 2-8°C - 5 units
MICROBIOLOGY-BACTERIOLOGY	Biosafety Cabinet Class II - 1 unit	Biosafety Cabinet Class II - 1 unit	Biosafety Cabinet Class II - 1 unit	Biosafety Cabinet Class II - 2 - 3 unit	Biosafety Cabinet Class II - 4- 6 units
MICROBIOLOGY-BACTERIOLOGY	Bactitionerator - 2 Units	Bactitionerator - 4 Units	Bactitionerator - 5 Units	Bactitionerator - 15 units	Bactitionerator -10 - 20 units
MICROBIOLOGY-BACTERIOLOGY	Binocular Microscope - 2 units	Binocular Microscope - 2 units	Binocular Microscope - 2 units	Binocular Microscope - 3-5 units	Binocular Microscope - 4 - 8 units
MICROBIOLOGY-BACTERIOLOGY	Slide warmer - 1 unit	Slide warmer - 2 units	Slide warmer - 2 units	Slide warmer - 6 units	Slide warmer - 8 units
MICROBIOLOGY-BACTERIOLOGY	-	-	Incubator CO <sub>2</sub> - 1 unit	Incubator CO <sub>2</sub> - 2 units	Incubator CO <sub>2</sub> - 3 units
MICROBIOLOGY-BACTERIOLOGY	-	-	Incubator 37°C - 2 unit	Incubator 37°C - 3 units	Incubator 37°C - 3 units
MICROBIOLOGY-BACTERIOLOGY	-	-	Incubator 42°C - 1 unit	Incubator 42°C - 1 unit	Incubator 42°C - 1 unit
MICROBIOLOGY-BACTERIOLOGY	-	-	Incubator 30°C - 1 unit	Incubator 30°C - 1 unit	Incubator 30°C - 2 units
MICROBIOLOGY-BACTERIOLOGY	-	-	Centrifuge (medium) - 1 unit	Centrifuge (medium) - 1 unit	Centrifuge (medium) 1 unit
MICROBIOLOGY-BACTERIOLOGY	-	-	Rotator - 1 unit	Rotator - 1 unit	Rotator - 1 unit



MICROBIOLOGY						
DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE /REGIONAL CENTRE	
MICROBIOLOGY- BACTERIOLOGY	-	Vortex - 1 unit	Vortex - 1 unit	Vortex - 1 unit	Vortex - 1 unit	
MICROBIOLOGY- BACTERIOLOGY	Pipette - 3 units	Pipette - 3 units	Pipette - 5 units	Pipette - 10 units	Pipette - 10 units	
MICROBIOLOGY- BACTERIOLOGY	-	-	McFarland densitometer - 1 unit	McFarland densitometer - 3 units	McFarland densitometer - 5 units	
MICROBIOLOGY – VIROLOGY /SEROLOGY	Centrifuge (medium) - 1 unit	Centrifuge (medium) - 1 unit	Centrifuge (medium) - 1 unit	Centrifuge (heavy) - 2 units	Centrifuge (heavy) - 2 units	
MICROBIOLOGY – VIROLOGY /SEROLOGY	-	-	Freezer 400L -70°C to -80°C - 1 unit	Freezer 400L -70°C to -80°C - 1 unit	Freezer 400L -70°C to -100°C - 1 unit	
MICROBIOLOGY – VIROLOGY /SEROLOGY	-	-	Freezer 700L -10°C to -30°C - units	Freezer -10°C to -30°C - 2 units	Freezer -10°C to -3°C - 2 units	
MICROBIOLOGY – VIROLOGY/SEROLOGY	Medical Lab Fridge 600 L, 2-8°C- 2 units	-	Medical Lab Fridge 1000 L(2-8°C) - 2Units	Medical Lab Fridge 1400 L (2-8°C) - 4 units	Medical Lab Fridge 1400 L (2-8°C) - 6 - 8 units	
MICROBIOLOGY – VIROLOGY/SEROLOGY	-	-	-	Fluorescence microscope (double viewer) - 1 unit	Fluorescence microscope (double viewer) - 1 unit	
MICROBIOLOGY – VIROLOGY/SEROLOGY	-	-	Automated enzyme immunoassay system, medium capacity - 1 unit	Automated enzyme immunoassay system, medium to high capacity - 1 unit	Automated enzyme immunoassay system, high capacity - 2 units	
MICROBIOLOGY – VIROLOGY/SEROLOGY	-	-	-	Biosafety Cabinet Class II - 1 unit	Biosafety Cabinet Class II - 1 unit	
MICROBIOLOGY – VIROLOGY/SEROLOGY	-	-	-	EIA reader - 1 unit	EIA reader - 1 unit	
MICROBIOLOGY – VIROLOGY/SEROLOGY	-	-	-	EIA washer - 1 unit	EIA washer - 1 unit	
MICROBIOLOGY – VIROLOGY/SEROLOGY	-	-	-	-	EIA analyzer - 2 units	

MICROBIOLOGY					
DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE /REGIONAL CENTRE
MICROBIOLOGY – VIROLOGY/SEROLOGY	-	-	-	Incubator - 1 unit	Incubator - 1 unit
MICROBIOLOGY – VIROLOGY/SEROLOGY	Shaker - 1 unit	Shaker - 1 unit	Shaker - 1 unit	Shaker - 2 units	Shaker - 2 units
MICROBIOLOGY – VIROLOGY/SEROLOGY	-	-	-	Slide warmer - 1 unit	Slide warmer - 2 units
MICROBIOLOGY – VIROLOGY/SEROLOGY	Pipette Single channel - 3 units	Pipette Single channel - 3 units	Pipette Single Channel - 10 units	Pipette Single Channel - 20 units	Pipette Single Channel - 20 - 24 units
MICROBIOLOGY -TB	Biosafety Cabinet Class II - 1 unit	Biosafety Cabinet Class II - 1 unit	Biosafety Cabinet Class II - 1 unit	Biosafety Cabinet Class II - 1 unit	Biosafety Cabinet Class II - 2 units
MICROBIOLOGY - TB	-	-	-	-	Incubator 37°C - 2 units
MICROBIOLOGY - TB	-	-	-	TB culture system - 1 unit	TB culture system - 2 units
MICROBIOLOGY - TB	-	-	-	Automated slide stainer - 1 unit	Automated slide stainer - 1 unit
MICROBIOLOGY - TB	-	-	-	-	Refrigerated centrifuge 50 ml, with aerosol tight lid
MICROBIOLOGY - TB	LED microscope - 1 unit	LED microscope - 1 unit	LED microscope - 1 unit	LED microscope - 2 units	LED microscope - 2 - 4 units
MICROBIOLOGY - TB	-	-	-	Pipette Single Channel - 3 units	Pipette Single Channel - 3 units
MICROBIOLOGY – MYCOLOGY	-	-	-	Biosafety Cabinet Class II - 1 unit	Biosafety Cabinet Class II - 1 unit
MICROBIOLOGY - MYCOLOGY	-	-	-	Incubator 37°C - 1 unit	Incubator 37°C - 2 units
MICROBIOLOGY - MYCOLOGY	-	-	-	Bactincinerator - 1unit	Bactincinerator - 2 units
MICROBIOLOGY - MYCOLOGY	-	-	-	Medical Lab Fridge 1000 L, 2-8°C - 2 units	Medical Lab Fridge 1000 L, 2-8°C - 2 units

