

Study inquiry questionnaire

Note:

For multiple choice, please tick the appropriate box, multiple choice is possible.
Some questions relate to specific types of studies and may not always apply to you. You can skip these points.

Click or tap here to enter date.

1. What kind of study is it and/or what kind of experiments are required?
 - Performance Evaluation Studies
 - Feasibility studies
 - Pre/clinical studies
 - Clinical approval study (not conducted in our laboratory, as not all GCP standards are met)
 - Prototype studies
 - Reproducibility studies
 - Studies related to CE/IVD approval
 - Comparative studies (assays and devices)
 - Workflow analysis
 - LoB
 - LoD
 - LoQ
 - Precision
2. Name of the study: Click or tap here to enter text.
3. Desired parameters/analyses (please check availability in the service specification: https://www.labor-limbach.de/olvz/3674_en/home).
Analysis available in the service specifications:
 - Yes
 - If no, please contact:
Sylvia Teutsch
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studien@labor-limbach.de
4. Parameters to be investigated:
Click or tap here to enter text.
5. Is the study externally funded? Yes. No.
6. Is there a study protocol available? Yes. No.
If yes, please send us a copy.
7. Sample type:
 - EDTA Heparin Citrate Lithium Heparin
 - Serum Other: Click or tap here to enter text.
8. Sample collection
 - I. Is already completed
 - a. In which kind of sample containers do we receive the samples (If possible, please send us the product number and company or a picture, thank you). Click or tap here to enter text.

b. How are the sample containers labeled?

Barcode – Barcode type: Click or tap here to enter text.

Manually

Others (Please fill in description or picture.) Click or tap here to enter text or picture below.

c. What is the maximum and minimum volume of the samples?

Click or tap here to enter text.

II. If no, prospective collection planned till: Click or tap here to enter date.

Please note that for measurements in our laboratory, barcodes provided by us and sample containers compatible with our equipment must be used. For this purpose, we will provide you with request forms with barcodes to affix to the samples. If samples need to be decanted or relabelled, this will be charged as an additional service.

d. Would you like us to collect samples for you?

No

Yes, number of samples: Click or tap here to enter text.

Measures parameter value range: Click or tap here to enter text.

Volume: Click or tap here to enter text.

9. Preanalytics -

I. Under what conditions should the samples be stored until measurement?

Click or tap here to enter text.

II. How should the samples be stored after thawing for measurement?

a. in the refrigerator: Yes. No.

b. refreeze: Yes. No.

III. May samples be refrozen and measured again after thawing?

Click or tap here to enter text.

IV. How long may the time interval between thawing and measuring be?

Click or tap here to enter text.

10. Are there multiple study sites? Yes, number No
Click or tap here to enter text.
11. Where are the study centers located (Country, cities)?
Please fill in their addresses for calculating the travel costs and planning the logistics if sample pick up in Germany should be provided.
Click or tap here to enter text.
12. Is a return of the remaining material desired or should it be destroyed by us after it has been processed? Please check the applicable box and indicate desired storage period, if applicable.
 Return
 Storage - How long should we store them in the Limbach laboratory?
Click or tap here to enter text. weeks after end of study
13. Planned period/duration of the study? Start End
Click or tap here to enter text. Click or tap here to enter text.
14. Does the study require special documentation requirements (raw data, calibration, quality control, instrument data, etc.) beyond the requirements of the ISO 15189 standard (accreditation)?
a) No
b) Yes – How much time is likely to be required each day for documentation:
Click or tap here to enter text.
c) What additional documents are required?
 raw data
 calibration data
 quality control data
 maintenance documents
 temperature logs (if samples are stored in fridge/freezer)
 others – how many pages or how many time is expected per day for documentation
Click or tap here to enter text.
15. How long should documents and/ or raw data be kept after the study has ended?
16. Which documents do you need from us before starting your studies?
 Accreditation certificate? – Please download here: <https://www.labor-limbach.de/unsere-labor/abteilungen/qualitaetsmanagement/>.
 Professional CV PI laboratory
 Professional CV of all participants
 GCP certificates of those involved in the study (normally only available to employees of the study department)
 temperature logs (if samples are stored in fridge/freezer)
 Others Click or tap here to enter text.
17. Meetings/status communication – are daily/weekly meetings or status updates planned?
 No
 Yes. If yes – how often and how long?
 Daily - Click or tap here to enter text. min
 Weekly - Click or tap here to enter text. min
18. Are there any audits to be conducted prior to the start/after the study?
 Yes No
19. Invoice recipient – postal address and email (if invoice should be sent by email):
Click or tap here to enter text.
20. For invoices- PO number or other identification required, if yes please add:
Click or tap here to enter text.
21. Your VAT-number: Click or tap here to enter text.
22. Is it a service outside of patient treatment that is exempt from VAT?
 Yes No
23. Information on the requisition form:

- patient code with a number of [Click or tap here to enter text.](#) characters
 Gender Date of birth Date of acceptance
24. Postal address for sending the request forms (will be further discussed):
Name: [Click or tap here to enter text.](#)
Attn: [Click or tap here to enter text.](#)
Street and number: [Click or tap here to enter text.](#)
City: [Click or tap here to enter text.](#)
25. Your customer number with us, if we have already worked together in the context of study so far: [Click or tap here to enter text.](#)
26. Workflow/practicability/usability analysis – how many questions, pages have to be filled daily/weekly? What kind of data will be collected and how often?
e.g. daily measurement of duration of measurements, hands on time on the instrument, user-friendliness of the user interface, questionnaire for evaluation of user-friendliness and feedback with 100 questions, 10 pages
[Click or tap here to enter text.](#)
27. Information required for device installations (System studies, device comparison studies):
- a) IT/EDV – should there be a remote access?
 No Yes
 - b) Electricity
 - c) Water – We provide water access but we don't have a filter system. Therefore a water filtration system has to be supplied together with the instrument if needed.
 - d) Footprint – what are the measurements of the instrument?
Height: [Click or tap here to enter text.](#)
Width: [Click or tap here to enter text.](#)
Depth: [Click or tap here to enter text.](#)

Information: Your results can be sent to you (fax, email) or accessed by you directly, depending on the setup. You can view your results, for example, via our web-based portal labGate, where you can log in yourself. https://www.labor-limbach.de/service/it-dienstleistungen/online-befundauskunft/?no_cache=1.

We will discuss with you how the results should be transmitted.

If needed, we design request forms with barcodes in consultation with you. Key points here are the header data you require and the type of parameter selection. Standard options for parameter selection include, for example, various profiles that contain all the necessary parameters for a visit, or individually listed parameters that can be checked off individually.

Creation usually takes two weeks, but can take up to four weeks. This should be taken into account when planning. We will be happy to provide you with information about the sample containers.

If you do not use our barcodes or the agreed sample containers compatible with our equipment, this will be included in the quote as an additional cost. Our standard barcode in the lab is Interleave 2 of 5.