



# ACCREDITATION REQUIREMENTS FOR MEDICAL FIELD OF TESTING

## DAC-REQ-010

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## FOREWORD

This document DAC-Req-10 describes the requirements for accreditation of Medical Field of Testing under the accreditation program operated by Dubai Accreditation Department (DAC).

The requirements for accreditation of Medical Laboratories are basically the ISO 15189 as well as the criteria for performing testing according to the technical standards defined in the scope of accreditation by each CAB.

The laboratories are required to comply with all the requirements listed in the international standard ISO 15189:2007 (Medical laboratories - Particular requirements for quality and competence). The Specific Criteria document must be used in conjunction with ISO 15189. It provides an interpretation of the latter document and describes specific requirements for those clauses of ISO 15189 which are general in nature. Further, the laboratory shall follow the national and local laws and regulations as applicable.

This document should be read in conjunction with the International Standard ISO 15189, Medical laboratories- Particular requirements for quality and competence, and DAC document DAC-Req-01, Accreditation Requirements.

DAC-Req-10 has been prepared by DAC in cooperation with the Department of Health and Medical Services (DOHMS) and Center for Healthcare Planning & Quality- Dubai Healthcare City.

While accreditation will normally be an indication of the quality of services offered by the Laboratories, it should not be regarded as a guarantee that the Laboratory will always maintain a particular level of performance. It shall not, in any way, diminish the contractual obligation between the Laboratory and its clients.

This document is subject to revision periodically when deemed necessary. It is the responsibility of the Accredited Laboratories to ensure that the latest version of this document is available for reference and implementation.

## 1. DEFINITIONS

The purpose of this section is to define the general and technical terminology that is used within the scope of this document.

### 1.1 Accreditation

Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks [ISO Guide 2].

### 1.2 Audit

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled [ISO 9000].

### 1.3 Corrective action

Action to eliminate the cause of a detected nonconformity or other undesirable situation.

NOTE Corrective action is taken to prevent reoccurrence whereas preventative action is taken to prevent occurrence [ISO 9000].

### 1.4 Department

Section of a laboratory in which a single pathology discipline pursues its activities.

### 1.5 Effectiveness

Extent to which planned activities are realized and planned results achieved [ISO 9000].

### 1.6 Efficiency

Relationship between the result achieved and the resources used [ISO 9000].

### 1.7 Examination

Set of operations having the object of determining the value or characteristics of a property.

NOTE: In some countries and disciplines (e.g. microbiology) examination is the total activity of a number of tests, observations or measurements [ISO 15189:2007].

### 1.8 Laboratory director

Competent person(s) with responsibility for, and authority over, a laboratory [ISO 15189:2007].

### 1.9 Laboratory management

Person(s) who manage the activities of the laboratory headed by the laboratory director [ISO 15189:2007].

## 1.10 Materials

Consumables, calibrators, reagents, calibration material used in the performance of an examination.

## 1.11 Medical laboratory

Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

NOTE: These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances of micro-organisms. Facilities which only collect or prepare specimens, or act as a mailing or distribution centre, are not considered to be medical or clinical laboratories, although they may be part of a larger laboratory network or system. [ISO 15189:2007].

## 1.12 Nonconformity

Non-fulfillment of a requirement [ISO 9000].

## 1.13 Organization

Group of people and facilities with an arrangement of responsibilities, authorities and relationships [ISO 9000].

## 1.14 Organizational structure

Arrangement of responsibilities, authorities and relationships between people [ISO 9000].

## 1.15 Post examination process

Post analytical phase processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of results and storage of samples of the examinations [based on ISO 15189:2007].

## 1.16 Pre examination process

Pre analytical phase steps starting in chronological order from the clinician's request, including examination requisition, preparation of the patient, collection of the primary sample, transportation to and within the laboratory and ending when the examination procedure starts [based on ISO 15189:2007].

## 1.17 Preventive action

Action to eliminate cause of a potential nonconformity or other undesirable potential situation.

NOTE: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent reoccurrence [ISO 9000].

### **1.18 Procedure**

Specified way to carry out an activity or process [ISO 9000].

NOTE: When the term 'procedure' is used in this document a written procedure is required which is subject to document control, regular review and revision.

### **1.19 Quality improvement**

Part of quality management focused on continually increasing effectiveness and efficiency.

NOTE: the term 'continual quality improvement' is used when quality improvement is progressive and the organization actively seeks and pursues improvement opportunities [based on ISO 9000].

### **1.20 Quality management system**

Management system to direct and control an organization with regard to quality [ISO 9000].

### **1.21 Quality manual**

Document specifying the quality management system of an organization.

NOTE: quality manuals may vary in detail and format to suit the size and complexity of an individual organization [ISO 9000].

### **1.22 Quality objective**

Something sought, or aimed for, related to quality.

NOTE Quality objectives are generally based on the organization's quality policy [ISO 9000].

### **1.23 Quality planning**

Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill quality objectives [ISO 9000].

### **1.24 Quality policy**

Overall intentions and direction of an organization related to the fulfillment of quality requirements as specified by laboratory management.

NOTE: the quality policy should be consistent with the overall policy of the organization and should provide a framework for the setting of quality objectives [based on ISO 9000].



**1.25 Record**

Document stating results achieved or providing evidence of activities performed [ISO 9000].

**1.26 Referral laboratory**

External laboratory to which a sample is submitted for supplementary or confirmatory examination procedure and report [ISO 15189:2007].

**1.27 Requirement**

Need or expectation that is stated, generally implied or obligatory [ISO 9000].

**1.28 Review**

Activity undertaken to ensure the suitability, adequacy, effectiveness and efficiency of the subject matter to achieve established objectives [based on ISO 9000].

