

General Terms and Conditions

1 Basis

- 1.1 These general terms and conditions apply to all quotations and agreements for the provision of services by the Department of Clinical Chemistry and Laboratory Medicine of the LUMC in Leiden (hereinafter referred to as: KCL) to the legal entity that purchases the relevant service from the KCL department (hereinafter referred to as: applicant), with the exclusion of the applicant's own general terms and conditions, unless explicitly accepted in writing by the KCL department.
- 1.2 Dutch law exclusively applies to all quotations and agreements with the Supplier.
- 1.3 In the event of versions of these General Terms and Conditions in a language other than Dutch, the Dutch text shall prevail.

2 Scope

- 2.1 The KCL department differentiates between three types of requests for analysis: CE-IVD (CE-standardized in vitro diagnostics) assays; fully validated assays; and RUO (research use only) assays. The first two types fall fully within the scope of the KCL department and will be processed accordingly. For the third type (research use only), the KCL department can often also assist; possibilities will be discussed in an intake meeting.
- 2.2 Specific supporting activities performed at the KCL department include:
 - a) Registration for adequate quality control, including track-and-trace of research samples;
 - b) Advice regarding appropriate material to be collected;
 - c) Advice on assays, measurement principles, and required analytical quality for the research question;
 - d) Pre-analytical support, including blood sampling or other specimen collection (e.g., saliva, urine);
 - e) Performing analyses and reporting results, including clinical chemistry consultation regarding interpretation;
 - f) Processing, storage, and registration of material, including for biobanking purposes;
- 2.3 The KCL department provides protocolized storage of biomaterials for biobanks and other purposes. The Laboratory Research Support (LRS) unit of the KCL department plays a central role in local processing and storage for the local CuraRata.

3 Delivery conditions

- 3.1 Requests for research support will only be processed if there is approval from the METC/CME/DEC (registered in Panama if applicable), a signed quotation, and a signed service level agreement.
- 3.2 The KCL department reserves the right to refuse material if it does not meet the agreed requirements regarding tube type, pre-analytical conditions, or required material volume.
- 3.3 The KCL department uses a limited and standardized set of collection tubes and containers. This is essential for enabling robotized track-and-trace of all sample materials.
- 3.4 In the case of long-term studies, the KCL department cannot guarantee that methods or analyzers will remain unchanged.
- 3.5 The KCL department is not responsible for the transport, packaging, and storage of biological material before it is delivered and received by the KCL department.
- 3.6 Agreements in the service level agreement take precedence over any laboratory manuals.

- 3.7 Stated (delivery) times by the KCL department are approximate and are not strict deadlines unless explicitly agreed otherwise in writing. Exceeding the estimated delivery time does not entitle the applicant to dissolve or cancel the agreement. In cases of excessive delay, the KCL department will consult with the applicant.
- 3.8 The owner of biobank material is authorized to decide on the release of the material; the manager holds full control over the release process. The manager is not responsible for unlawful use of biomaterial.
- 3.9 For biobanking activities, the KCL department cannot be held responsible for results of future analyses, as current processing and storage conditions may not meet future standards or quality requirements.
- 3.10 In long-term stored biomaterials, factors such as storage duration, temperature, tube type, and freeze-thaw cycles may negatively affect sample quality. If these factors are incompatible with analyte stability, the KCL department may refuse the analysis request.
- 3.11 Material must generally be delivered on working days between 08:30 and 16:00, unless otherwise agreed.
- 3.12 Unlabelled or unclearly labelled material, in any form, will not be processed by the KCL department.

4 Responsibilities

- 4.1 The applicant is responsible for the lawful acquisition of biological material and for obtaining the necessary patient consent for the services performed by the KCL department.
- 4.2 The KCL department provides standard organizational-logistical advice (LRS coordinator or delegate) and substantive advice regarding the feasibility of the request (consulting staff member).
- 4.3 The KCL department guarantees that the quality of CE-IVD test results is closely monitored through EQA and IQC in accordance with ISO 15189:2022.
- 4.4 Coordination of LRS activities is performed by the LRS Unit Coordinator within the KCL department. Responsibility for personnel and logistical alignment with other lab units lies with the LRS head analyst.
- 4.5 The head of the KCL department is responsible for assessing the feasibility of agreements, including financial arrangements and deployment of KCL staff, as well as the management of materials collected through freezing protocols. The department head also bears final responsibility for all other service-related activities.
- 4.6 The KCL department is accredited according to ISO 15189:2022 (registration number M042), periodically reaffirmed by the Dutch Accreditation Council. If the applicant (or sponsor) requests an audit, site visit, or staff training at the KCL department, this must be requested at least five weeks in advance from the LRS coordinator.

5 Advice

- 5.1 Scientific-technical advice is provided by a laboratory specialist from the KCL department. The goal is to jointly choose conditions that meet current and future standards. The involvement of consulting staff must be described in the service agreement.
- 5.2 Scientific-technical advice is included in the price and aims to achieve high-quality clinical chemistry advice to ensure medical test quality suitable for the research question.
- 5.3 Additional work (e.g., literature review, scientific contributions) may be arranged at an additional fee or via scientific collaboration.

6 Financial Settlement

- a) The KCL department charges the applicant for personnel and material costs related to trial preparation, processing, analysis, materials, and reporting. The applicant receives a quotation; once signed by both parties, it is binding.
- b) Actual invoicing may differ depending on the number of services ultimately provided.
- c) A service agreement includes a quotation and vice versa; these documents always share the same internal code assigned by the KCL department.
- d) For multi-year studies, automatic annual indexation applies. Indexation follows NZa (for analyses), the UMC Collective Labor Agreement (for labor hours), and national inflation/CPI (for other services/materials) and applies only to services actually performed in that year.
- e) If the applicant cancels the request (resulting in no analyses or patient inclusion), preparation costs and the start-up fee will still be charged.
- f) Payment must be made within 30 calendar days of the invoice date, as indicated by the KCL department. Objections to invoices or services do not suspend the applicant's payment obligation.
- g) The KCL department is not liable for damages resulting from incorrect or incomplete information provided by the applicant, unless the applicant proves that the KCL department should reasonably have recognized the inaccuracies.

7 Privacy and Ethics

- a) The KCL department adheres to the Dutch guideline Code of Proper Secondary Use of Human Tissue. This guideline describes how leftover biological material may be used after requested testing is completed. Residual material is occasionally used for evaluating new assays and research. This material is fully anonymized. If patients object to such use, they must inform their treating physician; the objection must be recorded in HiX.
- b) Material previously referred to as "spijtserum" (leftover serum) is not used for research purposes and may only be used in the context of a predefined primary question (after consultation).
- c) No medical treatment agreement, as defined in Article 7:446 of the Dutch Civil Code, is established between the KCL department and the patient.
- d) Both the applicant and the KCL department shall keep all confidential information exchanged before or after the agreement secret, unless there is a legal duty to disclose it. The applicant shall impose similar confidentiality obligations on third parties who receive such information.