SERVICE STANDARD 15 : PATHOLOGY SERVICES

PREAMBLE

Pathology Services may be provided by a laboratory or laboratories within, or external to the Facility. The Pathology Services may include Anatomical Pathology, Chemical Pathology, Haematology, Microbiology and Genetics. The services shall be organised and administered to provide a comprehensive and quality diagnostic service which is innovative, efficient and reliable for quality and safe patient care.

TOPIC TOPIC 15.1
ORGANISATION AND MANAGEMENT

STANDARD STANDARD 15.1.1
Where Pathology Services are provided, the Pathology Services shall be organised and administered to provide quality laboratory and diagnostic services appropriate to the clinical services provided by the Facility

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
15.1.1.1	Vision, Mission and values statements of the Facility are accessible. Goals and objectives that suit the scope of the Pathology Services are clearly documented and measurable that indicates safety, quality and patient centred care. These reflect the roles and aspirations of the service and the needs of the community. These statements are monitored, reviewed and revised as required accordingly and communicated to all staff.	NA			NA	
	EVIDENCE OF COMPLIANCE					
	1. Vision, Mission and values statements of the Facility are available, endorsed and dated by the Governing Body. — NA					
	2. Goals and objectives of the Pathology Services in line with the Facility statements are available, endorsed and dated. — NA					
	3. Evidence of planned reviews of the above statements. — NA					
	4. These statements are communicated to all staff (orientation programme, minutes of meeting, etc) — NA					
	5. Achievement of goals and objectives are monitored, reviewed and revised accordingly. — NA					
15.1.1.2 CORE	There is an organisation chart which: a) provides a clear representation of the structure, functions and reporting relationships between the Person In Charge (PIC), Head and staff of the Pathology Services;	NA			NA	

	b) includes linkage to parent company if the service is outsourced where applicable; c) is accessible to all staff and clients; d) includes off-site, satellite, cluster hospital laboratory (where applicable); e) is revised when there is a major change in any of the following: • i) organisation; • ii) functions; • iii) reporting relationships; • iv) staffing patterns. All off-site and satellite, cluster hopital laboratory under the purview of Pathology Services shall be included in the main organisation chart. EVIDENCE OF COMPLIANCE 1. Clearly delineated current organisation chart with line of functions and reporting relationships between the Person In Charge (PIC), Head and staff of the Pathology Services. — NA 2. Organisation chart of the service is endorsed, dated and accessible. — NA 3. The organisation chart is revised when there is a major change in any of the items (e)(i) to (iv). — NA					
15.1.1.3	Regular staff meetings are held between the Head of Service and staff with sufficient regularity to discuss issues and matters pertaining to the operations of the Pathology Services. Minutes are kept; decisions and resolutions made during meetings shall be communicated and accessible to all staff of the service and implemented. EVIDENCE OF COMPLIANCE 1. Minutes are accessible, disseminated and acknowledged by the staff. — NA 2. Attendance list of members with adequate representatives of the service. — NA 3. Frequency of meetings as scheduled. — NA 4. Discussion and resolutions are implemented (Problems not solved to be brought forward in the next meeting until resolved). — NA	NA			NA	
15.1.1.4	The Head of Pathology Services is involved in the planning, justification and management of the budget and resource utilisation of the services.	NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Minutes of Facility-wide management meeting	NA				
	2.	Documented evidence on request for allocation of budget and resources (staffing, equipment, etc) for the service.	NA				
	3.	Approved budget and resources.	NA				
15.1.1.5	The Head of the Pathology Services is involved in the appointment and/OR assignment of staff			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Records on staff interview (if applicable)	NA				
	2.	Appointment/assignment letter of Head of Service	NA				
	3.	Job description of Head of Service	NA				
	4.	Records on staff deployment	NA				
	5.	Duty roster	NA				
15.1.1.6	The Head of Pathology Services is responsible for the medical and technical aspects of the testing and is involved in the safety and performance improvement activities of the Facility as appropriate.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Credentials and job description of Head of Pathology Services.	NA				
15.1.1.7	There is cooperation from the staff of Pathology Services with other relevant staff in contributing to patient care on matters related to laboratory activities and knowledge.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Documented evidence of interaction with the relevant staff of the facility/services.	NA				
15.1.1.8	Appropriate statistics and records shall be maintained in relation to the provision of Pathology Services and used for managing the services and patient care purposes			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Records are available but not limited to the following:					
	a)	workload/census	NA				
	b)	annual report;	NA				

