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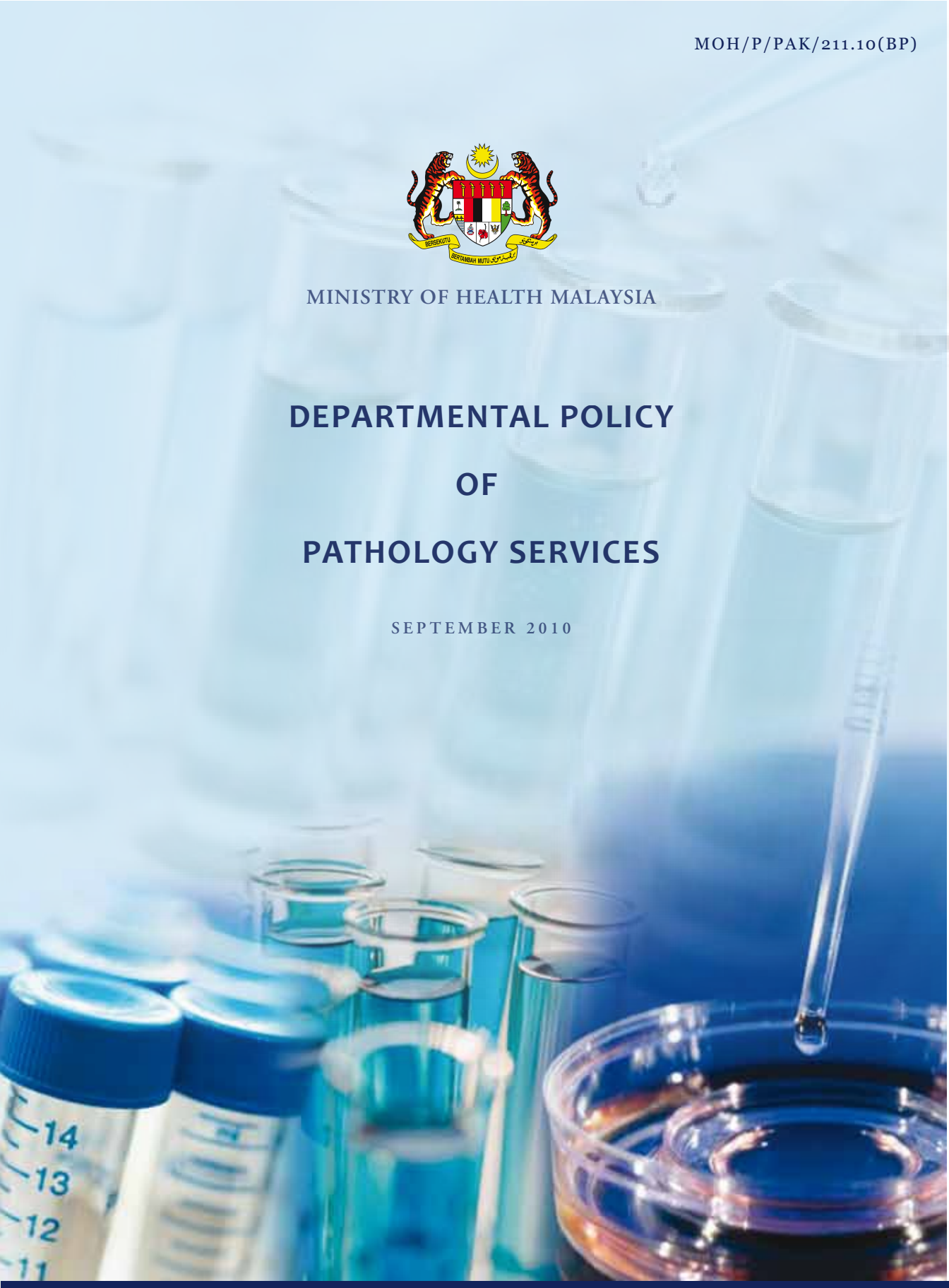
MINISTRY OF HEALTH MALAYSIA

DEPARTMENTAL POLICY

OF

PATHOLOGY SERVICES

SEPTEMBER 2010



CLINICAL SUPPORT SERVICES UNIT
MEDICAL DEVELOPMENT DIVISION

DEPARTMENTAL POLICY OF PATHOLOGY SERVICES

MEDICAL DEVELOPMENT DIVISION

MINISTRY OF HEALTH MALAYSIA

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The document outlines optimal achievable standards in accordance with best practices and guidelines.

Acknowledgement

Medical Development Division would like to acknowledge its grateful appreciation to the professional and technical staff of the Department of Pathology who have contributed in one way or another to the publication and development of this document.

CONTENT

FOREWORD

DIRECTOR GENERAL OF HEALTH MALAYSIA

Pathology Services are essential services provided by clinics and hospitals to help clinicians in the diagnosis and management of a disease as well as determine its prognosis.

Advancements in the field of medicine, in tandem with the rapid changes in technologies, necessitates the implementation of standard operational procedures in the various diciplines. Comprehensive national policies set forth the appropriate approaches toward realizing the Vision and Mission of the Ministry of Health, Malaysia.

Operational policies are intended to assist organizations to work in an orderly manner so that better services are delivered to the public. The Pathology Services Operational Policy is a comprehensive policy and procedure manual that outlines all service aspects of the Pathology Department. This policy will serve as a guide for all those involved in the provision of pathology services and help them provide better quality services for their clients.

I would like to congratulate the Medical Development Division of the Ministry of Health and the working committee for their commitment in developing this document which sets the standard for laboratory services in the Ministry of Health.

Tan Sri Dato' Seri Dr. Hj Mohd Ismail Merican

DEPUTY DIRECTOR GENERAL OF HEALTH MALAYSIA (MEDICAL)

Medical 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 Pathology Operational Policy will be able to provide information on the basic and specialized services that are provided at the hospitals.

I would like to take this opportunity to congratulate the Medical Development Division 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.

Datuk Dr. Noor Hisham Abdullah

NATIONAL ADVISOR OF PATHOLOGY SERVICES

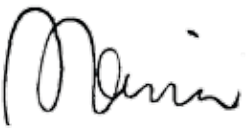
The universal need to convert an expanding mass of raw laboratory data into accessible, cost effective and clinically usable information has continued to be a matter of increasing significance throughout the medical community. The need for expeditious and unencumbered information has been confirmed in the daily practice of clinical Pathology and also in discussions with physicians. Laboratory tests are part of most patient-physician encounters and contribute greatly to the selection of additional diagnostic procedures. They often precede the history and physical examination.

The department has developed from a simple municipal set up into a modern multidisciplinary centre providing state of the art diagnostic, teaching and research services in Malaysia. Many of our clinical laboratories have been accredited by NATA, adopting Joint Committee International (JCI) standards internationally and the Department of Standards Malaysia (DSM), locally.

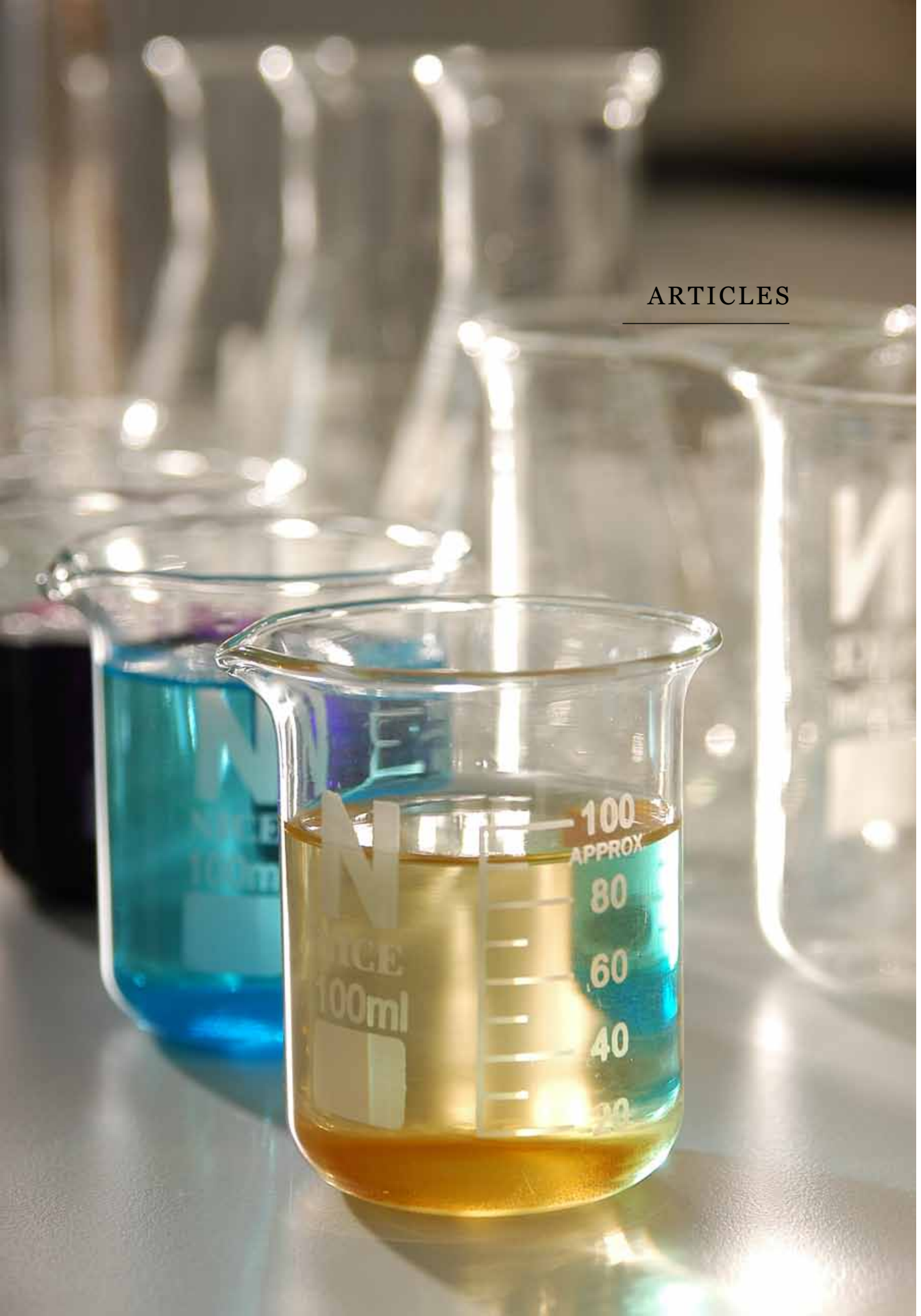
I am thankful and greatly indebted to all my colleagues in various parts of the hospital who shared with me their valuable experience in handling clinical and laboratory problems and encouraged the development of this document.

I am very grateful to the secretariat at the Medical Development Division, Ministry of Health Malaysia, whose insightful advice and dedicated efforts in editing this document were essential to its completion.

I hope you will find the information given in this edition of our Departmental Policy for Pathology Services in the Ministry of Health Hospitals to be useful. I look forward to continuing our partnership in the provision of optimal care to our patients.



Dato' Dr. Norain Karim



ARTICLES

1. GENERAL POLICY

Laboratory services in MOH hospitals are performed in Pathology laboratories. Point of care testing may be allowed in critical care areas and other areas, for tests that are required for immediate patient management and technological sound.

1.1 Services

a) Basic and specialized services are provided in hospital laboratories according to the category of the hospital as administratively classified by MOH. (Refer to Appendix 1 and 2).

b) Regionalization or centralization of services shall be based on tests that have low workload and are specialized, expensive and need highly skilled laboratory personnel.

c) Out-sourcing of the tests shall be between government laboratories. If this is not possible the out-sourcing of services should be arranged with accredited or technically competent private laboratories. The laboratory shall be responsible for out-sourcing according to a standardized or national Pathology outsourcing policy.

d) Proposals for new programs shall be submitted to the State Pathologist, heads of relevant disciplines, National Pathology Advisor and the Medical Development Division. All new programs submitted for approval must be sustainable through continued funds, trained manpower and relevant regular technical/ refresher courses and updates.

e) Hospitals planning for new tests shall notify and get approval from the State Pathologist and the Heads of the relevant Disciplines.

f) Point of Care Testing (POCT) services shall be implemented in consultation with the Pathologist or the Scientific Officer in charge

of the laboratory in the absence of a Pathologist. A POCT committee shall be formed in each organization. A Pathologist or designee shall be the secretary or coordinator for the committee. The laboratory shall take active role in monitoring quality performance and training of staff involved in these services.

1.2 Organization

1.2.1 National Level

a) The Medical Development Division is responsible for the overall planning and development of Pathology services in all MOH hospital laboratories in Malaysia. It shall be assisted by the State Pathologists, the Heads of Disciplines, Coordinators of Elements and the National Pathology Advisor. (Refer to Appendix 4)

b) National Heads of Disciplines shall be appointed for each Pathology discipline and are responsible for planning the development of the respective services, standardizing of practices, monitoring quality performance and taking remedial actions, proposing resources required and training initiatives in the respective disciplines.

c) Coordinators of Elements shall be responsible for the respective tasks given to them and may encompass across different disciplines.

d) The State Pathologist is responsible for ensuring all policies and procedures are implemented in all laboratories in MOH hospitals under his care, monitor the Quality performance and take appropriate action, coordinate training and propose required resources. They are also the technical advisors for the laboratory services in the health clinics in their respective states. They are also expected to arrange regular meetings at state level which are to be chaired by the state health director.

e) All State Hospital laboratories are to be headed by the most senior Pathologists, who will also act as the State Pathologists. He shall be assisted by the Heads of Units of the various disciplines.

f) Hospital Laboratories without Pathologists shall be headed by a resident Medical Officer trained in laboratory services.

g) Non specialist Hospital laboratories may be headed by the most senior Scientific Officer in the absence of a resident Medical Officer trained in laboratory services.

h) Supervisory visits to hospitals without Pathologists shall be conducted by the state Pathologist or designee at least annually and a visit report should be submitted to the National Pathology Advisor.

i) A State Hospital or a major specialist hospital laboratory without a Pathologist in a specific discipline shall have regular supervisory visits conducted by the relevant respective Pathologist from a nearby state major specialist hospital. (Refer to Appendix 5)

1.2.2 Statistics

Data collection for statistical analysis shall follow the latest guidelines on "Standardization of Data Collection for Pathology Services Malaysia"

1.3 Human Resources

a) Following promotional exercises for Scientific Officers and Medical Laboratory Technologists, MOH shall ensure that they are posted/ placed in specialty areas appropriate to their training and experience (of specialty).

b) Distribution of human resources shall depend on the service

needs based on geographic location, subspecialty distribution and workload. (Refer to Appendix 7).

c) Where relevant, the laboratory personnel shall be trained as a team for any new service/ program approved by MOH for the clinical discipline or patient care is concerned.

d) Newly appointed Scientific Officers shall be trained for at least 6 months in state hospitals before being posted to the peripheral laboratories in the same state.

e) Laboratory with LIS shall have IT personnel to manage the system (depends on the size of hospitals - State/major specialist hospitals only).

f) Competency/performance assessment for all technical staff shall be conducted at least once a year.

g) Credentialing and privileging procedures for all technical staff shall be in place.

h) Post graduate and post basic training for all categories of staff shall be in accordance with service needs.

i) Only appropriately qualified staff shall be allowed to perform laboratory work that affects the quality of patient's results.

j) All hospital MLTs are required to perform after hour's duty irrespective of their discipline.

k) SO shall carry out after hour's duty when required.

l) Medical Officers shall be placed in all Pathology disciplines.

m) Laboratory staffs that have left Pathology services for more than three months (for technical staff) need to be retrained and be competent before they are allowed to practice in

Pathology Professional staff not practicing Pathology for more than a year will need to undergo credentialing before practicing Pathology again.

