

Transition policy ALGERAC from ISO 15189:2012 to ISO 15189:2022 Version 00 - December 2022

1. Introduction :

The ISO 15189 standard contains the general requirements for the competence of medical laboratories - Requirements for quality and competence. ISO published on December 6, 2022 a new edition of ISO 15189, this new edition integrates ISO 22870:2016 Off-site medical laboratory examinations - Requirements for quality and competence.

Medical laboratories accredited to ISO 15189:2012 have a transition period of three years from the date of publication of the new edition to bring their processes into line with the requirements of the new standard.

2. Transition to the new ISO 15189:2022 standard

- **From 1er January 2024:** ALGERAC will be ready to carry out assessments according to the ISO 15189:2022 standard.

- **From 1er January 2025:** all initial assessments will be carried out according to the requirements of the latest version of ISO 15189:2022. From this date onwards, ALGERAC will not accept any new applications for accreditation to ISO 15189:2012.

- Laboratories currently accredited to ISO 15189:2012 must comply with the requirements of the latest edition of the standard in order to maintain their ALGERAC accreditation by 31 March 2025.

From 1 July 2025 accreditations according to ISO 15189:2012 will no longer be valid. Laboratories that have not upgraded to the 2022 version by this date will no longer be able to refer to the accreditation for their test results, their certificates and technical annexes will be withdrawn.

3. Transition process for accredited laboratories:

In preparation for the assessment of the transition to the new standard, accredited laboratories must complete at least the following steps:

Preparation of a documented action plan for the implementation of the new version, based on a comparison between the old and the new standard.

- Training of staff on the requirements of the new standard and the resulting adjustments and changes to the laboratory management system.

- Submit an application and transition plan to ALGERAC by 1er January 2025. The plan must present in sufficient detail the actions taken by the laboratory to meet the new requirements of the standard and the dates of implementation.

- The last possible date for the transition assessment to ISO 15189:2022 is 31 March 2025, in order to complete the whole transition process in time, corrective actions by laboratories to address deviations in relation to the new or modified requirements of the new version shall be completed by 30 June 2025. The assessments shall be carried out as far as possible in combination with the surveillance and renewal assessments scheduled in the surveillance and renewal plans of the accredited

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laboratories. If necessary, this assessment could be carried out as an additional assessment

Other provisions

- The minimum duration of the on-site transition assessment is one day (08 hours); depending on the risk analysis (FOR 77-1), this duration may be increased by ALGERAC. If the assessment is combined with a planned assessment (surveillance or renewal) the assessment time required for the transition will be added to the duration of the planned assessment.