مجلس أبـــوظبـي لـلـجـودة والـمـطـابـــقـة
ABU DHABI QUALITY & CONFORMITY COUNCIL

Abu Dhabi Specification

معايير أبوظبي الفنية

ADS 8/2014

م أ ف 8 / 2014

Quality Control in Medical Laboratories

ضبط الجودة في المختبرات الطبية

هاتف ٦٦٦٦ ٤٠٦ ٢ ٩٧١+ | فاكس ٦٦٧٧ ٤٠٦ ٢ ٩٧١+ | ص.ب. ٨٥٣ أبوظبي، الإمارات العربية المتحدة
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Amendment Page

To ensure that each controlled copy of this ADS contains a complete record of amendments, the Amendment Page is updated and issued with each set of revised/new pages of the document. This ADS is a live document which can be amended when necessary. QCC conducts what it takes to make this document available to all and collects all observations on it. QCC prepares for a meeting of the Medical Laboratories Working Group to discuss the comments made on the document in order to review and amend it.

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About the Abu Dhabi Quality and Conformity Council

The Abu Dhabi Quality and Conformity Council (QCC) was established by law No. 3 of 2009, issued by His Highness Sheikh Khalifa Bin Zayed Al Nahyan, President of the UAE.

QCC is responsible for the development of Abu Dhabi Emirate's Quality Infrastructure, which enables industry and regulators to ensure that products, systems and personnel can be tested and certified to UAE and International Standards.

Products certified by QCC receive the Abu Dhabi Trustmark. The Trustmark is designed to communicate that a product or system conforms to various safety and performance standards that are set by Abu Dhabi regulators.

Foreword

The QCC Working Group for Quality Control in Medical laboratories was formally established in July 2013 with a view to confirming a technical document for Quality Control in Medical Laboratories that shall improve the quality of services provided by medical laboratories in order to preserve public health and safety. This document is prepared in accordance with best international practices and technical documents issued in this regard and specially to meet the needs of the relevant in the Emirate of Abu Dhabi.

1. Scope

This Abu Dhabi Specification (ADS) defines the basic technical requirements for quality control in medical laboratories, including the following:

- General requirements for laboratories.
- General requirements for internal quality control in medical laboratories.
- External quality control scheme for laboratories.

2. Acknowledgements: QCC would like to thank the members of the Working Group listed below. The membership of the QCC Working Group is as follows:

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3. Terms and Definitions

For the purposes of application of this (ADS) Abu Dhabi Specification, the following terms shall have the following meanings unless the context clearly indicates otherwise:

The Council: Abu Dhabi Quality and Conformity Council

Competent Authority: Health Authority

Laboratory: medical laboratory working within the public or private sectors in the Emirate of Abu Dhabi.

Internal quality control samples: reference materials used by laboratories for the purpose of internal quality control.

Calibration: An operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards as well as corresponding indications with associated measurement uncertainties, and in a second step, uses this information to establish a relation to obtain a measurement result from an indication.

Verification: provision of objective evidence that a given item fulfils specified requirements.

Chain of Traceability: metrological traceability of measurement result where the metrological reference is the definition of a measurement unit through its practical realization.

Maximum Permissible error: extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system.

Reference material: material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

Intermediate check: repeatable calibration checks performed by the laboratory, at appropriate intervals, to maintain confidence in the calibration status of measuring and all test equipment's that affect the measurement results concerned.

4. Application

A laboratory shall comply with the requirements of this ADS only to the limit that does not conflict with the mandatory requirements for certain tests, calibration procedures or verifications specified by Emirates Authority for Standardization and Metrology (ESMA) in a form of technical regulations or approved standards that are mandatory or any specifications issued by federal or local authorities regarding medical laboratories.

5. Responsibilities:

- QCC is the entity responsible for the application of these technical standards in collaboration with the competent authorities in the emirate.
- The Health Authority is the competent authority in the Emirate of Abu Dhabi in this regard.

6. General requirements for laboratories

6.1 A medical laboratory shall meet the requirements specified in the international standard (ISO 15189), where the accreditation is not mandatory**.**

6.2 The laboratory shall establish the acceptance criteria of testing samples , which will include as a minimum the following:

- The patient's name on the application form and on the sample is clear and identical.
- Unique identification number.
- Sample is adequate and sufficient.
- Sample is properly kept within an appropriate container.