MICROBIOLOGY					
DISCIPLINE	PRIMARY CARE	NON-SPECIALIST HOSPITALS	MINOR SPECIALIST HOSPITALS	MAJOR SPECIALIST HOSPITALS	STATE / REGIONAL CENTRE
MICROBIOLOGY – MYCOLOGY	-	-	-	Microscope Binocular - 1 unit	Microscope Binocular - 1 unit
MICROBIOLOGY – MYCOLOGY	-	-	-	-	Microscope pathologist grade with camera – 1 unit
MICROBIOLOGY – MYCOLOGY	-	-	-	-	EIA reader - 1 unit
MICROBIOLOGY – MYCOLOGY	-	-	-	-	EIA washer - 1 unit
MICROBIOLOGY – MYCOLOGY	-	-	-	-	Waterbath - 1 unit
MICROBIOLOGY GENERAL	-	-	-	-	Microscope Multiview 5 viewer - 1 unit
MICROBIOLOGY GENERAL	-	-	-	Microscope Multiview double viewer - 1 unit	Microscope Multiview double viewer - 2 unit
MICROBIOLOGY GENERAL	-	-	-	Water Purification with deionizer System - 1 unit	Water Purification with deionizer System - 2 units
MICROBIOLOGY GENERAL	-	-	-	Cold room - 1	Cold room - 2
MICROBIOLOGY GENERAL	Temperature loggers with software for real time monitoring system according to number of fridges and freezers				
MICROBIOLOGY – WASHROOM	-	-	-	Automated glassware washer - 1 unit	Automated glassware washer - 2 units
MICROBIOLOGY – WASHROOM	-	-	Hot air oven - 1 unit	Hot air oven - 2 units	Hot air oven - 2 units
MICROBIOLOGY – WASHROOM	Autoclave Floor Standing - 1 unit	Autoclave Floor Standing - 1 unit	Autoclave Floor Standing - 1 unit	Autoclave Floor Standing (80L) - 1 - 2 units	Autoclave Floor Standing (80L) - 2 units

## APPENDIX 10: LIST OF MEDICAL EQUIPMENT FOR SPECIAL TESTS IN REFERRAL/ NICHE AREAS

ANATOMIC PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
ANATOMIC PATHOLOGY	Renal pathology / Dermatopathology / (Immunofluorescence stains)	State and major hospital with clinical subspecialty of nephrology and dermatology	Brights field Immunofluorescence microscope with image capture system
ANATOMIC PATHOLOGY	Cytopathology	AP centres in state and major hospital.	Liquid based cytology system (including sample processing and slide preparation)
ANATOMIC PATHOLOGY	Renal pathology	Regional Centre (HKL)	Electron microscope
ANATOMIC PATHOLOGY	Lymphoreticular pathology/Paediatric pathology / Perinatal pathology/ Bone & Soft Tissue pathology / Gynaepathology/ Lung pathology/ GIT & Hepatobiliary/ Neuropathology/ Breast and endocrine pathology/ Head and neck pathology/Ocular pathology (IHC stains)	Regional centre by subspecialty	Automated immunohistochemistry stainer with full range of antibodies relates to the specific subspecialty
ANATOMIC PATHOLOGY	Neuromuscular pathology	Regional centre (HKL)	Liquid nitrogen tank
			Cyrostast with dual compressor
			-80 Lab freezer
ANATOMIC PATHOLOGY	Molecular Anatomic Pathology	Regional centre (HKL)	<p><u>Pre PCR reagent preparation</u></p> <p>Vortex, Miniature Centrifuge Pipette set PCR Cabinet</p> <p><u>Pre PCR sample preparation</u></p> <p>18 <u>RNA extraction</u> Automated RNA extraction system Electronic pipette Centrifuge with rotor plate Vortex Microcentrifuge Blood rotator Refrigerated centrifuge Biosafety cabinet Class II (RNA) Pipette set Dispenser (various volume)</p> <p>18 Tissue preparation</p>

ANATOMIC PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
			Microtome Float bath Cold plate Dissecting microscope  18 DNA extraction Automated DNA extraction system Dispenser (various volume) Centrifuge with rotor plate Heater blocks Vortex Microcentrifuge Blood rotator Refrigerated centrifuge Pipette set PCR cabinet  18 Quality Quantitation Room Microvolume system with PC Fluorespectrophotometer Pipette (0.1 - 10ul) – 2unit, pipette (20ul) - 2 unit with carousel
			<u>Genome Mixing</u> PCR cabinet Automated PCR assay 96 well plate mixer 8 channels micropipette various set Vortex Microcentrifuge Centrifuge with rotor plate Electronic pipette Pipette sets
			<u>PCR</u> Conventional PCR machines Real time PCR PCR cabinet Immunomagnetic based PCR
			<u>Sequencer Room</u> Next Generation Sequencer Sanger sequencer Pyrosequencer 96 well thermomixer/shaker Water bath
			<u>Post PCR</u> Analytical balance pH meter Automated Gel electrophoresis Gel imaging system Horizontal electrophoresis Hybridization machine Automated purification system

ANATOMIC PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
			Pipette set 8 channels micropipette Waterbath HLA plate stirrer 96 well transfer device sonicator Micro SSP Gel system PCR cabinet Incubator Chiler LAB scan 3D
			<u>FISH/ISH Preparation &amp; Hybridization Room</u> Fume hood Safety cabinet type 2 Waterbath Incubator Hybridizer Vortex mixer Thermometer
			<u>FISH/ISH Analysis Room</u> Image capture system with microscope