1.4 Service Delivery

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

b) Automation shall replace manual methods where available.

c) Standardization of practices and procedures shall be implemented in all the laboratories where possible.

1.4.1 Pre-analytical

a) Department of Pathology is responsible to provide user manual as a guide for specimen collection, handling and transportation to the laboratory.

b) Tests shall only be requested by an authorized personnel involved in patient management.

c) 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 stability of the analytes. These requests shall be documented noting the person making the request, date and time requested, as well reason for the request.

d) Sample collection
Specimen collection shall follow the guidelines provided by the Pathology Department or any standard text book.

e) Sample Transport
Whenever possible, automated sample delivery e.g. via

pneumatic tube shall be made available. The department is responsible to monitor the transportation condition of the samples to the laboratory to ensure quality of test results is maintained.

f) Reception of Sample and Request Form (PER-PAT 301) in the laboratory;
Compromised samples/ request forms will be rejected by the laboratory. This will not apply for irreplaceable sample or timed sampling in functional tests or any request critical for patient management. In this situation clinical staff is required to verify patient's ID, signature and date in the request form if the rejection is due to inadequate or mismatched patient's ID. All compromised samples that are accepted for testing shall be documented in the patient's result slip and records are kept including the request form. Laboratory shall monitor rejection rate, inform the customer their performance and provide customer education.

1.4.2 Analytical

a) All methods shall be validated prior to use and all data record are kept.

b) The Laboratory must participate in External QA Programme or each test item they offer. When QA programme is unavailable, the national/state Pathology heads shall coordinate inter laboratory comparison programs.

c) Clinical interpretation of test result/report shall only be made by clinically qualified personnel (trained MO or Pathologist).

1.4.3 Post Analytical

a) The laboratory shall notify the ward/clinic of test results exceeding "critical values" that are established at national level.

b) ALL URGENT tests are to be given immediate attention, and results to be informed within the TAT established at National Level.

c) All patient records and specimens are to be retained following national guidelines.

d) All laboratories shall maintain the statistics of workload by tests following the guidelines set at national level Annual statistics are to be compiled by the State Pathologists and sent to the National Pathology Advisor.

e) All referrals for second opinion for tissue Pathology shall be arranged through the Pathologist in charge. Records or specimens shall not be removed from the primary laboratory without the approval of the Pathologist in charge.

1.5 Finance

a) Adequate and timely allocation for replacement of equipment and procurement of new equipment shall be provided (follow national guidelines).

b) Operating budget shall be allocated according to the modified budgeting system.

c) Budget shall also be allocated for outsourcing of services, training and provision of after hour services.

d) Budget should be allocated for external quality assessment and accreditation.

e) Additional allocation shall be provided to the laboratory for test requests not related to patient care.

1.6 Networking and Inter-sectoral Collaboration

a) There shall be active participation and support for research and development, which should be geared towards service needs and service development.

b) An efficient networking system shall be established between the MOH, universities and the private laboratories to ensure equity and accessibility of specialized and sub-specialized Pathology services throughout the country.

1.7 Safety

a) Laboratory safety practices shall comply with the existing laboratory safety requirements and all relevant statutory acts and regulations.

b) All personnel shall be given adequate training in laboratory safety.

2. DISCIPLINES

2.1 Anatomical Pathology

a) Anatomical Pathologists should only be posted to the identified AP Centers according to the norms based on workload 3000 cases. (Refer to Appendix 7)

b) There should not be any solo Anatomical Pathologist at any center.

c) All AP Center shall have at least two SO as well as adequate numbers of MLT and clerical staff based on the centre's workload.

d) Frozen section service must be retained in the major specialist hospitals which have been centralized to the AP centre. Requests for frozen section service shall be on 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 effective communication system.

e) Subspecialty services shall be provided by the regional centers or Central Referral lab, if the specialty is not available in the AP centers.

f) Only trained cyto-technologists shall be posted to the designated gynecological cytology centers.

g) All FNAC procedure can be done either by the Anatomical Pathologists or by trained doctors/clinicians.

h) All clinical autopsies shall be performed with input from a team of doctors, which shall include the Pathologist and clinician managing the case.

i) Training shall be geared towards the needs of the service. All major 16 sub specializations will be developed in phases and

numbers in accordance with the clinical demand.

2.2 Chemical Pathology

a) The service where appropriate shall be delivered in an integrated manner as part of clinical Pathology services.

b) Therapeutic Drug Monitoring service shall be performed in Pathology laboratory.

c) Drug of Abuse Testing shall not be undertaken by Pathology Service. Such testing shall be done by Forensic Service.

d) All tests that deal with numbers and required monitoring of IQC and EQA are to be performed in the chemical Pathology laboratory that can do such discipline-specific interpretation or if this is not possible one Biochemist shall be put in charge and be trained in the specifics for verification of results.

e) All functional tests should be validated by the Chemical Pathologist or MO trained in that area.

f) Lab running immunoassay test shall have at least a senior Biochemist (with more than 3 years guided experience).

2.3 Medical Microbiology

a) All state hospitals shall perform all routine bacteriology, virology, mycology, parasitological, immunology and infection control tests.

b) Culture for bacteriology shall only be done at state hospitals. This service may be provided at major and minor specialist hospitals if resident consultant Pathologists in medical microbiology are available.

2.4 Haematology

a) The cross matching laboratory services shall be managed by the haematologist within the Pathology organization.

b) There shall be a trained Medical Officer placed on a part or full time basis at the laboratory.

3. FUNCTIONAL AREAS

3.1 Facilities & Equipment

3.1.1 General

a) All laboratories in MOH Hospitals shall be equipped with the minimum standard list of equipments based on the level of hospital and workload.
(Refer to Appendix 7 and Appendix 8).

b) All critical equipments shall have a backup unit.

3.1.2 Procurement

a) Procurement of equipment can be made through direct purchase, reagent rental arrangement or donation following the policies and procedures as stipulated by MOH treasury.

b) All proposed procurements shall be submitted to the Head of discipline through the State Pathologist and Jawatankuasa Perolehan Peralatan Perkhidmatan Patologi.

c) All equipment procured shall meet the specifications for standard methodology used for the test to be performed as determined by the Head of Discipline.

d) All equipment procured is to be reported to and registered in the list of equipment kept by Jawatankuasa Perolehan Peralatan Perkhidmatan Patologi.

e) Equipment for replacement shall fulfill the criteria for BER or ASHE guidelines and endorsed by State Pathologist.

f) Procurement through reagent rental shall be based on total annual cost of consumable expenditure, and funded from operational budget.

g) Currently If the total annual cost of reagents/consumables is less than RM500,000 the PTJ can proceed with the procurement by quotation at hospital level, with input from State Pathologist or Head of Discipline.

ii. If the total annual cost is more than RM 500,000 procurement has to be by the tender process at hospital state level and submitted for final approval by the MOH.

iii. The procurement arrangement shall be reviewed on regular basis e.g. every 3 years or accordingly when necessary, and current financial procedures must be complied with.

h) Referral shall be made to State Pathologist or Head of discipline for any equipment donated for its suitability, usage and location. Acceptance of the donation must be in accordance with current MOH Treasury circular.

i) 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.

j) Proper testing and commissioning of all newly acquired equipment must be conducted in the presence of the end-user, SIHAT, support service personnel and supplier, after which the equipment must be entered into the hospitals' assets list.

3.1.3 Maintenance

a) All equipments shall have planned preventive maintenance as a minimum following the manufacturer's recommendation.

b) Specialized equipment shall be maintained and repaired by the vendor or personnel specifically trained for that

particular equipment.

3.1.4 Training

The vendor shall provide training and ensure competency of the laboratory staff before putting the equipment for routine use.

3.2 Human Resource

3.2.1 Personnel

a) All state hospitals should have all major disciplines staffed by adequate and appropriate numbers of Pathologists and Allied Health staff with relevant experience.
(Refer to Appendix 6).

b) Head of Department

i. The Head of Pathology at state hospital laboratories shall be a senior consultant in any discipline in Pathology, and appointed by the hospital/state director.

ii. Pathology laboratory in hospitals with specialists shall be headed by a Pathologist appointed by the hospital state director.

iii. Pathology laboratory in hospitals without specialist shall be headed by a trained Medical Officer in Pathology or senior scientist under the supervision of a visiting Pathologist, as appointed by the hospital director.

c) Head of Unit - A Pathologist heads the relevant discipline. If this is not possible a Pathologist from another discipline may be appointed as Head of Unit.

d) Quality Manager - An appropriate and trained Pathologist or SO shall be employed to manage the QMS in the laboratory (there should be at least one quality manager/

state laboratory).

e) Laboratory Manager – An appropriate and trained Medical Officer / SO shall be employed as manager of the laboratory.

f) Medical Officer – Medical Officers shall be adequate in numbers and appropriately placed in each state hospital, major and minor specialist hospital to cover for all units/ disciplines of Pathology (Refer to Appendix 6).

g) Scientific Officer – SO shall be appointed in all disciplines within the laboratory. SO shall be technical experts in their fields, reporting directly to the HOU / HOD / supervising Pathologist in their respective fields of expertise.

   i. All non-specialist hospital laboratories shall have at least one SO. Remedial refresher training shall be provided to the SO in the fields not related to his experience and training.

   ii. All specialist hospitals shall have at least one SO for each discipline appropriate for the workload.

   iii. All state hospital shall have at least one SO for each discipline in Pathology. The number shall follow the norm/ workload.

h) MLT–All hospitals shall have appropriate number of MLTs in accordance with the norms. There shall be various categories of MLTs in hospital laboratories, minimally as follows:

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

i) Pembantu Perawatan Kesihatan (PPK) – Reception counter should be manned by clerk or PPK. They can also function as personnel for packaging of specimens, dispatch of results and any other extended duties with training.

j) Clerical staff – Clerical staff shall be employed for administrative duties, data and demographic entry and other clerical works.

k) IT personnel – All state and major specialist laboratories shall, where possible employ IT Officers to manage the IT systems.

l) Store keeper – All state and major specialist hospitals shall, where possible employ store keepers in the Pathology Department.

m) Autoclave operator shall be provided in all state and major specialist hospitals.

3.3 Training

3.3.1 General Policy

a) Training for special services shall be on a team approach i.e. planning according to service needs.

b) All categories of staff (Pathologists, Medical Officers, SO, MLT and Infection Control Nurses) in Pathology service should be given opportunity to attend relevant courses during their service period in order to maintain efficiency and competency.

c) All personnel shall be appropriately orientated and trained via pre-training exposure and scheduled educational program.

d) The training of Scientists and MLTs must be relevant and should meet the current demand of the service.

e) Credentialing and privileging program shall be implemented for all categories of laboratory personnel.

3.3.2 Specific

a) Policy for Pathologists

i. Pre-training exposure in chosen area is a must (at least 6 months locally before going for the fellowship abroad).

ii. Training centers (local and abroad) must be identified by the Jawatan Kuasa Fellowship Perkhidmatan Patologi KKM.

iii. Post-training contribution to the discipline i.e. via a service network needs to be established. Regular dissemination of knowledge in the form of workshops or updates or courses shall be organized.

iv. Placement of the trained personnel shall be according to the plan and clinical needs/demands.

b) Policy for Medical Officers

i. As far as possible, all Medical Officers should have at least 6 months working experience in Pathology before posting to peripheral hospitals.

c) Policy for Scientific Officers (SO)

i. All newly employed Scientific Officers shall undergo training at state hospital for a period of 6 months before posting to peripheral hospitals. The training should encompass laboratory management which includes techniques, stringent quality control protocols, budget and equipment procurement.

ii. MOH and the Universities shall design the training program for the Scientific Officers. This should be relevant and shall meet current service needs.

d) Policy for Medical Laboratory Technologists (MLTs

i. All newly employed Medical Laborator Technologists to be posted to Klinik Kesihatan shall undergo training at state hospital for not less than 2 years before the posting. The training should pass laboratory management which includes techniques, stringent quality control protocols, budget and equipment procurement.

3.4 QAP & Accreditation

3.4.1 QA

a) All MOH hospital based medical laboratories must participate in the MOH Laboratory NIA programme without exception.

b) There shall be comprehensive participation of the laboratory in EQA programmes for the scope of services provided.

c) The state Pathologist shall provide direction and leadership in the enhancement and strengthening of the quality activities.

d) The state Pathologist shall ensure participation, monitor performance and coordinate the compilation and submission of the reports for all laboratories under their supervision.

e) The laboratory shall monitor the quality of all point of care testing (POCT) and provide a report to the relevant clinical department for their further action.

3.4.2 Accreditation

a) All medical laboratories in the MOH hospitals are to be accredited to the MS ISO 15189 standard.

b) All accredited laboratories must maintain the MS ISO 15189 accreditation status.