	c)	accident/incident reports;	NA				
	d)	staffing number and staff profile;	NA				
	e)	staff training records;	NA				
	f)	data on performance improvement activities, including performance indicators.	NA				
15.1.1.9 CORE	Where services are provided in areas other than in the main Pathology Services, for example, Intensive Care Units, neonatal nurseries, the following requirements shall be considered: a) responsibility for the operations of those services is clearly defined; b) staff are closely supervised and given appropriate instructions of operations of the services by assigned staff from the main Pathology Services; c) the equipment is properly maintained and quality control is carried out and documented.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Define responsibility for the operations of the services outside of the main Pathology Services.	NA				
	2.	Records on training	NA				
	3.	Records on staff supervision	NA				
	4.	Records on the equipment maintenance	NA				
	5.	Records on quality control (QC) carried out	NA				
	6.	Record on monitoring by laboratory staff	NA				

STANDARD STANDARD 15.1.2

Facilities that do not have their own Pathology Services or cannot provide a full range of laboratory services, shall arrange with an external laboratory or laboratories to provide the services needed. These laboratories shall be accredited by recognised body, e.g. Standards Malaysia (MS ISO 15189). The Facility shall appoint a registered medical practitioner or designated responsible officer to monitor the services provided by the external laboratories comply with the relevant MSQH Standards of Accreditation.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
15.1.2.1	The external providers of the Pathology Services shall conform to all relevant MSQH Standards of Accreditation.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	The off-site laboratory shall be MS ISO 15189 accredited.	NA				
	2.	There is written agreement between the external service provider and the Facility.	NA				
15.1.2.2 CORE	There is written agreement with the external service provider and the Facility specifying the following requirements: a) availability of a pathologist for consultation; b) provision of adequate numbers of appropriately qualified personnel to perform their duties; c) the type and nature of tests and investigation that are available; d) requests for tests/investigations shall be documented; e) effective and safe transmission of specimens; f) provision for immediate communication of results out of the normal range; g) arrangements for after-hours and emergency work; h) quality systems shall be in place, which include Internal Quality Control (IQC), External Quality Assurance (EQA), monitoring turnaround time (TAT), accreditation status.		NA			NA	
	EVIDENCE OF COMPLIANCE						

	1.	There is written agreement with the external service provider and the Facility specifying items (a) to (h).	NA				

TOPIC TOPIC 15.2
HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT

STANDARD STANDARD 15.2.1
Pathology Services shall be directed and supervised by a pathologist. The day-to-day operations of the service may be delegated to a suitably qualified and experienced officer, supported by appropriately qualified staff.

*Refer: Departmental Policy of Pathology Services in Ministry of Health, Malaysia

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
15.2.1.1 CORE	The direction and supervision of the services shall be by the pathologist. There is evidence that the pathologist and/or medical practitioner is actively practicing as evidenced by: a) regular on-site visits and inspection of the Pathology Services; b) ensuring and participating in continuing medical education programme EVIDENCE OF COMPLIANCE 1. Appointment/assignment letter — NA 2. Job description — NA 3. Records on regular on-site visit and inspection — NA 4. Documentation of participation in continuing medical education and meeting — NA	NA			NA	
15.2.1.2	The Head and staff of the Pathology Services shall be individuals qualified by education, training, experience currently licensed to practice pathology to commensurate with the requirements of the various positions and complexity of the services. All medical laboratory technologists shall be registered following the requirements of the Allied Health Professions Act. EVIDENCE OF COMPLIANCE	NA			NA	

