LABORATORY QUALITY MANUAL

MEDICAL LABORATORIES
HOSPITAL UNIVERSITI SAINS MALAYSIA

Prepared by: Assoc. Prof. Dr. Hasnan Jaafar
Approved by: Dato’ Dr. Zaidun Kamari
Effective Date: 01.08.2010
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| 2           | 01.08.2010      | Document was reviewed on the 14.7.2010  
Amendment 1: Page 2 of 70 
Appendix 4: Objektif Kualiti Makmal-Makmal Perubatan HUSM was deleted. The list is available in HUSM/LCD/QP-08  
Amendment 2: Page 3 of 70  
Version Date was replaced by Date of Amendment. Added record of review.  
Amendment 3: Page 8 of 70 and 16 of 70  
The word 'cytopathology' was deleted.  
Amendment 4: Page 17 of 70  
The word 'genetic testing' was replaced by Cytogenetic.  
Amendment 5: Page 30 of 70  
Level 4 documents were redefined as Level 3 documents. |                        |

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Approved by Dato' Dr Zaidun Kamari  
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**RECORD OF REVIEW**

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<tr>
<td>14 Jul 2010</td>
<td>Assoc. Prof. Dr. Fauziah Mohamad Idris</td>
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<td>Dr. Julia Omar</td>
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1. MEDICAL LABORATORIES, HOSPITAL USM (HUSM)

1.1 Introduction

HUSM first started operation in 1983. Medical laboratories are an integral part of HUSM. These laboratories are under various departments where the head of departments are responsible to the Hospital Director HUSM and/or to the Dean of School of Medical Sciences, USM Health Campus.

A laboratory director whom may or may not be the head of the department heads the medical laboratory is in-charge of the medical laboratory. A quality manager, assisting the laboratory director, is in-charge of the daily running of the Quality Management System in the laboratory.

The following is the list of all the medical laboratories and their respective departments:

i) Pathology Laboratory under the Department of Pathology

ii) Haematology Laboratory and Transfusion Medicine Laboratory under the Department of Haematology

iii) Medical Microbiology Laboratory and Parasitology Laboratory under the Department of Microbiology and Parasitology

iv) Chemical Pathology Laboratory under the Department of Chemical Pathology

v) Immunology Laboratory under the Department of Immunology

vi) Pharmacology Laboratory under the Department of Pharmacology

vii) Genetic Laboratory under the Human Genome Center

viii) Therapeutic Drug Monitoring Laboratory under the Department of Pharmacy
1.1.1 Function of Medical Laboratories HUSM:

a) To provide diagnostic testing in the following disciplines: Histopathology, Medical Microbiology, Virology, Serology, Chemical Pathology, Haematology, Transfusion Medicine, Toxicology, Genetic and Drug Monitoring.

These testing activities are done on patients' samples in the HUSM as well as referred samples from outside HUSM.

b) To provide consultative services in the various aspects of pathology to the specialists, medical officers and other relevant health staff of HUSM as well as those from referring centers.

c) To provide training in technical and analytical skills to laboratory personnel, staff and students from USM, HUSM, clinics, other institution of higher learning and Ministry of Health Hospital.
1.1.2 Quality Policy

The Hospital Director outlined the Quality Policy for medical laboratories as stated below and this is disseminated and explained to all staff. This policy is to be displayed at strategic locations so that it will be guidance to the staff to always maintain a high quality of laboratory services.

Universti Sains Malaysia Hospital is an excellent teaching and referral hospital with quality and advanced technology services. We promise to give the best services to all patients and practice the quality values in realizing the Hospital Client Charter. We are determined to prioritize customer well-being and satisfaction by implementing continuous improvement programs to fulfill the government aspiration. We are committed to provide adequate facilities in order to ensure excellent graduate produced by USM.
1.1.3 Quality Objectives

All medical laboratories, Hospital USM are determined and committed to carry out the following objectives:

a) To establish the implementation and maintenance of a Quality Management System.

b) To provide medical laboratory testing services in accordance with the applicable standards to satisfy the expectation of customers and satisfy the requirements of accrediting body and authorized body.

c) To ensure that all the laboratory personnel be familiarize and comply themselves with the documented quality system and competent in performing their assigned duties.

d) To ensure that all equipments related to the testing activities are properly maintained and monitored.

d) To provide conducive and safe working environment.

The staff of all laboratories are also determined and committed to fully adhere to the Specific Quality Objectives designed for their laboratories as stated in the document below.

Related Procedures:

i) HUSM/LCD/QP-08 : Pematuhan Objektif Qualiti (Lampiran 1)
1.1.4 Mission Statement for Medical Laboratories HUSM

In the spirit of teamwork and backed by trained, dedicated and knowledgeable laboratory staffs, together with adhering to current technology, we shall provide an efficient, reliable service towards achieving excellence in patient care and to pursue professional and technological advancement through continuous training, research and development.

1.1.5 Vision Statement for Medical Laboratories HUSM

To provide an efficient, precise and innovative laboratory service based on quality management system to achieve total customer satisfaction.
1.1.6 Service Hours:

a) The Haematology & Transfusion Medicine, Chemical Pathology, Medical Microbiology & Parasitology Laboratory and Therapeutic Drug Monitoring Laboratory provide 24 hours service. The laboratories of other disciplines operate only during working hours.

b) Normal working hours:

Sunday – Wednesday: 8.10 am – 4.55 pm
Thursday: 8.10 am – 4.40 pm

/Public holidays will change according to Government of Malaysia circular.

For laboratories that have 24 hours service, a Medical Laboratory Technologist, a Scientific Officer and/or a Pathologist are available for consultation or assistance after office hour.

1.1.7 Postal address of Hospital USM is as follows:

Hospital Director
Hospital Universiti Sains Malaysia
16150 Kota Bharu, Kelantan
West Malaysia
Telephone Number: 609-7673001
Fax Number: 609-7652198
1.2 Laboratory Quality Manual (LQM)

1.2.1 Introduction

a) The LQM shall provide an insight into the structure of Medical Laboratories, HUSM and their quality system policies and operating procedures for all the laboratory staff to carry out their job and related activities in accordance to the policies of hospital. This will demonstrate that the Medical Laboratories, HUSM are competent to operate as an accredited medical testing laboratory in accordance to the requirements of MS ISO 15189:2007 and MS ISO 9001:2008.

b) The LQM and related quality procedures shall be reviewed and revised accordingly from time to time to reflect its status and requirements of MS ISO 15189:2007 and MS ISO 9001:2008.

1.2.2 Contents of Laboratory Quality Manual

a) Each page of the Laboratory Quality Manual shall demonstrate

i) Title of Document

ii) Procedure No.

iii) Version No.

iv) Date of Issue

v) Page No.

b) The title shall be the name of the document.

c) The Procedure Number reflects its reference number

d) The Version Number shall be an increment by one (1) each time a modification (deletion/addition), amendment or change is made to a particular section or paragraph.

e) The Date of Issue shall be the implementation or effective date of the document.
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1) The Laboratory’s quality system policies and objectives are defined in the LQM.

2) The role and responsibilities of the top management, Quality Manager and Technical Manager shall be defined in the LQM (Section 4.1.6).

3) The structure of the documentation used in the laboratory quality system is outlined in the LQM (Section 4.2, Quality System). The document shall include or make reference to the supporting and technical procedures.