3.5 Information Technology

3.5.1 General

a) All hospital laboratories shall have LIS suitable for the scope of their service. The LIS could be standing alone LIS or part of HIS. The LIS should be able to communicate with each other using relevant open standard protocols.

b) The system shall comply with National LIS blueprint and laboratory quality system (e.g. MS ISO 15189) requirement.

c) Implementation of the LIS shall be after consultation with the Pathology LIS committee.

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

e) The system shall have a provision for efficient data backup with minimum downtime. The system shall be capable of handling manual processes when necessary. The data integrity shall be verified upon recovery of downtime.

f) System shall provide data mining capability as required by laboratory operation.

g) The LIS shall be developed and customized to meet local laboratory requirements.

h) Changes in computer system shall be approved by Head of department before being allowed to be used.

i) After installation, the LIS program shall be verified before use.

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

k) The relevant LIS and procedure documentation shall be reviewed annually.

l) There shall be provision for upgrading the LIS when necessary.

3.5.2 Security

a) The LIS program shall be adequately protected to prevent alteration or destruction by casual or unauthorized users.

b) Security system shall only allow access by authorized personnel.

c) The laboratory shall define the authorized users and their level of access to the LIS program or its data.

d) Appropriate security measure shall be in place to prevent jeopardy of LIS in situation when other computer system interfaces with LIS.

3.5.3 Environment

The system shall be placed in a secure environment and appropriately maintained. It shall have appropriate uninterruptible power supply and should be readily accessible to appropriate fire-fighting equipment.

3.5.4 Procedure Manual

a) A complete and current computer procedure manual shall be readily available to all authorized computer users.
b) Procedure to safeguard the data or computer equipment in case of fire or LIS system failure shall be available.

3.5.5 Data Entry and Reports

a) The system shall provide for data integrity and detection of errors during various stages of data transmission from various processes.

b) The report format shall be reviewed appropriately to ensure effective communication between the laboratory and medical staff.

c) The correctness of data entered into the computer system shall be regularly checked.

d) The provision shall be available to check the test results with predefined range of values to detect abnormal results before reporting.

e) The system shall be able to provide an audit trail of all users that had access to the system.

3.5.6 Data Retrieval and Storage

a) An efficient backup system shall be in place to prevent data loss and minimize downtime.

b) Stored patient result data should be readily retrievable within a time frame consistent with patient-care needs.

c) The system shall be able to reproduce archived examination results when required in a timely manner.

d) All reports shall remain online for 18 months from the date of reporting or otherwise specified by laboratories before archival.

3.6 Transportation

3.6.1 Organizational Policy

The transportation of clinical samples shall be the responsibility of the Pathology Services.

3.6.2 Scope of Service

a) The scope of services shall encompass from collection of specimens until results are received by sender. It shall include intra Laboratory (unit to unit in the same laboratory), Intra Hospital (sampling to the Lab), Inter Hospital and International referral.

b) The type of service chosen, ranging from human, mechanical, to dedicated Pathology transport or outsourcing courier service, shall depend on "best fit" and available resources. The same goes for dispatching of results which ranges from electronic transfer, automated transfer via pneumatic tube system, facsimile, mailing and manually through Pathology transport.

3.6.3 Human Resources

a) The Pathology Services shall take an active role in the supervision and user training of personnel collecting blood or specimens (i.e. phlebotomy).

b) All specimen collecting centers shall have a dedicated packaging centre and these centers shall be coordinated by trained laboratory personnel.

c) For dedicated Pathology transportation, there shall be not less than 2 vehicles and 2 drivers per centre.

3.6.4 Facilities and Equipments

The dedicated packaging centre shall be secure and well equipped to package clinical specimens appropriate to the level of the Laboratory.

3.6.5 Training

Training shall be provided to all staff concerned inclusive of staff of packaging centre, drivers, transporters and phlebotomists to comply with safety standards.

3.6.6 Quality and Accreditation

Measures shall be taken to comply with safety and quality standards as required by ISO/IEC 15189.

APPENDIX

APPENDIX

1. List of Category of Hospitals.
2. List of Tests According to Health Care Level.
3. List of Urgent Tests According to Health Care Level.
4. Organization structure of National Pathology Services MOH.
5. Organization Structure of Laboratories (State Hospitals) without Discipline Specific Pathologist.
6. Organization Structure of Laboratories According to Health Care Level.
7. Ratio of Workload to Various Categories of Lab Personnel.
8. Minimum Standard Requirement of Equipment.
9. List of Contributors.

APPENDIX 1; LIST OF CATEGORY OF HOSPITALS

TABLE OF HOSPITALS UNDER 9 MALAYSIA PLAN						
Specialist Hospitals & Institutions				Non-Specialist Hospitals		
HKL+ State Hosp.	Major Specialist Hospitals	Minor Specialist Hospitals	Special Medical Institutions			
14	21	20	7	75		
Kangar	Sg.Petani	Kulim	IPR	Baling	Mersing	Tambunan
Alor Setar	Sbg Jaya	Langkawi	Bahagia	Yan	Tangkak	Tenom
P.Pinang	Taiping	K.Batas	Permai	Jitra	Pontian	Beluran
Ipoh	T. Intan	Slim River	Mesra	Sik	Pekan	Semporna
Klang	Kajang	Sri Manjung	Sentosa	Kuala Nerang	Bentong	Sipitang
HKL	Sg.Buloh	Banting	PDN	Sg Bakap	Raub	Kota Marudu
Seremban	Selayang	P.Dickson	PKKN	Balik Pulau	Jerantut	Kinabatangan
Melaka	Ampang	Kluang		Parit Buntar	Mdzm Shah	Kunak
J.Bahru	Serdang	Segamat		Kuala Kangsar	Jengka	K. Penyu
Kuantan	Putrajaya	K.Lipis		Batu Gajah	Cameron H	Pitas
K.T'ganu	K. Pilah	T.Merah		Kampar	Dungun	Limbang
K.Bahru	S.I. Pandan	Keningau		Tapah	Besut	Serian
QE	Muar	Lahad Datu		Gerik	H. Trggu	Lundu
Kuching	B. Pahat	Labuan		Selama	Setiu	Saratok
	Temerloh	Sri Aman		Cht Melintang	Machang	Mukah
	Kemaman	Sarikei		Sg Siput	Tumpat	Kanowit
	K. Krai	Kapit		K Kubu Baru	Pasir Mas	Marudi
	Sandakan	Bintulu		Tg.Karang	Gua Musang	Lawas
	Tawau	Likas		S.Bernam	Pasir Puteh	Bau
	Sibu	B.Mertajam		Tampin	Jeli	Simunjan
	Miri			Jelebu	Kudat	Betong
				Jempol	Kota Belud	Daro
				A. Gajah	Papar	RCBM
				Jasin	Beaufort	Dalat
				K. Tinggi	Ranau	
				Kulai		
Target: 15 resident specialties/subspecialties		Target: 6 resident specialties	Specific resident specialties	Visting specialist services		

* Pusat Darah Negara, unlike other hospitals or institutions, has no hospital bed.

** PKKN, although not yet officially de-gazetted as a leprosarium, has been amalgamated into Hospital Sungai Buluh for administrative matte.

TABLE OF HOSPITALS UNDER 10 MALAYSIA PLAN (TENTATIVE)						
Specialist Hospitals & Institutions				Non-Specialist Hospitals		
HKL+ State Hosp.	Major Specialist Hospitals	Minor Specialist Hospitals	Special Medical Institutions			
14 (14)	26 (21)	27 (20)	11 (7)	66 (75)		
Kangar	Sg.Petani	Langkawi	IPR	Baling	Kulai	Papar
Alor Setar	Kulim	K.Batas	Bahagia	Yan	Mersing	Ranau
P.Pinang	Sbg Jaya	B.Mertajam	Permai	Jitra	Tangkak	Tambunan
Ipoh	Taiping	Slim River	Mesra	Sik	Pontian	Tenom
Klang	T. Intan	Sri Manjung	Sentosa	Kuala Nerang	Raub	Beluran
HKL	Kajang	K.Kangsar	PDN	Sg Bakap	Jerantut	Semporna
Seremban	Sg.Buloh	Grik	PKKN	Balik Pulau	Mdzm Shah	Sipitang
Melaka	Selayang	Banting	Rehab Cheras.	Parit Buntar	Jengka	Kinabatangan
J.Bahru	Ampang	P.Dickson	NCI	Batu Gajah	Cameron H	Kunak
Kuantan	Serdang	Kluang	W&CH Likas	Kampar	Rompin	K. Penyu
K.T'ganu	Shah Alam	K. Tinggi	W&CH KL	Tapah	Bera	Pitas
K.Bahru	Putrajaya	K.Lipis		Selama	Besut	Tuaran
QE	K. Pilah	Bentong		Changkat Melintang	H. Trggu	Serian
Kuching	S.I. Pandan	Pekan		Sg Siput	Setiu	Lundu
	Muar	Dungun		K Kubu Baru	Machang	Saratok
	B. Pahat	Keningau		Tg.Karang	Tumpat	Kanowit
	Segamat	Lahad Datu		S.Bernam	Pasir Mas	Marudi
	Temerloh	Kota Marudu		Jelebu	Pasir Puteh	Lawas
	K. Krai	Beaufort		Jempol	Jeli	Bau
	Kemaman	Labuan		A. Gajah	Kudat	Simunjan
	Sandakan	Sri Aman		Jasin	Kota Belud	Betong
	Tawau	Sarikei				Daro
	Sibu	Kapit				RCBM
	Miri	Limbang				Dalat
	Bintulu	Tampin				
	T.Merah	Mukah				
		Gua Musang				
Target: 44 / 20 resident specialty / subspecialties		Target: 10 resident specialties	Specific resident specialties	Visting specialist services		

APPENDIX 2; LIST OF TESTS ACCORDING TO HEALTH CARE LEVEL

1. MICROBIOLOGY

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Major Specialty	Basic	Regional Centre	Referral Centre
	BACTERIOLOGY (C&S)						
1.	Air Sampling			✓	✓	✓	✓
2.	Anaerobic culture & ID			✓	✓	✓	✓
3.	Body fluid (C&S)		✓	✓	✓		✓
4.	Blood (C&S) : Aerobic & Anaerobic		✓	✓	✓	✓	✓
5.	CSF (C&S)		✓	✓	✓	✓	✓
6.	Environmental screen		✓	✓	✓	✓	✓
7.	Stool (C&S)		✓	✓	✓	✓	✓
8.	Genital (C&S)		✓	✓	✓	✓	✓
9.	Peritoneal fluid (C&S)		✓	✓	✓	✓	✓
10.	Pus/Swab (C&S)		✓	✓	✓	✓	✓
11.	Respiratory (C&S)		✓	✓	✓	✓	✓
	TB						
12.	AFB direct smear	✓	✓	✓	✓	✓	✓
13.	Culture				✓	✓	✓
14.	ID					✓	✓
15.	Sensitivity					✓	✓
16.	Mycobacterium Genomic Detection					✓	✓
17.	Tissue		✓	✓	✓	✓	✓
18.	Urine (C&S)		✓	✓	✓	✓	✓
19.	Sterility A-Test		✓	✓	✓	✓	✓
20.	Sterility (C&S)		✓	✓	✓	✓	✓
	BACTERIOLOGY SEROLOGY						
21.	Chlamydia trachomatis IF			✓	✓	✓	✓
22.	Clostridium. diffifile toxin			✓	✓	✓	✓
23.	Chlamydia pneumonie IgG/IgM					✓	✓
24.	Chlamydia tracomatis IgG/IgM					✓	✓
25.	Chlamydia psittacii IgG/IgM					✓	✓
26.	Chlamydia pneumonia/ trachomatis/psittacii/IF					✓	✓
27.	Coxiella serology						✓
28.	Brucella serology						✓
29.	CSF VDRL						✓
30.	CSF Bacterial antigen		✓	✓	✓	✓	✓
31.	Indirect Immunoperoxidase (IIP) Rickettsial				✓	✓	✓
32.	Leptospira IgM				✓	✓	✓
33.	Legionella (IF)					✓	✓
34.	Legionella urinary antigen					✓	✓
35.	Mycoplasma pneumoniae IgM						
36.	TPHA			✓	✓	✓	✓
37.	RPR		✓	✓	✓	✓	✓
	IMMUNOLOGY						
A.	INFECTIOUS DISEASES SEROLOGY						
38.	ASOT			✓	✓	✓	✓
39.	Interferon gamma assays for latent tuberculosis diagnosis				✓	✓	✓
B.	AUTOIMMUNITY						
	Connective tissue disease					✓	✓
40.	Antinuclear antibody : ELISA screening			✓	✓	✓	✓
41.	ANA dilution/titre				✓	✓	✓
42.	Anti-ds DNA antibody IF screening		✓	✓	✓	✓	✓
43.	Anti-ds DNA titre/quantitation		✓	✓	✓	✓	✓

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Major Specialty	Basic	Regional Centre	Referral Centre
	Anti Phospholipid syndrome						
44.	Anti-cardiolipin antibody (IgG and IgM)					✓	✓
45.	Anti-Beta 2 glycoprotein 1 (IgG and IgM)					✓	✓
46.	Anti-Phosphatidylserine (IgG and IgM)					✓	✓
	Inflammatory myophaties						
47.	Anti-extractable nuclear antigen screen (ENA)					✓	✓
48.	Anti-extractable specific nuclear antigen quantitation if screening is positive					✓	✓
49.	Anti-ribonucleoprotein antobodies					✓	✓
50.	Anti Sm antibody					✓	✓
51.	Anti RO (SS-A) antibody					✓	✓
52.	Anti La (SS-A) antibody					✓	✓
53.	Anti Jo-1 antibody					✓	✓
54.	Anti-histones					✓	✓
55.	Anti CCP					✓	✓
	Rheumatoid factor						
56.	Qualitative		✓	✓	✓	✓	✓
57.	Quantitative				✓	✓	✓
	GASTROINTESTINAL DISEASE						
	Investigation of Coeliac disease						
58.	Anti endomysal antibody					✓	✓
59.	Anti gladin antibody					✓	✓
	Pernicious anaemia investigation						
60.	Gastric parietal cell antibodies					✓	✓
61.	Anti intrinsic factor antibodies						
	Inflammatory bowel disease					✓	✓
62.	Saccharomyces cerevisiae antibodies IgG and IgA					✓	✓
63.	Outer membrane protein (OMP) IgA					✓	✓
64.	Autoimmune hepatitis					✓	✓
65.	ANA Screen with specific liver substrates					✓	✓
	Liver autoantibody screening						
66.	Anti liver kidney antibodies					✓	✓
67.	Anti mitochondrial antibody					✓	✓
68.	Anti smooth muscle antibody					✓	✓
	Liver antibody follow up test						
69.	Anti-M2 ELISA/dot blot if IF is mitochondrial positive					✓	✓
70.	Anti-LKM1 ELISA/dot blot if IF is LKM positive						
	Liver specific antibody confirmatory and also for urgent request						
71.	Anti-M2					✓	✓
72.	Anti-LKM-1					✓	✓
73.	Anti-gp210					✓	✓
74.	Anti-LC-1					✓	✓
75.	Anti-SLA/LP					✓	✓
76.	Anti 3E (BPO)					✓	✓
77.	Anti-Ro-52					✓	✓
	Renal disease associated antibodies						
78.	C3 nephritic factor					✓	✓
79.	Anti glomerular basement membrane antibodies					✓	✓
80.	Anti neutrophil cytoplasmic antibodies IF screen					✓	✓