6.3 Calibration, verification and traceability of measuring instruments:

The laboratory shall ensure that all measurement devices that have a significant effect on the accuracy of the measurement results are duly calibrated and verified and has a calibration/ verification certificate to prove this and that shall be done in the following manner:

6.3.1 Devices that must have verification certificate

The devices that operate within a specified limit of permissible error determined by regulations or specifications relating thereto, or according to the lab special specifications. These devices shall not be used if the value of the permissible error in the measurement plus the value of the measurement uncertainty is not less than the value of the device maximum permissible error, according to the calibration results.

6.3.2 Devices that can be calibrated by measuring standards

The results of such devices can be compared with the results of a measurement standard, such as weights, scales and equipment's measuring temperature, pressure and speed. In which case the result of the calibration shall be used to compensate for measurement errors and the uncertainty result shall be used in determining the results matching of the values required.

6.3.3 Tools that can be calibrated by certified reference materials

The results of such devices can be compared with the results of the analysis of certified reference materials, such as chemical analysis devices, provided that these reference materials are manufactured by an entity approved by the Board. In this case, the laboratory shall be able to analyze the results obtained from the calibration process using certified reference materials and use them to compensate for measurement errors and the uncertainty result shall be used in determining the results matching of the values required.

6.3.4 Devices that can be calibrated using reference procedures:

The results of such devices can be compared to the results of reference procedures; such as defining the density of a specific liquid using a reference procedure based on measuring the temperature, pressure, humidity, weight and

reference tables. According to such procedure, measurement errors and any case of uncertainty of measurement can be detected. Such results can be used to correct the measurement errors and determine to what extent the results match the required values.

6.3.5 Determining the Re-verification and Calibration Period:

The laboratory shall determine the re-verification and calibration period using the measuring and calibration instruments in accordance with the instrument reliability, the frequency and nature of use and the consequences of the results. The laboratory shall have clear policy and procedures determining the calibration periods or the amendments thereof. Document OIML D10 issued by the International Organization for Legal Metrology as well as Guide G24 of the International Laboratory Accreditation Cooperation (ILAC) can be used with regard to such matters in conformity with the requirements of the manufacturer.

6.3.6 Calibration and Internal Verification:

The laboratory may conduct calibrations or internal verifications in case of the availability of the following requirements:

- Working procedures documented and verified in accordance with the international practices by way of example, and not limited to, the Clinical Lab Standards Institute;
- Record or calibration certificates for the instruments calibrated internally;
- Trained individuals with records proving the competency thereof;
- Appropriate measuring criteria and a series of national or international criteria. The criteria shall be set regularly by an approved laboratory, using reference materials manufactured by an authorized body or by a national center for metrology.
- Ability to detect any uncertainty of measurement in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM), provided that there is a working procedure for each type of the measuring instruments;
- Suitable environmental conditions.

6.3.7 Intermediate Check:

The laboratory shall implement intermediate checks pursuant to specific working procedures and schedules to maintain confidence in the calibration status for all measuring instruments influencing the measurement result.

6.4 Uncertainty of measurement:

6.4.1 Each laboratory shall be able to calculate the uncertainty of measurement for each quantitative test with confidence level of 95.45% minimum. Such value shall include all uncertainty causes that may influence the uncertainty check result. Documented and resolved instances for each test done by the laboratory shall be maintained.

6.4.2 In cases where there is a difficulty to calculate the value of the uncertainty of measurement practically or one of the causes thereof, the laboratory may estimate such value in accordance with expert estimation or based on researches published or equivalent.

6.4.3 Every laboratory shall provide the users with the uncertainty value in the following cases:

- If the uncertainty result leads to a change in the result from one level to another (from normal level to abnormal or critical level).
- If such result is required by the user.

6.4.4 The laboratory shall provide the users with the causes of the uncertainty taken into consideration when required thereby or by the related official bodies.