Prepared by
Assoc Prof Dr Hasnan Jaafar
Dato’ Dr Zaidun Kamari

Approved by

Effective date: 1.8.2010
1.2.3 Control of distribution

a) The LQM and its related documents are controlled documents and they shall be listed in the Master List of Documents, which shall be maintained and updated by Chief Document Controller.

b) Such controlled copies shall be conspicuously and clearly marked on the cover / title page as "CONTROLLED COPY".

c) The LQM shall be given only to those listed in the Distribution List.

d) The LQM shall not be removed from the premises of HUSM in any form or means.

1.2.4 Uncontrolled copies of Laboratory Quality Manual

a) Uncontrolled copies are LQM or documents, which are not listed in the master distribution list and are not kept up-to-date.

b) These uncontrolled documents are issued for draft, information, training, or reference purpose only.

c) Such uncontrolled documents shall be conspicuously and clearly marked on the cover / title page “APPROVED FOR USE” and endorsed by laboratory top management.

d) The holder or users of uncontrolled copies shall not receive any updated, revised or amended quality system document(s).
1.2.5. Changes and amendment

a) All changes, amendments, alteration or additions to the LQM shall follow the procedure on Document Control (see section 4.3).

b) Modification to any part or section of LQM shall be issued on a complete revised document bearing a new Version Number and date.

c) The change shall be identified in the copies kept by Document Controller of the Laboratory and Hospital.

d) All obsolete documents are removed from the circulation and point of use. Obsolete documents are recognized by a specific identification method. They may be retained for knowledge and teaching proposes.

Related Procedure:

i) HUSM/LCD/QP-01: Kawalan Dokumen
2. SCOPE FOR REGISTRATION

The scope for Medical Laboratories, Hospital USM in implementation of MS ISO 15189:2009 is on Medical Laboratory Testing Service by fulfilling MS ISO 9001:2008 and MS ISO 15189:2007 requirements and customer satisfaction.

The Medical Laboratories, Hospital USM carries out Medical Laboratory Testing Services in the following fields:

i) Histopathology
ii) Medical Microbiology
iii) Virology
iv) Immunology
v) Haematology
vi) Chemical Pathology
vii) Blood Banking/Transfusion service
viii) Cytogenetic
ix) Toxicology
x) Therapeutic drug monitoring
3. **GLOSSARY / DEFINITION**

**GLOSSARY**

a) **Top Management**: Constitutes Director, Deputy Director of Hospital USM and Head of Departments

b) **Laboratory Top Management**: Those person(s) who direct and manage the laboratory activities under the Head of the Department

c) **Medical Laboratories**: Medical Laboratory that examines material derived from the human for microbiological, biochemical, hematological, cytological, histopathological or other test analysis. The test results provide information for the diagnosis, prevention, treatment of disease or assessment of the health of human beings and the presence or absence of various substances.

d) **Organisation**: Medical Laboratories, Hospital USM.

e) **Management Representative**: A person with appropriate qualification and experience in laboratory quality management appointed by the Director of Hospital USM to assume the responsibilities of running the Quality Management System of the Medical Laboratories

f) **Chief Internal Auditor**: A person with appropriate qualification and experience in auditing medical laboratories according the requirements of MS ISO 15189 appointed by the Director of Hospital USM to assume the responsibilities of organizing the running of the internal audit of the Medical Laboratories

g) **Head of Department**: A person with appropriate qualifications and experience who is appointed by the Vice Chancellor of USM or Director of HUSM to lead and manage a department.
h) Laboratory Director: Senior Pathologist or Pharmacist with appropriate qualifications and experience, who have been formally designated by Head of Department and/or Director of HUSM to assume the overall management responsibilities of the laboratory.

i) Quality Manager: Pathologist or Pharmacist or Chief/Senior Scientific Officer with appropriate qualifications and experience, who have been formally designated by Head of Department and/or Director of HUSM to assume the responsibilities of everyday running of the Quality Management System of the laboratory.

j) Technical Manager: Chief/Senior Scientific Officer or Chief/Senior Medical Technologist is supervisory technical personnel who have been formally designated by the Head of the Department to oversee specific technical operations of the laboratory.

k) Clinical Personnel: Are those who provide clinical interpretation (or professional opinions or consultations) of laboratory results for the purpose of medical diagnosis or treatment of persons suffering from, any disease, injury or disability of mind or body.

Personnel providing such clinical interpretation or professional judgment shall possess such qualification, training and experience, relevant to the specialty of pathology in which they practice (e.g. Histocytopathology, Hematology, Chemical Pathology and Medical Microbiology).

l) Technical Personnel: Refers to personnel who perform the scientific and technical work in the laboratory. They shall have suitable qualifications or training and have sufficient experience and ability to perform the scientific and technical work required in the laboratory. This is evidenced by:
i) Bachelor of Science degree or a Bachelor of Biomedical Science degree or an equivalent in a relevant field, recognized by the Government of Malaysia and at least 6 months supervised training in the relevant area of laboratory service or

ii) Diploma or Certificate in Medical Laboratory Technology or an Equivalent in Medical Laboratory Technology, recognized by the Government of Malaysia and at least 6 months supervised training in the relevant area of laboratory service.

m) Laboratory Capability: Physical, environmental and information resources, personnel skills and expertise available for the testing in question.

n) Pre-analytical phase (pre-examination procedures): Steps starting, in chronological order, from the clinician’s request, preparation of the patient, collection of the primary sample and transportation to and within the laboratory and ending when the analytical examination procedure begins.

o) Examination (testing) (Analytical phase): Set of operation having the object of determining the value or characteristics of a property.

p) Post-analytical phase (post-examination procedures): Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results and storage of samples of the examinations.
4.0. MANAGEMENT REQUIREMENTS

4.1 Organisation and management

4.1.1 Organisation

The Medical Laboratories are under the department of the various respective laboratory disciplines, which in turn are part of the many departments under HOSPITAL UNIVERSITI SAINS MALAYSIA. Authority, interrelation and responsibilities of all laboratory personnel are on file in the form of job descriptions (JD) and organizational charts (please refer to Appendix 1 and 2: Organization Chart for the Medical Laboratories, Hospital USM). The laboratory quality management system shall cover testing carried out in all the laboratories in the locations as described in section: introduction – location.

4.1.2 Legal Status

The Hospital USM (thus Medical Laboratories) is a Government Hospital that is under the purview of the Ministry of Higher Education Malaysia.

4.1.3 Independence

The management ensures that the laboratories are independent from any commercial, financial or other pressures, which might adversely affect the quality of tests and test reports.
4.1.4 Confidentiality

The laboratories maintains the confidentiality and proprietary rights of all information including type of work performed and results of tests to the extent allowable by the Private Health Bill 1998 and General Orders Bab D. All laboratory personnel and staff are informed of this policy.