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Major Specialty	Basic	Regional Centre	Referral Centre
	Anti neutrophil cytoplasmic antibodies quantitation						
81.	Anti Proteinase-3 antibody ELISA quantitation					✓	✓
82.	Anti Myeloperoxidase antibody ELISA quantitation					✓	✓
83.	Urgent request : ANCA and GBM immunoblot			✓	✓	✓	✓
	Endoctrine disease						
84.	Anti adrenal antibodies					✓	✓
85.	Anti islet antibodies					✓	✓
86.	Anti steroid cell antibodies					✓	✓
	Thyroid specific antibodies						
87.	Anti thyroid microsomal/thyroid peroxiase antibody			✓	✓	✓	✓
88.	Anti thyroglobulin antibody			✓	✓	✓	✓
89.	Anti TSH receptor antibodies					✓	✓
	Neurological disease						
90.	Anti acetyl chlorine receptor antibody					✓	✓
91.	Myelin Associated Glycoprotein (MAG)					✓	✓
	Anti ganglioside IgG and IgM antibodies						
92.	Asialo-GM-1					✓	✓
93.	GM1					✓	✓
94.	GM2					✓	✓
95.	GD1a					✓	✓
96.	GD1b					✓	✓
97.	GQ1b					✓	✓
98.	Anti-glutamic acid decarboxylase antibodies					✓	✓
99.	Anti muscle specific kinase antibody						✓
	Anti paraneoplastic neurological antibodies						
100.	Anti-Hu (ANNA1)					✓	✓
101.	Anti-Yo (PCA1)					✓	✓
102.	Anti-CV2 (CRMP5)					✓	✓
103.	Anti-Ma2 (Ma/Ta)					✓	✓
104.	Anti-Ri (ANNA2)					✓	✓
105.	Anti-amphiphysin						
106.	Anti skeletal muscle antibody					✓	✓
107.	Anti voltage gated calcium chanel antibody						
108.	Anti voltage gated potassium						✓
	Other antibodies						
	Fertility						
109.	Sperm antibody						✓
110.	Skin reactive antobodies						✓
111.	Anti-IgA antibodies						✓
C.	ALLERGY						✓
112.	Total IgE			✓	✓	✓	✓
	Allergen specific IgE (RAST test)						
	Staple food mix						
113.	Egg white, milk, fish, wheat, peanut, soya bean					✓	✓
	Seafood mix						
114.	Fish, shrimp, blue mussel, tuna, salmon, Nutmix					✓	✓
115.	Peanut, hazel nut, brazil nut, almond and coconut					✓	✓
	Cereal mix						

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Major Specialty	Basic	Regional Centre	Referral Centre
116.	Wheat, oat, maize, sesame seed, buckwheat					✓	✓
	Animal mix						
117.	Cat dander, horse dander, cow dander, dog dander					✓	✓
	Dust/mite mix						
118.	House dust, derm, pteronyssinus, fainae, cockroach					✓	✓
	Mould mix						
119.	Penicillium notatum, clasdoparium, aspergillis, fumigatus, alternarta altermata					✓	✓
	Histamine						
120.	Mast cell tryptase (anaphylaxis investigation together with specific IgE (where appropriate), IgE, C3,C4 and CRP					✓	✓
121.	Extrinsic allergic alveolitis screen					✓	✓
122.	IgG antibodies to Aspergillus fumigatus					✓	✓
123.	IgG antibodies to Micropolyspora faeni					✓	✓
124.	IgG antibodies to avians proteins					✓	✓
D	CELLULAR IMMUNOROLOGY						
	Immunodeficiency						
125.	Lymphocyte phenotyping						✓
126.	Lymphocyte antigen and mitogen proliferation						✓
127.	Lympochyte T cell subset % and absolute count						✓
128.	Lympochyte Total Lympochyte enumeration						✓
129.	Phagocytic Function Test						✓
130.	Mixed Lympochyte Culture						✓
131.	Lympochyte Transformation Test						✓
132.	Immunoglolubins quantitation (IgG IgA, IgM)			✓	✓	✓	✓
133.	Immunoglobulins subclass quantitation					✓	✓
134.	Complement (C3, C4)			✓	✓	✓	✓
135.	Other complement assays						✓
	Acute phase reactants						
136.	C reactive protein			✓	✓	✓	✓
137.	TNF-alpha quantitation						✓
138.	HLA B27 Typing						✓
139.	HLA Paternity Testing						✓
E	TRANSPLANTATION IMMUNOLOGY						
140.	HLA phenotyping						✓
141.	HLA crossmatching						✓
142.	Class 1 HLA Typing						
143.	Class II HLA Typing						✓
144.	HLA Crossmatch (Ab Detection) for Cadaveric						✓
145.	HLA Crossmatch (Ab Detection) Living Related						✓

	Test	Non-Specialist	Specialist Hospital		Tertiary Level		
			Minor	Major	State	Regional Centre	Referral Centre
	VIROLOGY (SEROLOGY)						
146.	CMV IgG				✓	✓	✓
147.	CMV IgM				✓	✓	✓
148.	Dengue NS1 Antigen		✓	✓	✓	✓	✓
149.	Dengue Virus IgG			✓	✓	✓	✓
150.	Dengue Virus IgM			✓	✓	✓	✓
151.	EBV IgG				✓	✓	✓
152.	EBV IgM				✓	✓	✓
153.	HIV (screening)			✓	✓	✓	✓
154.	HIV (Supplementary)			✓	✓	✓	✓
155.	HIV (Confirmatory)				✓	✓	✓
156.	Hep. A IgM				✓	✓	✓
157.	Hep B e antigen					✓	✓
158.	Hep B e Antibody			✓	✓	✓	✓
159.	Hep B core – Total				✓	✓	✓
160.	Hep B core –IgM				✓	✓	✓
161.	Hep B – anti HBs				✓	✓	✓
162.	Hep. B surface Antigen				✓	✓	✓
163.	Hep C – anti HCV (screening)					✓	✓
164.	Hep C – (Supplementary)					✓	✓
165.	Herpes Simplex I & II (IF)					✓	✓
166.	Herpes Simplex I IgG					✓	✓
167.	Herpes Simplex I IgM					✓	✓
168.	Herpes Simplex II IgG					✓	✓
169.	Herpes Simplex II IgM					✓	✓
170.	HHV6 IgG/IgM					✓	✓
171.	HTLV 1 & 2 Antibody Screen					✓	✓
172.	Measles IgM					✓	✓
173.	Measles IgG					✓	✓
174.	Mumps IgG					✓	✓
175.	Mumps IgM					✓	✓
176.	Respiratory viruses detection IF				✓	✓	✓
177.	Rubella IgG					✓	✓
178.	Rubella IgM					✓	✓
179.	TORCHES Serology				✓	✓	✓
180.	Varicella Zoster IgG					✓	✓
181.	Varicella Zoster IgM					✓	✓
182.	Japanese Encephalitis IgM				✓	✓	✓
183.	Parvovirus B19 IgM					✓	✓
184.	Parvovirus B19 IgG					✓	✓
185.	Rota virus antigen				✓	✓	✓
186.	Viral Antigen Detection					✓	✓
187.	Viral Isolation					✓	✓
	MOLECULAR						
188.	HBV DNA Genome Detection					✓	✓
189.	(qualitative)					✓	✓
190. 191.	HBV DNA Genome Detection (quantitative)					✓	✓
192. 193.	HCV RNA Genome Detection (qualitative)					✓	✓
194. 195.	HCV RNA Genome Detection (quantitative)					✓	✓
196. 197.	HIV RNA Genome Detection (qualitative)					✓	✓
198.	HIV RNA Genome Detection (quantitative)					✓	✓
199.	CMV Viral Load PCR					✓	✓
200.	Dengue RNA Genome Detection (qualitative)						✓ ✓
201.	Dengue RNA Genome Detection (quantitative)						✓

2. HISTOPATHOLOGY

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Specialty	Basic	Regional Centre	Referral Centre
A.	ROUTINE H & E				✓	✓	✓
B.	FROZEN SECTION				✓	✓	✓
C.	HISTOCHEMISTRY						
1.	Connective tissue stain						
1.1	Martius Scarlet Blue				✓	✓	✓
1.2	Masson Trichrome				✓	✓	✓
1.3	PAAG				✓	✓	✓
1.4	PTAH				✓	✓	✓
1.5	Reticulin				✓	✓	✓
1.6	Van Gieson				✓	✓	✓
2.	Carbohydrate						
2.1	PAS				✓	✓	✓
2.2	PAS + D				✓	✓	✓
2.3	Mucicarmine				✓	✓	✓
2.4	Alcian Blue				✓	✓	✓
3.	Lipid						
3.1	Oil Red O				✓	✓	✓
4.	Melanin pigment						
4.1	Masson Fontana				✓	✓	✓
5.	Amyloid						
5.1	Congo Red				✓	✓	✓
6.	Micro-organisms						
6.1	Giemsa				✓	✓	✓
6.2	Gram				✓	✓	✓
6.3	GMS				✓	✓	✓
6.4	Wade Fite				✓	✓	✓
6.5	Warthin Starry				✓	✓	✓
6.6	Ziehl-Neelson				✓	✓	✓
7.	Cytoplasmic granules						
7.1	Toluidine blue				✓	✓	✓
7.2	Leder Giemsa				✓	✓	✓
8.	Neuropathological stains						
8.1	Bielschowsky's silver stain						✓
8.2	Heidenhain's iron Haematoxylin						✓
8.3	Luxol Fast Blue						✓
9.	Miscellaneous						
9.1	Fouchet				✓	✓	✓
9.2	Orcein				✓	✓	✓
9.3	Perl Prussian Stain				✓	✓	✓
9.4	Rubeanic acid					✓	✓
9.5	Schmorl's reaction				✓	✓	✓
D.	ENZYME HISTOCHEMISTRY						
1.	Acetylcholinesterase					✓	✓
2.	Acid phosphatase						✓
3.	ATPase (pH 4.2)						✓
4.	ATPase (pH 4.6)						✓
5.	ATPase (pH 9.4)						✓
6.	Cytochrome oxidase						✓
7.	NADH						✓
E.	IMMUNOHISTOCHEMISTRY						
1.	Epithelial markers						
1.1	Cytokeratin 34beta E12 (HMW)					✓	✓
1.2	Cytokeratin LMW					✓	✓
1.3	Cytokeratin PAN CK				✓	✓	✓
1.4	Epithelial membrane antigen				✓	✓	✓
2.	Mesenchymal markers						
2.1	CD 117 (Stromal tumour)					✓	✓
2.2	CD34					✓	✓
2.3	CD61 (Platelet marker)					✓	✓

	Test	Non-Specialist	Specialist Hospital		Tertiary Level		
			Minor	Major	State	Regional Centre	Referral Centre
2.4	Desmin				✓	✓	✓
2.5	Dystrophin I						✓
2.6	Dystrophin 2						✓
2.7	Dystrophin 3						✓
2.8	Endothelial cell CD31					✓	✓
2.9	Factor VIII				✓	✓	✓
2.10	Myoglobin					✓	✓
2.11	Sarcomeric Actin					✓	✓
2.11	Smooth muscle actin					✓	✓
2.12	Ulex Europeaus					✓	✓
2.13	Vimentin				✓	✓	✓
2.14	Ubiquitin						✓
3.	Lymphoid						
3.1	ALK (Anaplastic)					✓	✓
3.2	CD10 (CALLA)					✓	✓
3.3	CD15 (Hodgkin's)					✓	✓
3.4	CD20 (B cell)					✓	✓
3.5	CD23 (B cell)				✓	✓	✓
3.6	CD3 (T cell)				✓	✓	✓
3.7	CD30 (Ki-1)					✓	✓
3.8	CD45 (LCA)					✓	✓
3.9	CD45RO (T cell)					✓	✓
4.0	CD5 (T cell)					✓	✓
4.1	CD56 (NK T cell)					✓	✓
4.2	CD68 (Macrophage)					✓	✓
4.3	CD79a (B cell)				✓	✓	✓
4.4	CD5 (T cell)					✓	✓
4.5	mac 387					✓	✓
4.6	Kappa					✓	✓
4.7	Lambda					✓	✓
5.	Neural						
5.1	Glial fibrillary acidic protein				✓	✓	✓
5.2	Neurofilament					✓	✓
5.3	Tau Protein						✓
54	S 100				✓	✓	✓
6.	Oncogene						
6.1	bcl 2 oncoprotein					✓	✓
6.2	Cerb B2 oncoprotein				✓	✓	✓
6.3	p53 protein					✓	✓
6.4	Cyclin D1					✓	✓
7.	Hormones						
7.1	ACTH						✓
7.2	Calcitonin						✓
7.3	Estrogen receptor					✓	✓
7.4	Calretinin					✓	✓
7.5	FSH						✓
7.6	GH						✓
7.7	H. Chorionic Gonadotropin						
7.8	Human Placenta Lactogen						✓
7.9	LH						✓
7.10	Progesterone receptor				✓		✓
7.11	Prolactin						✓
7.12	Thyroglobulin						✓
7.13	TSH						✓
8.	Microorganisms						
8.1	Cytomegalovirus				✓	✓	✓
8.2	EBV					✓	✓
8.3	HBcAg					✓	✓
8.4	HBsAg					✓	✓
8.5	Helicobacter pylori					✓	✓
8.6	Human papilloma virus					✓	✓

