1- Object :

The purpose of this document is to present the policy of ALGERAC in order to define the accreditation scopes applicable to medical biology laboratories and the procedures for assessing those scopes.

2- Scopes

The present document is applicable to the laboratories that are accredited or candidate for accreditation in accordance with the standard ISO 15189.

Also concerned with this document are the staff of the technical structure, assessors, experts, and the members of ALGERAC's medical biology committee.

3- References

ISO/IEC 17011: Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies,

ISO/IEC 17025: general requirements for the competence of testing and calibration laboratories,

ISO 15189: requirements for quality and competence in medical laboratories,

EA-2/15: EA requirement for the accreditation of flexible scopes

EA-4/17: EA position paper on the description of scopes of accreditation for medical laboratories.

ILAC-G18: guideline for the formulation of the scopes of accreditation for laboratories.

PRO 12: Accreditation procedure

GEN 12: Specific requirements for accrediting medical biology laboratories.

4- Definitions:

Accreditation scope: specific activities for which accreditation may be requested or awarded.

Depending on the laboratory request, accreditation may be fixed or flexible:

- **Fixed scope:** it is an accreditation scope for which the sampling nature, the measured or desired characteristic as well as the method used cannot be modified without a prior assessment by ALGERAC.

- **Flexible scope :** it is an accreditation scope which is formulated in such a way as to allow medical biology laboratories to modify the metrology and other parameters relating to an equivalent competence of the laboratory as recognised by the accrediting body without prior assessment by ALGERAC under the guise of equivalence.

Recognised or reference methods:

These are :

- Methods which are found in international, regional, or national standards;
- Methods which are published by renowned bodies such as WHO, etc;
- Methods which are published in scientific publications with a recognised reading committee: texts, specialised scientific journals, works);
- Methods which are proposed by an equipment or testing kit manufacturer, the biography of whom makes it possible to apply those methods as such with international garantees.

Non-recognised methods:

Those are the methods implemented by the laboratory for its own use in order to meet the needs of its customers.
They may be the result of the modification of a recognised method (standardised method used outside its scope, adopted recognised method, supplier's instructions proposed by the manufacturer and needing further checkpoints, or methods developed entirely by the laboratory).
In the accreditation scope those methods are known as **''internal methods''**.

Method adopting: implementing and applying a recognised method with no modification on it.

Method adapting: modifying a method in order to meet the needs of a customer or laboratory.

Method developing: conceiving a new method.

Method validating: the act of confirming, through objective proofs, that the requirements related to a specific use or foreseen application are met.

Method verification: the act of confirming, through tangible proofs, that the specified requirements are met.

5- Policy:

In accordance with the requirements of the standard ISO 15189, and the documents EA-2/15, EA-4/17 and ILAC G18, ALGERAC shall apply a policy of promoting the scopes, fixed and flexible, towards the laboratories in order to allow them to adapt to the needs of their customers and the development of the market. Whatever the type of the scope, the laboratory shall be held responsible for the content of its scope of accreditation.

Requirements in terms of method implementation

- Prior to utilising a method which is recognised, the laboratory will have to test the mastery of its implementation in its own environment with regard to criteria and acceptable limits it has already set.

- Prior to using a method which is recognized, modified or adopted to the needs of the laboratory or to those of its clients, the laboratory must validate the method according to the modifications made
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- Before using an unrecognized method, the laboratory must validate the method

6 - Managing and expressing scopes for medical biology laboratories

The 2012 version of the standard ISO 15189 allows the use of methods that are recognized, and provides the possibility of using those which are modified and/or developed by the laboratory; and also differentiates between the validation of those latter methods and the verification of the recognized ones.

In an initial assessment, the laboratory is evaluated at fixed scopes (depending on the nature of the sample and analysis, principle of the method, etc.) as specified in its scope of accreditation.

The scope of accreditation can, thus, be expressed through two types:

1) **Fixed scope:** laboratories accredited at fixed scopes are not allowed to modify their scope of accreditation without previously notifying ALGERAC of it. Any modification of the scope of accreditation shall be made after a request for extension is submitted.

The evaluation of that scope shall deal, inter alia, with:
- The technical competence necessary to perform activities covered by the accreditation, or for which an accreditation is requested,
- The organizational and documentary aspects.

2) Flexible scope

Medical biology laboratories practice methods that are likely to evolve; an accreditation to a flexible scope is preferable as required by EA-4/17.

Flexible scopes can be expressed through two categories:

a) **Flexible standards:** to adopt a method . To include a recognised method in the scope of accreditation

In this case, the laboratory is allowed to perform, under accreditation between two assessments, analyses according to recognised methods based on the same technical principle in which case the reviewing of these methods does not require new competencies; without prior assessment by ALGERAC.

Accreditation according to this type of scope allows laboratories to do the following:

- To change equipment or reagent supplier in accordance with technological developments,
- To perform analyses from a pool of sample types previously determined.

