



**Guideline for the Formulation of Scopes of Accreditation for Medical
Laboratories ISO 15189**

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1. Purpose

This document demonstrates how to formulate the scope of accreditation for the medical laboratories at the Saudi Accreditation Center (SAAC), in accordance with the requirements of SAAC or the relevant international bodies.

2. Scope

This document is applicable to the accreditation scope of Medical Laboratories at SAAC.

3. Normative References

- Conformity Assessment- Requirements for accreditation bodies accrediting conformity assessment bodies ISO/ IEC 17011:2017.
- Medical laboratories — Requirements for quality and competence ISO 15189: 2012.
- ILAC-G26:11/2018 Guidance for the Implementation of a Medical Accreditation Scheme.

4. Terms and Definitions

- **The Saudi Accreditation Center (SAAC):** The official body which carries out the accreditation, referred to as "SAAC".
- **Medical Laboratories:** laboratories conducting chemical, immunological, medical microbiological, cytological, genetic or other examination of materials derived from the human body, for the purpose of providing information for the diagnosis, management, 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.
- **ILAC:** the International Laboratory Accreditation Cooperation for accreditation bodies of laboratories and inspection bodies, is the international organization that helps in harmonizing and recognizing the accreditation systems, in accordance with the international standard ISO/IEC 17011.
- **Scope of Accreditation:** A list of medical examinations that have been assessed and accredited by SAAC, including examination category, specimen type, specifications, standards (the examination methods), and the equipment used.
- **Examination Category:** the type of medical examinations (for example, chemical, immunological, medical microbiological, cytological, genetic, or other examination of materials derived from the human body...etc.)
- **Specimen Type:** the specimen type used (for example, blood, serum, plasma, urine, stool, swab, sputum, body fluids and tissues).
- **Examinations:** the tests or assays whose results are to be read in order to provide information and diagnosis (for example, enzymes, hormones, body fluids... etc.).
- **Specifications, Standards or Methods of Examination:** the standard reference examination, or the method that has been internally developed by the laboratory.

- **The Equipment Used:** the equipment used in medical examinations whose results are to be read (for example, Siemens ADVIA XPT, Dimension RXL 200), and in the absence of equipment, (N/A) shall be written accordingly.

5. Formulating the Scope of Accreditation

SAAC formulate the scope of accreditation for the activities that will be accredited for medical laboratories, in accordance with the requirements of the international standards ISO/IEC 17011: 2017, by specifying the following criteria:

- The examination category and the specimen type.
- The specific examinations and the equipment used.
- Specification, standard or method that contains the requirements, in accordance with which the examination will be conducted.

These guidelines must be strictly adhered to, when entering all the scopes to be accredited in the same format presented in the schedule (Appendix A) by the representatives of the medical laboratories and assessors in SAAC's electronic information system for accreditation. The provided schedule is only illustrative without the intention of being exhaustive. It is also possible to include the scope of accreditation in Arabic or English language alike, and SAAC will publish the scope of accreditation on the website of the accredited conformity assessment bodies, to demonstrate the types of activities/ examinations which have been assessed, evaluated, and accredited by SAAC.

5.1 The Symbols and Units

- The hyphen (-) must not be used to indicate a range of values, the word "to" should be used instead, for example:
 - **The Correct:** 0.8g/ml to 1.0g/ml
 - **The Incorrect:** 0.8g/ml - 1.0g/ml
- A space must be placed between the numerical value and the unit symbol, for example:
 - **The Correct:** 100 °C **The Incorrect:** 100°C
 - **The Correct:** 0.25 % **The Incorrect:** 0.25%
- A space must NOT be placed between mathematical calculations (such as signs: "+", "-") and the number associated with them.
 - **The Correct:** -20 °C
 - **The Incorrect:** - 20 °C

6. Related Documents

- Accreditation Process Procedure P-01

Appendix (A)

Representative Template for Formulating the Scope of Accreditation for the Medical Laboratories in SAAC's Electronic Information System for Accreditation

"The schedule is only illustrative without the intention of being exhaustive"

Equipment used	Specification, Standard (Method)	Specific Examination	Specimen type	Examination Category	#
Siemens ADVIA XPT	Enzymatic method	AST, ALT, ALP, etc.	Serum	Clinical chemistry	1
CBC sysmex	light scatter signal method	CBC	Blood	Hematology	2
iQ200 analyzer	Urea, Calcium, Microalbumin....etc.	Culture	Urine	Medical Microbiology	3