4.1.5 Ethics in Laboratory Medicine

The staffs have signed an Oath of Conduct (Surat Aku Janji) on commencement of their employment. They shall comply with Rules and Regulations, which govern staff in the Government of Malaysia under Peraturan-Peraturan Awam (Kelakuan dan Tatatertib) 1993, Perintah-Perintah Am (General Orders), Circulars and other rules and regulations issued by Government of Malaysia.
4.1.6 Responsibility

a) Responsibility of Director of Hospital USM
   i) Budget allocation
   ii) Approval of development and training programs
   iii) Advisory in the management of laboratory services
   iv) Provision of safe work environment

b) Responsibility of Management Representative
   i) The Management Representative is trained in the requirement of the standard and is responsible to the Director of Hospital USM
   ii) Implement and maintains the quality management system
   iii) Define, implement and monitors standards of performance and quality improvement of the laboratory
   iv) Monitoring of laboratory practices to verify continuing compliance with policies and procedures
   v) Ensure the laboratory participates in relevant proficiency tests or interlaboratory and intercollaborative studies

c) Responsibility of Chief Internal Auditor
   i) The Chief Internal Auditor is trained in the auditing of medical laboratory according to the requirement of the standard and is responsible to the Management Representative of Hospital USM
   ii) Scheduling & coordination of quality system audits of the medical laboratory
   iii) Monitoring the corrective actions on non conformances raised in auditing and report to top management in management review meeting
   iv) Organizing auditor training and updates on the standards and its requirement
d) Responsibility of Chief Document Controller

i) The Chief Document Controller is trained in the requirement of the standards especially in issues of document control and is responsible to the Management Representative of Hospital USM.

ii) Maintenance of laboratory quality manual and associated operations documentations (level 2 documents).

iii) Ensure the documents are reviewed at least once in 2 years to update with existing methodologies or procedures.

iv) Monitor and keep a list of updated level 3 documents which are maintained by document controller of each laboratory.

v) Record and keep the minutes of the Hospital USM MS ISO 15189 Task Force meetings.

vi) Record and keep the minutes of the Hospital USM Management Review Meeting.

vii) Responsible in organizing and facilitating the activities of assessment by Standards Malaysia on medical laboratory.


e) Responsibility of Head of Department

i) The head of department is responsible to the Dean of School of Medical Sciences, USM and/or Director of Hospital USM.

ii) Relate and function effectively with:
   - applicable accrediting and regulatory agencies
   - administrative officials in the Hospital USM, USM Health Campus and other agencies
   - the clinicians, nurses and all the staffs
   - the patients

iii) Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory.

Prepared by Assoc Prof Dr Hasnan Jaafar
Approved by Dato’ Dr Zaidun Kamari
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iv) Plan, set goals, develop and allocate resources appropriate to the medical laboratory.

v) Provide effective and efficient administration of the medical laboratory including budget planning and control with responsible financial management in accordance with Hospital USM assignment of such responsibilities.

vi) Provide resources and training opportunities for laboratory staff to facilitate testing activities in a safe work environment consistent with test requirements and personnel capabilities.

vii) Provide educational programs for the medical and laboratory staff and participate in educational programs of the institutions.

viii) Ensure all complaints, requests or suggestions are taken care appropriately.

ix) Ensure good staff morale.

f) Responsibility of Laboratory Director

i) The laboratory director is responsible to the Head of Department.

ii) Provide advice to those requesting information about choice of tests, the use of laboratory service and the interpretation of laboratory test results.

iii) Participate as members of various quality improvement committees in HUSM, USM Health Campus & other agencies.

iv) Relate and function effectively with:
   - applicable accrediting and regulatory agencies
   - administrative officials in the Hospital USM, USM Health Campus and other agencies
   - the clinicians, nurses and all the staffs
   - the patients

iv) Monitor all referral laboratories for quality of service.
v) Assign deputies for both technical and quality managers in the case of an absence

vi) Define, implement and monitors standards of performance and quality of the laboratory

vii) Ensure the laboratories participates in relevant proficiency tests, or interlaboratory collaborative studies

viii) Implement the quality management system

x) Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory

xi) Provide educational program for the medical and laboratory staff and participate in educational programs of the institutions.

xii) Responsible for staff training and competency

xiii) Implement a safe laboratory environment in compliance with good laboratory practice and applicable regulation

xiv) Address any complaints, request or suggestions from users of laboratory services

xv) Select and suggest suitable equipment and test methods for laboratory testing

xvi) Ensure good staff morale

g) Responsibility of Quality Manager

i) The Quality Manager is trained in the requirement of the standard and is responsible to the laboratory director.

ii) Scheduling & coordination of quality system audits of the laboratory

iii) Implement and maintains the quality management system

iv) Monitor all work performed in the laboratory to determine that reliable data are being generated

v) Select and monitor all referral laboratories for quality of service

Prepared by
Assoc Prof Dr Hasnan Jaafar
Effective date 1.8.2010
Approved by
Dato' Dr Zaidun Kamari
<table>
<thead>
<tr>
<th>Title: RESPONSIBILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>vi) Define, implement and monitors standards of performance and quality improvement of the laboratory</td>
</tr>
<tr>
<td>vii) Monitoring of laboratory practices to verify continuing compliance with policies and procedures</td>
</tr>
<tr>
<td>viii) Responsible for ensuring the effective control and operation of all test activities carried out in the laboratories</td>
</tr>
<tr>
<td>ix) Ensure the laboratory participates in relevant proficiency tests or interlaboratory and intercollaborative studies</td>
</tr>
<tr>
<td>x) Ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the quality management system</td>
</tr>
</tbody>
</table>

**h) Responsibility of Technical Manager**

- i) Trained in the requirement of the standard who coordinate the technical management team and is responsible to the laboratory director
- ii) Responsible for technical operations of the laboratory
- iii) Provide and manage resources needed to run the laboratory technical procedures
- iv) Evaluate instrument calibration and maintenance records
- v) Ensure validation of new technical procedures
- vi) Ensure approved methodologies are used
- vii) Ensure only competent personnel to carry out/perform tests

**Prepared by**

Assoc Prof Dr Hasnan Jaafar

**Approved by**

Dato' Dr Zaidun Kamari

**Effective date**

1.8.2010
i) Responsibility of Document Controller

i) Maintain a master list of documents that identifies the distribution of the documents

ii) Issue current authorized copies of the quality system documents according to the distribution list

iii) Ensure the documents are made available for active use at relevant location

iv) Ensure the procedure on document control is implemented and followed

v) Ensure all invalid or obsolete documents are removed from all points of use

vi) Ensure the documents are reviewed at least annually to update with existing methodologies or procedures

vii) Report to Chief Document Controller of any changes done on Level 3 documents
4.2 Quality Management System

a) The Medical Laboratories, HUSM establish documents, procedures and implement and maintained the Quality Management System. We shall ensure the QMS is continuously improved based on monitoring, analysis of the data on the activities and corrective efforts to be taken in accordance with the MS ISO 15189:2007.

b) Quality Policy - Please refer to Quality Policy in page 7 of this Manual

c) Procedural Policies

The laboratory quality system documentation structure is arranged in the following hierarchy as shown below: -
d) Document description

<table>
<thead>
<tr>
<th>Name of Document</th>
<th>Level</th>
<th>Description of Document</th>
<th>Enforcement Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Procedures</td>
<td>2</td>
<td>Operating Procedures - Relating to activities within the department and interfaces with other departments</td>
<td>Laboratory Top Management and supervisory Personnel</td>
</tr>
<tr>
<td>Supportive Document</td>
<td>3</td>
<td>Proof of work done - completed forms, checklists, minutes of meetings, etc.</td>
<td>All Personnel</td>
</tr>
</tbody>
</table>

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Approved by Dato' Dr Zaidun Kamari
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e) Quality System Flow Chart

The procedural policies and manuals for Diagnostic Laboratories, Hospital USM shall encompass all steps as shown in the Quality system flow chart below:

- **ORGANISATION AND QUALITY MANAGEMENT SYSTEM**
  - Organisation and management
  - Quality management system
  - Quality manual