**1.29 Revision**

Introduction of all necessary changes to the substance and presentation of a document to ensure its continuing suitability, adequacy, effectiveness to achieve established objectives.

**1.30 User**

Person or organization using the services of the laboratory user opinion of the degree to which the service provided has met their requirements.

**1.31 Validation**

Confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled [ISO 9000].

## 2. SCOPE

The scope of the accreditation is applicable to the following fields of medical laboratory testing services:

1. Anatomic Pathology (Cytopathology)
  - Gynecologic cytopathology
  - Non-gynecologic Cytopathology
  - FNAC
2. Anatomic Pathology(Histopathology)
  - Diagnostic HPE
  - Intraoperative frozen section
3. Clinical Biochemistry
  - General (Routine Urine, blood Chemistry including Electrolytes, Blood gases, therapeutic Drug monitoring)
  - Toxicology (Drugs of abuse, Heavy metals, trace elements)
  - Special Chemistry( Hormones, metabolites, tumour markers, Special ligands)
  - Biochemical genetics
4. Hematology
  - General
  - Coagulation
  - Immunohaematology and Transfusion medicine
  - Molecular Haematology
  - Flowcytometry for hematological applications
5. Microbiology
  - Isolation and Identification of Bacteria- aerobic
  - Isolation and Identification of Bacteria- Anaerobic
  - Isolation and Identification of Bacteria- Fungi
  - Mycobacteriology
  - Antibiotic sensitivity testing
  - Direct Examination of parasites
  - Antigen Detection
  - PCR
  - Serology of Infectious Diseases
  - Immunodiagnosics
6. Virology
  - Viral Serology
  - Viral Isolation
  - Non-culture methods
  - Immunoflourescence
  - Molecular virology

7. Clinical Pathology
  - Routine examination of Urine and Stool
  - Semen Analysis
8. Genetics

Scope may be extended for other parameters as per requirement.

**Note:**

- The other immunological tests can be listed under respective disciplines.
- The accreditation shall be considered only for those tests for which the laboratory has applied for, and shown its competency and compliance to standards.
- In case of Histopathology, however, a laboratory may use the services of another accredited laboratory for tissue processing (block making, sectioning and staining). The applicant laboratory shall perform gross examination, tissue sampling, microscopy and reporting.
- The facility for primary sample collection at sites other than its main laboratory shall also comply with the relevant requirements of ISO 15189. A representative sample of these facilities shall be assessed by DAC for their compliance with the requirements.

### 3 GENERAL REQUIREMENTS

- 3.1 The laboratory applying for accreditation as per this program must have a system, which includes the following as minimum:
  - 3.1.1 Proper Documentation System of its policies, procedures and operations starting from receiving the request for a test, performing contract review, performing Pre-examination procedures, performing examination procedures, performing post-examination procedures, recording results and up to the issuance of the final report/ in accordance with the documentation requirements of ISO 15189 and any additional requirements set by DAC here within this document and other related documents.
  - 3.1.2 Facilities properly equipped with the equipment and instruments appropriate for the type and range of tests under accreditation as minimum.
  - 3.1.3 Employ the suitable and qualified technical and administrative staff in the testing laboratory (see 5.1 also).
- 3.2 The laboratory must be licensed to operate in Dubai as per the requirements of Department of Health & Medical Services and/ or Dubai Health Care City.
- 3.3 The Laboratory shall operate in accordance with the requirements of ISO 15189 and the relevant standard of test methods according to which it would be accredited.

## **4 MANAGEMENT REQUIREMENTS**

### **4.1 Organization and management**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

The laboratory, run by the same management, operating at more than one location, each one performing tests and issuing reports will be considered as separate laboratories and if the laboratory requires separate certificates for individual locations, the application for accreditation should be submitted separately for each location.

### **4.2 Quality management system**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

### **4.3 Document control**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

### **4.4 Review of contracts**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

### **4.5 Examination by referral laboratories**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

Laboratory shall have documented policy and procedure for selecting and referring tests to other laboratories and for second opinion to consultants. The accredited tests can be referred only to a laboratory accredited by DAC or its MRA partner. In the test report the accredited laboratory shall specify the name of referral laboratory and identify the tests performed and the results obtained by such referral laboratory.

### **4.6 External services and supplies**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

Each lot of reagents shall be checked against earlier tested in-use reagent lots or with a suitable reference material before being placed in service and the results should be recorded. Each lot of antibiotic sensitivity discs shall be checked for activity/ potency before being placed in service.

### **4.7 Advisory Services**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

### **4.8 Resolution of complaints**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

### **4.9 Identification and control of nonconformities**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

#### 4.10 Corrective action

(The main text of this clause is the text of the same clause of ISO 15189:2007).

Corrective actions may be identified through internal audits, external assessments by accreditation bodies, customer and staff feedback and complaints, analysis of quality control data, performance in proficiency testing programs, incidence of non-conforming work, etc. Corrective actions shall be evaluated, prioritized and implemented according to an agreed timescale. Their effectiveness shall be monitored. Some corrective actions may involve a number of staff members as well as more than one division of the laboratory. Hence, it is important that the Quality Manager or other designated staff members shall coordinate the work arising from such corrective actions.

#### 4.11 Preventive action

(The main text of this clause is the text of the same clause of ISO 15189:2007).

#### 4.12 Continual improvement

(The main text of this clause is the text of the same clause of ISO 15189:2007).

The laboratory must have the comprehensive program for Quality Improvement, which shall incorporate salient quality indicators for monitoring laboratory's performance. This shall describe the evaluation of various aspects such as, but not limited to, the following:

- sample collection and identification
- transportation and processing
- analysis and reporting of results
- turnaround time
- complaints
- equipment downtime
- uncertainty of measurements (monthly % CV)
- performance in EQAS

In addition, each section is encouraged to have its own indicators for technical excellence and monitor them.

