Significance and characteristics of ISO/IEC 17025 accreditation (ACCREDIA)

Eurofins Biolab S.r.l. is an ISO/IEC/17025 Testing Laboratory accredited by ACCREDIA, the Italian Accreditation Body, with the accreditation number 00028. The validity of the accreditation of the Eurofins Biolab S.r.l. can be checked on the website:

https://services.accredia.it/accredia_labsearch.jsp?ID_LINK=1734&area=310&dipartimento=L&desc=Laboratori

Accreditation means the attestation by a national accreditation body (ACCREDIA in Italy) that a specific conformity assessment body (Eurofins Biolab Srl) meets the criteria established by harmonized standards and, where appropriate, any other additional requirements, including those defined in the relevant sectoral programs, to perform a specific conformity assessment activity.

Accreditation in accordance with UNI CEI EN ISO/IEC 17025:2018 is the formal recognition of the laboratory's compliance with the requirements of the system for testing activities and its technical competence in relation to accredited tests. Accreditation guarantees users, through periodic technical checks by ACCREDIA, the competence and impartiality of the laboratories , to carry out a specific conformity assessment activity.

https://www.accredia.it/en/

https://www.accredia.it/en/accreditation/mark/

1 Mutual recognition

Accreditation is part of a global system, which includes conformity assessment and market surveillance, designed to assess and ensure compliance with applicable standards in order to recognize, on the international market, the quality of the products and services provided by Customers themselves. The particular value of accreditation lies in the fact that it provides an attestation with the authority of the technical competence of the accreditation bodies responsible for ensuring compliance with the applicable standards.

Accreditation of laboratories is carried out all over the world according to the international standard ISO/IEC 17011, supplemented by the requirements of EC Regulation 765/2008 for the accreditation bodies of the European Union.

The accreditation mark of a signatory body affixed to the test report, or to the certificate of conformity, acts as a passport to international markets. By virtue of the presence of this mark, a product or a service can circulate without the need for further tests, inspections or verifications.

Therefore the mutual recognition of the results of the conformity assessments carried out by the accreditation bodies and laboratories belonging to the signatory countries has the aim of promoting the circulation of goods and services on international markets.

More information on the meaning and importance of Mutual Recognition Agreements (MLA/MRA) between Accreditation Bodies at European and global level, can be found on the website:
https://www.accredia.it/en/about-us/accredia-international-role/

The accreditation certifies the technical competence of the Eurofins Biolab Srl Testing Laboratory in relation to the accredited tests present in the accreditation field, consisting of the list of tests for whose execution the technical competence is certified in the following link:

Site A (Vimodrone)

https://services.accredia.it/accredia_labsearch.jsp?ID_LINK=1734&area=310&numeroaccr=00028&classification=A&isRestricted=false&dipartimento=L

Site B (Poggibonsi)

https://services.accredia.it/accredia_labsearch.jsp?ID_LINK=1734&area=310&numeroaccr=00028&classification=B&isRestricted=false&dipartimento=L

Section "Testing laboratories", accreditation number **00028**.

The list of tests shows the materials/matrices/test products, the measurands (the quantities to be determined) and the test methods used.

ACCREDIA is the accreditation body designated by the Italian government to certify the competence, independence and impartiality of the bodies and laboratories that verify the conformity of goods and services to the standards, to ensure effectiveness and uniformity of approach by the operators of the system, favoring the growth of the competitiveness of the production system and the improvement of citizens' well-being.

Accreditation to the Testing Laboratory is granted at the end of an in-depth verification process by ACCREDIA which demonstrates compliance with the requirements of the ISO/IEC 17025 standard. Accreditation certifies the laboratory's technical competence to carry out the tests indicated in the accreditation field and the implementation in the laboratory of a quality management system aligned with the requirements of UNI EN ISO 9001.

As an independent third party, ACCREDIA guarantees compliance with the standards by accredited laboratories, and the reliability of the certificates of conformity issued by them on the market, carrying out a service in the public interest to protect the health and safety of people and of the environment. ACCREDIA is a member of the international networks of accreditation bodies and is a signatory of the related international mutual recognition agreements.

Once accredited, the test Laboratories can issue on the market test reports relating to the tests accredited with the ACCREDIA accreditation mark. The technical skills, the adequacy of the equipment and the structure in which the tests are performed are periodically verified by means of random checks on the tests subject to accreditation and on the Quality Management System (management, technical and organizational requirements). Therefore, accreditation is a guarantee of impartiality, independence, fairness and competence, under the constant monitoring of the accreditation body.

The tests carried out under accreditation consist in the determination of one or more characteristics of the product according to well-defined methodologies.

Tests carried out by accredited laboratories according to ISO/IEC 17025 are services in support of production processes or conformity assessment activities.

From 2025, ACCREDIA organized accreditations according to a single registry. This has resulted in the reassignment of accreditation numbers for each legal entity.

At the following link:

https://certificati.accredia.it/unico/

a correlation table of accreditations as of 31/12/2024, between “previous” and “new” accreditation numbers and respective schemes, is available for each CAB (conformity assessment body), which ensures immediate correspondence, particularly during the transitional period (for which please refer to the specific circulars on the ACCREDIA website).