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Specialty	Basic	Regional Centre	Referral Centre
8.7	Nipah virus						✓
9.	Tumour Marker						
9.1	alfa-feto protein				✓	✓	✓
9.2	alfa-1 anti trypsin					✓	✓
9.3	CA-125					✓	✓
9.4	Carcinoembryonic antigen					✓	✓
9.5	Prostatic specific antigen				✓	✓	✓
10.	Neuro Endocrine						
10.1	Chromogranin				✓	✓	✓
10.2	NSE					✓	✓
10.3	Synaptopysin				✓	✓	✓
12.	Others						
12.1	Amyloid A						✓
12.2	Amyloid B						✓
12.3	CD99 (Mic2)					✓	✓
12.4	HMB45				✓	✓	✓
12.5	Lysozyme					✓	✓
12.6	PLAP					✓	✓
12.8	CD1a					✓	✓
12.9	Ki 67					✓	✓
F.	IMMUNOFLUORESCENSE						
1.	IgG					✓	✓
2.	IgA					✓	✓
3.	IgE					✓	✓
4.	IgM					✓	✓
5.	IgD					✓	✓
6.	Fibrinogen					✓	✓
7.	C3					✓	✓
8.	C4					✓	✓
9.	C1q					✓	✓
G.	MISCELLANEOUS						
1.	Her 2 Protein (FISH/ CISH)						✓
H.	SPECIALISED SERVICES						
1.	Muscle biopsy						✓
2.	NeuroPathology						✓
3.	Renal biopsy						✓

CYTOLOGY

	GYNAECOLOGICAL						
1.	Pappinicolau		✓	✓	✓		
	NON GYNAECOLOGICAL						
2.	Periodic Acid Shiff		✓	✓	✓		
3.	Alcian Blue		✓	✓	✓		
	FINE NEEDLE ASPIRATION						
5.	Quick stain		✓	✓	✓		
6.	Pappinicolau		✓	✓	✓		
7.	Giemsa		✓	✓	✓		
8.	Immunohistochemical		✓	✓	✓		

3. CHEMICAL PATHOLOGY

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Specialty	Basic	Regional Centre	Referral Centre
	GENERAL CHEMISTRY						
1.	Alanine transaminase	✓	✓	✓	✓	✓	
2.	Albumin	✓	✓	✓	✓	✓	
3.	Alkaline phosphatase	✓	✓	✓	✓	✓	
4.	Ammonia			✓	✓	✓	
5.	Amylase			✓	✓	✓	
6.	Aspartate Transaminase	✓	✓	✓	✓	✓	
7.	Bilirbin Total	✓	✓	✓	✓	✓	
8.	Bilirubin Direct	✓	✓	✓	✓	✓	
9.	Blood gases		✓	✓	✓	✓	
10.	Calcium		✓	✓	✓	✓	
11.	Chloride		✓	✓	✓	✓	
12.	Cholinesterase		✓	✓	✓	✓	✓
13.	Creatinine	✓	✓	✓	✓	✓	
14.	Creatinine Kinase		✓	✓	✓	✓	
15.	Creatinine Kinase Isoenzyme (CK-MB)		✓	✓	✓	✓	
16.	Creatinine clearance	✓	✓	✓	✓	✓	
17.	Cholesterol	✓	✓	✓	✓	✓	
18.	Gamma Glutamine Transaminase				✓	✓	
19.	Glucose	✓	✓	✓	✓	✓	
20.	Glucose Tolerance test	✓	✓	✓	✓	✓	
21.	Ferritin			✓	✓	✓	
22.	Folate				✓	✓	
23.	Hb A 1C	✓	✓	✓	✓	✓	
24.	High Density Lipoprotein		✓	✓	✓	✓	
25.	Homocysteine					✓	✓
26.	Iron		✓	✓	✓	✓	
27.	Lactate			✓	✓	✓	
28.	Lactate Dehydrogenase	✓	✓	✓	✓	✓	
29.	Lithium			✓	✓	✓	
30.	Magnesium			✓	✓	✓	
31.	Microalbumin (urine)	✓ (qualita)	✓ (qualita)	✓	✓	✓	
32.	Osmolality		✓	✓	✓	✓	
33.	Phosphate, Inorganic		✓	✓	✓	✓	
34.	Potassium	✓	✓	✓	✓	✓	
35.	Protein, total	✓	✓	✓	✓	✓	
36.	Sodium	✓	✓	✓	✓	✓	
37.	TIBC		✓	✓	✓	✓	
38.	Total Bicarbonate (TC02)		✓	✓	✓	✓	
39.	Urea	✓	✓	✓	✓	✓	
40.	Uric Acid	✓	✓	✓	✓	✓	
41.	Vitamin B 12			✓	✓	✓	
42.	CSF Biochemistry			✓	✓	✓	
43.	Stone Analysis				✓	✓	✓
44.	Bone ALP					✓	✓
	EARLY DETECTION CARDIAC MARKER						
45.	Troponin I / Troponin T						
46.	Myoglobin			✓	✓	✓	
47.	Apo B				✓	✓	✓
48.	Apo A						✓
49.	Lp (a)						✓
	ENDOCRINE						✓
50.	17-OH Progesterone						
51.	ACTH						✓
52.	Aldosterone					✓	✓
53.	Anti GAD – Ab						✓
54.	AVP – ADH						✓
55.	IGF1						✓
56.	IGFBP3						✓
57.	SHBP						✓

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Specialty	Basic	Regional Centre	Referral Centre
58.	25-OH-Vit D						✓
59.	1,25(OH2)-Vit D						✓
60.	Calcitonin						✓
61.	Catecholamines						✓
62.	C – Peptide					✓	✓
63.	Cortisol					✓	✓
64.	DHEA – S			✓	✓	✓	
65.	Estradiol				✓	✓	✓
66.	Follicular Stimulating Hormone			✓	✓	✓	✓
	(FSH)						
67.	Growth Hormone			✓	✓	✓	
68.	Insulin					✓	✓
69.	Intact Parathyroid Hormone (IPTH)			✓	✓	✓	
70.	Luteinising Hormone			✓	✓	✓	
71.	Progestrone			✓	✓	✓	
72.	Renin			✓	✓	✓	
73.	Testosterone						✓
74.	Thyroxine Free (FT 4)			✓	✓	✓	✓
75.	Thyroid Stimulating Hormone			✓	✓	✓	
76.	Triidothyronine Free (FT 3)				✓	✓	
77.	Functional Endocrine Tests			✓	✓	✓	
	SPECIFIC PROTEIN						
78.	Alpha – fetoprotein			✓	✓	✓	
79.	Beta – HCG			✓	✓	✓	
80.	C-Reactive Protein			✓	✓	✓	
81.	CA 125			✓	✓	✓	
82.	CA 19-9			✓	✓	✓	
83.	Carcinoembryonic Antigen			✓	✓	✓	
84.	Protein Electrophoresis					✓	✓
85.	Bone Markers					✓	✓
	PERINATAL SCREENING						
86.	Screening for Inborn Error of Metabolism				✓	✓	✓
87.	Screening Serum Amino Acid				✓	✓	✓
88.	Quantitative Serum Amino acid					✓	✓
89.	Quantitative Organic Acid					✓	✓
90.	Camitine						✓
91.	Orotic acid						✓
92.	Pyruvate			✓	✓	✓	
	THERAPEUTIC DRUG MONITORING AND CLINICAL TOXICOLOGY						
93.	Amikacine						
94.	Benzodiazepine			✓	✓	✓	
95.	Carbamezepine			✓	✓	✓	
96.	Cyclosporine			✓	✓	✓	
97.	Digoxin			✓	✓	✓	
98.	Gentamycin			✓	✓	✓	
99.	Phenobarbital			✓	✓	✓	
100.	Phenytoin			✓	✓	✓	
101.	Theophylline			✓	✓	✓	
102.	Valporoic Acid			✓	✓	✓	
103.	Vancomycin			✓	✓	✓	
104.	Serum Paracetamol			✓	✓	✓	
	DRUG OF ABUSE						
105.	Amphetamine				✓	✓	✓
106.	Benzodiazepine (Screening)		✓	✓	✓	✓	✓
107.	Cannabis		✓	✓	✓	✓	✓
108.	Ethanol				✓	✓	✓
109.	Heroin		✓	✓	✓	✓	✓
110.	Methamphetamine				✓	✓	✓
111.	MDMA (ectacy)				✓	✓	✓

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Specialty	Basic	Regional Centre	Referral Centre
112.	Morphine		✓	✓	✓	✓	✓
	TRACE ELEMENTS						
113.	Aluminum						✓
114.	Cadmium						✓
115.	Copper						✓
116.	Plumbm						✓
117.	Selenium						✓
118.	Zinc						✓
	OTHERS						
119.	Stool Occult Blood	✓	✓	✓	✓	✓	
120.	Urine Biochemistry	✓	✓	✓	✓	✓	
121.	Urine Porphobilinogen					✓	✓
122.	Xylose Absorption test			✓	✓	✓	

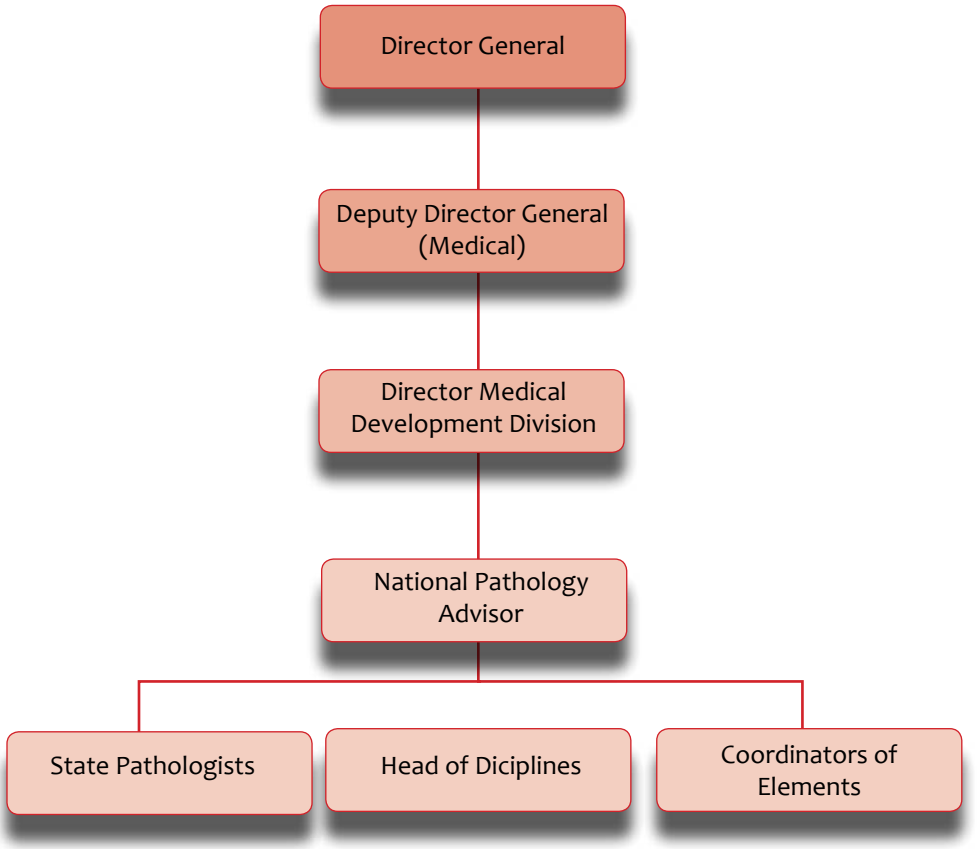
4. HAEMATOLOGY

	Test	Primary Level	Secondary Level		Tertiary Level		
			With Basic Specialty	With Specialty	Basic	Regional Centre	Referral Centre
	GENERAL HAEMATOLOGY						
1.	Full Blood Count	✓	✓	✓	✓	✓	✓
2.	Reticulocyte Count		✓	✓	✓	✓	✓
3.	ESR	✓	✓	✓	✓	✓	✓
4.	Full Blood Picture		✓	✓	✓	✓	✓
5.	PT/INR	✓	✓	✓	✓	✓	✓
6.	APTT	✓	✓	✓	✓	✓	✓
7.	Fibrinogen		✓	✓	✓	✓	✓
8.	D-Dimer		✓	✓	✓	✓	✓
	BONE MARROW ASPIRATE / TREPHINE						
9.	BMA smear		✓	✓	✓	✓	✓
10.	Routine stains (MGG & Perls')				✓	✓	✓
11.	Special stains				✓	✓	✓
	THALASSEMIA / HAEMOGLOBINOPATHY						
12.	Hemoglobin analysis (Hb electrophoresis/ HPLC)				✓	✓	✓
13.	H inclusion test				✓	✓	✓
14.	Sickling test				✓	✓	✓
15.	Kleihaur test				✓	✓	✓
16.	Molecular diagnosis of Thalassaemia / Hemoglobinopathy						✓
	HAEMOLYTIC ANAEMIAS						
17.	G6PD screening		✓	✓	✓	✓	✓
18.	G6PD assay					✓	✓
19.	Pyruvate kinase assay						✓
20.	Other red cell enzyme assays						✓
21.	Osmotic fragility test				✓	✓	✓
22.	Ham test				✓	✓	✓
23.	Flowcytometric analysis of intact red cells				✓	✓	✓ ✓
	HEMOSTASIS / THROMBOSIS					✓	✓
24.	Factor VIII & IX assays						✓
25.	Factors Inhibitor assay				✓	✓	✓
26.	Other Coagulation Factor assays						✓
27.	Reptilase Time						✓
28.	Antiphospholipid panel (LA & ACL)						✓
29.	Anti thrombin III antigen / activity						✓
30.	Protein C antigen / activity						✓
31.	Protein S antigen / activity						✓
32.	Molecular diagnosis of bleeding and thrombotic disorder						✓
	LYMPHOCYTE SUBSETS						
33.	T-lymphocytes subset enumeration (CD4/CD8)					✓	✓
34.	Lymphocyte subsets analysis for immune disorders (CD3/CD4/CD8/ CD19/NK)					✓	✓
	HAEMATO-ONCOLOGY						
35.	Immunophenotyping (IPT) for leukaemia/ lymphoma					✓	✓
36.	Cytogenetics & molecular genetics of Leukaemia / Lymphoma						✓
	STEM CELL TRANSPLANTATION						
37.	Stem cell processing & manipulation						✓
38.	Cryopreservation						✓
39.	Progenitor cells (CD34) assessment						✓
40.	Engraftment studies						✓
41.	CD34 Cell Selection						✓
42.	T-Cell Selection						✓
43.	Other Cell Selection						✓