#### 4.13 Quality and technical records

(The main text of this clause is the text of the same clause of ISO 15189:2007).

- (a) Each laboratory shall maintain a record system designed to suit its particular requirements. The system shall be in compliance with this document.
- (b) Technical records shall include all original observations and raw data and provide a traceable link between the examination specimens as received and the reports which are eventually issued. This applies equally to computer and manual record systems.
- (c) The system shall allow for ready retrieval of original observations and data pertinent to any issued report.

- (d) The record system shall include ready access to the following detailed information:
- (i) Full description of each sample examined;
  - (ii) Identification of the examined sample;
  - (iii) Identification of examination method used;
  - (iv) Identification of equipment and reference materials used;
  - (v) Original observations and calculations;
  - (vi) Identification of persons performing the work;
  - (vii) A full copy of the issued report or certificate.
- (e) Original observations shall be recorded into notebooks, or onto properly designed proforma worksheets. Where data processing systems are used, records of raw data shall be retained unless data are (electronically) fed directly into the processing system.
- (f) Sheets of plain paper shall not be used,
- (g) Errors in calculations and incorrect transfers of data are major causes of incorrect reports. Calculations and data transfers shall be checked and signed or initialed, preferably by a second person. It is desirable to design workbooks and worksheets so that there is a dedicated place for the signature of the checking person.
- (h) The laboratory shall decide the retention time of records as per the local requirements, if any. However, DAC requires that all documents and records be maintained for 5 years.

The minimum period for retention of test reports, blocks and slides shall be 5 years.

#### 4.14 Internal audits

(The main text of this clause is the text of the same clause of ISO 15189:2007).

Internal audits shall be conducted by personnel trained in 15189 standards and auditing techniques.

#### 4.15 Management review

(The main text of this clause is the text of the same clause of ISO 15189:2007).



## 5 TECHNICAL REQUIREMENTS

### 5.1 Personnel

(The main text of this clause is the text of the same clause of ISO 15189:2007)

- a) The authorized signatories shall demonstrate knowledge and competence in the concerned specialty.
- b) Qualification norms for Pathologist/Consultant in the specialty- as per DOHMS norms and should have obtained license to practice by DOHMS if the lab is located in Dubai and should have a valid license from DHCC if the lab is located in the DHCC area.

In addition, the testing and supervisory staff also should have valid license issued by the DOHMS or DHCC depending on the location of the laboratory. (Ref: Medical Laboratory Technology Guidelines v 1.0 20051023)

- c) DAC Policy on Approved Signatories for DAC accredited test Reports:

The accredited test reports shall be signed by an approved signatory. An approved signatory is a technically qualified and licensed staff member nominated by the laboratory and subsequently assessed and approved by DAC to sign such reports.

A person nominated for approved signatory shall be competent to make critical evaluation of the validity of examination results and spend sufficient time in the laboratory to enable him/her to make this evaluation, occupy a position in his/her organization's staff structure that makes him/her responsible for the adequacy of such results and be fully aware of the requirements detailed in this document and ISO 15189.

### 5.2 Accommodation and environmental conditions

(The main text of this clause is the text of the same clause of ISO 15189:2007)

Accommodation and environmental condition requirements vary greatly depending on the nature of the samples to be examined or tested and the order of accuracy required of the examinations or tests. The laboratory and its personnel shall follow local and international bio-safety requirements. Suitability of the accommodation and environmental conditions for a specific range of examinations and tests will be judged against how they affect:

- (a) The integrity of the samples tested or examined;
- (b) The performance of laboratory equipment;
- (c) The competent performance of laboratory staff;
- (d) Compliance with the conditions set in test or examination methods;
- (e) Safety of laboratory staff.

Towards effectiveness of operations, the laboratory shall ensure adequate space in relation to the following:

- Patient reception

- Sample collection
- Workbench
- Equipment
- Storage of volatile and inflammable reagents
- Washing
- Isolation for bio-hazardous materials

The laboratory should have adequate lighting, power plugs and uninterrupted power supply. The laboratory shall ensure that adequate electrical service is available so that there is no interruption in power supply that may lead to compromise of stored data. The laboratory shall have procedures in place to ensure the integrity of refrigerated and/or frozen stored samples/reagents/consumables in the event of an electrical failure.

### 5.3 Laboratory equipment

(The main text of this clause is the text of the same clause of ISO 15189:2007).

- a) The laboratory shall select equipments consistent with the type and load of work. All equipments shall be validated and shown to satisfy performance requirements upon installation and thereafter annually or as specified by the manufacturer. All automated equipments shall be calibrated by the manufacturer and others by an accredited agency. The calibrators and reference materials shall be traceable to an international standard. Controls often lack absolute accuracy and are not recommended for use as calibrators. Sometimes, however, calibrators are not readily available and controls with assigned values may have to be used as calibrators. In such cases the laboratory must ensure that the values of the controls have been assigned reliably by a reference method.

Certain items of equipment may be calibrated by laboratory itself without the service of external calibration bodies, provided the laboratories have the necessary reference standards and materials and such calibration procedures do not demand specialist techniques which are outside the capabilities and experience of the laboratory staff.

All reagents, consumables, stains, media, kits and antimicrobials should be stored as recommended by the manufacturer and used within their indicated expiry dates. The label should bear the following information: content and quantity, concentration or titer, date received/prepared, date of opening, storage requirements and expiry dates, wherever applicable.

The laboratory shall use adequate controls for reagents, stains, media, kits, antimicrobials, etc to check their performance where a built-in control does not exist. Each lot of reagents shall be checked against earlier tested in-use reagent lots or with suitable reference material before being placed in service and the results should be recorded.