- **EVALUATION & QUALITY ASSURANCE**
  - Resolution of complaints
  - Identification and control of non-conformities
  - Corrective action
  - Preventive action
  - Continual improvement

- **RESOURCE MANAGEMENT**
  - External supplies and Services
  - Personnel
  - Accommodation and Environmental conditions
  - Laboratory equipments

- **PRE-ANALYTICAL PROCESSES**
  - Subcontracting of tests
  - Advisory services
  - Pre-examination procedures
  - Review of contracts

- **ANALYTICAL PROCESSES**
  - Test methods
  - Assuring the quality of the results

- **POST ANALYTICAL PROCESSES**
  - Post examination procedures
  - Reporting the results

Customer Satisfaction of Dissatisfaction
LABORATORY QUALITY MANUAL (HUSM/LCD/LQM)  

Title: DOCUMENT CONTROL  
Version 2  

4.2 f) Laboratory safety

- The laboratory management shall ensure that a standard laboratory safety procedure is practiced and observed at all time in the laboratory.
- A laboratory safety manual shall be maintained at the laboratory.
- Due consideration shall be given to separating certain procedures from the main work area for the safety of workers and the protection of the environment. Such procedures include test using radioactive isotopes, mycobacteriology, tissue culture, polymerase chain reaction (PCR) work and cytology screening.
- There shall be demarcation between 'clean' areas, i.e. areas used for clerical aspects of laboratory work and 'dirty' areas, i.e. areas used for testing procedures.
- Access to the work areas shall be controlled and areas for members of the public shall be clearly segregated from the work areas.
- A safety officer shall be identified to monitor and implement safety procedures in the laboratory.

4.2 g) Research and development (R&D)

- Research and development of diagnostic procedures in the laboratory shall be identified and supervised by the technical manager.
- Where standard methods are prescribed/followed, the laboratory shall maintain current version and up-to-date laboratory bench methods. The laboratory shall verify performance with respect to specified limits of detection, selectivity, repeatability and reproducibility.
- Where in-house methods are prescribed/followed, validation shall be performed according to relevant recognized guidelines. The means of validation shall be documented and referenced.

4.2 h) Laboratory information system (LIS)

- The laboratory management shall establish a LIS to record and archive the results and information of the medical laboratory.
- A policy shall be established to protect patients from harm caused by loss or change of data.
- The computer facilities and equipment should be clean, well maintained, appropriately located and adequately protected.
- A complete computer procedure manual for LIS shall be maintained and made available to the authorized computer users.
- Stored patient result data and archival information should be easily and readily retrievable within a time frame consistent with patient-care needs.

Prepared by Assoc Prof Dr Hasnan Jaafar  
Approved by Dato' Dr Zaidun Kamari  
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4.3 Document control

a) A procedure for document control including all quality system, quality procedures and records has been established.

b) Document Approval and Issue

The Laboratory Director has the designated authority to review and approved any quality system documents prior to issue. He is also responsible for ensuring all invalid or obsolete documents are removed and suitably identified. A detailed list of controlled documents with revision date, retention periods and locations is maintained.

All quality documents (along with associated appendices and reference) are available to all laboratory staff and management. It is the responsibility of the quality manager to ensure that the most current quality document is issued and followed by all staff. A list of name, controlled number and locations of all controlled copies is maintained in the master list of the laboratory files by the document controller.

c) Document Changes

Changes to quality system documents including all documents maintained in computerized system are reviewed by the quality manager and technical manager and approved by the Head of Department and/or Laboratory Director. Amendment to document is done by hand, pending the reissue of the amended document as soon as practicable. All QMS document shell be review annually.

d) Document Archives

Archived documents are kept at one place in the laboratory concerned and is supervised by the document controller.

Related Procedure:

i) HUSM/LCD/QP-01: Kawalan Dokumen
4.4 Review of contracts

a) The procedure for review of contracts has been established. The laboratory reviews contracts to ensure that the requirements including the methods used are adequately defined, documented and understood. The laboratory shall also review its capability and resources to meet the requirement and that appropriate test method is selected and capable of meeting the client's requirement. The laboratory shall resolve any differences between the contracts before commencing work.

b) Records of reviews and pertinent discussions with a client relating to the clients requirement or the result after work during the period of the execution of the contract is maintained by the laboratory. This review of contract shall be documented and approved by the head of unit and clinician in the form of checklist.

c) Work that is subcontracted by the laboratory is also reviewed based on the timeliness of the report and quality of the result.

d) Clients are informed of any deviation from the contract.

e) Reviews of contracts are made again if amendments to the contract are made after work has commenced. All personnel are notified of the deviations.

Related Procedures/Documents:

i) HUSM/LCD/QP-20: Pemilihan dan Penilaian Pembekal

ii) Department’s policy and information of each laboratory

iii) Procedure for receipt of specimens of each laboratory

iv) Procedure for subcontracting of tests of each laboratory
4.5 Examination by referral laboratories

a) Selection of Subcontractors

The laboratory subcontracts tests whether because of unforeseen reasons (workload, need for further expertise or temporary incapacity) or on continuing basis. Subcontracting of test is done whenever possible within the Ministry of Health or Ministry of Education laboratories throughout the country. If the referring laboratories are unable to meet the requirement, the test shall be referred to the private laboratories, whenever possible, laboratories which need the requirements of MS ISO 15189:2007 standard.

b) Advising the client

The Technical Manager shall advise clients of subcontracted arrangement and where necessary gains approval in writing prior to commencement of work.

c) Responsibility for subcontracted work

The laboratory shall maintain responsibility for all subcontracted work except in circumstances where the client or regulatory authorities specifies otherwise.

d) Subcontractor Register

The laboratory shall maintain a list of all subcontracting laboratories and work.
e) Responsibility of dissemination of the laboratory report
   
i) The referring laboratory shall be responsible for ensuring that referral laboratory examination results and findings are provided to the person making the request.

ii) If the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory without alterations that could affect clinical interpretation.

Related Procedures:

i) HUSM/LCD/QP-20: Pemilihan dan Penilaian Pembekal
ii) Department’s policy and information of each laboratory
iii) Procedure for receipt of specimens of each laboratory
iv) Procedure for subcontracting laboratory test of each laboratory
v) HUSM/LCD/QP-21: Examination of Referral Laboratory
4.6 External services and supplies

a) The laboratory shall comply with a policy and procedures for purchasing of items and supplies develop by the hospital.

b) The laboratory shall ensure that purchased supplies and reagents and consumable materials that effect the quality of tests shall not be used until they have been inspected or otherwise verified as complying with standard specifications. Record of actions to check compliance is maintained.

c) The purchasing documents for items affecting the quality of laboratory shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

d) The laboratory shall evaluate suppliers of critical consumables, supplies and services, which affect the quality of testing. Records are maintained for these evaluations and list of those approved.

e) The laboratory shall have an inventory control system for supplies. The quality records of external services, supplies and purchased shall be established and maintained for a minimum period of 7 years. These records shall be available for laboratory management review.

