L'AGENZIA DELLE ACCISE, DOGANE E MONOPOLI

GENERAL CONDITIONS FOR THE PROVISION OF CHEMICAL ANALYSIS

BY THE LAB TO ITS CUSTOMERS

1. Accreditation – obtaining official recognition

The Customs and Monopolies Agency's Chem Labs (hereinafter referred to as the Agency) are accredited by ACCREDIA, the single national accreditation body, as a multi-site Lab with accreditation number no. 1831. The multi-site Lab is divided into a central office and several branch offices throughout national territory, each referred to hereinafter also with the single term Lab.

The various activities of the offices are related to a single quality management system compliant with the international standard UNI CEI EN ISO/IEC 17025: 2018.

The accreditation certifies the technical competence, independence and impartiality of the Labs' activities in accordance with the requirements of the above UNI CEI EN ISO/IEC 17025: 2018 standard, and ACCREDIA documents. Accreditation ensures that the results of accredited analytical tests are accepted with confidence both in Italy and abroad.

The updated list of tests accredited by each site of the multi-site Lab is available on the www.accredia.it website.

2. Analysis Request

Customers[1] of the Lab can be institutional or private, and access the analysis service by way of a request. The General Conditions, also published on the Agency's website (www.adm.gov.it), apply to all samples accepted by the Lab, by selecting the path "The Agency/Labs and Chemical Activities/Activities of Chem Labs", where the form for submitting your request for analysis as well as the tariff of the services offered by the Lab is also available.

3. Sampling

1 Customer: subject who in any capacity takes advantage from the Lab's services and performances. Customers can be:
- Institutional Clients: subjects who access the Lab's services free of charge for the performance of institutional tasks or for legislative provisions (e.g. Customs Offices, Finance Police, etc.).
- Private Customers: subjects who request the Lab's services with charges (e.g. Public Administrations, companies, private subjects, etc.).

Each activity, procedure and methodology provided for in the identification and preparation of the sample to be tested is defined as "sampling" and, unless otherwise agreed, it is intended to be run by the Customer.

Upon request, the Lab ensures availability to provide information on procedures, techniques and/or sampling and conservation methods of the sample to be tested.

The Lab runs sampling activities exclusively on narcotic substances findings.

The overall quantity to be sampled and the possible number of additional fractions of the sample, depends on the type of analysis to be performed and will be agreed with the Customer, as well as defined in the internal procedures of the Lab.

As regards institutional samples, further samples - in addition to the one delivered to the Lab - are considered as reserve and must be kept by the sampler and left available for any further checks. These reserve samples must be stored in appropriate conditions, as provided in the "Minimum Quantity List" available on the SISLAB system.

The sampling activity is not subject to ACCREDIA certification.

4. Delivery of samples to the Lab

The material to be analysed is delivered to the Lab by the Customer, unless otherwise agreed. The customer is responsible for the packaging, transport and the delivery of the sample. The sample must be transported in such a way as not to undergo changes in temperature or other parameters, which could affect the analytical result.

The analysis conducted by the Lab will always refer to the condition of the sample at the time of delivery.

Samples can also be delivered directly to the Lab by customers; addresses and telephone numbers are available on the Agency's website.

The Customer must inform the Lab about any potential hazards inherent to the material to be analysed by detailing the dangers associated with it; the Customer must also give advice on the correct method for handling the samples (elimination, reduction, protection).

Samples must reach the Lab properly sealed, or unsealed in the case of samples taken by private paying customers for analyses. The affixing of the seals must be done in such a way as to avoid any opening or

tampering without breaking them; samples must also be identified from the time of collection until the beginning of the analytical process in the Lab.

5. Sample storage and residual sample.

Upon receipt of the sample, the Lab ensures its conservation in a suitable manner to guarantee the adequate maintenance of its chemical and physical conditions.

If the Customer wishes to remain anonymous on the sample to be analysed as well as on any other related service, he must inform the Lab and provide the sample in anonymous containers.

A reserve sample may be requested by the Lab for justifiable reasons, that is to say, with samples subject to analysis for institutional purposes, where applicable, it can be used in cases of dispute/litigation or where a second expert opinion is requested by one of the parties.

If, at the end of the tests, the Customer requests the return of the sample, the Lab and the Customer will agree on a case-by-case basis on the packaging conditions and methods of collection or shipment of the samples.

The remnants samples analysed in the Lab for institutional purposes are kept only for the period necessary to run the analyses and until the issue of the Test Report, unless otherwise and expressly requested and unless otherwise provided by law.

However, the management of the remnants of the samples analysed for consideration is agreed between the Lab and the private Customer in the contractual process (Offer/Agreement).

Once the Test Report has been issued, or after any agreed storage term has elapsed, the Lab will destroy the remnant sample or deliver it to third parties for disposal or, where applicable, return it to the Customer.