Each lot of antibiotic sensitivity discs should be checked for activity/potency before being placed in service and at least weekly thereafter with reference strains.

b) Calibration Requirements

Equipments	Calibration Interval	Remarks
Autoclave	Once a Year (external calibration)	Check on effectiveness of sterilization with each cycle with indicator strips and once a month with biological indicators
Balances	Once a year (external calibration)	Balances with in-built calibration check facility must also have six monthly checks Electronic balances with more than one range must have six monthly checks carried out on all ranges. Checks include repeatability checks and one-point check using a known mass close to balance capacity
Biological safety cabinets	Once a year (external calibration)	
Centrifuges	Every six months (external calibration)	
Pipettes	Every six months	For gravimetric checks, volume delivery and weighing under specified conditions must be repeated at least ten times. For adjustable devices check volume delivered at several settings. Delivery of volumes less than 100 microlitre may be verified by spectrometry using a dye solution.
Temperature-controlled equipment (water baths, incubators, ovens and refrigerators etc.)	Once a year (external calibration)	Internal verification by calibrated reference thermometer every six months the calibration points are decided based on the temperatures to be monitored in the laboratory e.g., 37 C if there are incubators, 4 degree C for refrigerators/cold rooms, -20 or- 70 for deep freezers, etc.

- c) The following is the list of analytical instruments that can be calibrated primarily in-house by use of certified reference materials traceable to national/international standards

**pH meter:**

Calibrate on use with at least two standard buffer solutions appropriate to the expected pH of the sample being tested. A record of the calibration must be kept.

### **Spectrophotometer and colorimeter:**

Calibration checks on all spectrophotometers or colorimeters shall be performed at six months interval. Such calibration shall include checks on absorbance, linearity, matching of cells and must be carried out in accordance with the manufacturer's instructions and/or appropriate procedures using standard/reference materials. A blank and at least two points on the calibration curve must also be checked. These calibrations should be compared over time to detect any system deterioration.

### **Chromatograph**

- a. Gas chromatograph: performance shall be routinely monitored during use with certified reference materials.
- b. Liquid chromatograph, including high performance liquid chromatograph (HPLC):  
The total system must be monitored during use with certified reference materials. Loss of efficiency may be detected by chronological comparison of reference material measurements. System components (e.g. pumping system and detectors) shall be subject to periodic checks and details shall be recorded.

### **Electrophoresis**

Instrument performance shall be routinely monitored during use with appropriate controls. System components (e.g. electrodes, tank and power supply), must be checked periodically.

### **Microscopes**

Regular cleaning and maintenance of microscopes is essential for satisfactory operation. The stage and lenses shall be cleaned after use and maintenance and servicing shall be carried out by competent personnel.

### **Temperature-controlled equipment**

The performance of temperature-controlled equipment such as water baths, incubators, ovens and refrigerators etc., shall be monitored routinely to ensure compliance with the temperature requirements of test methods. Accordingly, daily recorded checks of the temperature within the load space of these items of equipment shall be maintained. The use of continuous temperature monitors is strongly recommended where temperature control is critical. The thermometers used to monitor the performance of temperature-controlled equipment shall be of sufficient accuracy to ensure that this equipment complies with the temperature tolerances specified in the test methods. The spatial distribution of temperatures throughout the load space of temperature-controlled equipment shall be checked following installation of equipment and at appropriate intervals thereafter. Temperature recording devices shall be checked at six monthly intervals against a reference thermometer and the results recorded.

External calibration shall be carried out at accredited calibration laboratory. "See DAC Policy on Traceability of Measurement and Calibration of Instruments DAC-G2-04.

## Microbiology

A separate biological safety cabinet, certified at least annually to ensure that filters are functioning properly and that air flow rates meet specifications, must be available for mycobacteriological work and for mycological work.

The laboratory performing fungus culture shall be equipped with heating and cooling (BOD) incubator to meet with the environmental conditions for the isolation of fungi.

## Media

Laboratory shall ensure that in-house prepared media are sterile, able to support growth and are appropriately reactive bio-chemically. Therefore, the laboratory must maintain the stock of reference organisms. These should be used to test the media. Blood-based media shall be prepared using appropriate animal blood procured from an authorized source.

## Reagents/ Kits/ Antibiotic discs

Stains and reagents must be labeled, dated and stored properly and not used beyond their expiry date or if they show signs of deterioration, such as abnormal turbidity and/or discoloration. At regular intervals and whenever new stain is prepared, control smears should be stained.

## Histopathology

### i) Tissue Processing

- a. Depending on the workload the laboratory shall develop a procedure to change the tissue processing fluids and maintain a record of it.
- b. A log recording of the 'time setting schedule' for an automatic tissue processor shall be maintained.
- c. Temperature of the wax bath shall be checked and recorded daily.

### ii) Microtome

- a. The setting of the microtome indicating the thickness of sections shall be checked before use.
- b. Microtome with non-disposable knife shall have a safety shield.

### iii) Slide warming stage

- a. Temperature of slide warming stage shall be checked weekly.

### iv) Flotation bath

- a. The fluid in the flotation bath shall be changed at least once a day.
- b. The surface of the water bath shall be skimmed regularly during section cutting to remove floaters.

## Cytopathology

- A. Microscopes used for screening shall have 10 X and 40 X objectives. Spare bulbs and fuses shall be available in the laboratory.



- B. All equipment such as centrifuges capable of creating bio-hazardous aerosols should be used in extractor cabinets or rooms fitted with extractor facilities.
- C. The laboratory performing Cytopathology tests on CSF must use cytocentrifuge for processing the samples.