Related Procedures:

i) HUSM/LCD/QP-02: Control of Quality Record

ii) HUSM/LCD/QP-14 : Perolehan Peralatan

iii) HUSM/LCD/QP-20 : Pemilihan dan Penilaian Pembekal

iv) Checklist for Evaluation of Supplier in each laboratory
4.7 Advisory services

The laboratory shall provide the clients the necessary clarification to their request and the cooperation to monitor the laboratory's performance of the work performed, provided that the confidentiality of the other clients is maintained. If requested by the client, the laboratory shall undertake the appropriate measure to dispatch the test item for verification purpose. If there is problem in performing the test including delay, the client will be informed. Feedback from clients will regularly be obtained and assessed.

Related Procedures:

i) HUSM/LCD/QP-02: Control of Quality Record
ii) HUSM/LCD/QP-05: Tindakan Pembetulan Untuk Ketidakpatuhan
iii) HUSM/LCD/QP-06: Tindakan Pencegahan Untuk Ketidakpatuhan
iv) HUSM/LCD/QP-09: Aduan Pelanggan
v) HUSM/LCD/QP-14: Perolehan Peralatan
iv) HUSM/LCD/QP-20: Pemilihan dan Penilaian Pembekal
4.8 Resolution of complaints

In the event of complaint the laboratory ensures that, those areas of activity and responsibility involved are promptly investigated. A resolution of the adverse situation is promptly sought.

All written complaints from the hospital shall be channeled through an incident reporting committee in Hospital USM and a copy will be given to the laboratory.

The laboratory shall examine all document and records associated with complaint. The investigation seeks to identify specific root causes and initiate necessary corrective action. Records of complaint and action taken by the laboratory to resolve the problem to prevent future recurrence are maintained. Procedures for handling complaints are maintained by the laboratory.

Related Procedures:

i) HUSM/LCD/QP-05: Tindakan Pembetulan Untuk Ketidakpatuhan
ii) HUSM/LCD/QP-06: Tindakan Pencegahan Untuk Ketidakpatuhan
iii) HUSM/LCD/QP-09: Aduan Pelanggan
iv) HUSM/LCD/QP-11: Laporan Insiden
4.9 Identification and control of non-conformities

a) Procedures for controlling non-conforming test work shall be implemented when any aspects of testing do not conform to its own procedures or the agreed requirement of the client.

The Technical Manager shall be responsible for managing non-conforming test work.

An evaluation of the significance of the non-conforming test work is made, corrective action taken immediately together with decision about the acceptability of the non-conforming work, and where necessary the client is notified and work is recalled.

The laboratory shall define the responsibility for authorizing the resumption of work.

b) The corrective action procedure given in 4.10 shall be promptly followed if non-conforming work could recur or that there is doubt about the compliance of the laboratory’s operation.

Related Procedures:

i) All Quality Procedures (Level 3 Documents) for each Medical Laboratory

ii) HUSM/LCD/QP-05: Tindakan Pembetulan Untuk Ketidakpatuhan

iii) HUSM/LCD/QP-06: Tindakan Pencegahan Untuk Ketidakpatuhan

iii) Checklist for Corrective Action Request (CAR) for Non-Conformity
4.10 Corrective action

a) The laboratory management shall immediately fix any error that occurs in the quality or technical system to control any non-conformity.

b) The laboratory shall have a procedure for implementing corrective action if the fault persists. (Overall responsibility for managing corrective action lies with the Technical Manager - to delete). The overall responsibility for managing corrective action lies with the Head of Department, Laboratory Director and the management staff.

c) Cause analysis

   The root cause shall be investigated first.

d) Selection and implementation of corrective action

   The laboratory shall identify and institute appropriate corrective action. All procedures shall be documented and its implementation of corrective action taken promptly.

e) All corrective action shall be monitored, reviewed and presented at department meeting and laboratory management review meeting.

f) Additional Audits

   Areas of non-conformity shall be subjected to additional audit in accordance to 4.14 (Internal audit) when it casts doubt on the laboratory's compliance with its own policies and procedures.
4.11 Preventive action

a) The laboratory shall identify needed improvement and any potential sources of non-conformance, either technical or concerning the quality system. If preventive action is required, the laboratory shall develop action plan, implement it and monitor regularly to reduce any possible occurrence.

b) The laboratory shall comply with relevant procedure for preventive action that includes initiation and application of action to ensure that there are effective. This might include analysis of data, including trend and risk analyses and external quality assurance.

c) Preventive action taken shall be documented in minutes of laboratory, hospital management review meeting and departmental meeting.

Related Procedures

i) HUSM/LCD/QP-03: Audit Dalaman

ii) HUSM/LCD/QP-05: Tindakan Pembetulan Untuk Ketidakpatuhan

iii) HUSM/LCD/QP-06: Tindakan Pencegahan Untuk Ketidakpatuhan

iv) HUSM/LCD/QP-07: Management Review Meeting

v) HUSM/LCD/QP-08: Pematuhan Objektif Kualiti

vi) HUSM/LCD/QP-09: Aduan Pelanggan
4.12 Continual improvement

a) The laboratory Management shall systemically reviewed all operational procedures at regular intervals during unit and departmental meeting in order to identify any non-conformance or other opportunities for improvement in the quality management system or technical practices.

b) Action plans for improvement shall be develop, documented, implemented and reviewed as appropriate.

c) Laboratory management shall implement quality indicators for systematically monitoring and evaluating the laboratory's contribution to patient. Laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas.

d) Laboratory management shall provide access to suitable education and training opportunities for all laboratory personnel and relevant users of laboratory services.

Related Records:

i) Specific Quality Objective of each laboratory

ii) External Quality Assurance Program of each laboratory

iii) Training Records of Staffs of each laboratory

iv) Quality Assurance Program/ Quality Control of each laboratory
4.13 Quality and technical records

a) The laboratory shall ensure that all Quality Records and Technical Records are effectively identified, indexed, accessible, filed and stored appropriately, maintained and disposed where necessary. Procedures shall be established to ensure the above requirements are carried out effectively.

i) All records shall be legible, stored securely, in confidence and easily retrievable by authorized personnel, and each type of record allocate specific retention time according to local requirements.

ii) Establish procedure for back up of all records including computerized records.

iii) Establish specific procedure for correcting mistakes and alterations.

b) Technical Records

The laboratory shall ensure that all technical records inclusive of original observations, data and calculations, calibration records, staff records, a copy of each test reports and other necessary information be retained in each unit for a defined period so as to enable audit trail.

This is done by ensuring that:-

i) For records maintained in the laboratory information system:
   - Back up of data is made to protect against loss or deterioration
   - Passwords are used according to level of security determined by the laboratory management to maintain confidentiality and prevent unauthorized access to and amendment of data.
ii) No erasure or white out are made on the original data. Corrections are made to the data by drawing a single line through the entry and initial the change.

iii) Promptly and systematically document all technical records (including all records electronically stored) and to ensure that any corrections or alterations to any part of the records are legibly undertaken by authorized personnel.

iv) A copy of each report issued by the subcontracting laboratory is reproduced and kept in the laboratory.

c) Retention period

Minimum retention periods for patient records and specimens shall conform to relevant national guidelines where available. The record system shall include but shall not be limited to the following:

i) the specimen identification

ii) the test methodology and/or test equipment

iii) the date of test

iv) the name of test

v) original test observations and calculations

vi) the identity of the person performing the test

vii) an indication that calculations and manual data transfers have been checked

Related Procedures:

i) HUSM/LCD/QP-02: Control of Quality Record

ii) Procedure for subcontracting of tests in each laboratory

Prepared by

Assoc Prof Dr Hasnan Jaafar

Dato' Dr Zaidun Kamari

Approved by

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4.14 Internal audits

a) Internal Audits are conducted at the request of management and at predetermined scheduled to ensure that the laboratory’s activities comply with the requirements of MS ISO 15189:2007. The Quality Manager is responsible for planning and organizing the audits. Audits are conducted by personnel who are qualified and preferably independent of the activity being audited.

b) Timely corrective actions are taken in cases of non-conformance. Clients are noted in writing if the test results may have been affected.

c) Records pertaining to activity audited, audit findings and corrective actions shall be kept.

d) Follow-up audits are conducted to verify that the corrective actions implemented are effective.