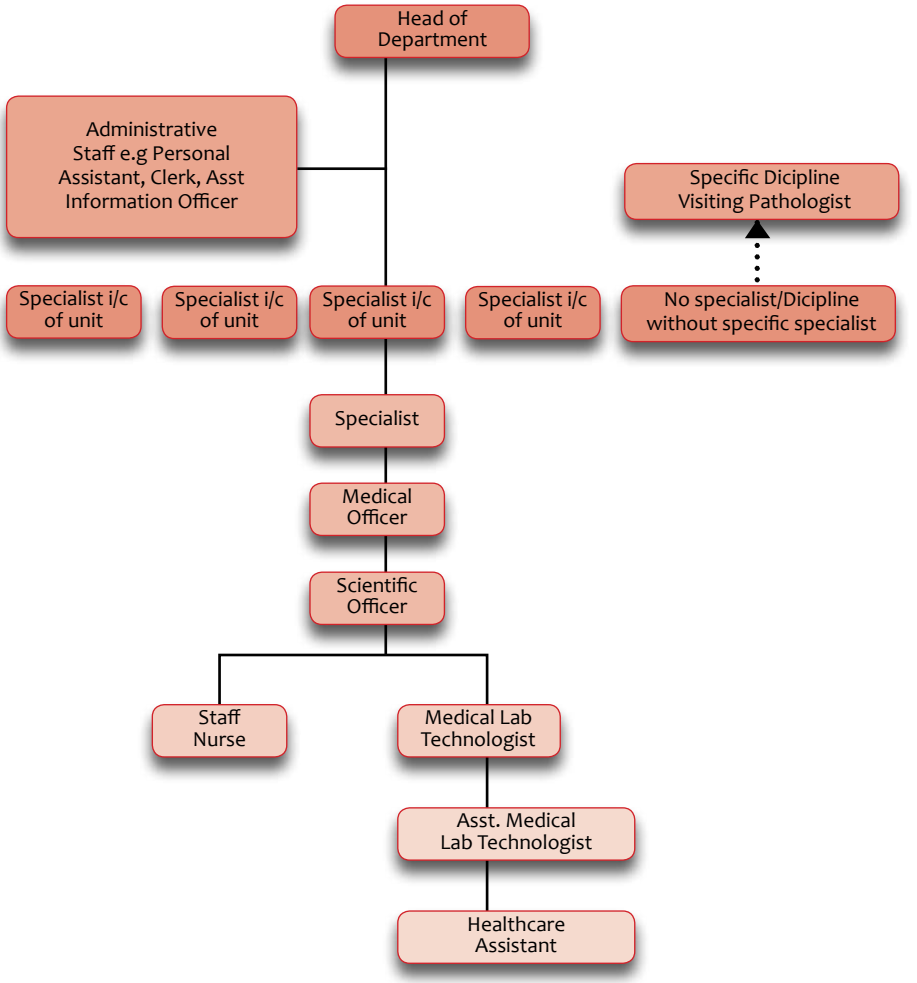
Appendix 3; LIST OF URGENT TESTS ACCORDING TO HEALTHCARE LEVEL

	Services	Non-specialist	Specialist	State
	CHEMICAL PATHOLOGY			
1.	BUSE	✓	✓	✓
2.	RBS	✓	✓	✓
3.	Serum Salicylate	✓	✓	✓
4.	Urine 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		✓	✓
	MEDICAL MICROBIOLOGY			
17.	CSF Microscopy	✓	✓	✓
18.	BFMP	✓	✓	✓
19.	Ziehl Neelson Acid fast bacilli	✓	✓	✓
20.	Blood C&S	✓	✓	✓
21.	Sterile body fluid microscopy		✓	✓
22.	Tissue microscopy		✓	✓
23.	Eye swab N. gonorrhoea	✓	✓	✓
	HAEMATOLOGY/TRANSFUSION			
24.	FBP		✓	✓
25.	Prothrombin Time / INR	✓	✓	✓
26.	APTT	✓	✓	✓
27.	Fibrinogen		✓	✓
28.	FDPS/D-Dimer		✓	✓
29.	Antibody Screening		✓	✓
30.	Antibody Identification		✓	✓
31.	Bone Marrow Aspirate		✓	✓
32.	Leukemia Immunophenotyping		✓	✓
33.	Group and cross match	✓	✓	✓
34.	Full Blood Count	✓	✓	✓

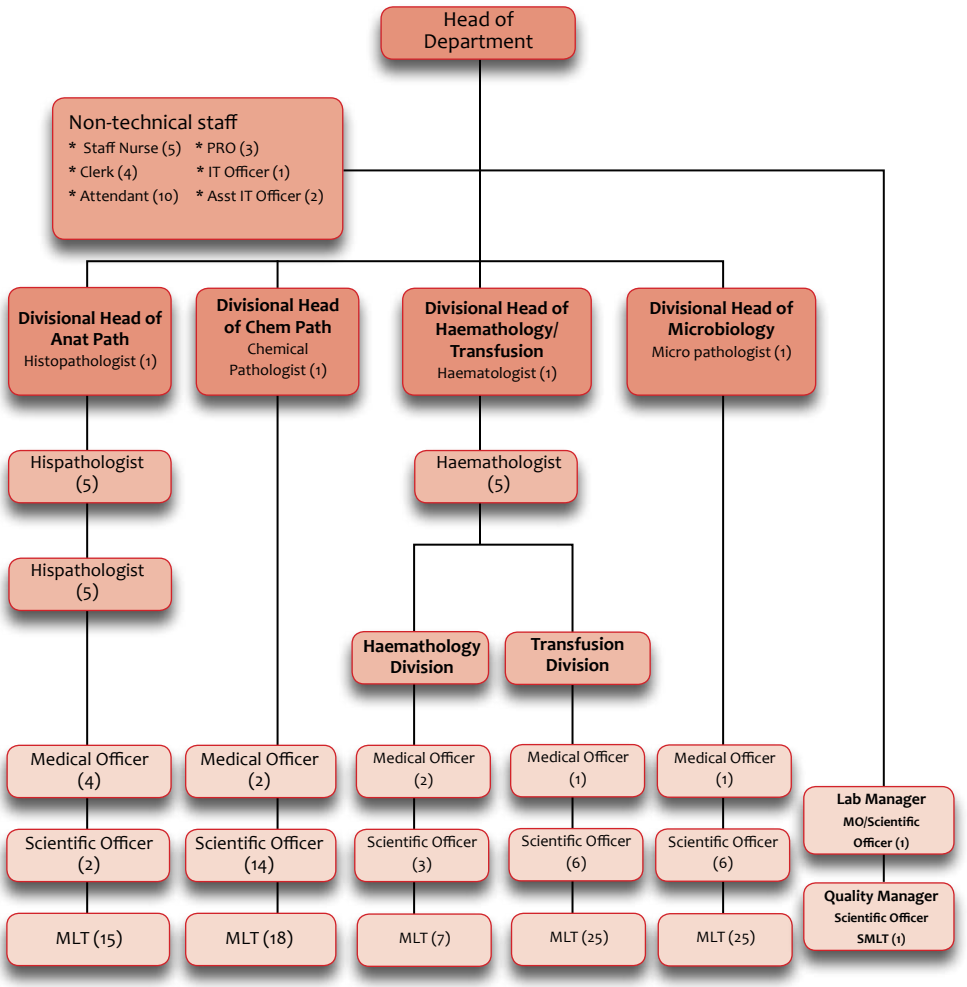
Appendix 4;
ORGANISATION STRUCTURE OF NATIONAL PATHOLOGY SERVICES, MOH



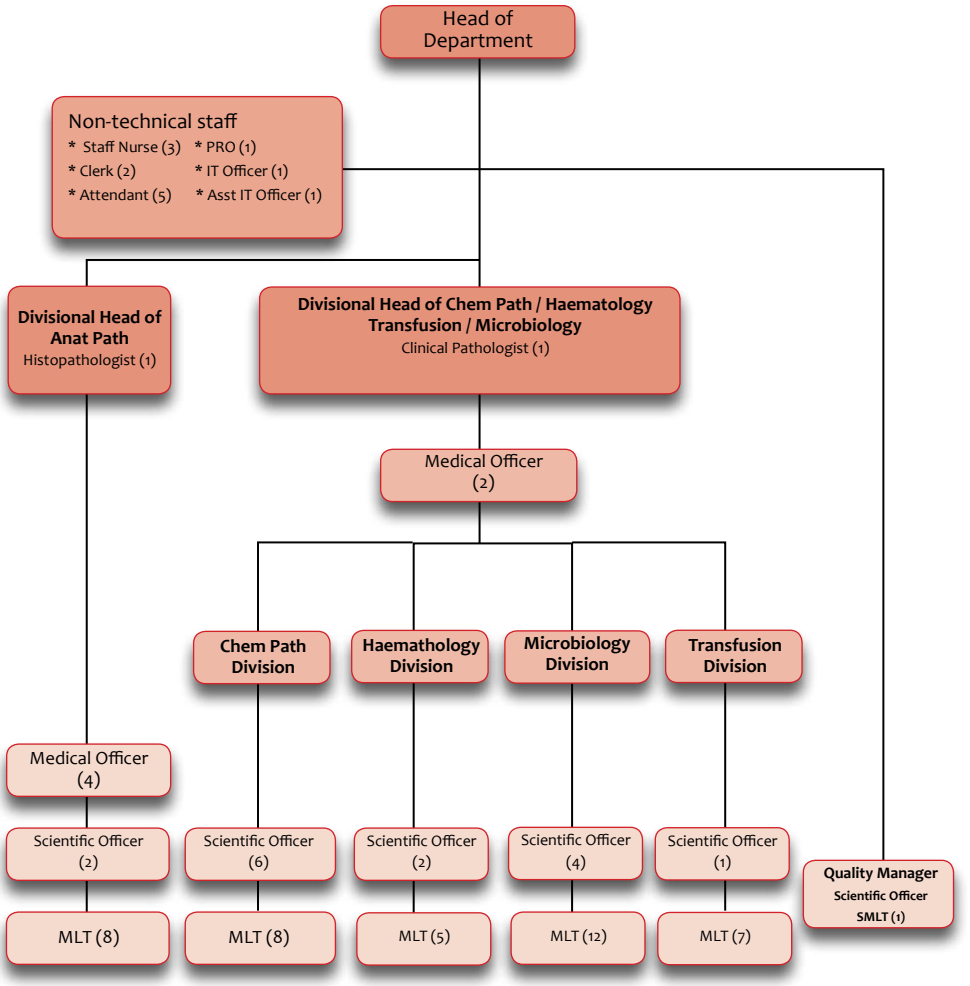
Appendix 5; ORGANISATION STRUCTURE OF LABORATORIES (STATE HOSPITALS) WITHOUT DICIPLINE SPECIFIC PATHOLOGIST



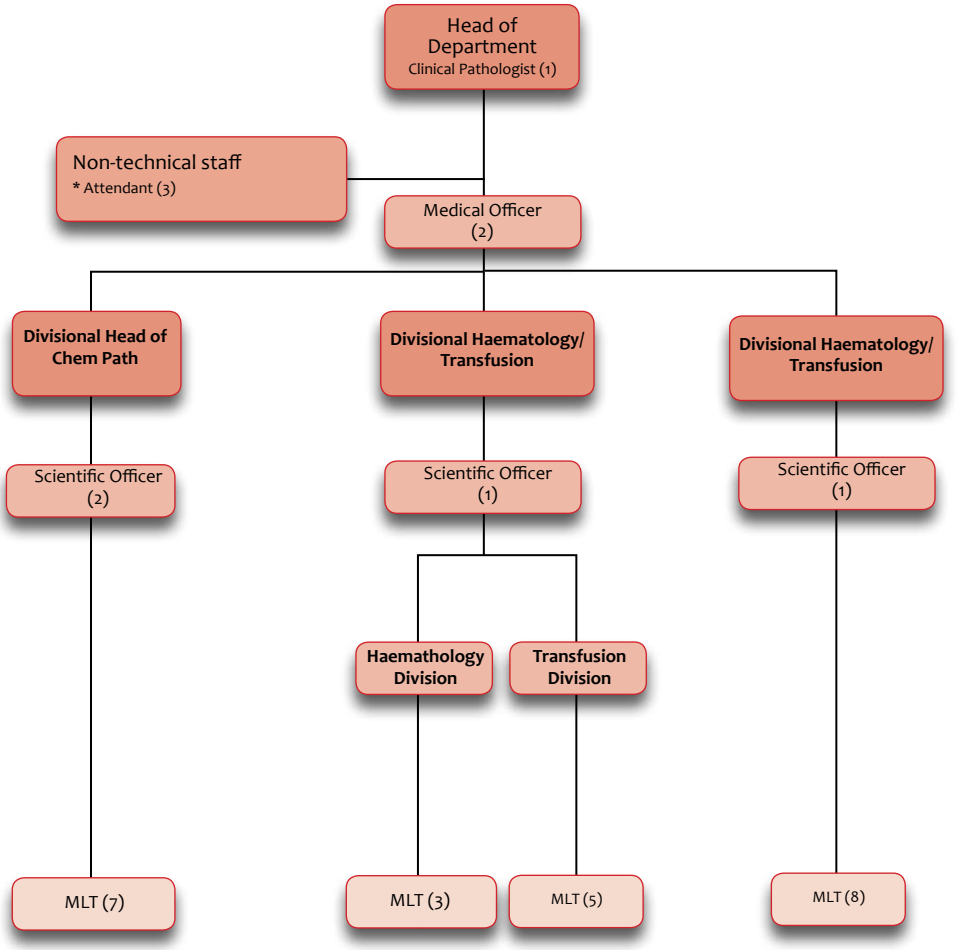
Appendix 6; PATHOLOGY STAFFING STRUCTURE AT STATE HOSPITAL