### **Flow Cytometry**

Diagnostic flow cytometry should be performed on flow cytometers made by standard companies that provide precise and verifiable procedures for operating and evaluating the performance of the machine. This would include procedures for calibration of the flow cytometer for instrument setup, optical alignment, test specific settings, color compensation and daily performance, monitoring and verification. The flow cytometers must be operated and maintained exactly as per the standard operating procedures prescribed by the manufacturers.

## **5.4 Pre examination procedure**

(The main text of this clause is the text of the same clause of ISO 15189:2007).

Both the examination request document and the specimen submitted shall bear the unique identification of the patient. This identification may include, for example, the name of the patient, as well as the number of his/her identity document, such as identity card or passport number.

Specific instructions for the proper collection and handling of primary samples shall be documented in a primary sample collection manual. This shall be applicable for the collection facility at main laboratory and the sites/clinics other than the main laboratory from where samples are collected and sent to the laboratory for testing and reporting.

The laboratory as a policy shall not accept samples, with labile analyte such as ammonia, acid phosphatase and lactate, not collected in-house.

### **Haematology**

For the tests for monitoring anticoagulant therapy the request forms must have a column for the physician ordering the test to indicate the purpose of the test e.g. monitoring heparin/ low molecular weight heparin and/or oral anticoagulant therapy as applicable.

#### Indwelling Lines or Catheters:

Phlebotomists drawing blood from indwelling (arterial, central venous) or umbilical lines should have thorough training. While drawing blood from indwelling lines or catheters errors due to dilution and or contamination from flushing solution should be avoided.

Relevant clinical data are necessary for most specialized tests. Request forms should be designed so that the requesting physician provides this information.

There must be guidelines for rejection of samples especially for under- or over- filled collection tubes for coagulation tests. Reasons for rejection of sample must be stated or communicated in writing to the nursing staff/ physician/ laboratory personnel responsible for sample collection.

### Microbiology

Specimens for culture and sensitivity must be processed immediately after collection. In case of delay in processing the specimen may be stored in refrigerator except CSF, blood and anaerobic culture. In situations where the sample has to be transported it must be collected in an appropriate transport medium.

### Cytopathology

- i) The procedure describing the sampling requirement for each specimen shall be readily available at all submitting locations (laboratory/ clinic/ hospital) and shall contain the following information:
  - a. Preparation of patient for sampling.
  - b. Consent form for Fine-Needle Aspiration (FNA).
  - c. Collection techniques.
  - d. Specimen identification and labeling.
  - e. Fixation requirement e.g. anticoagulant used, fixative (wet fixed and/ or air dried) and storage requirements.
  - f. Transportation instructions.
  - g. Safety precaution for all of the above (with special reference to HIV and Hepatitis).
  - h. All laboratory staff handling infected material shall be vaccinated against HBV.
- ii) Where possible, FNA shall be carried out by the Pathologist. In the absence of a Pathologist, a clinician/ radiologist may perform FNA, following documented procedures as provided by the laboratory and sign the requisition form.
- iii) A request form should accompany every specimen and contain the following information:
  - a. Full demographic data
  - b. Relevant clinical history and clinical findings with provisional diagnosis
  - c. Anatomical site of collected specimen
  - d. Date and time of specimen collection
  - e. Information regarding previous cytology report
- iv) For gynecological cytology the request form shall also contain:
  - a. Details of menstrual phase and hormonal status
  - b. Details of hormone therapy
  - c. Details of contraception
  - d. Details of previous surgery
- v) For intra-operative imprint/ aspiration cytology, the request form shall also contain detailed surgical information observed at the time of procedure.

## **Flow Cytometry**

### Sample Handling:

Blood/ bone marrow specimens collected in EDTA are stable up to 24h and in heparin up to 72h at room temperature. Samples must be transported and stored at ambient temperature (10-30°C).

### Sub-optimal and unacceptable samples include:

- Presence of clot, hemolysis, improper container.
- Samples received beyond 48h after collection or if inappropriately labeled.
- Samples received beyond 24h showing <80% viability on being tested by trypan blue test.

Presence of malignant cells should be verified microscopically by a pathologist prior to analyzing for suspected malignancies.

### Storage period of examined specimen

The examined specimens shall be stored for re-examination and/ or additional tests for a minimum period as determined by the laboratory. Integrity of such stored samples shall be demonstrated the laboratory before arriving at the storage period. Some common practices are as follows:

### **Haematology:**

Complete Blood Counts: 24 hours at 2-8°C

Coagulation screening test – 6-8 hours at 2-8°C

Haemoglobin electrophoresis and HPLC – 1 week at 2-8°C or longer below -20°C

Bone Marrow slides – 5 years \*

HLA typing cell preparation – 3 days

### **Serology:**

Three days at 2-8°C

### **Histopathology:**

Specimens – 15 days

Slides/ Blocks – 5 years\*

Bone marrow aspirate and corresponding blood film and biopsy – 5 years

### **Cytopathology:**

Fluids – 24 hours at 2-8°C

Slides – 5 years\*

## 5.5 Examination procedures

(The main text of this clause is the text of the same clause of ISO 15189:2007).

All the procedures followed in the laboratory shall be in accordance with national/international/CLSI guidelines/text book references. In-house procedures, if any, shall be validated against a standard procedure and proven to be superior to/equal to standard protocols.

### Hematology

CBC specimens must be checked for clots (visually, by applicator sticks, or by automated analyzer histogram inspection or flags), haemolysis and lipaemia before reporting results. CBC processing, either automated or manual, should be done within 8 hours.

Specimens for coagulation tests must be checked for presence of clots. Coagulation tests must be performed within 4 hrs of collection. If delay is expected, plasma should be separated and kept frozen until test can be performed (at -200C for up to 2 weeks or at -700C for up to 6 months).