6. Test reports

Test Reports containing the analytical results are issued in compliance with the UNI CEI EN ISO/IEC 17025: 2018 standard, and can have the ACCREDIA mark if at least one test performed by the Lab is accredited; the use of the trademark respects what is indicated in the prescriptive documents of ACCREDIA. Test Reports are identified by the ASI number, that is the unique identification number of the sample allocated during registration on the SISLAB system; Test Reports also contain the

references indicated by the Customer to ensure correct matching between the Test Report and the analysed sample.

Test Reports are always issued in Italian, automatically generated by the Lab's SISLAB computer system where wet ink signature is replaced by electronic signature. When explicitly requested by the Customer, it is possible to get translated versions of Test Reports (e.g. Italian and English), which will be provided hand signed by the head of department.

Upon the written request of the Customer, the issue of duplicates takes place in the original format.

With institutional customers, in the case of compliant samples only the Certificate of Analysis is to be delivered, on which the Lab generally reports the Sample Response, and/or the Declaration of Conformity and/or the views and Interpretations. However, in the case of non-compliant or different samples with respect to that declared, the Test Report is delivered containing the details of the results of the analyses performed, the Declaration of Conformity as well as any other fields deemed necessary.

For private customers, unless otherwise agreed, the delivery of the Test Report is envisaged, which also contains the Declaration of Conformity, if requested in the contractual phase.

There are cases, for example for some types of institutional clients or at the request of the judicial authority, when test results performed by the Lab are released in a report on the activity undertaken.

The Lab is only responsible for the analytical results referring to test results run on the analysed samples. Test Report results and the Certificate of Analysis are only representative of the tested sample, in the condition in which it was received by the Lab.

All information contained in the Test Report and in the Certificate of Analysis exclusively refer to the sample subjected to analysis and to the parameters analysed, and do not constitute inspection and/or product certification.

It is possible that part of the sample will be sent to a second Lab of the Agency to undergo one or more specific tests that cannot be run at the first Lab where the sample arrived, due for example, to the temporary unavailability of resources or materials: this activity is called "unpacking" and is fully charged to and under the responsibility of the first Lab. The Test Report will show all the required analytical results, including any obtained following unpacking.

Unless otherwise agreed, the Test Reports and Analysis Certificates will be delivered to the Customer where required through the SISLAB system, or by ordinary mail, by hand or sent by PEC (Certified electronic mail).

Upon the Customer's request, Test Reports can be sent in advance by e-mail or ordinary mail.

If it is sent by e-mail, certified e-mail or ordinary mail, the Lab takes no responsibility for the loss, alteration or uncontrolled dissemination of data due to unforeseeable external events that go beyond the Lab's control.

For each type of exam performed, Test Reports are always available at the Lab on the SISLAB IT platform and available pursuant to Law no. 241/90 et seq. mm.

The delivery time for the Test Report may vary according to the sample matrix, the number and type of tests performed, hence they are released during the contract process (offer, framework agreement, agreement, etc.), except for unforeseeable and exceptional situations that should take place after the acceptance of the sample, which the Lab will promptly communicate to the Customer in writing.

The Lab takes no responsibility for any damage caused to the Customer or to third parties by the use of test results.

Test Reports cannot be reproduced, even partially, without explicit authorization from the Lab.

The Lab provides for the archiving of test reports and related documentation for 10 years from the dispatch of the Test Report, in accordance with the procedures provided for by current legislation and where there are no more onerous mandatory obligations; at the end of this period, conservation is not guaranteed.

Information released by the Customer in the Test Report, including those relating to sampling, will be indicated as such, i.e. the responsibility of the Customer. When the Customer requests that the sample be tested, while recognizing any deviation from the specified conditions (e.g. unsuitable quantities or environmental conditions), in the Test Report there will be a note in which the Lab declines its responsibility and indicates which results may be affected by the deviation accepted by the Client.

Usually the multi-site lab does not subcontract tests for private clients, while situations may arise in which it is possible to subcontract tests, generally not accredited, for institutional clients. In this case, the Lab may entrust non-accredited tests to external labs such as other public administrations, universities or other bodies. The analytical results are then communicated to the Customer by sending a

Certificate of Analysis or Test Report specifying in the "Notes" field which tests have been performed in subcontracting.

7. Identification of test methods

Upon the Customer's request, the Lab will provide clarification on the methods or procedures that will be used. Specific requests in relation to test methods must be agreed before accepting the sample and in writing.

In order to guarantee the quality of the service, the Lab's quality system provides for a timely updating of the methods adopted.

In the event of delays or shifts in the execution of the tests or other information relevant to the Customer, the Lab will inform the latter in writing of the problems that have emerged and, if necessary, will also adopt advance telephone notification.

Recordings made by the Lab are valid for any changes and additions not resulting from requests and/or written agreements.

8. Declaration of conformity in Test Reports

Only when explicitly requested by the Customer in the contractual process, be it institutional or private, does the Lab report the Declaration of Conformity, referring only to the sample/parameter analysed, within the Test Report and possibly also in the Certificate of Analysis.