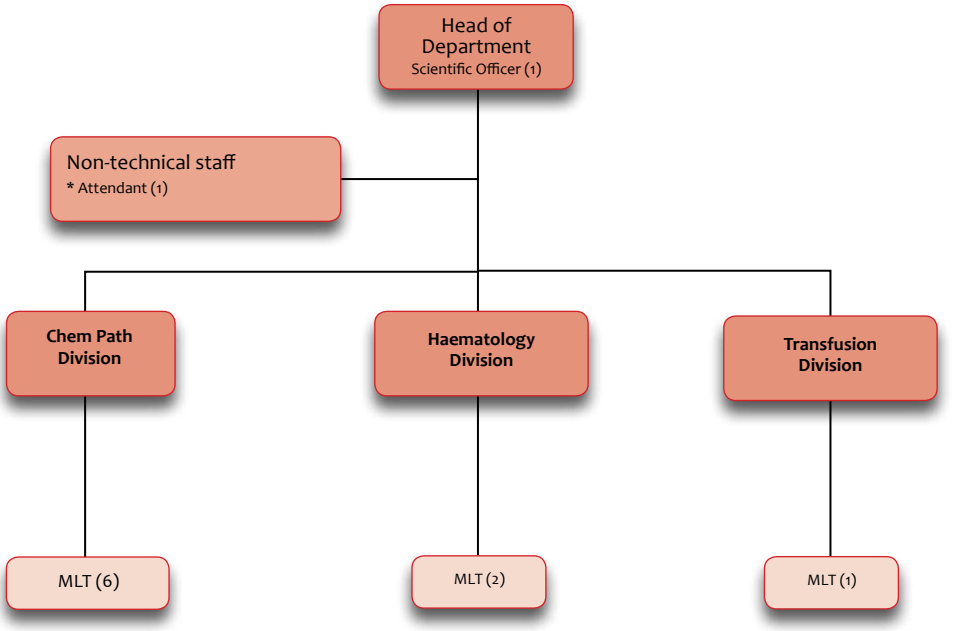
Appendix 6; PATHOLOGY STAFFING STRUCTURE AT MAJOR SPECIALIST HOSPITAL



Appendix 6; PATHOLOGY STAFFING STRUCTURE AT MINOR SPECIALIST HOSPITAL



Appendix 6; PATHOLOGY STAFFING STRUCTURE AT NON-SPECIALIST HOSPITAL



Appendix 7; RATIO WORKLOAD TO VARIOUS CATEGORIES OF LAB PERSONNEL

No	Catogories of Lab Personnel	Ratio Of Specific Discipline To Workload
1.	Pathologist	1 Chemical Pathologist : 300,000samples/year 1 Haematologist : 100,000 samples/year 1 Anatomic Pathologist (Histo) : 2,000 cases / year 1 Anatomic Pathologist (Cyto) : 4,000 cases / year 1 Clinical Microbiologist : 50,000 samples/year
2.	Medical Officer	1 Medical Officer (Chem. Path.): 300,000 samples/year 1 Medical Officer (Hemato.) : 50,000 samples/year 1 Medical Officer (Histo : 4,000 cases / year 1 Medical Officer (Cyto) : 8,000 cases / year 1 Medical Officer (Micro.) : 25,000 samples/year
3.	Scientific Officers (SO)	1 SO Chem. Pathology : 80,000 samples/year (for routine test) 1 SO Chem. Pathology : 40,000 samples/year (for specialized test) 1 SO Haematology (routine) : 300,000 samples/year 1 SO Haematology (spec) : 1,000 samples/year 1 SO Histopatholgy : 5,000 cases / year 1 SO Microbiology : 25,000 samples/year
4.	Medical Laboratory Technologists (MLT)	1 MLT Chemical Pathology : 40,000 samplesyear 1 MLT Haematology : 25,000 samples/year (for routine test) 1 MLT Haematology : 2,000 samples/year (for specialized test) 1 MLT Histopatholgy : 5,000 cases / year (for routine test) 1 MLT Histopatholgy : 5,000 cases / year (for specialized test) 1 MLT Cytotechnologist : 5,000 cases / year (for routine test) 1 MLT Cytoscreeners : 3,000 cases / year (for routine test) 1 MLT Microbiology : 5, 000 samples/year

Appendix 8; RATIO WORKLOAD TO VARIOUS CATEGORIES OF LAB PERSONNEL

1. CHEMICAL PATOLOGY

No.	Test	Hospital Category									
		Non Specialist		Minor Specialist		Major Specialist		State		Regional/ Referral	
		Capacity	No	Capacity	No	Capacity	No	Capacity	No	Capacity	No
A.	PREANALYTICAL										
1.	Pneumatic tube						✓		✓		✓
2.	Preanalytical Automated System								✓		✓
3.	Auto sampler Sorter						✓				
B.	ROUTINE CLINICAL CHEMISTRY										
1.	Chemistry analyzer with ISE	700 t/hr		1200 t/h		1200 t/h		2400 t / hr		2400 thr	
2.	Blood Gas analyzer	80 t/hr units		80 t/hr units		80 t/hr units		80 t/hr units		80 t/hr units	
3.	Fully automated Urine analyzer w microscopic								✓		✓
4.	Automated Urine analyzer strip (manual microscopic)		✓		✓		✓				
5.	Osmometer		✓		✓		✓		✓		✓
6.	HbA1c-HPLC automated with auto-sampler	50 test /hr		50 test /hr		50 test /hr		100 test /hr		100 test/ hr	
7.	Analyser for Microalbumin		✓		✓		✓		✓		✓
C.	HORMONES/ TUMOUR MARKERS										
1.	Immunoassay analyzer (routine hormones)	50-100 t/hr		200 t/hr		200 t/hr		200 t/hr		200 t/hr	
2.	Immunoassay analyzer (extended hormones)									200 t/hr	
3.	Gamma counter (for Hormone test RIA method)										✓
4.	HPLC (Catecholamine)										✓
D.	IEM										✓
1.	GCMS (Organicacid)										
2.	HPLC (amino acids)										✓
3.	HPLC (purine & pyrimidine)										✓
4.	Spectrophotometer										✓
5.	Tandem mass spectrophometry										✓
A.	CLINICAL TOXICOLOGY										
1.	Chemistry Analyzer without ISE				✓		✓		✓		✓
2.	Immunoassay (TDM) analyzer	200 t/hr		200 t/hr		200 t/hr					
3.	GCMS										✓
4.	LC MS/MS										✓
5.	HPLC										✓
6.	Horizontal Shaker medium speed										✓
7.	Centrifuge floor stand for 50 cc type (Drug)										✓
8.	Sample Vacuum Concentrator										
9.	Autoclave floor model										✓
10.	Automated SPE System										✓
11.	Electrolyte analyzer with lithium										✓
12.	Atomic Absorption Spectrophotometer										✓
F.	PROTEIN AND PROTEONOMIC										
1.	1D Electrophoresis									Hosp Ampang	✓
2.	2D electrophoresis										✓
3.	Image Scanner										
4.	2DPlatinum Analyser										✓
5.	Spot picker										✓
6.	Gel Digester & Spotter										✓
7.	Automated Spot Handler										✓

No.	Test	Hospital Category									
		Non Specialist		Minor Specialist		Major Specialist		State		Regional/ Referral	
		Capacity	No	Capacity	No	Capacity	No	Capacity	No	Capacity	No
8.	HPLC										✓
9.	2D Gel Imaging Sys & Protein spot picker										✓
10.	Gel Documentation										✓
11.	Hydrasys Electrophoresis										✓
12.	Microarray Analyser										✓
13.	Gel electrophoresis										✓
14.	Immunochemiluminescence Analyser										✓
15.	Macintosh computer software										
16.	LC/MS/MS(Q-TOF)										✓
17.	Ampliprep										
18.	Refrigerated centrifuge										✓
19.	Amplificator Analyser &Datastation										✓
20.	Radiograph developer										✓
21.	UV spectrophotometer										✓
22.	Flurorescene scanner										✓
23.	Light Cycle										✓
24.	Automatic stainer										✓
25.	Capillary electrophoresis										✓
26.	Pure LC automated Nucleic acid purufication system										✓
27.	Automated sample homogeniser system										✓
28.	Biological Safety Cabinnette Class II										✓
29.	Agarose gel electrophoresis system										✓
30.	Gene Micro/Nanoarray										✓
31.	Automated nucleic acid extraction										✓
32.	Centrifuge high speed with rotor										✓
33.	Incubator shaker										✓
G.	COMMMON (Pre / Analiyical / Post)										
1.	Bench Top Centrifuge										
2.	Microcentrifuge										
3.	Refrigerator										
4.	Freezer (-70)										
5.	Freezer -20										
6.	Refrigerator Medical 1000L										
7.	Refrigerator 480 L										
8.	Fume Hood										
9.	Balance analytical 200 G, 0.01g										
10.	Balance weighing 1200g										

2. MICROBIOLOGY

No.	Test	Hospital Category									
		Non Specialist		Minor Specialist		Major Specialist		State		Regional/ Referral	
		Capacity	No	Capacity	No	Capacity	No	Capacity	No	Capacity	No
A.	BACTERIOLOGY CULTURE										
1.	Microscope - binocular		✓		✓		✓		✓		✓
2.	- inverted				✓		✓		✓		✓
3.	Slide heater		✓		✓		✓		✓		✓
4.	Incubator – CO_2				✓		✓				
5.	- 370C				✓		✓		✓		✓
6.	Centrifuge		✓		✓		✓		✓		✓
7.	Fridges				✓		✓		✓		✓
8.	Safety Cabinet Class II		✓		✓		✓		✓		✓
9.	Autoclave		✓		✓		✓		✓		✓
10.	Cytospin				✓		✓		✓		✓
11.	Water bath				✓		✓		✓		✓
12.	Water deioniser				✓		✓		✓		✓
13.	Automated urine analyzer/ quantitative				✓		✓		✓		✓
14.	Automated blood Culture system				✓		✓		✓		✓
15.	Automated bacte identification & susceptibility								✓		✓
16.	Automated media dispenser								✓		✓
17.	Automated media preparation system								✓		✓
18.	Immunofluorescene microscope								✓		✓
19.	Air sampler								✓		✓
20.	Automated Antibiotic reader								✓		✓
21.	Anaerobic culture workstation				✓		✓		✓		✓
22.	Automated glassware washer								✓		✓
B.	TB LAB										
23.	Incubator for – CO_2								✓		✓
24.	Incubator - 370C								✓		✓
25.	Centrifuge								✓		✓
26.	Fridge		✓		✓		✓				
27.	Microscope binocular		✓		✓		✓		✓		✓
28.	Safety Cabinet		✓		✓		✓		✓		✓
29.	TB culture & identification system								✓		✓
C.	BACTERIOLOGY SEROLOGY										
30.	Safety cabinet class II				✓		✓		✓		✓
31.	Centrifuge				✓		✓		✓		✓
32.	Fridge				✓		✓		✓		✓
33.	Freezer-20C				✓		✓		✓		✓
34.	-70C										
35.	Automated enzyme immunoassay system				✓		✓		✓		✓
36.	EIA reader				✓		✓		✓		✓
37.	EIA washer				✓		✓		✓		✓
38.	Shaker/Rotator				✓		✓		✓		✓
39.	Microscope				✓		✓		✓		✓
40.	Water bath				✓		✓		✓		✓
D.	VIROLOGY										
41.	Automated enzyme immunoassay system				✓		✓		✓		✓
42.	Centrifuge				✓		✓		✓		✓
43.	Fridge				✓		✓		✓		✓
44.	Freezer – 20 ° C				✓		✓		✓		✓
45.	- 70 ° C				✓		✓		✓		✓
46.	Safety cabinet class II				✓		✓		✓		✓
47.	Binocular microscope				✓		✓		✓		✓
C.	IMMUNOLOGY										
48.	Safety cabinet class II						✓		✓		✓

No.	Test	Hospital Category									
		Non Specialist		Minor Specialist		Major Specialist		State		Regional/ Referral	
		Capacity	No	Capacity	No	Capacity	No	Capacity	No	Capacity	No
49.	Centrifuge						✓		✓		✓
50.	Fridge						✓		✓		✓
51.	Freezer - 20C						✓		✓		✓
52.	- 70C						✓		✓		✓
53.	Automated enzyme immunoassay system						✓		✓		✓
54.	EIA reader						✓		✓		✓
55.	EIA washer						✓		✓		✓
56.	Shaker						✓		✓		✓
57.	Microscope-binocular						✓		✓		✓
F.	MYCOLOGY										
58.	Mycology blood system						✓		✓		✓
59.	Safety cabinet class II						✓		✓		✓
60.	Fridge						✓		✓		✓
61.	Microscope - binocular						✓		✓		✓
62.	- inverted						✓		✓		✓
63.	Incubator - CO_2						✓		✓		✓
64.	- 37C						✓		✓		✓
65.	- 40C										
66.	Centrifuge										
G.	PARASITOLOGY										
67.	Safety cabinet class II				✓		✓		✓		✓
68.	Fridge		✓		✓		✓		✓		✓
69.	Incubator - CO_2				✓		✓		✓		✓
70	- 37C				✓		✓		✓		✓
71.	Safety cabinet class II				✓		✓		✓		✓
72.	Fridge				✓		✓		✓		✓
73.	Incubator - CO_2				✓		✓		✓		✓
74.	- 37C				✓		✓		✓		✓
75.	Water bath				✓		✓		✓		✓
76.	Water bath		✓		✓		✓		✓		✓
77.	Microscope - binocular		✓		✓		✓		✓		✓
78.	Inverted		✓		✓		✓		✓		✓
H.	MOLECULAR LAB										
79.	Thermal Cycler Machine										✓
80.	Electrophoretic set										✓
81.	Gel Imaging System										✓
82.	Dry block										✓
83.	BSC II										✓
84.	Spectrophotometer										✓
85.	Refrigerated Centrifuge										✓
86.	Microcentrifuge										✓
87.	Micropipettor										✓
88.	Vortex										✓
89.	Fridge										✓
90.	Ice Flaker Machine										✓
91.	Freezer -30										✓
92.	Freezer -80										✓
93.	Automated PCR System										✓
I.	LAB FOR UNKNOWN ORGANISM										
94	BSC II										✓
95	Microscope binocular										✓
96	Incubator 370C										✓
97	Incubator CO_2										✓
98	Bench top Centrifuge										✓
99	Freezer -200C										✓
100	Refrigerator										✓
101	Autoclave										✓
102	Bacticinerator										✓
103	Automated EIA Analyser										✓

