

## General principles

The contracts between WhiteLab srl 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 WhiteLab srl in one of the following ways:

- (a) WhiteLab resumes processing of the Order, or
- (b) WhiteLab srl confirms the Order in writing.

WhiteLab srl 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 WhiteLab srl 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.

WhiteLab srl 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.

WhiteLab srl 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).

WhiteLab srl 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;

WhiteLab srl 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**

The sampling activity, if carried out by the laboratory rather than by the Client, must be reflected in the offer and/or on the M001 form; in the event that this activity is carried out by the Customer - including the representativeness of the sample - it is under his direct and full responsibility.

The costs of transport and packaging of the Samples are fully borne by the Customer.

Unless otherwise formally agreed, the material to be subjected to analysis is delivered to the Laboratory by the Customer. Packaging, transport and delivery of the sample are the responsibility of the Customer. The sample must be transported in such a way that it does not undergo alterations, for example to the packaging, temperature or other parameters, which could influence the analytical result.

The Customer guarantees that no Sample is capable of constituting a danger for White Lab. 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 WhiteLab srl regarding any health and safety risks associated with the Samples. The Customer undertakes to fully compensate and hold WhiteLab srl harmless from all possible damages and liabilities towards third parties which WhiteLab srl 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 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 WhiteLab srl 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 WhiteLab srl 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").

WhiteLab srl stores all samples exceeding those subjected to biocompatibility testing for 1 year at an uncontrolled temperature; at the end of this retention period they will be disposed of and/or returned. Samples not subjected to biocompatibility tests 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**

WhiteLab srl is an ACCREDIA accredited laboratory n°0283L. The accreditation certifies the technical competence of the Laboratory in relation to the accredited tests, in compliance with the UNI CEI EN ISO/IEC 17025:2018 standard. The system requirements reported in the ISO/IEC 17025 standard are written in a language relevant to laboratory activities and are generally in accordance with the principles of the ISO 9001 standard. 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 request from the Customer connected to the test report (such as, for example: opinions, interpretations, graphs, reports, comments, comparisons with legal and/or specification limits), normally constitutes a separate service and may be subject to a charge.

If the Customer requests that a declaration of conformity to the limits of a specification or law be expressed on the RdP, as a rule, the Laboratory expresses this declaration without taking into account the uncertainty, unless otherwise agreed.

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 WhiteLab srl exclusively in written form and WhiteLab srl will evaluate the possibility of drawing up a Supplement to the Test Report or re-issuing the Test Report itself with cancellation of the previous one (possible only if the Customer declares the presence of an error on a piece of data provided). 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, WhiteLab srl will adopt standard sample processing conditions in accordance with the regulations in force, and in this case the Customer exempts WhiteLab srl from any other obligation in this regard.

WhiteLab srl 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