6.4.5 The laboratory shall take the uncertainty value into consideration when evaluating the test result.

6.5 Maximum Permissible Error (MPE): the term is medically known as Total allowable error.

6.5.1 Tests with specific mandatory requirements:

The error value in addition to the uncertainty value of measurement shall not exceed the limits stated in the requirements of the test.

6.5.2 Tests in Appendix (1):

The error value in addition to the uncertainty value of measurement shall not exceed the limits stated in Appendix (1). The concerned body shall be entitled to add any test not stated in the Appendix or amend the mentioned tests.

6.6 Test Report:

The content of the report shall comply with the requirements stated in the international standard specification (ISO 15189) at minimum.

6.7 Units of Measurement:

Test results shall be issued using the legal units of measurement in accordance with decision no. (5/1) of the Emirates Authority for Standardization and Metrology issued on 18/6/2009 regarding the regulations organizing the legal metrology acts in the state and any amendment thereof.

6.8 Storing Samples:

Samples shall be stored in compliance with the legislation and regulatory documents issued by the health authority with this regard.

6.9 Retaining Test Results and Documents:

The laboratory shall retain the test results and the documents related thereto in compliance with the legislation and regulatory documents issued by the health authority with this regard.

6.10 Destroying Test Samples:

The laboratory shall damage all the hazardous materials resulting therefrom in compliance with the legislations applied in such cases.

6.11 Subcontracting:

- In case the laboratory conducted any tests in other laboratories authorized or approved by the Council, the laboratory shall state clearly and explicitly the names of the tests done outside the laboratory and the names of such laboratories as well.

- In case the laboratory conducted a contract with another laboratory unauthorized or not approved by the Council, the laboratory shall be deemed responsible in full for verifying the efficiency of such laboratory contracted therewith or for any errors resulting therefrom.

7. General Requirements of Internal Quality Control in Laboratories

- The limits of the allowed Maximum Permissible Error (MPE) shall be determined in accordance with what is stated in Appendix (1).
- The internal quality control shall be implemented in laboratories in compliance with what is issued from the Clinical and Laboratory Standards Institute with this regard.
- The limits of uncertainty of the reference material shall be at confidence level of 99.73% equalling (3 ±standard deviation).
- The internal quality control round shall usually be 20 readings in different days.
- The laboratory shall document the results of the internal quality control samples in an appropriate manner facilitating the determination of the control limits, pinpointing the issues, and making the development of the internal quality system easy.
- The limits of control for the internal quality control rounds shall be threefold of the standard deviation calculated in the previous quality control round provided that no value of the previous round exceeds the warning limit equalling (2 standard deviations).

8. External Quality Assessment Scheme for Laboratories:

8.1 General Procedure of the External Quality Assessment Scheme:

- Appendix (1) determining the limits of the allowed Maximum Permissible Error (MPE) shall be accredited in the External Quality Assessment Scheme for laboratories.
- The Council shall determine the providers of the Proficiency Testing Programs (PTP) approved thereby.
- The laboratory shall define the main scopes of the tests delivered thereby. Each main scope shall include a set of similar tests classified according to the measurement principle, the test method and the accuracy level. Therefore, the efficiency of the laboratory could be proven by proving the efficiency of a sub-scope of the main scope according to what is stared in Appendix (2).

- The laboratory shall record the main scopes of the tests done thereby at the Council while determining the sub-tests for each scope.
- The laboratory shall contract directly with the providers of the Proficiency Testing Programs (PTP) to provide them with the reference samples four times a year for each main scope, so the sub-scopes can be covered at least one time every two years in case there are enough Proficiency Testing Programs.
- The provider of the Proficiency Testing Program shall send the reference samples to the laboratory using the appropriate methods.
- The laboratory shall test such samples following the same methods of the routine testing and send the results and the uncertainty value (if required) officially, in compliance with the models approved for such purpose and accredited by the laboratory duly, during the period determined by the provider of the Proficiency Testing Program.
- The first result sent by the laboratory to the provider shall be deemed the final result.
- The provider of the Proficiency Testing Programs shall inform the Council and the laboratory with the result of the participation during the period agreed on between the parties.
- The Council shall publish and circulate the results of the Proficiency Testing Programs using the appropriate methods.