The Lab states the conformity of the samples subjected to analysis based on the legislative and/or technical provisions in force such as, for example, rules, regulations, decrees, notes, circulars, sector specifications, and any contractual agreements present. Where documented beyond the permitted limits, the decision-making rules to be applied and to which the Lab strictly adheres the test results and references (Regulations, Decrees, standards, etc.) are always clearly indicated on the Test Report containing the declaration of conformity in which the limits to which the conformity (or non-conformity) refers are reported, and the references in which the decision rule applied is defined.

In the above cases where the decision-making rule applied is based on legislative provisions, technical specifications or dictated by the Customer, the Lab does not indicate in the Test Report any consideration on the level of risk nor necessarily explicit the value of the limits allowed.

Where there is no legal source on which to base the declaration of conformity of the analysed sample, nor has the Client provided its own criteria, the Agency's Lab applies a decision rule based on a type of error (equal to 5%) aiming at minimizing the risk of erroneously judging non-compliant samples (*in dubio pro-reo*). The decision rule applied is based on "correct rejection", i.e. it establishes the decision limit beyond which the sample is declared non-compliant, accepting the 5% risk of a false non-compliant.

The limit decision value takes into account the measurement uncertainty and generally corresponds to the guard band (g = 0.84U) as described in the specific Lab procedures, as well as in international reference documents and guidelines.

Besides the guard band, the tolerance that may be envisaged by specific technical or legislative provisions can also be considered in the decision rule.

If the private customer is also interested in the samples/parameters declaration of conformity for the required tests, the decision-making rules applied will be shared in detail in the contractual process (Offer, Agreement).

The institutional client has been informed on the decision-making rules applied by the headquarters of the multi-site Lab.

Furthermore, the decision rule applied in the declaration of conformity of the sample is shown also in the Test Report (or in the Certificate of Analysis if deemed appropriate), unless it has already been indicated in the references cited within the Test Report itself.

9. Opinions and Interpretations in the Test Reports

In some cases, the Lab may issue in the Test Report and/or in the Certificate of Analysis, views and Interpretations based on the analytical results obtained, on the additional information relating to the sample analysed that the Customer may provide, as well as on their own experience and competence.

As in the analytical results and the Declaration of Conformity, the Views and Interpretations issued by the Lab must never be confused with the product certification, but refer exclusively to the tested sample.

The Views and Interpretations are not subject to ACCREDIA accreditation.

10. Data security and confidentiality

The data provided by the Customer is processed by the Lab pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27/4/2016 (GDPR), for the purposes related to the provision of the service and for any subsequent obligations. The Lab processes such data with manual/digital means with a guarantee of security and confidentiality and with the commitment of non-disclosure to undetermined subjects. In relation to the processing of data, the Customer may exercise the rights provided by the aforementioned Regulation.

The Agency will ensure that the confidentiality of the evidence and official secrecy are guaranteed by taking all necessary precautions.

The data provided by the Customer will be kept for 10 years.

11. Access to the Lab

The Lab, in the cases considered by the provisions of the law (see art.223 disp att. Of the CPP, analysis of samples and guarantees for the interested party) or by the judicial authority for which the presence of the Customer or his representative is expected, grants access to the areas used for testing, under the following conditions:

•that the Customer signs a declaration of commitment to comply with the Lab's internal safety procedures and a commitment to confidentiality on any information acquired during his presence in the Lab;

•that the authorization request is addressed to the Lab Manager who will issue written authorization.

12. Complaints

The Customer, when he deems it appropriate, may make complaints about the work of the Lab which will be taken into consideration only if lodged with the Lab in writing.

Following investigation of the complaint received, the Head of the Lab, in collaboration with the staff, will decide in which of the following 2 categories in which to include it:

- •Complaints which are judged unfounded following investigation;
- •Complaints which establish a non-compliant product or service.

For complaints that prove to be unfounded, the Lab will send the Customer a letter of clarification within one month, signed by the Lab Manager in which he explains the groundlessness of the complaint.

For Complaints which establish the existence of a non-compliant product or service, the Lab will supply action aimed at resolving the complaint; this may include initiating a Non-Conformity and Corrective Action. Following the actions carried out or in any event within one month, the Lab will send the Customer a letter regarding the conclusion or the complaint processing progress, signed by the Lab Manager. Any documentation produced is archived at the Lab.

13. Amendments and updating of the General Conditions

In the event of variations and updates to the General Conditions described so far, it will be the Lab's responsibility to communicate to the private Customer with whom it has an ongoing contract, the updated version of the General Conditions and proceed with a review of the contract.

The updated version is available to institutional clients on SISLAB.

The revision index and the date of issue of the General Conditions are shown in the header at the bottom left of each page of this document.

The "General Conditions for the supply of the analysis service applied by the Lab to its customers" is available on the Customs and Monopolies Agency official website.