

General principles

Contracts between Biochem S.r.l. and its Customers may have as their object a "Sample", that is, a material to be examined or provision of services, whose content must be specified in writing between the parties.

This content and any agreements varying from the general terms and conditions will be agreed upon, from time to time, between the parties, which must also define their scope of application.

A Contract is considered concluded when an Order is accepted by Biochem in one of the following manners:

- (a) Biochem begins filling the Order, or
- (b) Biochem confirms the Order in writing.

Biochem reserves the right to change these Terms and Conditions over time. The Terms and Conditions in effect at the time the Order is placed are those that are applicable to each Contract. These Terms and Conditions replace all previous agreements, whether verbal or written, that may exist between the Parties.

Any General Purchasing Terms and Conditions of the Customer are not accepted and, in any case, are replaced by these Terms and Conditions. Any variation from the contract must be notified to the other party and approved by both parties.

The choice of the test to be conducted on a specific sample or series of samples is the exclusive responsibility of the customer. The reference method to be considered is solely the one specified in the quotation.

Assistance in selecting the tests is generally a service requiring an additional fee. The customer can confer to Biochem also the drafting of the justifying rationale for the selection of the tests to be conducted.

Every order must be placed with complete information regarding the customer and the service to be provided; it must be identifiable not only in relation to the customer, but also in relation to the person placing it by means of his/her signature on it.

The times for the execution of the work orders, listed in the quotation, are understood to be indicative and valid as of the time the quotation was issued; the meeting of any customer requirements is contingent upon their notification in writing and the receipt of formal acknowledgement from the laboratory.

Biochem is responsible to the customer for subcontracted work, except in the case the customer or the authorities in the legislative framework specify which subcontractor must be used.

Biochem with this document, also in according to the principles of UNI CEI EN ISO/IEC 17025:2018, ensures the confidentiality of the information received from the Customer and generated by the order received. Such confidentiality shall not be applied to Notified Bodies, Accreditation Body or GLP Inspection Body.

Biochem provides the Customer with an assurance of its commitment to impartiality in the performance of Laboratory activities, as required by the UNI CEI EN ISO/IEC 17025:2018 standard and internal procedures.

How to make a complaint: the complaint must be sent in addition to commerciale@biochem-bcm.com to qualita@biochem-bcm.com and biochemsas@cgn.legalmail.it: in the email must be indicated as SUBJECT Complaint referred to Order No. or order date. Reference must be made to the service requested, any report generated by the order and any other information relating to the deviation from the offer, order, conditions of supply, service provided. The letter of complaint must contain the full details of the company and the person who submits it, as well as the function of who makes the complaint and contact details.

Prices and payment terms

All prices exclude VAT and all other taxes, duties, or customs duties that may be applicable.

Any dispute regarding the invoice must be notified with acknowledgement of receipt no later than 30 days from when it is issued; in the case of severe documented and acknowledged errors, Biochem shall be liable for the damage caused up to 3 times the value of the test performed.

Biochem has the right to stop filling the Order at any time or to stop any activity for the Customer, if they are more than fifteen days late, with respect to the due date, in making payment for any service commissioned; taxes have been introduced which, for whatever reason, have a significant impact on the cost of testing.

The reversal of advances paid by the client may be made 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.

Managing the samples

Whether the sampling activity is the responsibility of the laboratory or the customer must be specified on the quotation and/or on form M001; if it is performed by the Customer, this activity is their direct responsibility.

The costs for transporting and packing the Samples are the complete responsibility of the Customer.

Unless otherwise and formally agreed, the material to be submitted for analysis is to be delivered to the Laboratory under the Customer's responsibility. Packing, transport, and delivery of the sample are the Customer's responsibility. The sample must be transported in such a manner as not to undergo variations in temperature or other parameters that could affect the analytic results.

The Customer guarantees that no Sample could constitute a danger for Biochem. The Customer is responsible for the compliance of Samples with current legislation in Italy regarding dangerous waste, and for informing Biochem in relation to any risks to health or safety in connection with the Samples. The Customer pledges to compensate and hold Biochem harmless from any damages and third-party liability that could be incurred by Biochem or their personnel due to the Samples. Any expenses and costs in connection with the disposal of dangerous waste resulting from the Sample are the Customer's responsibility.