Related Procedures:

HUSM/LCD/QP-03: Audit Dalaman
4.15 Management review

a) To ensure continual improvement of its quality system, the laboratory management shall conduct periodic reviews according to a predetermined schedule and procedures.

The review shall take account of:

i) follow-up of previous management reviews

ii) status of corrective actions taken and required preventive actions

iii) reports from managerial and supervisory personnel

iv) the outcome of recent internal audits

v) assessments by external bodies

vi) the outcome of external quality assessment and other forms of interlaboratory comparison or proficiency test

vii) any changes in the volume and type of work undertaken

viii) feedback, including complaints and other relevant factors form clinicians, patients, and other parties

ix) quality indicators for monitoring the laboratory's contribution to patient care

x) nonconformities

xi) monitoring of turnaround time

xii) results of continuous improvement processes

xiii) suitability of policies and procedures

xiv) evaluation of suppliers, and

xv) other relevant factors such as Quality Control activities, resources and staff training.
b) Recommendations and introduction of necessary changes and improvement shall be made based on the outcome of the reviews.

The records of the outcome of the reviews and the corresponding action taken shall be maintained.

The necessary changes and actions shall be implemented at an appropriate time frame.

Related Procedures:

HUSM/LCD/QP-07: Management Review Meeting
5. TECHNICAL REQUIREMENTS

GENERAL

a) Factors that determine the correctness and reliability of the tests performed are:

i) Human factors

ii) Accommodation and environmental conditions

iii) Test, method and method validation

iv) Equipment

v) Measurement traceability

vi) Sampling

vii) The handling of test and calibration items

b) The laboratory shall ensure that the factors that contribute to the total uncertainty of measurement are also considered.

i) When developing test procedures

ii) In the training and qualification of personnel and

iii) In the selection and calibration of equipment
5.1. Personnel
   a) The laboratory management shall have an organizational plan, personnel policies and job descriptions that define qualifications and duties for all personnel.
   b) The laboratory shall ensure personnel performing the tests or providing the services are competent. Their level of competency is regularly monitored. Staffs undergoing training are appropriately supervised.
   c) The laboratory shall have procedure on identifying training needs and providing training of personnel
   d) The laboratory shall ensure contract staffs are competent and duly supervised.
   e) All staff shall have their job descriptions which define:
      i) Responsibilities with respect to planning & performing tests, evaluating & reporting results, reporting opinion & interpretation.
      ii) Responsibilities with respect to validation of new methods
      iii) Expertise and experienced required
      iv) Qualification and training programs and
      v) Managerial duties
5.1

f) The management shall authorize specific personnel to perform tests, to issue reports and to provide interpretations. The laboratory shall also maintain records of the relevant educational and professional qualifications, training and experience, immunization status and competence of all personnel.

g) There shall be staff resources adequate to undertake work required and carry out other functions of the QMS.

h) Personnel shall have training specific to quality assurance and quality management for services offered.

i) The management shall establish policies which define who may use the computer system, who may access patient data and who is authorized to enter and change patient results, correct billing or modify computer programs.

j) The management shall ensure that employees are trained to prevent or contain the effects of adverse incidents.

k) The personnel making professional judgements with reference to examinations shall have the applicable theoretical and practical background as well as recent experience. Professional judgements can be expressed as opinions, interpretations, predictions, simulations and models, and value and should be in accordance with national, regional and local regulations.

l) Personnel shall take part in regular professional development or other professional liaison.

Related Procedures/Records:

i) HUSM/LCD/QP-12: Orientation for New Staff

ii) HUSM/LCD/QP-13: Pengurusan Latihan Staf Makmal

iii) Staff credential and training record of each laboratory

iv) Staff Job Description & File of each laboratory

v) Department policy of each laboratory/department

Prepared by
Assoc Prof Dr Hasnan Jaafar

Approved by
Dato' Dr Zaidun Kamari

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5.2. Accommodation and environmental conditions

a) The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures and safety of personnel or patient care services.

b) Patients, employees and visitors shall be protected from recognized hazards.

c) When primary sample collection facilities are provided, consideration shall be given to the accommodation of patient disabilities, comfort and privacy, in addition to the optimization of collection conditions.

d) The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results.

e) There shall be effective separation between adjacent laboratory sections in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

f) Access to, and use of, areas affecting the quality of the examinations shall be controlled. Appropriate measures shall be taken to safeguard samples and resources from unauthorized access.

g) Communication systems within the laboratory shall be those appropriate to the size and complexity of the facility and the efficient transfer of messages.

h) Work areas shall be clean and well maintained. Storage and disposal of dangerous materials shall be those specified by relevant regulations.

i) Good housekeeping shall be instituted. Each individual is responsible for the housekeeping of his/her work area.
j) Relevant storage space and conditions shall be provided to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records and results.

Related Procedures:

i) HUSM/LCD/QP-18: Management of Consumable and Reagent

ii) HUSM/LCD/QP-19: Pengurusan Sisa Hospital

iii) Guidelines on retention of Pathology Records and Materials (version 1/2005) College of Pathologist Malaysia

iv) Guidelines on laboratory construction and design (version 1/2004) College of Pathologist Malaysia
5.3. Laboratory equipment

a) The Technical Manager shall identify and ensure that the laboratory be furnished with equipments that fit for purpose, ie.
   i) meet the required accuracy
   ii) comply to specification
   iii) be calibrated before being put into service/ before use
   iv) being calibrated as scheduled and
   v) handled by authorized/trained personnel

b) In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this international standard are met.

c) Each item of equipment and its software shall be uniquely identified.

d) Records of each items of equipment and its software shall be maintained.
   The record shall include:
   i) identify of the equipment
   ii) manufacturer's name, type identification and serial number or other unique identification
   iii) manufacturer's contact person and telephone number, as appropriate
   iv) date of receiving and date of putting into service
   v) current location, where appropriate
vi) condition when received (e.g. new, used or reconditioned)

vii) manufacturer’s instruction if available

viii) equipment performance records that confirm the equipment’s suitability for use

ix) maintenance carried out and that planned for the future

x) dates, result and copies of reports and certificate of all calibrations, adjustment, acceptance criteria and the due date of next calibration

xi) maintenance plan, and maintenance carried out to date and

xii) damage to, or malfunction, modification or repair of the equipment

e) Procedures on handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

f) Equipment that is subjected to overload or mishandling shall not be used until its defect has been corrected and certified to be so by authorized personnel.

g) All equipments under the control of laboratory are identified with respect to its calibration status, where applicable, by means of a calibration record tag attached to the equipment.

h) All equipment leaving the direct control of the laboratory shall be ascertained to be satisfactory by the authorized personnel before being returned to service.

i) Where applicable, the laboratory maintains a record of all current correction factors arising from calibration and ensures that these are appropriately communicated to the relevant personnel and used.
j) Only authorized personnel is allowed to make adjustments to the equipment, including hardware and software, so as to safeguard from any adjustments which would invalidate the test results.

k) For the computers and automated testing equipments which are used for processing of test specimen, recording, reporting, storage or retrieval of test results, the authorized personnel shall ensure that:
   i) Procedures are establish and implemented for protecting the integrity of the results at all times and
   ii) The computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary to maintain the integrity of data.