ESR: Westergren or an equivalent method approved by ICSH or CLSI shall be followed. ESR is to be performed within 6 hrs of collection. Sample kept at 40C can be processed up to 24 h.

Manual platelet count and white cell count: The haemocytometer shall be examined regularly to ensure that the lines are bright and free from scratch marks and dust particles. The correct standard thickness cover slips shall be used. The diluting fluid shall be filtered before use and checked periodically for background count.

Bone marrow Examination: The bone marrow film should exhibit satisfactory quality for, staining properties, cell morphology and their distribution. A pathologist or medical specialist in haematology shall report all bone marrow slides.

Reticulocyte count (manual or automated) must be performed within 24h of collection. Stain should be filtered before use. The reticulocyte percentage should be based on the count of at least 1000 red blood cells.

Malarial parasites: Thick and thin films stained by Romanowsky is the method of choice.

Quantitative Buffy Coat (QBC) used as a screening test must be followed up by thin film microscopy to identify the species. Ensure that the Buffer for the Romanowsky dye is at pH 7.0-7.2. At least 100 oil immersion fields should be screened before reporting negative.

Manual Haemoglobin (Cyanmethaemoglobin method): At least four concentrations must be used to construct a calibration curve.

### Molecular Testing:

- i) Sample identification must be assured through all applicable phases of analysis, including all of the following:

Specimen receipt, nucleic acid extraction, nucleic acid quantification, endonuclease digestion, electrophoresis, transfer, hybridization, detection, in-situ hybridization, enzymatic amplification, photography, storage.

- ii) Autoradiographs or electrophoretic gels should be interpreted independently by at least two qualified readers using an objective method
- iii) Positive, negative and sensitivity controls must be run for each assay, when available and appropriate
- iv) DNA contamination must be monitored in different areas by swipe tests, using the regular detection for testing. Results of monitoring and corrective action taken when contamination is detected must be documented

#### Flow Cytometry:

Clinical and morphological correlation with flow cytometric data should be carried out and should be taken into consideration when developing gating strategies.

### **Clinical Pathology**

#### Urinalysis:

- i) Refractometers or dipsticks with specific gravity capability must be checked periodically with appropriate controls.
- ii) Criteria must be documented for identifying urine samples that may give erroneous results by the dipstick reader, and thus require visual evaluation. Intensely colored urine samples may result in false positive dipstick reactions with automated reflectance readers.

### **Microbiology**

The number of antibiotic discs applied on the Petri dish to test antibiotic sensitivity shall be as per CLSI (formerly NCCLS) recommendation.

The laboratory located in the hospital shall test against the antibiotics as per the hospital antibiotic policy, wherever possible. The stand-alone laboratory shall have an antibiotic sensitivity testing policy on the basis of site of infection, antibiotic susceptibility pattern, availability of drug and cost.

Enrichment and selective media should be used for isolation of organisms from stools, sputum, throat/urethral/cervical swabs, etc. For urine samples, the laboratory should perform and report quantitative cultures and use media and procedures that permit isolation of Gram positive, Gram negative bacteria and fungi.

For culture of mycobacteria, the lab will have BSL3 facility and practices and for identification of *M. tuberculosis* the laboratory will have at least consider the following: Slow growth rate, growth temperature 35-37°C only, no pigmentation, niacin positive, catalase negative at 68°C and no growth on LJ medium containing p-nitro benzoic acid.

#### HIV testing

Laboratories performing HIV testing shall follow DOHMS policy for reporting of results.

### **Histopathology:**

- i) The specimens shall be grossed and the findings recorded by a pathologist deemed competent.
- ii) Staining
  - a. The frequency of changing the deparafinizing solutions (xylene/ chloroform/ alcohol) and stains should be recorded. This is based on workload.
  - b. Special Stains: A positive control should be stained with each batch. The control slides shall be filed and retained for the same time period as the test slides.
- iii) Frozen section/squash smear:
  - a. A specific area should be demarcated for performing frozen sections.
  - b. Fresh tissue received for frozen section should be treated as infective and universal precautions should be taken.
  - c. Frozen sections/squash smears should be recorded like other specimens in the request form. Left over tissue must be processed for permanent section.
  - d. The turnaround time for frozen section/squash smears should not exceed 30 minutes.
  - e. Frozen section/squash smears shall be retained and filed along with the permanent sections for the stipulated time.

### **Prion disease suspected specimens:**

In a suspected case of prion disease, facilities should be available for safe handling of specimens. The biopsy specimen shall be considered as bio-hazardous and transferred to concentrated formic acid (96%) for 48 hours, subsequently to 10% formalin for 24 hours and then processed. The blocks should be labeled biohazardous. The trimmings of the block shall be disposed by incineration. All instruments used for sectioning be left in 2M NaOH for 1 hour and washed in running water for 15 minutes and reused. The microtome should be wiped clean with 2M NaOH and left for 1 hour. Subsequently the instrument should be wiped clean with tap water followed by alcohol before reuse.

### **Electron Microscopy:**

1. Processing of specimens shall be done by a trained technician under supervision/authorization of the Officer-in-charge of electron microscope laboratory.
2. A procedure manual shall be readily available with detailed procedure for the safe handling of epoxy resins.

### **Cytopathology**

All exfoliative cytology slides shall be stained by Papanicolaou technique. FNAC slides shall be stained with May-Grundwald Giemsa with or without PAP/H&E staining for interpretation.

## Flow Cytometry

Laboratory should have procedures in place to distinguish leukemic/ lymphoma cells based on their light scatter properties and differential expression of antigens and to distinguish fluorescent cells from nonfluorescent cells in flow cytometry analysis.

