| **Details of the medical laboratory** |
| --- |
| Name: |  |
| Address: |       |
| File number: |       |       |  |
| Case number | Phase |  |
| Date of assessment: |       |
| Accreditation process: | Please select |
| Assessment type[[1]](#endnote-1) : |       |
| Medical laboratory with several locations: | [ ]  Yes | [ ]  No |
| Name / Address of assessed locations: |
|       |
|       |
| **Details of the assessor** |
| Name: |       |
| Status[[2]](#endnote-2) : | [ ]  LA | [ ]  SA | [ ]  TA | [ ]  TE | [ ]  O |
| **Subject of the assessment** |
|  |

In addition to the checklist/report for medical laboratories according to DIN EN ISO 15189:2023 in this checklist the additional requirements for the laboratory for POCT that are distinct from, or in addition to, those outlined in the main text are described. These requirements specify the laboratory’s responsibilities towards organizations, departments and their personnel regarding the selection of devices, training of personnel, quality assurance, and the management review of the complete POCT process.

This checklist/report does **NOT** repeat the objective evidence (ON) and inspected documents (ED) or text passages and descriptions of non-conformities already listed in the report on DIN EN ISO 15189:2023. However, the responsible assessor MAY note supplementary documents and comments.

**Notes on usage by the laboratory (blue colored sectors):**

* On page one only the name and address of the medical laboratory shall be entered.
* Please enter the following information in the column “Reference documents“:
Where is the implementation of the requirement documented?
(State the specific reference documents, e.g. specification of the document/chapter/section)
Requirements of the standard for POCT that are not applicable shall be indicated accordingly.

No further entries shall be made by the medical laboratory.

**Notes on usage by the assessor (orange colored sectors):**

* The column “Appraisal” and “No of NC” shall be entered by the assessor (evaluation key see final marks).
* The appraisal indicates the overall appraisal after the assessment, including the prior review of documents and records.
* In the lines marked "A", the assessor has the option of entering further findings, reasons for non-conformities, special features and notes.

|  | **Requirement** | **Reference documents** | **Appraisal [[3]](#endnote-3)** | **No. of.** |
| --- | --- | --- | --- | --- |
|  |  | **for the implementation** | **1** | **2** | **3** | **NC[[4]](#endnote-4)** |
| **A.2** | **Governance** |
|  | The governing body of the organization shall be ultimately responsible for ensuring that appropriate processes are in place to monitor the accuracy and quality of POCT conducted within the organization.Service agreements between the laboratory and all locations using laboratory supported POCT shall ensure that respective responsibilities and authorities are specified and communicated within the organization.These agreements shall have clinical approval, and where applicable, financial approval.These service agreements shall be with POCT areas and may be managed via a health professional grouping (e.g. medical advisory committee). |       |[ ] [ ] [ ]        |
| A |       |
| **A.3** | **Quality assurance programme** |
|  | The laboratory shall appoint a person with appropriate training and experience to be responsible for POCT quality, which includes review of and conformity with the requirements of this document as related to POCT. |       |[ ] [ ] [ ]        |
| A |       |
| **A.4** | **Training programme** |
|  | A person with appropriate training and experience shall be appointed to manage training and competency assessment of personnel performing POCT.The trainer shall develop, implement, and maintain an appropriate theoretical and practical training programme for all POCT personnel. |       |[ ] [ ] [ ]        |
| A |       |

|  |
| --- |
| **The report was prepared as an annex to the report according to ISO 15189:2022** [[5]](#endnote-5)**:** |
| Place: |       | Date: |       | Signed *ASSESSOR NAME:* [[6]](#endnote-6) |       |

|  |
| --- |
| **Berichtsprüfung durch den Verfahrensmanager:** |
| Place: |       | Date: |       | Signed *Case Manager:* |  |

Note: The assessor does not confirm the complete correctness of the reference documents of the conformity assessment body.

1. Under assessment type, the assessment technique is to be indicated, whereby several assessment types can be used in the context of an assessment. Please select the applicable element or combination of elements from the following options to indicate the type of assessment:

On-site assessment / Remote assessment / Witness audit (on-site) / Witness audit (remote) / Witness examination / Document review / Other assessment activity (please specify if necessary) [↑](#endnote-ref-1)
2. Status in the assessment team:
LA=Lead Assessor; SA=System Assessor; TA=Technical Assessor; TE=Technical expert; O=Observer [↑](#endnote-ref-2)
3. Grading of fulfilment the requirements of a section of the standard to be entered by the assessor:
1 No non-conformity
2 Non critical non-conformity
3 Critical non-conformity [↑](#endnote-ref-3)
4. NC = Non conformity [↑](#endnote-ref-4)
5. The assessment of the fulfilment of the requirements as well as the recommendation for accreditation are documented in the assessment report for ISO 15189:2022. [↑](#endnote-ref-5)
6. This report was prepared personally by on . [↑](#endnote-ref-6)