*Please update the table of contents before closing the document.*

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# Name of the assessed CAB

Type of assessment

(ex : P1S1+E1)

According to standard ISO 15189: 2022

*« Medical laboratories —* *Requirements for quality and competence »*

(File no 20xx/x/0xx)

*Please find all necessary information with regard to the type of assessment and file n° on your mission order*

## Assessment plan

|  |  |
| --- | --- |
| **Name of the CAB:** |  |

**Assessment criteria and objectives**

|  |  |
| --- | --- |
| **Accreditation standard:** |  |
| **Type of assessment:** | initial  renewal  surveillance  extension  additional |

*The above table is to be repeated for each accreditation standard concerned, cf. mission order.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Notified body:** | yes  no | **Directive(s) / regulation(s) assessed:** |  |
| **Multisite CAB?** | yes  no |

**Assessment scope, team, sites and dates**

| Name of the assessor | Function\* | Assessed activities | Site | Date | Flexible scope of accreditation? | Modifications of the scope (extensions, flexibility) | Findings to be closed and any other follow-up actions |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | yes  no |  |  |
|  |  |  |  |  | yes  no |  |  |
|  |  |  |  |  | yes  no |  |  |
|  |  |  |  |  | yes  no |  |  |
|  |  |  |  |  | yes  no |  |  |
|  |  |  |  |  | yes  no |  |  |
|  |  |  |  |  | yes  no |  |  |
| \* TL = Team leader, TA = Technical Assessor, Expert = E, JA = Junior Assessor | | | | | | | |

|  |  |
| --- | --- |
| For initial assessments: date of documentary review by the team leader |  |

**Schedule**

*Do plan intermediate closing meetings if not all assessors are present at the final closing meeting.*

| Date and time: | | Reference section: | Names of assessors: | Persons encountered: |
| --- | --- | --- | --- | --- |
|  |  | Opening meeting  - Presentation of assessors and participants,  - Confirmation of rules of confidentiality,  - The audit objectives and criteria for accreditation,  - Review of the scope of accreditation,  - Approval of the audit plan,  - Evolution since last assessment (organisation, MQS, equipment,…) | Form *F003G - Attendance list* to be completed | |
|  |  |  | Team leader | Quality manager |
|  |  |  | Technical assessor | Technical manager and technicians |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  | If necessary, exchange of point of views of audit team members | Audit team | / |
| Lunch Break | | | | |
|  |  | If necessary, exchange of point of views of audit team members | Audit team | / |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  | Set up of possible findings,  Preparation of the closing meeting | Audit team | / |
|  |  | Closing meeting  - Presentation of findings and signature/approval of findings,  - Presentation and comments with regard to the summary audit report,  - Fix final date for reception of corrective actions (max. 15 workdays),  - Define changes to be realized to the scope of accreditation (if applicable)  - Inform CAB of next steps with regard to accreditation procedure. | Form *F003G - Attendance list* to be completed | |

|  |
| --- |
| Remark: Planning of the different phases of the management system audit and technical audit is likely to adjustments depending on constraints of the planning of the body which will be specified during the opening meeting. |

## Attendance list opening meeting/closing

|  |  |  |  |
| --- | --- | --- | --- |
| **Opening meeting:** | check the box | **Meeting date:** |  |
| **Closing meeting** | check the box |

| **CAB’s audited personnel** | **Function** | **Signature** |
| --- | --- | --- |
|  |  | Original signed |
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| **Assessors** | **Function (TL, TA, E, JA) and technical domain** | **Signature** |
| --- | --- | --- |
|  |  | Original signed |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Summaries and conclusions of assessment