The sampling activity and/or the collection of the material to be examined at the Customer's address (or another address indicated by them) performed by Biochem personnel, or by personnel designated by them, is considered an additional service and is subject a separate charge, unless otherwise agreed. The sample must always be delivered together with form M001, signed and duly and completely filled out, including the number of the quotation to which the requested analysis refers and any administrative order issued by the customer.

The identification of the sample and the requested analyses or services listed on form M001 is the customer's responsibility; it must be thorough, complete, and clear. Any incomplete or incorrect identification by the customer does not constitute responsibility for Biochem; the services requested by the customer will begin when all the documents required by 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 the issuance of the Test Report, must be received by Biochem exclusively in writing. Once the test report has been issued, it cannot be modified, except in a limited number of cases (refer to the "Test report" section).

Biochem stores all samples in excess of those tested, where applicable, at room temperature for a period of 3 months from the date of completion of the analysis, with the exception of samples tested for biocompatibility, which are stored for 1 year at room temperature.

At the end of the specified retention period the samples will be returned to the customer at their expense. If it is not possible to return the samples, they will be destroyed and disposed of. The return of the samples submitted for testing is mandatory in the case of substances and/or materials that would require particular and/or special disposal. In that case they will be returned according to the procedures agreed on, at the customer's expense. The return of samples for any reason whatsoever shall normally be onerous for the client.

Use of the ACCREDIA brand

Biochem is ACCREDIA accredited laboratory no. 0283. Its accreditation certifies the Laboratory's technical expertise with regard to the accredited tests, in conformity with standard UNI CEI EN ISO/IEC 17025:2018. The operational requirements of standard UNI CEI EN ISO/IEC 17025:2018 are aligned with those of standard ISO 9001:2015. The laboratory is a signatory of the ACCREDIA convention and is subject to annual surveillance audits and, every four years, renewal of accreditation.

The ACCREDIA brand found on the Test Report refers only to the test conducted under accreditation and cannot be used by the Customer for advertising or promotional purposes.

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

The list of the Laboratory's accredited tests is available on the website <http://www.accredia.it> in the databases section, and the link can be found in the last page of each quotation.

Test reports

Any request by the Customer in connection with the test report (such as, for example: opinions, interpretations, graphics, reports, comments, comparisons with legal limits and/or specification limits), is usually considered a separate service and can result in a charge.

If the Client requests that a declaration of compliance with the limits of a specification or law be expressed on the RdP, as a rule, the Laboratory will express this declaration without taking into account the uncertainty, unless otherwise agreed.

As a result of Resolution EA 2014 (33) 31 approved by the EA General Meeting of May 27-28, 2014, the Test Report cannot be modified after it is issued: any issuance that results in a change in the name of the product and/or the customer is not normally allowed. All requests by the Customer for any changes to the Test Report after it is issued must be received by Biochem exclusively in writing, and Biochem will evaluate the possibility of drafting a Test Report Supplement or reissuing the Test Report itself together with the cancellation of the prior Test Report (this is possible only if the Customer reports the presence of an error in the data provided). Such modifications will normally incur a charge if they are made after the first issue.

The adoption of a Test Protocol is advisable in general, but especially in the case of samples with complex geometries for which need to be defined the conditions of removal, etc. If the customer decides not to request the preparation of a Test Protocol, Biochem will adopt the standard conditions for handling the sample in compliance with the provisions of the standards; in this case the customer releases Biochem from any other related obligation.

Biochem retains the records of their original observations regarding the tests and a copy of the Test Reports for a period of 10 years; the retention period for implantables is 15 years.

For any dispute concerning the interpretation and application of these supply conditions, the Court of Bologna shall have jurisdiction.

The Chief Executive Officer
Eng. Bassini Giovanni

DATE

STAMP AND SIGNATURE FOR ACCEPTANCE