8.2 The result of participation in the external Proficiency Testing Programs shall be cancelled in the following cases:

- The laboratory did not submit the result within the stated period completely in compliance with the required models or the results are not approved by the laboratory duly.
- -It is proven that the laboratory collaborated with any other laboratory to set the result in any form.
- It is proven that the laboratory has dealt with the sample following a method other than what is followed in routine tests.

8.3 The result of the participation in the external Proficiency Testing Programs shall be deemed unacceptable if one test result or more exceeded the limits of the allowed Maximum Permissible Error (MPE) stated clearly in Appendix (1). In such case the laboratory shall:

- Work on determining the root cause and the solution thereof while documenting what is happening.
- Immediately stop issuing any test result for all the tests subject to the main scope till the error is corrected through a final and documented solution in case it is proven that the cause is due to a technical error.
- The laboratory shall search for any wrong results issued during the last period and inform all the concerned bodies with the result if it is proven that the result will affect the patient safety.

9. Validation and Verification

Issues of the Clinical and Laboratory Standards Institute regarding such matter (EP05-A2, EP06-A, EP09-A2, EP10-A3, EP12-A2, and EP15-A2) shall be approved.

10. Final Provisions

- QCC and the competent authorities are not responsible for any violation of this ADS caused by the laboratory,
- If any controversy erupt that can't be handled under the provisions of this ADS, or any discrepancy arose about its interpretation or application, it shall be referred to the appropriate standing technical committee in the Emirate of Abu Dhabi to find convenient to handle such a matter based on international practice and in public interest.

- If, as a result of the implementation, any deficiency is found in this document, or any inadequacy of requirements is proved, which may cause any harm to the safety or health of the community members, the Board may take any action it deems appropriate to address this deficiency in best public interest.

- This ADS shall be published in the Official Gazette and will come into effect one year after the date of its publication.

APPENDIX (1) Mandatory

Table for Maximum permissible Error and Coefficient of Variation in Internal and External Quality Control

CLIA Proficiency Testing Criteria for Acceptable performance

Toxicology	
Analyte or Test	**Acceptable Performance**
ROUTINE CHEMISTRY	
Alanine aminotransferase	Target value ±20%
Albumin	Target value ±10%
Alkaline phosphatase	Target value ±30%
Amylase	Target value ±30%
Aspartate aminotransferase	Target value ±20%
Bilirubin, total	Target value ±0.4 mg/dL or ±0% (greater)
Blood gas PCO_2	Target value ±5 mm/Hg or ±8% (greater)
Blood gas pH	Target value ±0.04
Blood gas PO2	Target value ±3 standard deviations (SD)
Calcium, total	Target value ±1.0 mg/dL
Chloride	Target value ±5%
Cholesterol, high-density lipoprotein	Target value ±30%
Cholesterol, total	Target value ±10%
Creatine kinase	Target value ±30%
Creatine kinase isoenzymes	MB elevated (presence or absence) or target value ±3 SD
Creatinine	Target value ±0.3mg/dL or ±15% (greater)
Glucose	Target value ±6 mg/dL or ±10% (greater)
Iron, total	Target value ±20%
Lactate dehydrogenase (LD)	Target value ±20%

LD isoenzymes	LD 1/LD 2 positive or negative or Target ±30%
Magnesium	Target value ±25%
Potassium	Target value ±0.5 mmol/L
Sodium	Target value ±4 mmol/L
Total protein	Target value ±10%
Triglycerides	Target value ±25%
Urea nitrogen	Target value ±2mg/dL or ±9% (greater)
Uric acid	Target value ±17%
Endocrinology	
Cortisol	Target value ±25%
Free thyroxine	Target value ±3 SD
Human chorionic gonadotropin	Target value ±3 SD or positive or negative
Triiodothyronine	Target value ±3 SD
Thyroid-stimulating harmone	Target value ±3 SD
thyroxine	Target value ±20% or 1.0 µg/dL (greater)
Alcohol, blood	Target value ±25%
Blood lead	Target value ±10% or ±4µg/dL(greater)
Carbamazepine	Target value ±25%
Digoxin	Target value ±20% or ±0.2 ng/mL(greater)
Ethosuximide	Target value ±20%
Gentamicin	Target value ±25%
Lithium	Target value ±0.3 mmol/L or ±0% (greater)
Phenobarbital	Target value ±20%
Phenytoin	Target value ±25%
Primidone	Target value ±25%