|  |  |  |  |
| --- | --- | --- | --- |
| Nom of the team leader: NAME First name | | | |
| Summary of the team leader  Please fill out all boxes below mentioning your observations and related assessment evidences.  For all not examined or not applicable points, please state this clearly in the corresponding field. | | | |
| Important amendments since the previous assessment | | | |
|  | | | |
| Legal structure and description of the activities of the organization | | | |
| 5.1 Legal entity *(§ 4.1.1.2 v.2012)* | | | |
|  | | | |
| 5.3 Laboratory activities *(§ 4.1.2.2 v.2012)* | | | |
|  | | | |
| General organisation (organisation charts, position within the structure), roles and responsibilities | | | |
| 5.2 Laboratory director *(§ 4.1.1.4 v.2012)* | | | |
|  | | | |
| 5.4.1 General *(§ 4.1.2.5 v.2012)* | | | |
|  | | | |
| 5.4.2 Quality management (*§ 4.1.2.1 v.2012)* | | | |
|  | | | |
| 5.5 Objectives and policies (*§ 4.1.2.3 et § 4.1.2.4 v.2012)* | | | |
|  | | | |
| For multisite CABs:  Respect of the requirements of OLAS annex [A013](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/a013-accreditation-multisite/A013-accreditation-multisite-en.pdf) | | | |
|  | | | |
| Ethical conduct *(§ 4.1.1.3 v.2012)* | | | |
| 4.1 Impartiality | | | |
|  | | | |
| 4.2 Confidentiality | | | |
|  | | | |
| 4.3 Requirements regarding patients *(not applicable v.2012)* | | | |
|  | | | |
| Resource requirements | | | |
| 6.2 Personnel  Management of staff competence (contract, training, qualification, authorization, competence and performance, records…) *(§ 5.1 v.2012)* | | | |
|  | | | |
| A.4 Training programme for staff carrying out Point-of-Care Testing (POCT)  *(not applicable v.2012)* | | | |
|  | | | |
| 6.3 Facilities and environmental conditions *(§ 5.2 v.2012)* | | | |
|  | | | |
| 6.4 & 6.5 Equipment / Equipment calibration and metrological traceability *(§ 5.3 v.2012)*  OLAS annex [A016](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/a016-tracabilite-etalons-internationaux/A016-tracabilite-etalons-internationaux-en.pdf)  ILAC document [P10](https://ilac.org/?ddownload=123220) | | | |
|  | | | |
| Competence of service providers performing calibrations via the *3rd route (internal and/or external)*  OLAS annex [A016](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/a016-tracabilite-etalons-internationaux/A016-tracabilite-etalons-internationaux-en.pdf)  LAC document [P10](https://ilac.org/?ddownload=123220)  In-house calibration: documents EA-[4/02](https://european-accreditation.org/publications/ea-4-02-m/) and ILAC [P14](https://ilac.org/?ddownload=123348) | | | |
|  | | | |
| 6.6 Reagents and consumables *(§ 5.3 v.2012)* | | | |
|  | | | |
| Agreements | | | |
| 6.7 Service agreements *(§ 4.4 et § 4.7 v.2012)* | | | |
|  | | | |
| A.2 Governance of Point-of-Care Testing (POCT)  *(non applicable v.2012)* | | | |
|  | | | |
| 6.8 Externally provided products and services *(§ 4.5 v.2012)* | | | |
|  | | | |
| Process requirements | | | |
| Vertical traceability audit  Please indicate the of assessed file(s) | | | |
|  | | | |
| Respect of the guidelines for the use of the OLAS accreditation symbol  OLAS annex [A003](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/A003-regles-logo/A003-regles-logo-en.pdf) | | | |
|  | | | |
| Management of the (fixed and/or flexible) accreditation scope  OLAS annex [A012](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/a012-portees-fixes-et-flexibles/A012-portees-fixes-et-flexibles-en.pdf)  EA document EA-[2/15](https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-15-m.pdf) | | | |
|  | | | |
| 7.6 Control of data and information management  (built-in software, data transfer, data protection and security, software version management …)  *(§ 5.10 v.2012)* | | | |
|  | | | |
| 7.8 Continuity and emergency preparedness planning  *(not applicable v.2012)* | | | |
|  | | | |
| Requirements with regard to Management System of the CAB | | | |