	1.	Records on credentials of Head of Service and staff required to fill up the posts within the service (to match the complexity of the Facility and services) and certification/registration.	NA				
	2.	Current Annual Practising Certificate (APC)	NA				
	3.	Appointment/assignment letters	NA				
	4.	National Specialist Register (NSR) for Pathologist	NA				
	5.	Training and competency record	NA				
15.2.1.3	The authority, responsibilities and accountabilities of the Head of Pathology Services are clearly delineated and documented. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Appointment/assignment letter for Head of Service.	NA				
	2.	Description of duties and responsibilities	NA				
15.2.1.4 CORE	Sufficient numbers of personnel and support staff with appropriate qualifications are employed to meet the need of the services. Notes/Explanations Staff are adequately trained and qualified to perform the tasks required of them. The number of staff employed shall commensurate with the workload of the Pathology Services. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Number of staff and qualification should commensurate with workload.	NA				
	2.	Staffing pattern	NA				
	3.	Duty roster	NA				
	4.	Census and statistics	NA				
15.2.1.5	There are written and dated specific job descriptions for all categories of staff that include: a) qualifications, training, experience and certification required for the position; b) lines of authority; c) accountability, functions and responsibilities;			NA			NA	

	d) reviewed when required and when there is a major change in any of the following: • i) nature and scope of work; • ii) duties and responsibilities; • iii) general and specific accountabilities; • iv) qualifications required and privileges granted; • v) staffing patterns; • vi) Statutory Regulations. e) administrative and clinical functions. **EVIDENCE OF COMPLIANCE** 1. Updated specific job description is available for each staff that includes but not limited to as listed in (a) to (e). — NA 2. Job description includes specialisation skills — NA 3. Relevant privileges granted where applicable — NA 4. The job description is acknowledged by the staff and signed by the Head of Service and dated. — NA					
15.2.1.6	Personnel records on training, staff development, leave and others are maintained for every staff. Note: Staff personal record may be kept in Human Resource Department as per Facility policy **EVIDENCE OF COMPLIANCE** 1. Staff personal records include: a) staff biodata; — NA b) qualification and experience; — NA c) evidence of current registration; — NA d) training record; — NA e) competency record and privileging; — NA f) leave record; — NA	NA			NA	

	g)	confidentiality agreement;	NA				
	h)	health screening status;	NA				
	i)	immunisation status.	NA				
15.2.1.7	There is a comprehensive and structured orientation and induction programme where new staff including medical practitioners are briefed on their services, operational policies and relevant aspects of the Facility to prepare them for their roles and responsibilities. This includes but not limited to: a) rules and regulations, especially those related to health hazards and safety precautions; b) requirements for immunisation against certain high-risk diseases; c) policies and procedures on all aspects of Pathology Services; d) all relevant manuals, e.g. health and safety manual.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Policy requiring all new staff to attend a structured orientation programme.	NA				
	2.	There is Pathology Services orientation programme with relevant topics not limited to topics covered from (a) to (d).	NA				
	3.	Attendance list	NA				
15.2.1.8	There is evidence of training needs assessment and staff development plan which provides the knowledge and skills required for staff to maintain competency in their current positions and future advancement.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Training needs assessment is carried out and gaps identified.	NA				
	2.	A staff development plan based on training needs assessment is available.	NA				
	3.	Training schedule/calendar is in place.	NA				
	4.	Training module	NA				
15.2.1.9	There are continuing education activities for staff to pursue professional interests and to prepare for current and future changes in practice.			NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Training calendar includes in-house/external courses/ workshop/conferences	NA				
	2.	Contents of training programme	NA				
	3.	Training records on continuing education activities are kept and maintained for each staff including training in life support.	NA				
	4.	Certificate of attendance/degree/post basic training.	NA				
15.2.1.10	The Pathology Services shall provide a continuing education activity for non-laboratory health professional staff to keep them informed of matters related to Pathology Services.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Continuing medical education for non-laboratory health professional staff.	NA				
	2.	Records on attendance	NA				
15.2.1.11	Staff including medical practitioners receive evaluation of their performance at the completion of the probationary period and annually thereafter, or as defined by the Facility.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Performance appraisal for staff including medical practitioners are completed upon probationary period and as an annual exercise.	NA				
15.2.1.12	Where applicable, the functions of the Pathology Services include undergraduate, postgraduate and other health professional education, research projects and special studies, as appropriate.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Memorandum of Understanding (MOU)	NA				
	2.	Records on training	NA				

