

### General principles

The contracts between White Lab S.r.l. - Biochem and the Customers may have as their object a "Sample", i.e. a material to be examined or a provision of services whose content must be identified, in writing, between the parties. The content of any agreements varying the general conditions will be agreed from time to time between the parties who will also have to specify their scope of application.

A Contract is considered finalized when an Order is accepted by White Lab S.r.l. - Biochem in one of the following ways:

- (a) White Lab S.r.l. - Biochem resumes processing of the Order, or
- (b) White Lab S.r.l. - Biochem confirms the Order in writing.

White Lab S.r.l. - Biochem reserves the right to modify these Terms and Conditions over time. The Terms and Conditions in force at the time of transmission of the Order are applicable to each Contract. These Terms and Conditions replace any previous agreement, verbal or written, that may have existed between the Parties.

Any general purchase conditions of the Customer are not accepted and in any case are waived in favor of these Terms and Conditions. Any possible deviation from the contract must be communicated to the other party and approved by both parties.

The choice of tests to be carried out on a specific sample or family of samples is under the exclusive responsibility of the Client. The reference method to be considered is only the one reported in the offer.

Assistance in choosing tests is normally a paid service. The Client can also assign to White Lab S.r.l. - Biochem the drafting of the justification rationale for the choice of tests to be carried out.

Each order must be sent complete with all data relating to the Client and the service to be performed; it must be identifiable not only with respect to the Client but also with respect to the person who forwards it through the affixing of his signature.

The order fulfillment times reported in the offers are to be understood as indicative and valid at the time of issuing the offer; In order to be satisfied, any Customer needs must be communicated in writing and receive formal feedback from the laboratory.

White Lab S.r.l. - Biochem is responsible to the Customer for the subcontracted work, except in the case in which the Customer or the legislative authority specifies which subcontracted entity must be used.

White Lab S.r.l. - Biochem with this document, also in accordance with the principles of UNI CEI EN ISO/IEC 17025:2018, ensures the confidentiality of the information received from the Customer and generated by the assignment received. This confidentiality will not be practiced towards Notified Bodies, Accreditation or GLP Inspection Bodies, in which case the laboratory will take care to inform the Customer (unless this is prohibited by law).

White Lab S.r.l. - Biochem assures the Customer of its commitment to impartiality in carrying out laboratory activities, as required by the UNI CEI EN ISO/IEC 17025:2018 standard and internal procedures.

How to lodge a complaint: the complaint must be sent to [commerciale@biochem-bcm.com](mailto:commerciale@biochem-bcm.com) as well as [qualita@biochem-bcm.com](mailto:qualita@biochem-bcm.com): in the email it must be indicated as SUBJECT Complaint referring to Order No. or order date. Reference must be made to the service requested, to any relationship generated by the order and any other information relating to the deviation from the offer, order, supply conditions, service provided must be provided. The complaint email letter must contain the complete details of the company and the person submitting it, as well as the function of the person making the complaint and contact details.

### Prices and payment terms

Prices are net of VAT and all applicable taxes, duties and customs charges.

Any dispute regarding the services and/or the invoice must be communicated via certified email or registered letter no later than thirty days from its issue;

White Lab S.r.l. - Biochem has the right to cease processing the Order at any time, or to cease any activity in favor of the Customer where: the latter is more than thirty days late on the agreed deadline with respect to the payment of any commissioned service; taxes have been introduced which in any way significantly affect the costs of the tests. The reversal of advances paid by the customer may take place for justified reasons to the extent of the state of processing and only following a written request to be received within 30 days of the occurrence of the causes justifying it.

### **Sample Management**

If sampling is performed by the laboratory rather than the Client, it must be confirmed in the quotation and/or on the M001 form. If sampling is performed by the Client, this activity—including the representativeness of the sample—is the Client's direct and full responsibility.

Sample transportation and packaging costs are the Client's sole responsibility.

Unless otherwise formally agreed, the material to be analyzed is delivered to the Laboratory by the Client. Packaging, transportation, and delivery of the sample are the Client's responsibility. The sample must be transported in such a way that it is not subject to alterations, such as to the packaging, temperature, or other parameters, which could affect the analytical result. If the sample requires temperature-controlled storage, it is the Client's responsibility to report this in the M001 form, specifying the temperature range. Furthermore, it is the Customer's responsibility to monitor the temperature during transport. Upon the sample's arrival at the laboratory, the temperature will be measured and the evidence and results of the test will be reported in the Notes field of the M001. In the event of deviations from the required specifications, the Customer will be notified, who will decide whether or not to proceed with the tests (in which case, written documentation of the Customer's decision will be attached).