CHEMICAL PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
CHEMICAL PATHOLOGY	Protein and para-protein	IMR (Molecular Diagnostic & Protein Unit)	Automated Clinical Chemistry Analyser (150T/Hr) -1 unit
CHEMICAL PATHOLOGY	Protein and para-protein	IMR (Molecular Diagnostic & Protein Unit)	Automated Immunochemistry Analyser (200T/Hr) – 1 unit
CHEMICAL PATHOLOGY	Biochemical Genetics -Newborn Screening of IEM (Multianalytes screening)	IMR (Biochemistry Unit)	LCMS-MS - 2 Unit
CHEMICAL PATHOLOGY	Biochemical Genetics Analysis of sugars & polyols and organic acids	IMR (Biochemistry Unit)	GCMS -1 unit
CHEMICAL PATHOLOGY	Biochemical Genetics- Mucopolysaccharides	IMR (Biochemistry Unit)	Densitometer
CHEMICAL PATHOLOGY	Biochemical Genetics -Organic acids and newborn screening	IMR (Biochemistry Unit)	Nitrogen generator- 2 unit
CHEMICAL PATHOLOGY	In-born Error Metabolism – Molecular genetics	IMR (Molecular Diagnostic & Protein Unit)	Automated Electrophoresis Analyzer - 1unit
CHEMICAL PATHOLOGY	In-born Error Metabolism – Molecular genetics	IMR (Molecular Diagnostic & Protein Unit)	Next generation sequencing (medium throughput) - 1 unit
CHEMICAL PATHOLOGY	In-born Error Metabolism – Biochemical Genetics	IMR (Biochemistry Unit)	Medical Lab Fridge (700L) – 1 units
CHEMICAL PATHOLOGY	Protein and para-protein	IMR (Molecular Diagnostic & Protein Unit)	Blood Bank Refrigerators, 2-doors (1/00L) - 2 units
CHEMICAL PATHOLOGY	Test for Heavy metal in biological sample – urine & serum copper, blood lead,	IMR (Pharmacology & Toxicology Unit)	Atomic Absorption Spectrophotometer. Available machine is in process for BER (> 10yrs and frequent breakdown)
CHEMICAL PATHOLOGY	Drug Confirmation & General Drug Screening	Hospital Kuala Lumpur	LCMS-MS -1 Unit
CHEMICAL PATHOLOGY	Drug Confirmation (Designer Drugs) * (Perancangan untuk upgrade metodologi (daripada kaedah kualitatif kepada kaedah kuantitatif yang lebih sensitive, spesifik dan tepat) mengikut piawaian antarabangsa di semua Hospital Negeri)	HKL / HPP / HRPZII/ HSA /HQE /HUS * (Perancangan untuk upgrade metodologi mengikut piawaian antarabangsa di semua hospital negeri)	GCMS - 2 units
			LCMS-MS - 1 Unit
			Automated Solid Phase Extraction (SPE) System - 1 Unit
			Sample Concentrator - 1 Unit

CHEMICAL PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
CHEMICAL PATHOLOGY	Trace Elements	Hospital Kuala Lumpur	ICPMS - 1 unit
	Renin & Aldosterone	Hospital Putrajaya	Tandem Mass Spectrometry - 1 unit
	Biogenic Amines - Catecholamine	HKL & Hospital Putrajaya	HPLC - 2 units
	Biochemical Genetic	Hospital Kuala Lumpur	GCMS for Organic Acid 1 Unit
	Amino Acids (IEM)	Hospital Kuala Lumpur	HPLC - 1 unit
	Protein Proteomic	Hospital Ampang	Automated Electrophoresis Analyser
	Protein Proteomic	Hospital Ampang	Automated Clinical Chemistry Analyser (800T/Hr) - 1 unit
	Protein Proteomic	Hospital Ampang	Freezer (-20°C) (for samples) - 1 unit
	Protein Proteomic	Hospital Ampang	Freezer (-40°C) (for QC) - 1 unit
	Protein Proteomic	Hospital Ampang	Centrifuge - 1 unit
	Protein Proteomic	Hospital Ampang	Fridge (2-8 °C) (for reagents/gels) - 1 unit
	Protein Proteomic	Hospital Ampang	Vortex mixer - 1 unit
	Protein Proteomic	Hospital Ampang	Micropipette: - 10-100µL - 1 unit - 100-1000 µL- 1 unit
	Protein Proteomic	Hospital Ampang	Fume Hood - 1 unit
	Protein Proteomic	Hospital Ampang	Electronic Balance -1 unit
	Protein Proteomic	Hospital Ampang	X-ray box (Viewer)
Protein Proteomic	Hospital Ampang	1D & 2D Electrophoresis system with Image Scanner	



HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
HAEMATOLOGY	HAEMOGLOBIN DISORDERS : Haemoglobin analysis - Thalassemia/ Haemoglobinopathy	<b>i. All State hospitals</b> (Both HPLC and CE methods except in HTF Kangar only 1 as first line method. Samples with variants detected will be referred to HSB for 2nd line method verification)  <b>ii. Selected Major hospitals</b> (minimum by 1 method as 1st line testing)	High performance liquid chromatography (HPLC) system– Min 1 unit
			Automated Capillary electrophoresis (CE) system – Min 1 unit
			Automated electrophoresis system (Alkaline and acid gel electrophoresis) – 1 unit
			Water bath. Temp: Up to 100°C; Capacity: 20 L – 1 unit
			Centrifuge. Multipurpose. Rack capacity 2 – 64 tubes– 1 unit
			Analytical balance - 1 unit
			Vortex mixer - 1 unit
HAEMATOLOGY	RED BLOOD CELL DISORDERS: Haemolytic anaemia & Red cell disorders: - G6PD screening - RBC enzyme assays * - Misc**: • OFT • Kleihauer test etc	<b>HTA (WCHKL)</b> (National referral centre) (**Misc. tests performed in HKL)  Future plan: * <b>Regional centres</b> (Under RMK 12 by pooled procurement)	<b>i. All State hospitals</b> (Both HPLC and CE methods except in HTF Kangar only 1 as first line method. Samples with variants detected will be referred to HSB for 2nd line method verification)
			<b>ii. Selected Major hospitals</b> (minimum by 1 method as 1st line testing)
			<b>i. All State hospitals</b> (Both HPLC and CE methods except in HTF Kangar only 1 as first line method. Samples with variants detected will be referred to HSB for 2nd line method verification)
			<b>ii. Selected Major hospitals</b> (minimum by 1 method as 1st line testing)
			<b>i. All State hospitals</b> (Both HPLC and CE methods except in HTF Kangar only 1 as first line method. Samples with variants detected will be referred to HSB for 2nd line method verification)
HAEMATOLOGY	IMMUNOPHENOTYPING (FLOWCYTOMETRY): Immunophenotyping for leukaemia, lymphoma and other haematological disorders and cell enumerations (including CD4/CD8 enumeration).	<b>HTA</b> (National referral centre),  <b>HPP, HRPB, HSAJB, HRPZII, HQE, HUS</b> (for State level. Other State hospitals depending on justification)	Flowcytometry analyser (Haematology services) Min. 8 -colour system – 1 unit
			Biosafety Cabinet Class II - 1 unit
			Centrifuge, Table top, multiuse (min. 28 – 68 tubes) – 1 unit (for haematology services)
			Blood mixer / vortex - 1 unit

HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
			Pipette: - 1000µL – 2 unit - 200 µL – 2 unit - 100 µL – 2 unit - 20 µL – 2 unit  Haematology analyser (for automated cell counts of IPT samples. May be shared wit routine service within department)
HAEMATOLOGY	Immunophenotyping for CD4/CD8 enumeration	<b>i. All State hospitals</b> (except HTF Kangar - refer to HSB Alor Setar)  <b>ii. Selected Major specialist hospitals</b> (depending on workload & presence of in-house or frequency of visits of ID Physicians): <ul style="list-style-type: none"> <li>• Hospital Sg Buloh</li> <li>• Hospital Kajang</li> <li>• HOSHAS Temerloh</li> </ul>	CD4/CD8 analyser. Dedicated for CD4 absolute enumeration and percentage. Bench top.  Number of analyzers and throughput would depend on the workload Min. number: i. 1 unit (if testing 100 samples per day or less) <b>OR</b> ii. 2 units (testing more than 100 samples per day) iii. lab with minimal number of workload (less than 5 per day) will outsource to the nearest referral lab
	SPECIALISED HAEMOSTASIS & THROMBOSIS: i. Basic Specialized Tests: <ul style="list-style-type: none"> <li>• Factor VIII &amp; IX activity assay</li> <li>• Factor VIII &amp; IX inhibitor assay</li> <li>• LA testing</li> </ul>	<b>All State hospitals:</b> <b>HTF Kangar, HSB Alor Setar, HPP, HRPB, HTAR, HTA KL, HTJS, HM, HSAJB, HTAA, HSNZ KT, HRPZII, HUS, HQE</b>	High Throughput Fully Automated Coagulometer  (PT > 200 tests/hour, APTT > 150 tests/hour) - 2 unit  Table top Centrifuge - 2 unit  37°C Water bath (22 L) - 1 unit  Medical Laboratory Refrigerator - 2 unit  Medical Lab Freezer (-30°C) – 1 unit  Pipette 10 – 100 µL (2 units)  Pipette 50 – 200 µL (2 units)  Pipette 100 – 1000 µL (2 units)  Pipette 1000-5000 µL (2 units)  Vortex – 1 unit  Mechanical stopwatch – 1 unit  Timer – 1 unit

HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
HAEMATOLOGY	i. VWF profile & Platelet Aggregation Test/ PAT (in addition to Basic Specialized Tests)	Future plan: Regional centres: <b>HPP, HSNZ, HSAJB, HUS &amp; HQE</b> (PAT only in HUS and HQE due to logistic reason and low volume test)	High Throughput Fully Automated Coagulometer (PT > 200 tests/hour, APTT > 150 tests/hour) - 2 unit (*minimum of 1 unit equipped with automated platelet aggregation capacity) ELISA Plate Shaker & Reader - 1 unit Table top Centrifuge - 2 unit 37°C Water bath (22 L) - 1 unit Medical Laboratory Refrigerator - 2 unit Medical Lab Freezer (-30°C) - 1 unit Medical Lab Freezer (-80°C) - 1 unit Pipette 5 µL (2 units) Pipette 10 – 100 µL (2 units) Pipette 50 – 200 µL (2 units) Pipette 100 – 1000 µL (2 units) <i>Pipette 1000-5000 µL (2 units)</i> 8 channels micropipette -1 unit Vortex – 1 unit Mechanical stopwatch – 1 unit Timer – 1 unit
HAEMATOLOGY	SPECIALISED HAEMOSTASIS & THROMBOSIS: III) Advanced Specialized Tests: • VWF Profile • Rare Coagulation Factor Activity Assay • Platelet Aggregation Test • Antiphospholipid Antibodies (ACA & Anti-β2GP1) • Heritable Thrombophilia Tests (Protein C, Protein S, Antithrombin and APCR)	<b>PDN</b> (National referral centre)  Future plan: <b>HTA</b> (Referral centre for Haemostasis & Thrombosis)	High Throughput Fully Automated Coagulometer (PT > 200 tests/hour, APTT > 150 tests/hour) - 2 unit (*minimum of 1 unit equipped with automated platelet aggregation capacity) Medium Throughput Fully Automated Coagulometer (PT > 100 tests/hour, APTT > 100 tests/hour) - 1 unit Platelet Aggregometer with assessment of platelet function release Fully Automated Open System ELISA

HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
	(in addition to Basic Specialized Tests)		Fully Automated Immunoassay Analyzer for Antiphospholipid Antibodies Flowcytometer (min 4 colour system) - 1 unit ELISA Plate Shaker & Reader - 1 unit Tabletop Centrifuge - 2 unit Tabletop Refrigerated Centrifuge - 1 unit 37°C Water bath (22 L) - 2 unit Medical Laboratory Refrigerator - 3 unit Medical Lab Freezer (-30°C) - 1 unit Medical Lab Freezer (-80°C) - 2 unit Pipette 5 µL (3 unit) Pipette 10 – 100 µL (3 unit) Pipette 100 – 1000 µL (6 unit) Pipette 1000-5000 µL (3 unit) 8 channels micropipette -1 unit Vortex - 1 unit Mechanical stopwatch - 2 unit Timer – 2 unit
HAEMATOLOGY	SPECIALISED HAEMOSTASIS & THROMBOSIS: IV) Molecular analysis for Haemophilia	<b>PDN</b> (for Molecular Haemophilia A) <b>IMR</b> (for Molecular Haemophilia B) Future plan: <b>IMR</b> to provide all molecular haemophilia service.	Thermocycler Gradient PCR - 2 units Fully Automated High resolution Capillary Electrophoresis System Nanodrop spectrophotometer Biosafety cabinet - 1 unit Medical Laboratory Refrigerator - 2 unit Medical Lab Freezer (-20°C) - 1 unit Medical Lab Freezer (-80°C) - 1 unit Thermoblock Minicentrifuge - 1 unit Microcentrifuge - 1 unit Vortex Mixer - 2 units Analytical Balance - 2 units Multichannel pipettor 10µl - 1 unit

HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
HAEMATOLOGY	MOLECULAR HAEMATOLOGY:  i. MOLECULAR HAEMATO-ONCOLOGY  <ul style="list-style-type: none"> <li>• Mutation/translocation detection in leukaemia</li> <li>• BCR-ABL1 Qualitative</li> <li>• BCR-ABL1 Quantitation</li> <li>• AML mutation</li> <li>• Chimerism</li> </ul>	<b>IMR</b> (except BCR-ABL1 quantitation)  <b>HTAKL</b> (except AML mutation)  <b>Hosp. Ampang</b> (Makmal Haematologi Klinikal)  <b>HPP</b> } BCR-ABL1 <b>HSAJB</b> } quantitation  Future plan: <b>HQE</b>	Multichannel pipettor 20µl - 1 unit
			Multichannel pipettor 30µl - 1 unit
			Micropipetter 0.1 - 2 µl - 1 unit
			Micropipetter 2 - 10 µl - 1 unit
			Micropipetter 2 - 20 µl - 1 unit
			Micropipetter 2 -100 µl - 1 unit
			Micropipetter 2 - 200 µl - 1 unit
			Micropipetter 100 -1000 - 1 unit
			Automated RNA Extraction System (low throughput) - 1 unit
			Automated DNA Extraction System (low throughput) - 1 unit ( <i>for tests using DNA</i> )
			Low throughput Microvolume Spectrophotometer + PC - 1 unit
			High throughput Microvolume Spectrophotometer + PC - 1 unit ( <i>for high workload</i> )
			Automated PCR Assay - 1 unit ( <i>for high workload</i> )
			Thermal-cycler - 2 units
			Real Time PCR - 1 unit
			Automated system: Automated Gel Electrophoresis / Automated Gel Hybridization / Reverse Dot Blot - 1 unit – ( <i>depending on method used</i> )
			Horizontal electrophoresis system - 2 unit
Automated Gel Imaging Capture System - 1 unit			
Biosafety Cabinet (Class III) – 1 unit			
PCR Cabinet - 3 units ( <i>additional 2 units if involve tests using DNA</i> )			
Refrigerated centrifuge with 2 rotor - 1 unit			
Microcentrifuge with 2 rotor - 3 unit			
Miniature Microcentrifuge (With 2 rotor) – 4 units ( <i>additional 2 units if involve tests using DNA</i> )			
Vortex mixer - 4 units ( <i>additional 2 units if involve tests using DNA</i> )			
96 well plate mixer - 1 unit			

HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
			Blood Rotator - 1 unit
			Heater block - 2 units
			Sets of pipettes (various volumes) with carousels - 4 units (additional 2 units if involve tests using DNA)
			Multichannel pipette:
			- 10 µL - 1 unit
			- 100 µL - 1 unit
			Electronic pipette - 1 unit
			Dispenser (various volume) - 1 unit
			Medical Lab Freezer -30°C - 2 units
			Biomedical Freezer -80°C - 1 unit
			Medical Lab Fridge 2-8°C - 3 units
			Centralised temperature monitoring system for fridge & freezer (logger temperature min/ max)
			Thermohygrometer
			Autoclave - 1 unit
			Microwave Oven - 1 unit
			Ice maker - 1 unit
			Analytical Balance - 1 unit
			pH meter - 1 unit
			Water bath - 1 unit
			High-capacity ultra-pure water system - 1 unit
			<b>FOR REFERRAL LABORATORY</b>
			Next Generation Sequencer (NGS) - 1 unit
			Sanger Sequencer - 1 unit
			Flourospectrophotometer - 1 unit
			Automated Purification System - 1 unit
HAEMATOLOGY	ii. NON-MALIGNANT MOLECULAR HAEMATOLOGY  Thalassaemia/ Haemoglobinopathy <ul style="list-style-type: none"> <li>• Alpha thalassaemia</li> <li>• Beta thalassaemia</li> </ul>	<b>HSB</b> Alor Setar (Northern zone for Alpha thalassaemia)  <b>IMR</b> (Referral centre for beta thalassaemia, Haemoglobinopathy and alpha thalassaemia)	<b>I. DNA EXTRACTION:</b>  <b>1. Automated extraction:</b> Automated System ( <i>high/low throughput depending on workload</i> )  <b>2. Manual DNA extraction:</b> Set of Micropipette with Carousel

HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
	<ul style="list-style-type: none"> <li>Haemoglobinopathy</li> </ul> Red cells enzyme disorders	other than common alpha globin gene mutation done in HKL & HSB)  Future plan: <b>HKL</b> - G6PD molecular tests. - Referral centre for alpha thalassaemia, beta thalassaemia and haemoglobinopathy (Molecular testing for beta thalassaemia and haemoglobinopathy will be offered to Peninsular Malaysia, Sabah and Sarawak in stages under RMK12)	Microcentrifuge -1 unit Heater blocks - 2 unit Vortex mixer- 2 unit Blood rotator - 1 unit PCR cabinet - 1 unit <b>II. DNA QUANTIFICATION /DNA PURITY ANALYSIS</b> Microvolume Spectrophotometer (high/low throughput depending on workload) 8-channels micropipette (high workload) Micropipette (low workload) Fluorospectrophotometer/ Fluorometric Assay Systems <b>III. PRE PCR ASSAY PREPARATION:</b> <b>1. Automated Pre-PCR Assay Preparation:</b> Automated Pre-PCR Assay System - 1 unit 96 well plate mixer - 2 unit Plate centrifuge -1 <b>2. Manual Pre-PCR Assay Preparation</b> Miniature microcentrifuge - 1 unit Vortex mixer- 2 unit Set of micropipette with carousel PCR cabinet - 1 unit <b>III. PCR (GENE AMPLIFICATION)</b> Thermal-cycler- 2 unit <b>IV. POST PCR (depend on method used/selected)</b> <b>1. Automated system</b> ( <i>depend on method used/ selected</i> ): Automated Gel Electrophoresis ( <i>throughput depending on workload</i> ) / Automated Hybridization / Reverse dot blot System <b>2. Manual technique</b>

HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
			Automated Gel Imaging Capture system - 1 unit
			Horizontal electrophoresis system - 2 unit
			Set of pipettes -2 unit
			8-channels micropipette-1 unit
			Waterbath - 1 unit
			Analytical balance - 1 unit
			Microwave oven - 1 unit
			<b>Other equipment:</b>
			Medical Lab Freezer -20°C – 2 unit (reagent and DNA sample)
			Medical Lab Freezer -80°C – 1 unit
			Medical Lab Fridge – 2 unit (reagent and blood sample)
			Autoclave - 1 unit
			Ice maker - 1 unit
			pH meter - 1 unit
			Deioniser / RO water purification system
			Logger temperature and Min-Max
			Thermohygrometer
			Biohazard Safety Cabinet Class II-1 unit (if necessary)
			<b>SEQUENCING (Referral lab only)</b>
			Automated purification system-1 unit
			Sanger sequencing analysis-1 unit
			Next Generation Sequencing (Targeted/ Whole Genome Sequencing system) - 1 unit
<i>Equipment for malignant &amp; non- malignant molecular haematology (including for Haemophilia) will be shared where and when possible if both the scopes for molecular haematology are available within the same laboratory area in the hospital.</i>			
HAEMATOLOGY	BONE MARROW CYTOGENETICS: Testing for malignant haematological disorders	HTAKL (National referral centre for cytogenetics and molecular genetics including bone marrow for malignant haematological disorder)  HPP (Northern zone)	Biosafety cabinet – 1 unit
			Fume hood – 1 unit
			Haemocytometer – 2 unit
			Incubator – choice of normal or CO2 incubator – min. 1 unit (depending on workload)



HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
		<p><b>Hospital Ampang</b> (Makmal Haematologi Klinikal)</p> <p>Future plan:</p> <ul style="list-style-type: none"> <li>• <b>HQE/HWKK</b> Likas (Sabah)</li> <li>• <b>HUS</b> (Sarawak)</li> <li>• <b>HSA/HSI</b> (Southern zone)</li> </ul>	<p>Centrifuge (swing out - to fit culture tube size 110x16mm) -1 unit</p> <p>Brighfield Microscope (10x, 40x &amp; 100x Objectives)- 2 unit</p> <p>Medical lab refrigerator 4°C</p> <p>Medical lab freezer -20°C</p> <p>Environment Controlled Chamber - 1 unit</p> <p>Hot plate – 1 unit</p> <p>Microscope with attached camera and cytogenetic software for automated metaphase image capturing. Minimum 1 unit (depending on workload and capacity of the automated system)</p> <p>Workstations-PC with software for cytogenetic karyotyping and analysis – minimum 2 units (depending on workload)</p> <p>England Finder - 1 unit</p> <p>Network Printer - 1 unit</p> <p>Waterbath - 1 unit</p> <p>Denaturation/Hibridization system - 1 unit</p> <p>Fluorescence Microscope with FISH capturing and analysis software system - 1 unit</p> <p>Workstations-PC with FISH analysis software – min. 1 unit.</p> <p>Microcentrifuge ( to fit for 0.5 -2 ml tubes)</p>
	<p>HAEMOPOIETIC STEM CELL (HSC) LABORATORY SERVICE:</p> <ul style="list-style-type: none"> <li>• CD34 enumeration</li> <li>• HSC cryopreservation</li> <li>• T cell cryopreservation</li> <li>• Buffy Coat enrichment</li> <li>• RBC depletion</li> <li>• Plasma depletion</li> <li>• CD34 selection</li> </ul>	<p><b>HTAKL</b> <b>HWKK Likas</b></p> <p>Future plan: HPP</p>	<p>The lab requires 2 connected rooms namely:</p> <ol style="list-style-type: none"> <li>1.Processing room</li> <li>2. Stem cell storage room, and</li> <li>3. Clean Room facility with HEPA filter if the lab offers CD34 selection and T cell / B cell depletion or more complicated procedure.</li> </ol> <p><b>1. Processing room:</b> Biosafety Cabinet Class 2 (Ductless) - 1 unit Refrigerated Centrifuge (for blood bag) - 1 unit Balance - 1 unit</p>

HAEMATOLOGY			
Discipline	Scope of special test	Location	Equipment
	<ul style="list-style-type: none"> <li>• TCRαβ/B cell depletion</li> <li>• Chimerism assay for engraftment (performed using Molecular Laboratory facilities)</li> </ul>		Biosealer - 1 unit Portable hand sealer - 2 unit Sterile tubing welder - 1 unit Rotator suspension - 1 unit Cell Separator (COBE 2991) or equivalent - 1 unit
			<b>2. Stem cell storage room :</b> Controlled rate freezer - 1 unit Ultra-low freezer -80°C - 1 unit Liquid nitrogen freezer - 1 unit Liquid nitrogen supply tank - 1 unit
			<b>3. Clean Room facility with HEPA filter :</b> Biosafety Cabinet Class 2 (Ductless) - 1 unit Refrigerated Centrifuge (for blood bag) - 1 unit Balance - 1 unit Biosealer - 1 unit Portable hand sealer - 2 unit Sterile tubing welder - 1 unit Magnetic separator - 1 unit (optional depend on service offered)
			4 colour flowcytometer (may be shared with FCM service within department)
			Haematology analyser (may be shared with routine service within department)

MICROBIOLOGY			
Discipline	Scope of special test	Location	Equipment
MICROBIOLOGY	Molecular Microbiology for bacteriology, virology, mycology and parasitology	All State hospitals, regional hospitals, HKL	Biosafety Cabinet Class 2 - 2 unit
			PCR workstations - 2 units
			DNA/RNA Extraction System - 2 units
			Liquid handling system - 1 unit
			Real time PCR thermal cycler - 2 units
			Medical Lab Fridge 1400 L (2-8°C) - 2 Units
			Freezer -10°C to -30°C -2 units
			Freezer 400L -70°C to - 100°C - 2 units
			Refrigerated microcentrifuge – 2 unit
			Microcentrifuge - 2 units
			Heat block - 2 unit
			Vortex - 3 units
			Mini spin - 2 units
			Ice maker - 1 unit
	Single channel pipette - 24 units		
Multichannel pipette - 1 unit			
	<i>M. tuberculosis</i> detection and resistance	Regional tuberculosis centres	Automated Nucleic Acid Amplification System
	Regional for anaerobic isolation, identification and sensitivity testing reference laboratory	All State hospitals, regional hospitals, HKL	Anaerobic culture workstation - 1 unit