Provided the general principle of the method is equivalent

The assessment of such kind of scope shall, inter alia, focus on:

- The competence and capacity of the personnel to master each principle and critical points of the methods,
- The measures used to ensure monitoring and take into account revisions of recognized methods
- The review process, confirmation and authorization of the use of the reviewed or adopted methods
- The competence criteria for the personnel directly involved in those steps and their capacity to evaluate the measure uncertainties, and master the risks on the results of the analyses.
- Method verification process

b) **Flexible extent:** adapting a method : modifying a recognized method/developing a method, to adjust it to the needs of the laboratory and customer (patient/prescriber). The laboratory is allowed to perform, under accreditation between two assessments, analyses according to a set of techniques validated and developed using similar procedures to meet the different variable requests of its customers (patients/prescribers) without previous assessment by ALGERAC.
Processes and responsibilities in terms of adaptation and development of methods shall be documented.

The assessment shall, inter alia, focus on :

- The competence and ability to practice each of the individual techniques within the limits of the scope,
- The procedure for flexible scope management (performing residual risk analyses for methods newly introduced in the scope that integrates the assessment of uncertainty estimates, if need be, for quantitative methods or qualitative methods with quantifiable values; and implementing monitoring processes that are good enough to ensure validity, as specified in ISO 15189 standard).
- The process of adaptation, development, validation, and authorization to use new and/or modified methods within the limits of accreditation,
- The competence criteria retained for the accreditation of the personnel directly involved in those steps and their ability to assess uncertainties.

- The application of the full process, based on the method validation files The laboratory shall keep updated a list of analysis methods that included the following:

  - the revisions in the recognized methods within to the scope,
  - the methods that are newly adopted and included in the scope.

The laboratory shall keep ALGERAC informed about any method brought into the scope, whether this method is adopted, adapted, or developed (included) within the limits of that scope; and submit a detailed list of the updated tests.

NB : Whatever the flexibility type of the accreditation request, the laboratory is not allowed to implement, under accreditation, a new non-equivalent measuring principle without previously evaluating it.

In such case, the laboratory shall submit to ALGERAC a request for the extension of its scope

In case of a request for accreditation with a flexible application scope, the laboratory shall provide to ALGERAC, at least, the following information:

- The validation/verification reports for each of the specific analyses,
- A management procedure of the flexible scope describing the organizational arrangements implemented with the aim of providing the necessary guarantee with regard to the mastery of its accreditation scope,
- Qualification and accreditation criteria for people in charge of managing new analysis methods and/or matrix or parameters, including the verification and final approval of analysis methods.

Laboratory evaluation has an additional focus on: what follows:

The assessment of the review of the customer's contract and information: the laboratory shall allow enough time to explain to its customers (patients/prescribers, etc) the possibilities and limits of its scope of accreditation.

7 - Obligations linked to the flexible scope

The laboratory is responsible for implementing an organization and controls capable of insuring the introduction of new methods (or new versions of the methods) in its flexible scope is mastered.

If it turns out that the laboratory has failed to meet its obligations, ALGERAC shall make an decision adapted to the severity and extent of the situation.

That shall depend on the nature, implications and frequency of non-conformities, and may consist of the following actions :

- ✓ reducing the type of flexibility (re-expressing the scope of accreditation)
- ✓ suspending the accreditation for the field of activity concerned with non-conformities, (see PRO 23)
- ✓ totally suspending the accreditation awarded (see PRO 23)

The decision may include the recall of analysis reports duly issued with reference to the accreditation, and/or an explicit item of information of the customers concerned.

Moreover, the laboratory has the obligation to update in real time the detailed scope, and submit it to ALGERAC each time a development occurs.

8 - Scope publication

The accreditation certificate refers to the technical annex which describes the scope of accreditation of the laboratory, with the flexibility type specified.

The current version is available on ALGERAC's website (www .algerac.dz)

Directeur Général

Fixed Scope

Medical biology/Biochemistry/General biochemistry			
Nature of the biological sample	**Nature of the analysis**	**The principle of the method**	**Reference of the method (*)**
Biological sample of human origin	Blood sugar	Colorimetry	Supplier methods caller package

Fixed scope: none of the characteristics (nature of the biological sample, nature of the analysis, principle of the method, and reference of the method) shall be not modified.

A flexible scope in medical biology **Example: A flexible scope S**

Medical biology/Biochemistry/General biochemistry			
Nature of the biological sample	**Nature of the analysis**	**The principle of the method**	**Reference of the method (*)**
Biological samples of human origin	Blood sugar	Coloriometrty	Recognised methods
	ALAT ASAT	Enzymatic	

Flexible scope S: The laboratory is judged competent to adopt and implement any recognised method according to the same principle of the method. The complete list of the methods is kept updated by the laboratory

Example: Flexible scope E

Medical biology/Biochemistry/General biochemistry			
Nature of the biological sample	**Nature of the analysis**	**The principle of the method**	**Reference of the method (*)**
Biological samples of human origin Other samples ((linked toan intravascular apparatus, dialysis fluid, etc) Parasitic culture	Finding and identifying parasites	fresh,direct, macro- and microscopic morphologic examination; in fresh state and/or after preparation (concentration, centrifugation, fixation, colouring, culture, marking, etc) Phenotypic determination through immune chromatography	Internal methods MO- XX

Flexible scope extent (E): The laboratory is judged competent to adapt any recognized method or even develop its own. The exhaustive list of methods in maintained of the laboratory