Related Procedures/Records:

i) HUSM/LCD/QP-15: Receiving and Commissioning New Equipment

ii) HUSM/LCD/QP-16: Calibration and Maintenance of Equipment

iii) HUSM/LCD/QP-17: Pelupusan Aset dan Barang atau Harta Benda
5.4. Pre-examination procedures

5.4.1 The request form shall contain information sufficient to identify the patient and the authorized requester, as well as providing pertinent date, according to local requirement.

5.4.2 The request form should allow space for the inclusion of the following:
   a) unique identification of the patient
   b) name or other unique identifier of the physician or other person legally authorized to request examinations and their address
   c) type of primary sample and the anatomic site of origin, where appropriate
   d) examinations requested
   e) clinical information relevant to the patient, which should include gender and date of birth as a minimum, for interpretation purposes
   f) date of time of primary sample collection
   g) date and time of receipt of samples by the laboratory

5.4.3 The laboratory shall develop a manual for the proper collection and handling of primary samples and made available to those responsible for primary sample collection.
5.4.4 The primary sample collection manual shall include the following:

a) copies or reference to
   i) lists of available laboratory examinations offered
   ii) information and instructions provided to patients in relation to their own preparation before sample collection, and
   iii) information for users of laboratory services on medical indications and appropriate selection of available procedures

b) procedures for:
   i) preparation of the patient
   ii) identification of the primary sample and
   iii) primary sample collection (e.g. phlebotomy, skin puncture, blood, urine and other body fluids), with descriptions of the primary sample containers and any necessary additives

c) instructions for:
   i) completion of request form
   ii) type and amount of the primary sample to be collected special timing of collection, if required
   iii) any special handling needed between the time of collection and time received by the laboratory (transport requirements, refrigeration, immediate delivery, etc)
   iv) labeling of primary sample
   v) clinical information (e.g. history of administration of drug)
   vi) positive identification, in detail, of the patient from whom a primary sample is collected and

d) The primary sample collection shall be distributed according to the distribution list, maintained by the laboratory.
5.4.5 The laboratory shall monitor the transportation of samples to the laboratory such that they are transported.

   a) within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned

   b) within a specified transportation requirement and with the designated preservatives to ensure the integrity of the sample and

   c) in a manner that ensures safety for the carrier, the general public and the receiving laboratory, in compliance with hospital requirement.

5.4.6 All primary samples received shall be recorded in the dispatch book from the clinics and wards in HUSM, worksheet and computers. The date and time of receipt of samples, as well as identity of the receiving officer shall be recorded.

5.4.7 Criteria shall be developed and documented for acceptance or rejection of primary samples. If compromised primary samples are accepted, the final report shall indicate the nature of the problem and if applicable, that caution is required when interpreting the result.

5.4.8 The laboratory shall periodically review its sample volume requirements for phlebotomy and other sample such as cerebrospinal fluid to ensure that neither insufficient nor excessive amounts of samples collected.

5.4.9 Authorized personnel shall systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them.
5.4.10 The laboratory shall have a documented procedure for the receipt, labeling, processing and reporting of those primary samples received by the laboratory and specifically marked as urgent. The procedure shall include details of any special labeling of the request form and primary sample, the mechanism of transfer of the primary sample to the examination area of the laboratory, any rapid processing made to be used and any special reporting criteria to be followed.

5.4.11 Sample portion shall also be traceable to the original primary sample.

5.4.12 The laboratory shall have a written policy concerning verbal request for sample examinations.

5.4.13 Samples shall be stored, if appropriate for a specified time, under conditions ensuring stability of samples proportion to enable repetition of the examination after reporting of the result or for additional examinations.

Related Procedures/Document:

i) Department’s policy and information of each laboratory

ii) Procedure for Receipt of Specimens of each laboratory

iii) Procedure for Subcontracting of tests of each laboratory

Prepared by
Assoc Prof Dr Hasnan Jaafar
Approved by
Dato’ Dr Zaidun Kamari
Effective date
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5.5. Examination procedures

5.5.1 The laboratory shall use examination procedures, including those for selecting sample portions, which meet the needs of the users of laboratory services and are appropriate for the examinations. Preferred procedures are those that have been published in established/authoritative textbooks, peer reviewed texts or journals, or in international, national or regional guidelines.

5.5.2 The laboratory shall use only validated procedures for confirming that the examination procedures are suitable for the intended use. The laboratory shall record the results obtained and the procedure use for the validation.

5.5.3 All procedures shall be documented and be available at the workstation for relevant staff. Documented procedure and necessary instructions shall be in language commonly understood by the staff in the laboratory.

5.5.4 Card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar system shall correspond to the complete manual. Any such abridged procedures shall be part of the document control system.
5.5.5 The procedures shall be based in whole or in part on the instructions for use e.g. package insert) written by the manufacturers, and that they describe the procedure as it is performed in the laboratory and are written in the language commonly understood by the staff of the laboratory. Any deviation shall be reviewed and documented. Additional information that could be required to perform the examination shall also be documented. Additional examination that could be required to perform the examination shall also be documented. Each new version of examination kits with major changes in reagents or procedure shall be checked for performance and suitability for intended use. Any procedural changes shall be dated and authorized as for other procedures.

5.5.6 In addition to document control identifiers, documentation should include, when applicable the following:

a) purpose of the examination
b) principle of the procedure used for the examinations
c) performance specifications (e.g. linearity, precision, accuracy expressed as uncertainty of measurement, detection limit, measuring interval, trueness of measurement, sensitivity and specificity)
d) primary sample system (e.g. plasma, serum, urine)
e) type of container and additive
f) required equipment and reagents
g) calibration procedures (metrological traceability)
h) procedural steps
i) quality control procedures
j) interferences (e.g. lipidemia, hemolysis, bilirubinemia) and cross reactions.
k) principle of procedure for calculating results including measurement uncertainty
5.5.7 The laboratory director shall be responsible for ensuring that the contents of examination procedures are complete, current and have been thoroughly reviewed.

5.5.8 Performance specifications for each procedure used in an examination shall relate to the intended use of that procedure.

5.5.9 If the laboratory intends to change an examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services in writing, prior to the introduction of the change.

Related Procedures/Document
i) Department’s policy and information of each medical laboratory.
ii) All the Standard Technical Manual (Level 3 documents) in the medical laboratories in Hospital USM.
5.6. Assuring the quality of test results

5.6.1 The laboratory shall use appropriate quality control procedures for monitoring the validity of tests. Records shall be maintained to detect trends. Statistical techniques shall be used when reviewing the results, whenever applicable.

5.6.2 This monitoring process shall be planned and reviewed to include but not limited to the following:-

a) regular use of certified reference materials and/or internal quality control using secondary reference material.

b) participation in interlaboratory comparison or proficiency testing program.

c) replicate tests using the same or different methods.

d) retesting of retained items.

e) correlation of results for different characteristics of an item.

f) all critical steps in the testing process should be traceable to the person performing the task (e.g. name stamped on the worksheet/workbook).