TOPIC TOPIC 15.3
POLICIES AND PROCEDURES

STANDARD STANDARD 15.3.1
There are written and dated policies and procedures that reflect current knowledge and principles of laboratory practice. They are consistent with statutory requirements and the objectives of the Pathology Services. There are current Laboratory User Manual and documented Standard Operating Procedures Manual available for staff reference.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
15.3.1.1 CORE	There are written policies and procedures for each unit of the Pathology Services that reflect the roles of the Facility and guide the activities of Pathology Services. They are consistent with the overall policies of the Facility, regulatory requirements and current standard practices. The policies and procedures include but not limited to the following: a) the conduct of professional activities in accordance with the ethical standards of the professions involved; b) provide ready but controlled access to laboratory results; c) introduction of new tests, improvement on techniques, and undertaking research, where appropriate; d) provision of services on a 24-hour basis; e) contribution to the provision of high quality patient care by assisting in the review and evaluation of clinical practice within the Facility; f) provision of consultative service for the medical profession and other relevant staff in the selection of the laboratory investigations, their interpretation, and repeat test if required; g) communication with medical, nursing, and other relevant staff on matters related to the services provided. h) internal and external disaster plan; i) identify, assess and manage risks.	NA			NA	

	These policies and procedures are signed, authorised and dated. There is a mechanism for and evidence of a periodic review at least once in every three years. **EVIDENCE OF COMPLIANCE** 1. Documented policies and procedures for the service include but not limited to items (a) to (g). — NA 2. Policies and procedures are consistent with the regulatory requirements and current standard practices. — NA 3. Evidence of periodic review of policies and procedures. — NA 4. The policies and procedures are endorsed and dated. — NA					
15.3.1.2	Policies and procedures are developed by a committee in collaboration with staff, medical practitioners, Management and where required with other external service providers and with reference to relevant sources involved. Cross departmental collaboration is practised in developing relevant policies and procedures where applicable. **EVIDENCE OF COMPLIANCE** 1. Minutes of committee meetings on development and revision on policies and procedures. — NA 2. Minutes of meeting with evidence of cross reference with other departments — NA 3. Documented cross departmental policies — NA	NA			NA	
15.3.1.3	Current policies and procedures are communicated to all staff. **EVIDENCE OF COMPLIANCE** 1. Training and briefing on the current policies and procedures/Minutes of meetings — NA 2. Circulation list and acknowledgement — NA	NA			NA	
15.3.1.4 CORE	There is evidence of compliance with policies and procedures. **EVIDENCE OF COMPLIANCE** 1. Compliance with policies and procedures through: a) interview of staff on practices; — NA b) verify with observation on practices; — NA	NA			NA	

	c)	results of audit on practices;	NA				
	d)	practices in line with established policies and procedures	NA				
15.3.1.5	Copies of policies and procedures including Standard Operating Procedure Manual, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible for staff reference. EVIDENCE OF COMPLIANCE 1. Copies of policies and procedures including Standard Operating Procedure Manual, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible on-site for staff reference. — NA		NA			NA	
15.3.1.6	There are policies and procedures relating to requests for laboratory tests which include: a) authorised person; b) written confirmation of all verbal requests; c) identification of the patient by full name, medical record number, date of birth, sex, identity card (IC) number; d) relevant medical history of patient; e) relevant medications of patient; f) tests requested; g) name of the requesting doctor; h) identification of the nature of the specimen on the request form and clear labelling of specimens requiring precautionary handling. EVIDENCE OF COMPLIANCE 1. Documented policies and procedures relating to requests for laboratory tests which include items listed (a) to (h). — NA		NA			NA	
15.3.1.7	There are written instructions for the proper collection, labelling, storage, preservation and transportation of specimens; and safety measures to be observed.		NA			NA	