No.	Test	Hospital Category									
		Non Specialist		Minor Specialist		Major Specialist		State		Regional/ Referral	
		Capacity	No	Capacity	No	Capacity	No	Capacity	No	Capacity	No
104.	UV microscope										✓
105.	Rotater										✓

3. HAEMATOLOGY

No.	Test	Hospital Category									
		Non Specialist		Minor Specialist		Major Specialist		State		Regional/ Referral	
		Capacity	No	Capacity	No	Capacity	No	Capacity	No	Capacity	No
A. GENERAL HAEMATOLOGY (Integrated laboratory for State Hospitals & HKL)											
1.	Haematology Analyser. High range,min 22 parameters + slide maker stainer,		0		0		0	CBC >100/hr	1	CBC>100/hr	1
2.	Haematology Analyser. High range min 22 parameters.		0		0		0	CBC>100/hr	1	CBC>100/hr	1
3.	Haematology Analyser, Medium range,min 22 parameters	CBC60-99/hr	1	CBC60-99/hr	1	CBC60-99/hr	1		0		0
4.	Haematology Analyser, Medium Range, 18 parameters		0	CBC60-99/hr	1	CBC60-90/hr	1		0		0
5.	Haematology Analyser, Low Range, 12-18 parameters (3 – 5 pt diff)	CBC60-99/hr	1		0		0		0		0
6.	Haemoglobinometer: For Antenatal and Haj pilgrimage checkup		2		2		2		2		2
7.	ESR Analyzer, Automated	Min 20 tests/hr	2	Min 20 tests/hr	2	Min 20 tests/hr	2	Min 20 tests/hr	2	Min 20 tests/hr	2
8.	**Coagulation Analysers :** Coagulation Analyzer. Automated, Medium through put			100-200 PTs/hr	1	100-200 PTs/hr	2	100-200 PTs/hr	2	100-200 PTs/hr	2
9.	Coagulation Analyzer. Semi-automated, bench-top	Operator Dependant	2	Operator Dependant	1	1 backup	0		0		0
10.	Centrifuge,Bench top,refrigerated		1		1		1		1		1
B. FULL BLOOD PICTURE / BONE MARROW ASPIRATION											
1.	Haematology Analyser, Medium range, min 22 parameters		0		0	CBC60-90/hr	0	CBC60-90/hr	1		1
2.	Automated Hematology Slide Stainer		1		1		1		1		1
C. THALASSEMIA / HAEMOGLOBINOPATHY											
1.	Automated Hb electrophoresis		0		0		0	Fully auto 10 samples	1	Fully auto 10 samples	1
2.	HPLC		0		0		0		2		2
3.	Water bath		0		0		0		1		1
D. HAEMOLYTIC ANAEMIAS											
1.	UV box (G6PD Screening)		1		1		1		1		1
2.	Water bath		1		1		1		1		1
3.	UV Visible Spectrophotometer (RBC Enzyme Assay)		0		0		0	(HKL only)	1	(HKL only)	1
4.	Block Heater(RBC Enzyme Assay)		0		0		0	(HKL only)	1	(HKL only)	1
E. HEMOSTASIS / THROMBOSIS											
1.	Regionalised service for Extended Basic Haemostasis & Thrombosis in PP,SAJB,KT,QE,Kuching only)										
2.	Coagulation Analyzer , Automated, High Throughput (Extended basic Haemostasis & Thrombosis)		0		0		0	1 each (hosp as above)		1 each (hosp as above)	
3.	Centrifuge, Bench top, refrigerated		0		0		0	1 each (hosp as above)		1 each (hosp as above)	
4.	Waterbath		0		0		0	1 each (hosp as above)		1 each (hosp as above)	
F. LYMPOCHYTE SUBSETS MERATION											
	Regionalised service in state hospital - HKL,Ipoh,SAJB,KB,QE & Kuching and in Hospital Sungai Buloh										

No	Test	Hospital									
		Non Specialist		Minor Specialist		Major Specialist		State		Regional/ Referral	
		Capacity	No	Capacity	No	Capacity	No	Capacity		Capacity	No
1	Biohazard safety cabinet		0		0	1(Hosp Sg Buloh)		1 each (Excluding Hosp. Sg. Buloh)		1 each (Excluding Hosp. Sg. Buloh)	
2	Flow cytometer		0		0	1(Hosp Sg Buloh)		1 each (Excluding Hosp. Sg. Buloh)		1 each (Excluding Hosp. Sg. Buloh)	
3	Vortex Mixer		0		0	1(Hosp Sg Buloh)		1 each (Excluding Hosp. Sg. Buloh)		1 each (Excluding Hosp. Sg. Buloh)	
	A. HEMATO-ONCOLOGY										
	Regionalised service in HKL,KB,SAJB,PP,QE & Kuching										
1	Flow cytometer		0		0		0	1 each (hosp as above)		1 each (hosp as above)	
2	Centrifuge,Table top,multiuse		0		0		0	1 each (hosp as above)		1 each (hosp as above)	
	B. STEM CELL TRANSPLANTATION										
	Currently available in HKL only. Planned for HPP , pending approval of DB 2010/11										
1	Cell Processing system		0		0		0		1 each		1 each
2	Automated blood component separator		0		0		0		1 each		1 each
3	Liquid Nitrogen Storage system including liquid nitrogen tanks		0		0		0		2 each		2 each
4	Sterile tubing connector		0		0		0		1 each		1 each
5	Controlled Rate Freezeing system		0		0		0		1 each		1 each
6	Flowcytometer		0		0		0		1 each		1 each
7	Freezer,-80^{o}C		0		0		0		1 each		1 each
8	Refrigerator, laboratory		0		0		0		1 each		1 each
9	Biohazard Safety Cabinet		0		0		0		2 each		2 each
10	Centrifuge		0		0		0		1 each		1 each
11	Stem cell separation system		0		0		0		1 each		1 each

4. ANATOMICAL PATHOLOGY

No	Test	Hospital									
		Non Specialist		Minor Specialist		Major Specialist		State		Regional/ Referral	
		Capacity	No	Capacity	No	Capacity	No	Capacity	No	Capacity	No
A. DEMOGRAPHY											
1	Computer						1		1		2
2	Bar code scanner						1		1		2
3	Acroprinter						1		1		2
B. GROSSING SECTION											
1	Grossing station						1		2		3
2	Digital electronic weighing balance (general purpose)						1		2		3
3	Refrigerator						1		1		1
4	Transcription/Dictation system						1		2		3
5	Grossing set						1		4		6
6	Automated cassette labeler						1		1		2
7	Biohazzard cabinet class 2						1		1		1
8	Photography system						1		1		1
9	Computer						1		1		2
C. TISSUE PROCESSING SECTION											
1	Tissue processor (low/medium capacity)						2				
2	Tissue processor (high capacity)								2		3
D. EMBEDDING SECTION											
1	Tissue embedding centre						2		2		3
2	Hot air oven						1		1		1
E. SECTIONING SECTION											
1	Freezer 0°C						1		1		1
2	Cold plate						2		2		3
3	Microtome						2		3		4
4	Tissue float bath						2		3		4
F. STAINING AND MOUNTING SECTION											
1	Fume cabinet						1		1		1
2	Automated slide stainer					Low	2	Low	1		
3	Automated Slide Stainer					High	1	High	1	High	2
4	Automatic slide labeller						1		2		2
5	Automatic cover slipper						1		2		2
6	Binocular microscope						1		1		1
7	Cryocut						1		1		1

No	Test	Hospital									
		Non Specialist		Minor Specialist		Major Specialist		State		Regional/ Referral	
		Capacity	No	Capacity	No	Capacity	No	Capacity		Capacity	No
A. IMMUNOFLUORENCE AND HISTOCHEMICAL ENZYME											
1	Trinocular dissecting microscope(renal, rectal and muscle bx)						1		1		1
2	Cryocut						1		1		2
3	Ultra low freezer(-80C)										1
4	Freezer(-30C)						1		1		1
5	2 door chiller for reagents						1		1		2
B. SPECIAL STAIN AND IMMUNOHISTOCHEMISTRY											
1	Analytical measuring balance						1		1		1
2	Fully Automated immunostainer						1		1		2
3	Binocular microscope						1		1		1
4	Graduated pipette with disposable tips						1		1		1
5	Hot air oven 37C/hotplate for slide drying						1		1		1
6	Microtome; semi-thin rotary(renal bx)						1		1		1
7	Microwave oven; scientific(Ag retrieval)						1		1		1
8	pH meter						1		1		1
9	Pressure cooker; scientific (Ag retrieval)						1				
10	Tissue float bath						1		1		1
11	Water distiller						1		1		1
C. DIAGNOSTIC											
1	Binocular microscope(1 for each MO according to workload norm)						3		4		6
2	Double viewer microscope						3		4		5
3	Multiviewer microscope						1		2		3
4	Trinocular dissecting microscope with CCD attachment with software and hardware(1 for each pathologist according to workload norm)						5		8		11
5	Computer (for reporting 1 each reporting doctor)						8		12		16

APPENDIX 9

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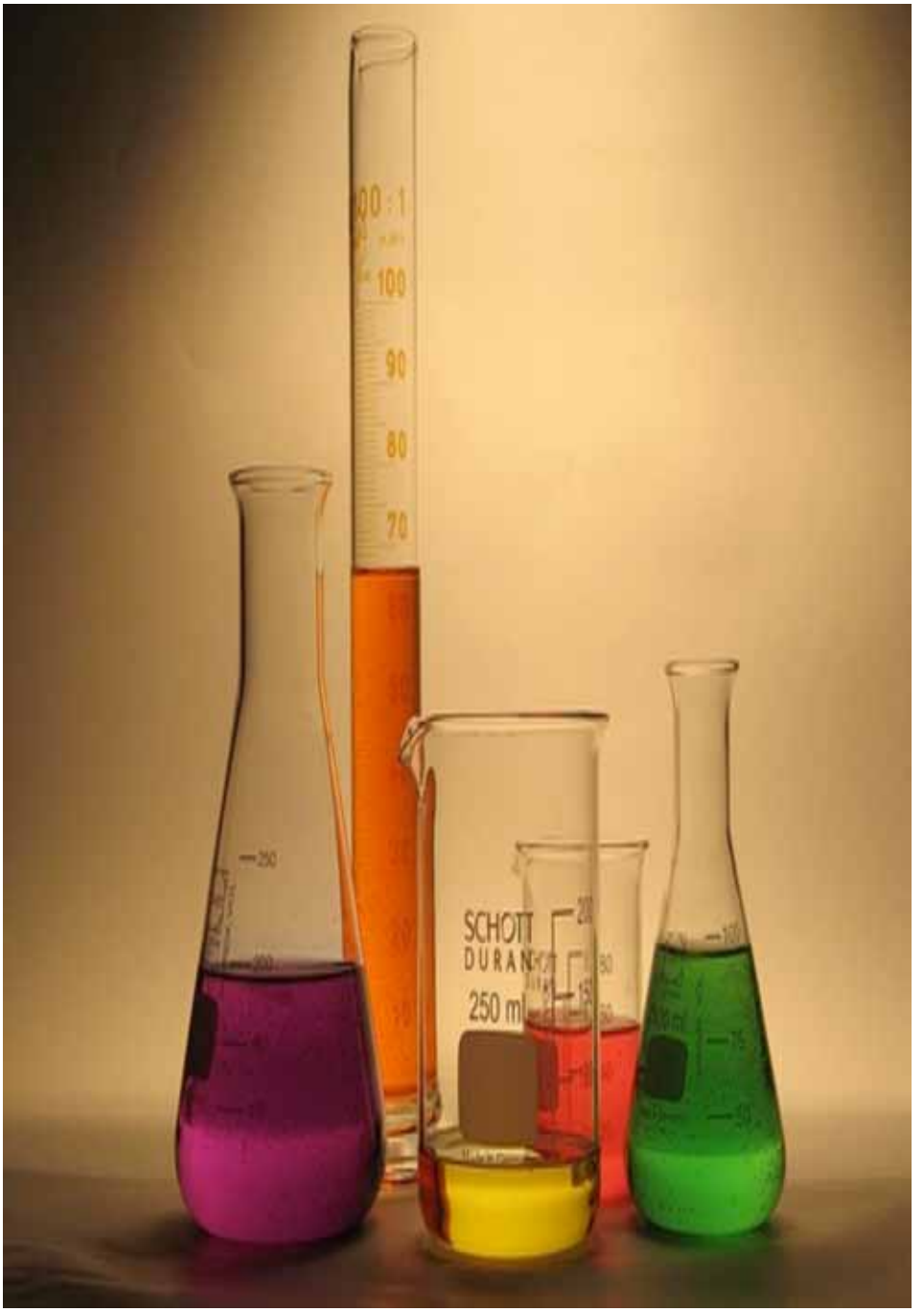
ABBREVIATIONS

AP	Anatomical Pathology
ASHE	American Society for Healthcare Engineering
BER	Beyond Economic Repair
DSM	Department of Standards Malaysia
EQA	External Quality Assurance
FNAC	Fine Needle Aspiration Cytology
HOD	Head of Department
HOU	Head of Unit
IEC	International Electro technical Commission
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
MLT	Medical Laboratory Technologist
MO	Medical Officer
MOH	Ministry of Health
MS	Malaysian Standard
NATA	National Association of Testing Authorities Australia
NIA	National Indicator Approach
POCT	Point of Care Testing
PPK	Pembantu Perawatan Kesihatan
PTJ	Pusat Tanggungjawab
QA	Quality Assurance
QAP	Quality Assurance Program
QMS	Quality Management System
SIHAT	Sistem Hospital Awasan Taraf Sdn Bhd
SO	Scientific Officer
TAT	Turn Around Time



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