### 5.6 Assuring quality of examination procedures

(The main text of this clause is the text of the same clause of ISO 15189:2007).

Each DAC accredited laboratory shall adopt an appropriate set of quality control procedures suitable to the range of work done and to the number of testing staff available. The results of such procedures shall be fully recorded and be available for review during assessments. Where a standard specifies a quality control procedure, it shall be followed.

The laboratory shall participate in at least one proficiency testing program annually for each discipline. The programme(s) shall cover all accredited test areas in each discipline.

When developing new examination procedures, the laboratory shall consider carefully their quality control requirements. This should be documented as part of the quality assurance plan for those examination procedures. Where necessary, the existing quality control procedures should be extended to cover the new work or new procedures. The adequacy of the quality control procedures will be examined critically during assessments.

The quality control plan, together with the acceptable criteria and actions to be taken in out of control situations, shall be documented. Quality control plans shall include, where relevant, the use of control samples (positive and/or negative, relevant levels), duplicates, blanks, spikes, etc. Control samples shall be of a similar matrix as the patient samples. Correlation of results in a sample shall be reviewed, where relevant.

Quality control samples, external proficiency testing and other alternative performance assessment samples shall be examined using exactly the same procedures as for patient samples and analyzed by personnel who routinely examined patient samples. In applying the criteria for measurement traceability, the following shall be noted:

- (a) Not all items of equipment used need to be calibrated. Only those items of equipment having a significant effect on the accuracy or validity of the results need to be calibrated. For any particular item of equipment, the laboratory should evaluate its applications and how it affects the final results. Such evaluations require the knowledge on how the measurements obtained using that item of equipment affect the final measurement uncertainty or validity of the final results. The calibrations and the required calibration uncertainties shall meet the requirements of those applications.
- (b) Where traceability to the International System of Units (SI) is required, the calibration is to be performed by a “competent calibration body”. Procedures exist

that are applicable to patient samples. The lists, which will be Reference cultures in microbiology

To establish traceability in microbiology laboratories, laboratories must hold and maintain a collection of cultures of organisms required to perform verification checks on methods and to conduct performance checks on batches of media prepared. Cultures used by laboratories must be traceable to a recognized culture collection such as American Type Culture Collection (ATCC), National Collection of Type Culture (NCTC), etc. Additional wild strains (e.g. isolates from samples) may only be used to supplement reference strains, but not to replace them.

### **Clinical Biochemistry**

The Laboratory must establish and document procedures for monitoring and evaluating analysis of testing processes including procedures for resolving 'out-of-control' situations. The laboratory is encouraged to use control material similar to or identical with patient sample matrix. The laboratory shall incorporate in the procedure, the multi-control QC rules used to detect systematic (trends or shifts) and random errors.

The laboratory shall include a minimum of one level QC at least once a day. However, where the number of patient samples analyzed for any parameter exceeds 25 per day, the laboratory shall employ 2 levels of QC at least once a day for such parameters. Further, if the number of patient samples analyzed for any parameter exceeds 75 per day, the laboratory shall employ 2 levels of QC at least twice a day at appropriate intervals. The daily QC values shall be documented along with the calculation of %CV from the monthly QC data. The laboratory shall maintain control charts to demonstrate stability of the analytical measuring systems.

The laboratory shall follow the multi control QC rules as described below:

#### The rules to follow when one level QC material is used:

Reject QC if:

- a. it is outside 3 SD (13s)
- b. Two consecutive values obtained are outside 2 SD on the same side but within 3 SD (22s)
- c. Ten consecutive values are above or below the mean, but within 2 SD (10x)

#### The rules to follow when 2 level QC materials are used:

Reject QC if:

- a. Either QC values is outside 3 SD (13s)
- b. Both QC values are outside 2 SD on the same side, but within 3 SD (22s)
- c. Difference between both QC values is  $>4$  SD i.e. one level QC is  $> 2$  SD and other level QC is  $<2$ SD (R4s).
- d. Ten consecutive values of the same level QC are  $>/<$  the mean, but within 2 SD (10x).
- e. Five consecutive values of one level QC and five consecutive values of other level QC are  $>/<$  the mean but within 2 SD (10x)

The laboratory shall have step-by-step flow chart to manage 'out-of-control situation' such as:

- Search for recent events that could have caused changes
- Examine environmental conditions.
- Follow manufacturer's troubleshooting guide.
- Refer to manufacturers of equipment, reagents or QC/calibrator.

The laboratory shall employ suitable reference material traceable to international standards for calibration of measuring systems and methods. Traceability certificates for calibrators shall be obtained from kit suppliers and appropriately documented.

Alternate methods shall be employed for verifying accuracy of results of such of those tests for which calibration and control materials are not available.

### **Haematology**

Internal quality control is necessary to ensure precision and repeatability. It is desirable to use stable controls (prepared in-house or procured from commercial sources) for this. The data should be plotted on Control Charts (L.J. Charts or Cusum Charts).

### **Microbiology**

The laboratory shall practice quality control of all the biochemical and sensitivity tests using appropriate reference strains. Control strains of known susceptibility should be used along with the test sample while performing drug susceptibility testing. In case of susceptibility testing against Mycobacterium, a standard strain of M. tuberculosis with known resistance pattern to different drugs shall be used with each batch of tests as a check on procedures. Stains for acid fast bacilli should be checked with the known positive and negative control organisms and the results recorded for each new batch. Control smears for acid fast stain should include smears with few to moderate number of acid fast bacilli. Positive and negative control smears should be included daily.

### **Histopathology**

When repeat specimen for Histopathology from a patient is received, all previous slides must be reviewed and reflected in the final report. Frozen section results must be compared with the final assessment and both results must be reflected in the final report.