	These instructions are readily accessible to all staff who may be involved in obtaining specimens from patients. EVIDENCE OF COMPLIANCE 1. Laboratory User Manual/User guide is available in hard/softcopy. NA 2. Distribution list of item (1). NA 3. Verification of practice during survey NA					
15.3.1.8	Complete records are kept of all specimens received by the laboratory. These are accurately identified and retrievable in the laboratory: a) records on specimens received and forwarded to other laboratories; b) there are written policies determining the length of time for which reports and specimens are retained. EVIDENCE OF COMPLIANCE 1. Complete records for specimens received and forwarded to other laboratories; NA 2. Policies determining the length of time for which reports and specimens are retained. NA	NA			NA	
15.3.1.9	All pathology reports of investigations done on-site or off-site are included in the patient's medical record: a) copies of all pathology reports are promptly sent to be reviewed and filed in the patient's medical record. b) report/forms/results are designed to facilitate comparison of sequential tests/reports. EVIDENCE OF COMPLIANCE 1. Evidences of (a) and (b) in patient’s medical record. NA	NA			NA	
15.3.1.10	There is provision for immediate communication of results with critical range. EVIDENCE OF COMPLIANCE 1. Policy on management of critical laboratory results NA	NA			NA	

	2.	Evidence of communication of the critical level to the requesting medical practitioner/specialist/unit/ward.	NA				
15.3.1.11	When reports are communicated through telephone or similar means, documentation is available. a) the responsibility of receiving the report by phone is delegated to a responsible staff; b) a hard copy of the report shall follow with minimum delay; c) a documented system records the following: i) the person providing the report; ii) the person receiving the report; iii) patient identity; iv) pathology results; v) date and time of receipt.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Standard operating procedures for releasing the result.	NA				
	2.	Copy of laboratory report in patient's medical record	NA				
	3.	Records on (c)(i) to (c)(v).	NA				
15.3.1.12	Frozen section reports are transmitted directly to the surgeon concerned and followed by a written report.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Evidence of communication with respective surgeon	NA				
	2.	Written report in patient's medical record	NA				
15.3.1.13	There are written safety procedures specific to the Pathology Services.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Documented safety procedures specific to the Pathology Services.	NA				
15.3.1.14	There is evidence that all pathology staff practice Standard Precautions and Safety Guidelines.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Records on training on Standard Precautions and Safety Guidelines	NA				

	2.	Compliance of Standard Precautions and Safety Guidelines.	NA					
15.3.1.15	There is a manual on pathology hazards and safety.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Authorised and dated Pathology Safety Manual.	NA					

TOPIC TOPIC 15.4
FACILITIES AND EQUIPMENT

STANDARD STANDARD 15.4.1
Adequate facilities and equipment are available for the safe and efficient provision of Pathology Services taking into consideration the potentially hazardous circumstances of the operations.