GENETIC PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
GENETIC PATHOLOGY	General	Hospital Tunku Azizah (HTA), Kuala Lumpur	Temperature Monitoring System - 1 unit
	General	HTA	Logger Temperature - 2 units
	General	HTA	Medical Lab Fridge 4°C - 1 unit
	General	HTA	Centrifuge, benchtop - 1 unit
	General	HTA	Deioniser/ Water purification System - 1 unit
	General	HTA	Water distiller 8L/hr - 1 unit
	General	HTA	Autoclave 65L - 1 unit Dry Oven - 1 unit
GENETIC PATHOLOGY	Molecular Genetics	HTA	Automated DNA Extraction Machine - 1 unit
	Molecular Genetics	HTA	PIPETTE  Micropipette: - 1000µL - 5 units - 200 µL - 5 units - 100 µL - 5 units - 20 µL - 5 units - 10 µL - 5 units - 2µL - 5 units  Multichannel pipette: - 100 µL - 2 units - 200 µL - 2 units
	Molecular Genetics	HTA	Biohazard Safety Cabinet (Class III) - 1 unit
	Molecular Genetics	HTA	Microcentrifuge - 2 units
	Molecular Genetics	HTA	Centrifuge, Table top, refrigerated multiuse (min 28 - 68 tubes) - 1 unit
	Molecular Genetics	HTA	Microcentrifuge, Table top, refrigerated multiuse - 1 unit
	Molecular Genetics	HTA	Plate Centrifuge, Refrigerated
	Molecular Genetics	HTA	Thermal-cycler - 5 Units
	Molecular Genetics	HTA	Medical Lab Freezer -20°C - 1 unit
	Molecular Genetics	HTA	Biomedical Freezer -80°C - 2 units
	Molecular Genetics	HTA	Medical Lab Fridge 4°C - 1 unit
	Molecular Genetics	HTA	Nanodrop spectrophotometer - 2 units
	Molecular Genetics	HTA	PCR Cabinet - 3 units
	Molecular Genetics	HTA	Autoclave - 1 unit
	Molecular Genetics	HTA	Microwave Oven - 1 unit

GENETIC PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
	Molecular Genetics	HTA	Machine ice flacking – 1 unit
	Molecular Genetics	HTA	Heat block - 2 units
	Molecular Genetics	HTA	Vortex mixer - 2 units
	Molecular Genetics	HTA	Water bath (22L) - 1 unit
	Molecular Genetics	HTA	Fume Hood - 1 unit
	Molecular Genetics	HTA	Deioniser / RO Water purification system - 1 unit
	Molecular Genetics	HTA	Dry Oven (400L) - 1 unit
	Molecular Genetics	HTA	D HPLC machine - 1 unit
	Molecular Genetics	HTA	COBAS System for EGFR - 1 unit
	Molecular Genetics	HTA	Refrigerated Plate Centrifuge - 1 unit
	Molecular Genetics	HTA	Electrophoresis Gel System with Imager - 1 unit
	Molecular Genetics	HTA	Sequencer - 1 unit
	Molecular Genetics	HTA	Plate Shaker - 1 unit
	Molecular Genetics	HTA	Universal Power Supply (UPS) - 5 units
	Molecular Genetics	HTA	Realtime PCR Machine - 1 unit
	Molecular Genetics	HTA	Transgenomic Wave Machine - 1 unit
	Molecular Genetics	HTA	Chamber Hybridization Oven - 1 unit
	Molecular Genetics	HTA	Microwave - 1 unit
	Molecular Genetics	HTA	Array CGH Scanner - 1 unit
	Molecular Genetics	HTA	Ozone free chamber - 1 unit
	Molecular Genetics	HTA	DNA Concentrator - 1 unit
	Molecular Genetics	HTA	Small Waterbath for Array - 1 unit
	Molecular Genetics	HTA	Bioanalyzer Instrument - 1 unit
	Molecular Genetics	HTA	Next Generation Sequencing System for Targeted Sequencing - 1 unit
Molecular Genetics	HTA	Next Generation Sequencing System for Whole Genome Sequencing System - 1 unit	
GENETIC PATHOLOGY	Cytogenetics	HTA	System Server – 1 unit
	Cytogenetics	HTA	Metaphase capture system – 3 units
	Cytogenetics	HTA	Metaphase analysis system – 5 units
	Cytogenetics	HTA	FISH capture system – 1 unit
	Cytogenetics	HTA	Automated capture system – 1 unit
	Cytogenetics	HTA	Network printer

GENETIC PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
	Cytogenetics	HTA	Slide file cabinet – 60 units
	Cytogenetics	HTA	Light microscope BX60 – 8 units
	Cytogenetics	HTA	Microscope Pathology Grade – 3 units
	Cytogenetics	HTA	Micropipette: - 1000µL – 5 units - 200 µL – 5 units - 100 µL – 5 units - 20 µL – 5 units - 10 µL – 5 units - 2µL – 5 units
	Cytogenetics	HTA	Automated hybridizer – 1 unit
	Cytogenetics	HTA	Hybridization Instrument (Hybrite) - 2 units
	Cytogenetics	HTA	Automated harvester – 1 unit
	Cytogenetics	HTA	Biohazard Safety Cabinet (Class III) – 1 unit
	Cytogenetics	HTA	Serological pipette electronic controller – 2 units
	Cytogenetics	HTA	CO2 Incubator - 1 unit
	Cytogenetics	HTA	Centrifuge – 2 units
	Cytogenetics	HTA	Dry oven – 1 unit
	Cytogenetics	HTA	Medical Lab Fridge 4°C – 2 units
	Cytogenetics	HTA	Medical Lab Freezer -20°C – 5 units
	Cytogenetics	HTA	Fume Hood – 1 unit
	Cytogenetics	HTA	Vortex mixer – 1 unit
	Cytogenetics	HTA	Microcentrifuge, – 1 unit
	Cytogenetics	HTA	Water bath (22 L) -1 unit
	Cytogenetics	HTA	Magnetic stirrer – 1 unit
	Cytogenetics	HTA	Analytical balance – 1 unit
	Cytogenetics	HTA	pH/ temp meter digital – 1 unit
	Cytogenetics	HTA	Water distiller 4L/hr – 1 unit
GENETIC PATHOLOGY	Biochemical Genetics	HTA	Refrigerator • Refrigerator Lab Single Glass Door 9CF (255L) 2° - 14°C: 3 units
	Biochemical Genetics	HTA	Freezer • Freezer Medical 7.4CF (210L) -20 - 40°C: 1 unit • Medfrez freezer: - 86°C : 1 unit