Procainamide (and metabolite)	Target value ±25%
Quinidine	Target value ±25%
Theophylline	Target value ±25%
Tobramycin	Target value ±25%
Valproic acid	Target value ±25%
Hematology	
Cell identification	90% or greater consensus on identification
White cell differentiation	Target ±3 SD based on percentage of different types of white cells
Erythrocyte count	Target ±6%
Hematocrit	Target ±6%
Hemoglobin	Target ±7%
Leukocyte count	Target ±15%
Platelet count	Target ±25%
Fibrinogen	Target ±20%
Partial thromboplastin time	Target ±15%
Prothrombin time	Target ±15%
General Immunology	
α^1 - antitrypsin	Target value ±3 SD
α - fetoprotein	Target value ±3 SD
Antinuclear antibody	Target value ±2 dilution or positive or negative
Antistreptolysin O	Target value ±2 dilution or positive or negative
Anti-human immunodeficiency virus	Reactive or nonreactive
Complement C3	Target value ±3 SD
Complement C4	Target value ±3 SD
Hepatitis (HbsAg, anti-HBc, HbeAg	Reactive (positive) or nonreactive (negative)
Immunoglobulin (Ig)A	Target value ±3 SD

IgE	Target value ±3 SD
IgG	Target value ±25%
IgM	Target value ±3 SD
Infectious mononucleosis	Target ±2 dilution or positive or negative
Rheumatoid factor	Target ±2 dilution or positive or negative
Rubella	Target ±2 dilution or positive or negative

Appendix 2 (Mandatory)

Main Category and Sub-Category Tests Used in Internal and External Quality Control Schemes. (MAIN CATEGORIES OF LABORATORY SPECIALITIES).

S.no.	Main Field	Sub Field
1	Anatomic Pathology	Surgical pathology
		Special stains & Immunohistochemistry
		Predictive Markers
		Specialty Anatomic Pathology
		Cytopathology
2	Clinical Chemistry and Therapeutic Drug Monitoring	General chemistry and therapeutic drug monitoring
		Urine chemistry
		Special chemistry
		Endocrinology
3	Blood gas and oximetry	
4	Toxicology	
5	Hematology and Coagulation	General Hematology
		Clinical Microscopy
		Coagulation
		Flow cytometry
		Special hematology
6	Microbiology	Bacteriology
		Mycobacteriology
		Mycology
		Parasitology
		Virology
		Molecular microbiology

		Infectious disease serology
7	Immunology and flow cytometry	Immunology
		Flow cytometry
8	Transfusion medicine	Transfusion medicine
		Viral markers
9	Histocompatibility	
10	Genetics and molecular pathology	Cytogenetics
		Biochemical disorder
		Molecular genetics
		Molecular oncology - solid tumors
		Molecular oncology - hematologic
11	Reproductive medicine	Andrology and embryology
12	Forensic pathology	
13	Point of care testing	

References

- ISO 15189: Medical laboratories — Particular requirements for quality and competence.
- OIML V1: International vocabulary of terms in legal metrology (VIML) And its translation approved by Arab Industrial Development and Mining Organization
- ISO guide 34: General requirements for the competence of reference material producers
- OIML D10: Guidelines for the determination of calibration Intervals of measuring instruments, 2007
- ILAC-G24: Guidelines for the determination of calibration Intervals of measuring instruments, 2007
- BIPM: Evaluation of Measurement data- Guide to the expression of Uncertainty in measurement, JCGM 100:2008
- CLSI: Clinical and Laboratory Standards Institute.
- CAP Guidelines for Samples Retention-Retention of (Laboratory Records and Materials)
- Health Policy and Regulation Version 1.0, HAAD Clinical Laboratory Standards (Policy on Clinical Laboratory specifications)
- Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline-Third Edition.C24-A3 Volume 26 No .25.

- Emirates Authority for Standardization and Metrology board decision no. (5/1) Dated 18/6/2009, concerning Regulations of legal metrology system in the country, issued by virtue of article 16 of Cabinet Resolution No. (31) of (2006) regarding the National Measurement System.