### **Cytopathology**

1. Screening current work shall include
  - a. Re-screening by the consultant of at least 10% of the gynecologic smears reported negative by the cyto-technologist.
  - b. Re-screening of previously reported slides on receiving fresh smears from the same patient, during follow up.
  - c. Checking for staining quality.
2. Volume of workload for each screener shall be recorded. The laboratory shall avoid overloading the screener.
3. Procedures and records for follow up shall comply with:



- a. Reviewing all previous slides for an individual patient.
  - b. Matching previously reported abnormal smears with histopathology sections submitted for examination from the patient.
  - c. Comparison of all abnormal cytological findings with results of colposcopy or biopsy.
4. The laboratory shall have procedures for following up discrepancies identified between biopsy result and cytology report.
  5. For gynecological cytology the ASCUS:SIL ratio shall comply with the latest Bethesda Recommendations
  6. The laboratory may implement a system to notify the state cancer registry of patients diagnosed with malignancy. This list may be maintained and updated regularly

Note: The above criteria/procedures shall be applied to fluids cytology/ FNAC where applicable.

#### **Uncertainty of Measurement:**

The laboratory shall determine the uncertainty of results, where relevant and possible. The uncertainty evaluation follows the general principle in the Guide to the expression of Uncertainty in Measurement (GUM)6 and in the Eurachem/ CITAC Guide Quantifying Uncertainty in Analytical Measurement.

#### **Proficiency Testing**

Proficiency testing (PT) is a process for checking actual laboratory performance usually by means of inter-laboratory data comparisons or an External quality assurance scheme (EQAS). DAC requires successful participation in approved PT programs and PT is a requirement for accreditation to ISO 15189.

Results from proficiency testing are an indication of a laboratory's competence and are an integral part of the assessment and accreditation process. The laboratory shall document any corrective actions taken based on the EQAS evaluation report. For those analytes where a formal EQAS is not available the laboratory shall exchange samples with other accredited laboratories.

The laboratory shall adopt alternate methods to validate performance for certain tests for which inter-laboratory comparisons are not possible. For some rare analytes where such comparisons are not possible the laboratory will ensure accuracy and precision by one or more of the following: replicate testing, examination of split samples, testing of retained samples and use of reference of materials, where available. EQAS samples must be integrated within the routine laboratory workload, and analyzed by personnel who routinely test patient samples, using primary method systems. Rotate personnel for analysis in case of one time sampling on EQAS sample.

If slides are to be reported it has to be reported by all the appropriate level of staff involved in the department with no sharing of data. Then they should be discussed

collectively before the results are dispatched. If the laboratory uses more than one measuring system as well as alternate methods for specific reasons towards proper laboratory management, it is essential to perform a comparability study between the systems and prove the agreement in performance through appropriate statistical evaluation from the data generated. Such exercise shall be conducted as and when this is warranted.

For the above comparability study, the laboratory can use a built-in statistical programme or the well established manual statistical procedure. A written procedure and complete record of all such data shall be retained for a reasonable period of time as decided by the laboratory.

### 5.7 Post- examination procedures

(The main text of this clause is the text of the same clause of ISO 15189:2007).

### 5.8 Reporting of results

(The main text of this clause is the text of the same clause of ISO 15189:2007).

Laboratories should report results of normal controls when they are necessary for the proper interpretations of the examination results. There shall be established protocol to review clinically significantly abnormal examination results. The laboratory shall establish critical limits for tests which require immediate attention for patient management. Test results in the critical limits shall be communicated to the concerned after proper documentation. Moreover, there shall be a hierarchical method of review of examination results, that is, a sequential review of the same specimen, when indicated, by individuals with increasing levels of experience and/or responsibilities. Evidence of such activities shall be recorded. For services accredited for performing examinations only, the laboratory shall fully understand its limitation. It shall, where necessary, state on the report that clinical interpretation by a qualified pathologist is recommended.

Where possible, age- and sex-specific biological reference intervals should be provided when reporting results, where relevant. Generally, such reference intervals shall be verified or determined by the laboratory. If a reference interval study is not possible or practical, then the laboratory shall carefully evaluate the use of published data or data provided by the equipment manufacturer for its own reference intervals, and retain record of this evaluation.

Laboratories shall note the following in addition to the criteria specified in clause 5.8:

- (a) Numerical expression of results and rounding of numbers in accordance with international practice and guidelines.
- (b) Where results are transmitted by electronic or electromagnetic means, particular attention should be paid to the security and integrity of the data being transmitted. Transmission may be handled by the method agreed by the customer in writing, however, it is the responsibility of the laboratory to point out any risk of such methods.



## 6. ACCREDITATION FEES

The accreditation fees shall be charged in accordance with DAC document DAC-G2-03 *Accreditation Fee Structure*.

## 7. OTHER RELEVANT ACCREDITATION REQUIREMENTS

The relevant provisions of the 'Accreditation Requirement DAC-Req-01' shall apply to the accredited laboratories unless otherwise superseded by the provisions of this document.

## 8. REFERENCES

- 8.1 BS/ EN/ ISO 15189: 2007, Medical laboratories- Particular requirements for quality and competence,
- 8.2 BS/ EN/ ISO 9001: 2008, Quality Management Systems- Requirements.
- 8.3 DAC-Req-01 Accreditation Requirements
- 8.4 DAC-Req-05 Conditions for using DAC symbol
- 8.5 DAC-G2-03 'Accreditation Fee Structure'
- 8.6 DAC-G2-04 'Traceability on Measurement and Calibration of Instruments'
- 8.7 DAC- G2-07 'Code of Conduct of the Unannounced Surveillance Visits'