2 Use of the ACCREDIA mark

The use of the ACCREDIA mark is defined in regulation RG-09 available on the body's website at:

https://www.accredia.it/en/accreditation/mark/

The ACCREDIA mark or any reference to accreditation must not be applied to a test sample or product (or part thereof) or used to imply product certification, nor used in documentation relating to a product. The ACCREDIA mark is granted for use only to accredited entities. Use of the mark and/or reference to accreditation is subject to authorization by ACCREDIA.

The Testing Laboratory has the duty to inform its customers of these limitations and to monitor their application. The mark or any reference to accreditation must not be used in such a way as to create the impression that the accreditation body accepts responsibility for the result of the tests or for any opinions and interpretations which may arise from it or which are given. approval of a test sample or product.

In view of the principle of transparency, the Laboratory that issues a test report/report for the conformity assessment activities covered by its accreditation, must operate under accreditation (using the brand/reference), unless it has been explicitly agreed in a legal or documented agreement with the customer. In these cases, the accredited entity must inform their clients that such test reports/reports are not accredited and consequently are not covered by EA MLA.

However, the latter possibility cannot be applied when test reports/reports containing results covered by accreditation are issued in an area where accreditation is mandatory by law or contractually required or when test reports / reports must be presented or transmitted to third parties (public or authorities). In such cases, the use of the mark or reference to accreditation is mandatory, unless the affixing is prevented by mandatory requirements.

3 Decision rule

The standard in the ISO/IEC/17025:2018 version introduces the concept of "decision rule" that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.
Decision rules allow the laboratory to formulate declarations of compliance with specific requirements. The decision rule applied must be clear in the test report (unless it is already contained in the standard or in the specific request).

The laboratory cannot exclude a priori issuing declarations of conformity if requested by the customer, unless it is forbidden by mandatory provisions.

Where decision rules can be chosen, the laboratory shall discuss with the customer the risk levels associated with the probability of false acceptance and false rejection associated with the available decision rules.

When decision rules for conformity assessment are not explicitly defined by reference standards (technical or legal) or by customers, the laboratory applies the "simple acceptance" approach, according to which measurement uncertainty is not taken into account. In other words, to determine the conformity or non-conformity of a measured value with respect to a defined limit, the result itself, the point value obtained from the analysis, is considered without taking into account the range of uncertainty. In this case, the risk level of making an incorrect conformity assessment is 50%.

If the customer requests a declaration of conformity to a specification, the "decision rules" must be clearly defined, communicated, and agreed upon with the customer during the contractual phase and will be subject to contract review.

Additional guidance for the purposes of accreditation is provided by ILAC in the form of policy requirements and guidance. In particular, ILAC-G8 "Guidelines on Decision Rules and Statements of Conformity" provides an overview of the requirements stated in ISO/IEC 17025:2017 that concern statements of conformity and describes how certain decision rules can be selected and how uncertainty can (and must) be taken into account.

4 Procedure for request to modify issued test reports

The reissuance of test reports follows the provisions of the European Co-operation for Accreditation (EA) released at the 33rd General Assembly on May 27-28, 2014.

A unique sample identification must be provided and any labeling or manufacturer's brand identified as such may be shown. The product tested must be clearly identified in both the contract review and the test report.

Reissuance of test reports when the trade name/brand of the product tested varies is governed by paragraph 5.8.8 of ISO/IEC 17025: test reports are reissued only when errors are corrected and information/data omitted but available at the time of testing (e.g., new/additional information related to sample detail) is included. and that does not result in a substantial change in product identification (e.g. new/different Lot number, new/different product name/brand).

Test reports must be corrected and reissued in case of:

- → incorrect or misleading use of the ACCREDIA mark or reference to accreditation;
- → errors in test results (Laboratory error in transcribing information/data);
- → any other deficiency or error that may result in incorrect use of the test report by the client or third parties, or compromise the correct understanding of the test results by the client's third parties, third parties, or the authority.

It is permissible to make changes necessitated by any errors made in the transfer of information from the client to the laboratory in the identification of the sample and/or in the compilation of the order that do not result in a substantial change in the identification of the product (such as new/different Lot number, new/different product name/brand, etc.).

The practice of reissuing a test report under accreditation is not allowed when the trade name/brand (including manufacturer's name, lot number, etc.) of the product tested has changed from what was previously indicated by the client (without having re-tested), even when there is a clear reference to the initial report being replaced.

In the event that the customer needs to obtain a test report in which different sample identification data is given in terms of the product's Trade Name or Trademark, it will be necessary to send a new sample from which the product is uniquely and clearly identified. The sample will be retested and a new Test Report will be issued in which the product will be identified according to the new/different instructions.

The laboratory does not take responsibility for declaring that the product with the new trade name/mark is strictly identical to the one previously tested; this responsibility belongs to the customer.

5 References

- RT-08 – Requirements for the accreditation of Testing Laboratories;
- RT-23 - Rules for the definition of accreditation scope
- RG-02 – Regulation for the accreditation of Testing and Medical Laboratories;
- RG-09 – Regulation for the use of the ACCREDIA logo and mark;
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products;
- ILAC G8 – Guidelines on Decision Rules and Statements of Conformity;
- EA Resolution 2014 (33) 31 Reissuance of test reports when the trade name/trademark of the tested product has changed (clause 5.10.9 of ISO/IEC 17025).