GENETIC PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
	Biochemical Genetics	HTA	Filtration Set with Pump: 1 unit
	Biochemical Genetics	HTA	Fume Hood • Fume Hood Ducted 1200 mm length with SSO Water: 4 units
	Biochemical Genetics	HTA	Cabinet Biosafety • Cabinet Biosafety Class II Type B2 (Ducted) 1420: 1 unit
	Biochemical Genetics	HTA	Nitrogen Gas Generator • Nitrogen Gas Generator Simplex: 3 units • Nitrogen Gas Generator Duplex: 1 unit
	Biochemical Genetics	HTA	Micropipettes: single channel • 100-1000: 7 units • 10-100: 7 units • 20-200: 2 units • 2.0-20: 4 units • 0.5-10: 3 units  Micropipes: multichannel • 15-300: 1 unit • 5µL - 100µL: 1 unit • 1200 (HKL) 1 unit • 30 - 300: 1 unit
	Biochemical Genetics	HTA	pH meter • Handy Lab (SI analytical): 2 units
	Biochemical Genetics	HTA	Balance • Balance Top Loading Electronic 10mg Maximum Capacity 2500g: 1 unit • Balance Analytical 0.1mg 200g: 1 unit
	Biochemical Genetics	HTA	Centrifuge • Microcentrifuge 12 Place, 13,000RPM – Mini: 2 units • Microcentrifuge 14,000 RPM - 1-5 ml Max: 2 units • Ultracentrifuge Floor Model: 1 unit • Centrifuge Benchtop 4 Rotor Capacity 10ml - 2400ml: 1 unit • Microcentrifuge with 2 Rotors, 17,000 RPM: 2 units • Kubota 4000: 1 units • Kubota 4200: 2 units
	Biochemical Genetics	HTA	• Sample Concentrator with Dry - Block - Nitrogen Gas 15 LPM 2 psi Max: 1 unit
	Biochemical Genetics	HTA	• Dryer - Plate with Shaker: 1 unit

GENETIC PATHOLOGY			
Discipline	Scope of special test	Location	Equipment
	Biochemical Genetics	HTA	Waterbath • Waterbath Lab 14L 100°C with SS Cover: 1 unit • Waterbath Shaking 10L 99°C with Cover 1 unit
	Biochemical Genetics	HTA	• Stirrer lab magnetic with Hot Plate: 3 units
	Biochemical Genetics	HTA	• Heater Dry Block 40 Tube: 1 unit
	Biochemical Genetics	HTA	• Shaker/ Rotator 3D Gyrotory Motion: 1 unit
	Biochemical Genetics	HTA	Homogeniser • Homogeniser for Large Biopsy 20l: 1 unit • Homogeniser for Tissue: 1 unit
	Biochemical Genetics	HTA	• Sonicator Wave 20 kHz 55watt: 1 unit
	Biochemical Genetics	HTA	• Spectrometer Tandem Mass (LCMS/ MS) for Neonatal Screening: 1 unit
	Biochemical Genetics	HTA	• Bio-Samples Dried (BSD) Automated Puncher: 1 unit
	Biochemical Genetics	HTA	• Chromatography Gas/ Mass Spectrometry System (GCMS): 2 units
	Biochemical Genetics	HTA	• Amino Acid Analyser with Auto sample: 2 units
	Biochemical Genetics	HTA	• UHPLC with PC: 1 unit
	Biochemical Genetics	HTA	• Analyser Biochemistry 180 Test/ Hour 1 unit
	Biochemical Genetics	HTA	• Spectrophotometers UV/Vi: 1 unit



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## ABBREVIATIONS

ABBREVIATIONS	DEFINITION
AP	Anatomic Pathology
ASHE	American Society for Healthcare Engineering
BER	Beyond Economic Repair
CSF	Cerebrospinal Fluid
DOA	Drug of Abuse
DSM	Department of Standards Malaysia
EQA	External Quality Assurance
FBP	Full Blood Picture
FISH	Fluorescence In-Situ Hybridisation
FNAC	Fine Needle Aspiration Cytology
GCMS	Gas chromatography/Mass Spectrometry
Hb	Hemoglobin
HCW	Healthcare Worker
HOD	Head of Department
HOU	Head of Unit
HTAKL	Hospital Tunku Azizah Kuala Lumpur
HTF	Hospital Tuanku Fauziah
HPE	Histopathological Examination
IEC	International Electro Technical Commission
IEM	Inborn Error Metabolism
IMR	Institute of Medical Research
IQC	Internal Quality Control
ISO	International Organization for Standardization
IT	Information Technology
JCI	Joint Commission International
KKM	Kementerian Kesihatan Malaysia
HIS	Health Information System
LIS	Laboratory Information System
LTAT	Laboratory Turn Around Time
MDA	Medical Device Act
MLT	Medical Laboratory Technologist
MO	Medical Officer
MOH	Ministry of Health
MTB	Mycobacterium Tuberculosis
MS	Malaysian Standard

ABBREVIATIONS	DEFINITION
NATA	National Association of Testing Authorities Australia
NIA	National Indicator Approach
OT	Operation Theatre
PCR	Polymerase Chain Reaction
PKKN	Pusat Kawalan Kusta Negara
POCT	Point of Care Testing
PPK	Pembantu Perawatan Kesihatan
PTJ	Pusat Tanggungjawab
QA	Quality Assurance
QAP	Quality Assurance Programme
QMS	Quality Management System
R&D	Research and Development
SME	Subject Matter Expert
SO	Science Officer
TAT	Turn Around Time
TDM	Total Drug Monitoring
TOR	Term of Reference



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(2nd Edition)

**MEDICAL DEVELOPMENT DIVISION  
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ISBN 978-967-2634-80-5



9 78 967 2634 80 5