5.6.3 The laboratory shall participate in interlaboratory comparisons such as those organized by external quality assessment schemes. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled.
5.6.4 For those examination performed using different procedures or equipment or at different sites, or all these, there shall be defined mechanism for verifying the comparability of results throughout the clinically appropriate intervals. Such verification shall be performed at defined periods of time appropriate to the characteristics of the procedure or instrument.

Related Procedures:

i) HUSM/LCD/QP-02: Control of Quality Record

ii) HUSM/LCD/QP-08: Pematuhan Objektif Kualiti

iii) Procedure for Assuring the Quality of Test Results of each laboratory
5.7. Post examination procedures

a) Authorized personnel shall systematically review the results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorize the release of the results.

b) Storage of the primary sample and other laboratory samples shall be in accordance with approved policy.

c) Safe disposal of samples no longer required for examination shall be carried out in accordance with approved policy.

Related Procedures:

i) Procedures for processing specimen for testing in each laboratory

ii) HUSM/LCD/QP-19 : Pengurusan Sisa Hospital
5.8. Reporting of result

a) Laboratory management shall be responsible for formatting reports

b) Laboratory share responsibility with the requester for ensuring that reports are received by the appropriate individuals within an-agreed-upon time interval.

c) Results shall be legible, reported accurately, clearly, unambiguously, without mistakes in transcription and reported to persons authorized to receive and use medical information.

d) In issuing test result the laboratory shall ensure that the format for test report shall accommodate each type of test and minimize any possibility of misunderstanding.

5.8.1 Test Reports:

Each test report shall include at least the following information, unless the laboratory has valid reasons for not doing so:

a) a title

b) the name and address of the laboratory, and location where the test were carried out

c) unique identification of test report (such as serial number) and page number and total number of pages

d) unique identification and location of the patient

e) name of the requester and requester's address

f) date and time of primary sample collection, when available and relevant to patient care, and time of receipt by the laboratory.

g) date and time of release report, which if not on the report, shall be readily accessible when needed.

h) source and system (or primary sample type)

i) identification of method used
j) results of the examination reported in SI units or units traceable to SI units, where applicable

k) biological reference intervals, where applicable

l) interpretation of result, where appropriate

m) other comments (e.g. quality of primary sample which may have compromised the result, results interpretations from referral laboratories)

n) identification of the person authorizing the release of the report

o) if relevant, original and corrected results and

p) where relevant, a statement to the effect that the results relate only to the items tested.

5.8.2 The report shall indicate if the quality of primary sample received was unsuitable for examination or could have compromised the result.

5.8.3 Copies or files of reported results shall be retained by the laboratory such that prompt retrieval of the information is possible. The length of time that reported data are retained may vary; however, the reported results shall be retrievable for as long as medically relevant or as required by local requirement. See related procedures page 67.

5.8.4 The laboratory shall have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established “alert” or “critical” intervals. This includes results received on samples sent to referral laboratories, whenever applicable.

5.8.5 For results transmitted as the interim report, the final report shall always be forwarded to the requester.

Prepared by
Assoc Prof Dr Hasnan Jaafar

Approved by
Dato’ Dr Zaidun Kamari

Effective date
1.8.2010
5.8.6 Records of actions taken in response to results in the critical intervals shall be maintained. These shall include date, time, responsible laboratory staff member, person notified and examination results. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during audits.

5.8.7 The laboratory shall have clearly documented procedures for the release of examination results. The procedures shall also include guidelines for the release of results directly to patients.

5.8.8 The laboratory shall establish policies and procedures for ensuring that results distributed by telephone or other electronic means reach only authorized receivers. Results provided verbally shall be followed by a properly recorded report.

5.8.9 The laboratory shall ensure that the alteration of report shall be recorded to show the time, date and name of the person responsible for the change. Original entries shall remain legible when alterations are made.

5.8.10 Original electronic records shall be retained and alterations added to the record through appropriate editing procedures so that report clearly indicates the alteration.

5.8.11 Laboratory management shall establish turnaround times for each of its examination. A turnaround time shall reflect clinical needs.
5.8.12 There shall be a policy for notifying the requester when an examination is delayed. Turnaround times as well as any feedback from clinicians in relation to it shall be monitored, recorded and reviewed by laboratory management. Where necessary, corrective action shall be taken to address any problems so identified.

5.8.13 When examination results from a referral laboratory need to be transcribed by referring laboratory, procedures for verifying the correctness of all transcriptions shall be in place.

5.8.14 Results that have been available for clinical decision-making and revised shall be retained in subsequent cumulative reports and clearly identified as having been revised. If the reporting system cannot capture amendments, changes or alterations, an audit log shall be used.

Related Procedures:

i) Procedure for transmission of laboratory results in each laboratory

ii) Guidelines on retention of pathology records and materials, version 1/2005 College of Pathologists

HUSM/LCD/QP-21: Examination by Referral Laboratory

HUSM/LCD/QP-22: Review of contracts
Appendix 1

Organization Chart

Health Campus Director

Hospital Director,
Hospital USM,
Health Campus

Dean,
School of Medical Sciences,
USM, Health Campus

Chairman of Laboratory-Based
Department Committee

Heads of Department/ Center Director
- Pathology Department
- Hematology Department
- Chemical Pathology Department
- Microbiology & Parasitology Department
- Pharmacology Department
- Human Genome Center
- Immunology Department

Head of Pharmacy Department

Laboratory Director
- Therapeutic Drug Monitoring Laboratory

Laboratory Directors
- Pathology Laboratory
- Hematology Laboratory
- Chemical Pathology Laboratory
- Microbiology & Parasitology Laboratory
- Pharmacology Laboratory
- Genetic Laboratory
- Immunology Laboratory
List of Laboratory Core Documents

1. HUSM/LCD/QP-01: Kawalan Dokumen
2. HUSM/LCD/QP-02: Control of Quality Record
3. HUSM/LCD/QP-03: Audit Dalaman
4. HUSM/LCD/QP-04: Pengawalan Produk Yang Tidak Menepati Spesifikasi
5. HUSM/LCD/QP-05: Tindakan Pembetulan Untuk Ketidakpatuhan
6. HUSM/LCD/QP-06: Tindakan Pencegahan Untuk Ketidakpatuhan
7. HUSM/LCD/QP-07: Management Review Meeting
8. HUSM/LCD/QP-08: Pematuhan Objektif Kualiti
9. HUSM/LCD/QP-09: Aduan Pelanggan
10. HUSM/LCD/QP-10: Laboratory Safety
11. HUSM/LCD/QP-11: Laporan Insiden
12. HUSM/LCD/QP-12: Orientation for New Staff
13. HUSM/LCD/QP-13: Pengurusan Latihan Staf Makmal
14. HUSM/LCD/QP-14: Perolehan Item Melalui Pembekal
15. HUSM/LCD/QP-15: Receiving and Commissioning New Equipment
16. HUSM/LCD/QP-16: Calibration and Maintenance of Equipment
17. HUSM/LCD/QP-17: Pelupusan Aset dan Barang atau Harta Benda
18. HUSM/LCD/QP-18: Management of Consumable and Reagent
19. HUSM/LCD/QP-19: Pengurusan Sisa Hospital
20. HUSM/LCD/QP-20: Pemilihan dan Penilaian Pembekal
21. HUSM/LCD/QP-21: Examination by Referral Laboratory
22. HUSM/LCD/QP-22: Review of Contracts