The Customer guarantees that no Sample is capable of constituting a danger for White Lab S.r.l. - Biochem. The Customer is responsible for the compliance of the Samples with the legislation in force in Italy regarding hazardous waste, as well as for informing White Lab S.r.l. - Biochem regarding any health and safety risks associated with the Samples. The Customer undertakes to fully compensate and hold White Lab S.r.l. - Biochem harmless from all possible damages and liabilities towards third parties which White Lab S.r.l. - Biochem or its staff may incur due to the Samples. The expenses and costs related to the disposal of hazardous waste from the Sample are borne by the Customer.

The sampling activity and/or collection of the material to be examined at the Customer's home (or at another place indicated by the same) carried out by White Lab S.r.l. - Biochem personnel, or appointed by it, constitutes an additional service, and is subject to a separate charge, unless otherwise agreed. The sample must always be delivered accompanied by the M001 form signed and duly completed in its entirety including the offer number to which the requested analysis refers and any administrative order from the client.

The identification of the sample and the analyzes or services requested reported in form M001 is the responsibility of the Client and under his responsibility; it must be exhaustive, complete and clear. Any incomplete or incorrect identification by the Client does not constitute liability for White Lab; the services requested by the Customer and the timing to be considered will begin when all the documents requested by White Lab S.r.l. - Biochem have been received correctly completed.

Any requests by the Customer to modify the description of the sample and/or the ownership of the test before issuing the Test Report must be received by White Lab S.r.l. - Biochem exclusively in written form. Once the test report has been issued, it cannot be modified except in certain specific cases (See the paragraph "Test Reports").

White Lab S.r.l. - Biochem stores all samples exceeding those subjected to biocompatibility testing for 1 year at the temperature indicated on form M001 or at room temperature unless otherwise specified (uncontrolled temperature), and for 3 months for samples involved in all other tests. At the end of this retention period, they will be disposed of and/or returned in the agreed manner. In particular, the sample will be returned if the customer has explicitly requested it through the appropriate section on form M001, indicating the methods. The sample is normally returned at the end of the retention period, but the return can be brought forward (after the end of the test and the issuance of the Test Report) if the customer explicitly requests it in writing. Samples not subjected to biocompatibility testing will be disposed of or returned to the Customer if requested and/or if possible.

The return of the samples subjected to testing is mandatory in the case of substances and/or materials that would require particular/special disposal. In this case, the return will be made according to the agreed methods and with costs borne by the Customer. The return of samples for any reason is normally costly for the Client.

#### **Use of the ACCREDIA brand**

White Lab S.r.l. - Biochem is an ACCREDIA accredited laboratory under the number 00254 Testing. This accreditation certifies the laboratory's technical competence, impartiality, and consistent performance of accredited tests, in compliance with the UNI CEI EN ISO/IEC 17025:2018 standard. The management system requirements in ISO/IEC 17025 are written in language relevant to laboratories operations and are generally operate in accordance with the principles of ISO 9001. The laboratory is a signatory of the ACCREDIA convention, is subject to annual surveillance and renewal of accreditation every four years.

The ACCREDIA trademark present on the Test Report refers only to the test carried out under accreditation and cannot be used for advertising or promotional purposes by the Customer.

Laboratory Accreditation does not imply in any way the approval of a product by the Laboratory itself or the Accrediting Body. ACCREDIA is not responsible for the results of tests placed under accreditation.

The list of the Laboratory's accredited tests can be consulted on the website <http://www.accredia.it> in the databases section and the link is present in the offers.

#### **Test reports**

Any Client requests related to the test report (such as opinions, interpretations, graphs, reports, comments, comparisons with legal and/or specification limits) generally constitute a separate service and may be subject to a charge.

If the Client requests a declaration of compliance with the limits of a specification or legal requirement be included in the Test Report (RdP), the Laboratory generally issues this declaration without taking uncertainty into account, with a risk level of 50%.

As shown by the EA resolution 2014 (33) 31 approved by the EA General Assembly of 27-28/05/2014, the Test Report cannot be modified after its issue: any issue that involves changing the name of the product and/or of the client is not normally permitted. Any request by the Customer for any changes to the Test Report after its issue must be received by White Lab S.r.l. - Biochem exclusively in written form and White Lab S.r.l. - Biochem will evaluate the possibility of re-issuing the Test Report itself with cancellation of the previous one. These changes will normally be costly if subsequent to the first issue.

If the Customer decides not to request the drafting of the Test Protocol, White Lab S.r.l. - Biochem will adopt standard sample processing conditions in accordance with the regulations in force, and in this case the Customer exempts White Lab S.r.l. - Biochem from any other obligation in this regard.

White Lab S.r.l. - Biochem keeps the records of the original observations relating to the tests for a period of 10 years; the shelf life for implantables and Test Reports is 15 years.

For any dispute regarding the interpretation and application of these supply conditions, the Court of Milan will be competent.

The Location Manager

STAMP AND SIGNATURE FOR ACCEPTANCE