CRITERION NO.	CRITERIA FOR COMPLIANCE			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
15.4.1.1	The office is separated from the technical laboratory area.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	On-site observation of office space complies with the above.	NA					
	2.	Layout of laboratory as per set requirements.	NA					
15.4.1.2	There are designated areas for handling of potentially hazardous specimen.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Designated areas includes:						
	a)	reception;	NA					
	b)	separation;	NA					
	c)	storage;	NA					
	d)	dispatch.	NA					
15.4.1.3	Work benches shall be adequately spaced and arranged in such a way as to ensure safety and efficiency in the use of equipment in accordance with manufacturer's recommendation and safety regulations.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	On-site observation evidenced on:						
	a)	adequately spaced work benches;	NA					
	b)	equipment arrangement ensures safety and efficiency of the laboratory's operation.	NA					
15.4.1.4	There are adequate and proper storage areas of reagents, tissue specimens, consumables and other materials			NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	On-site observation evidenced on:					
	a)	adequate storage areas;	NA				
	b)	designated storage area for reagents, tissue specimens, consumables and other materials.	NA				
15.4.1.5	There are separate and suitable stores for inflammable solvents and acid.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Separate storage for inflammables and acids according to set regulations.	NA				
15.4.1.6	There are suitably located staff facilities for emergency shower and eye wash, changing room, locker facilities and storage for protective clothing.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Availability of:					
	a)	emergency shower;	NA				
	b)	eye wash;	NA				
	c)	locker facilities;	NA				
	d)	storage for protective clothing.	NA				
15.4.1.7	There is suitable, adequate and safe provision for air conditioning, ventilation, lighting, power, gases, water and drainage in the laboratory. These include the following: a) air conditioning shall be efficient to maintain low humidity, constant and comfortable room temperature; b) adequate ventilation with fume extraction, where appropriate; c) power supply shall be adequate, and there are sufficient suitably located power sockets; d) adequate and appropriate lighting; e) supply and use of gases shall follow current safety regulations; f) regular supply of distilled and deionised water for laboratory use.			NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Provisions for (a) to (f) are available on-site.	NA				
15.4.1.8 CORE	The pathology equipment are appropriate and adequate to meet the demands of the service and are properly maintained.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Adequate equipment	NA				
	2.	Appropriate equipment commensurate with the scope of services provided	NA				
	3.	Proper equipment maintenance	NA				
	4.	Back-up system	NA				
15.4.1.9 CORE	The laboratory shall have adequate and appropriate data processing storage, retrieval system and communication facilities. There is a secure system for result/report submission.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Adequate and appropriate data processing storage	NA				
	2.	Easy retrieval of data.	NA				
	3.	Appropriate communication facilities	NA				
	4.	Secured system for result or report transmission	NA				
15.4.1.10	Where specialised equipment is used, there is evidence that only staff who are trained and authorised by the Facility operate such equipment.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	User training records	NA				
	2.	Competency assessment record	NA				
	3.	Letter of authorisation	NA				
	4.	List of staff trained and privileged to operate and maintain specialised equipment.	NA				
15.4.1.11	There is documented evidence that equipment complies with relevant national/international standards and current statutory requirements.		NA			NA	
	EVIDENCE OF COMPLIANCE						

	1.	Testing, commissioning and calibration records (certificates or stickers)	NA				
	2.	Certification of equipment from certified bodies, e.g. Standards and Industrial Research Institute of Malaysia (SIRIM), etc as EVIDENCE OF COMPLIANCE to the relevant standards and Acts.	NA				
15.4.1.12	Inventory of equipment, reagents and consumables shall be maintained.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Record of equipment inventory	NA				
	2.	Record of reagent inventory	NA				
	3.	Record of consumable inventory	NA				
15.4.1.13	Each equipment/instrument has a logbook and maintenance records and these shall be made available when required.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Equipment/Instrument log book	NA				
	2.	Equipment/Instrument maintenance record	NA				
15.4.1.14 CORE	There is evidence that the facility has a comprehensive maintenance programme such as predictive maintenance, planned preventive maintenance and calibration activities, to ensure the facilities and equipment are in good working order.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Planned Preventive Maintenance records such as schedule, stickers, etc.	NA				
	2.	Planned Replacement Programme where applicable	NA				
	3.	Complaint records	NA				
	4.	Asset inventory	NA				
15.4.1.15	There is evidence of general cleanliness in the laboratory.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Good housekeeping is evidenced.	NA				
	2.	Cleaning schedule	NA				

15.4.1.16	There are proper facilities for the disposal of biohazard material as either effluent or containerised material. EVIDENCE OF COMPLIANCE 1. Proper disposal of biohazard material as containerised material or effluent according to regulations evidenced on-site. NA		NA			NA	

TOPIC TOPIC 15.5
SAFETY AND PERFORMANCE IMPROVEMENT ACTIVITIES

STANDARD STANDARD 15.5.1
The Head of Pathology Services shall ensure the provision of quality performance with staff involvement in the continuous safety and performance improvement activities of the Pathology Services.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
15.5.1.1	There are planned and systematic safety and performance improvement activities to monitor and evaluate the performance of the Pathology Services. The process includes: a) Planned activities b) Data collection c) Monitoring and evaluation of the performance d) Action plan for improvement e) Implementation of action plan f) Re-evaluation for improvement Innovation is advocated.	NA			NA	
	EVIDENCE OF COMPLIANCE					
	1. Planned performance improvement activities include (a) to (f) — NA					
	2. Records on performance improvement activities — NA					
	3. Minutes of performance improvement meetings — NA					
	4. Performance improvement studies — NA					
	5. Records on innovation if available — NA					
15.5.1.2	The Head of Pathology Services has assigned the responsibilities for planning, monitoring and managing safety and performance improvement to appropriate individual/personnel within the respective services.	NA			NA	
	EVIDENCE OF COMPLIANCE					

	1.	Designated officer or committee assigned for performance improvement activities.	NA				
	2.	Designated safety officer or committee to monitor laboratory safety	NA				
15.5.1.3	The Head of the Pathology Services shall ensure that the staff are trained and complete incident reports which are promptly reported, investigated, discussed by the staff with learning objectives and forwarded to the Person In Charge (PIC) of the Facility. Incidents reported have had Root Cause Analysis done and action taken within the agreed time frame to prevent recurrence.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	System for incident reporting is in place, which include:					
	a)	Training of staff	NA				
	b)	Policy on incident reporting	NA				
	c)	Methodology of incident reporting	NA				
	d)	Register/records of incidents	NA				
	2.	Completed incident reports	NA				
	3.	Root Cause Analysis	NA				
	4.	Corrective and preventive action plans	NA				
	5.	Remedial measure	NA				
	6.	Minutes of meetings	NA				
	7.	Acknowledgment by Head of Service and PIC/Hospital Director	NA				
	8.	Feedback given to staff regarding incident reporting.	NA				
15.5.1.4 CORE	There is tracking and trending of specific performance indicators that covers the following: a) timeliness of urgent requests b) rejection rate of specimens (Target: <1%) c) notification of critical results. Targets of performance indicators shall meet patient care need of the Facility.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Specific performance indicators monitored.	NA				

	2.	Records on tracking and trending analysis.	NA				
	3.	Remedial measures taken where appropriate	NA				
15.5.1.5	The Pathology Services shall have quality control programme for all tests provided.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Internal Quality Control (IQC) Programme	NA				
	2.	External Quality Assurance (EQA) Programme	NA				
15.5.1.6	The results of the internal and external quality programmes shall be available and readily understood by relevant staff.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Evidence of participation in IQC and EQA.	NA				
	2.	Performance reviewed	NA				
	3.	Documented evidence of discussion.	NA				
15.5.1.7	There shall be evidence of corrective and preventive actions for any shortfall in quality.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Evidence of corrective actions	NA				
	2.	Evidence of preventive actions	NA				
15.5.1.8	Pathology staff shall participate in clinical audit activities with other clinical specialties.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Evidence of participation in clinical audit activities with other services, i.e. mortality and morbidity audits.	NA				
15.5.1.9	Feedback on results of safety and performance improvement activities are regularly communicated to the staff.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Results on safety and performance improvement activities are accessible to staff.	NA				

	2.	Evidence of feedback via communication on results of performance improvement activities through continuing education activities/meetings.	NA				
	3.	Minutes of service/unit/committee meetings	NA				
15.5.1.10	Appropriate documentation of safety and performance improvement activities is kept and confidentiality of medical practitioners, staff and patients is preserved.			NA			NA
	EVIDENCE OF COMPLIANCE						
	1.	Documentation on performance improvement activities and performance indicators.	NA				
	2.	Policy statement on anonymity on patients and providers involved in performance improvement activities.	NA				

SERVICE SUMMARY	
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OVERALL RATING :	NA
OVERALL RISK :	-