| 8.1 General requirements | | | |
|  | | | |
| 8.2 & 8.3 Management system documentation and control of management system documents, monitoring of document updates *(§ 4.2 et §4.3 v.2012)* | | | |
|  | | | |
| 8.4 Control of records *(§ 4.13 v.2012)* | | | |
|  | | | |
| 8.5 Actions to address risks and opportunities for improvement *(not applicable v.2012)*  5.6 Risk management *(§ 4.14.6 v.2012)* | | | |
|  | | | |
| 8.6 Improvement (continual improvement, laboratory patients, user, and personnel feedback)  *(§ 4.14.3 et § 4.14.4 v.2012)* | | | |
|  | | | |
| 8.7 Nonconformities and corrective actions - 7.5 Nonconforming work -7.7 Complaints  *(§ 4.8, 4.9 et § 4.10 v.2012)* | | | |
|  | | | |
| 8.8 Evaluations *(§ 4.14 v.2012)* | | | |
|  | | | |
| 8.9 Management reviews *(§ 4.15 v.2012)* | | | |
|  | | | |
| Control of corrective actions of the previous assessment  Please do also check the intermediary report of the CAB (F037) | | | |
|  | | | |
| Only mention those findings which have not been closed in the table below | | | |
| Identification n° of the finding from the previous assessment | | Identification n° of this assessment’s finding | Comment: |
|  | |  |  |
| Additional comments (if relevant): | | | |
|  | | | |
| Strong areas: | | | |
|  | | | |
| Sensitive areas: | | | |
|  | | | |
| Final conclusions of team leader on improving the efficiency of the quality system: | | | |
|  | | | |
| **Clear statement** of the team leader as to the granting, maintaining, withdrawing, etc. of accreditation status: | | | |
|  | | | |
| **Validation of the accreditation scope** and the granted flexibility (if applicable) by the team in collaboration with the CAB before publication:  *Please do specify any* ***changes*** *of the accreditation scope, if applicable..* | | | |
|  | | | |
| Persons encountered: | | | |
| NAME- First name | Function - Service | | |
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| --- | --- | --- | --- | --- | --- |
| Name of the technical assessor: NAME First name | | | | | |
| Summary of the technical assessor  Please complete all boxes below, mentioning your observations and related assessment proofs.  With regard to non-assessed points or if not applicable, please do state this clearly in the corresponding field. | | | | | |
| Methods or equipments checked during this assessment | | | | | |
|  | | | | | |
| Witness of on-site sampling and/or realisation of analyses | | | | | |
| Witnessed analyses and/or sampling | | | Observed personnel | | Comments on the observation |
|  | | |  | |  |
|  | | |  | |  |
|  | | |  | |  |
| Resource requirements | | | | | |
| 6.2 Personnel  Management of staff competence (contract, training, qualification, authorization, competence and performance, records…) *(§ 5.1 v.2012)* | | | | | |
|  | | | | | |
| A.4 Training programme for staff carrying out Point-of-Care Testing (POCT)  *(not applicable v.2012)* | | | | | |
|  | | | | | |
| 6.3 Facilities and environmental conditions *(§ 5.2 v.2012)* | | | | | |
|  | | | | | |
| 6.4 & 6.5 Equipment / Equipment calibration and metrological traceability *(§ 5.3 v.2012)*  OLAS annex [A016](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/a016-tracabilite-etalons-internationaux/A016-tracabilite-etalons-internationaux-en.pdf)  ILAC document [P10](https://ilac.org/?ddownload=123220) | | | | | |
|  | | | | | |
| Competence of service providers performing calibrations via the *3rd route (internal and/or external)*  OLAS annex [A016](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/a016-tracabilite-etalons-internationaux/A016-tracabilite-etalons-internationaux-en.pdf)  LAC document [P10](https://ilac.org/?ddownload=123220)  In-house calibration: documents EA-[4/02](https://european-accreditation.org/publications/ea-4-02-m/) and ILAC [P14](https://ilac.org/?ddownload=123348) | | | | | |
|  | | | | | |
| 6.6 Reagents and consumables *(§ 5.3 v.2012)* | | | | | |
|  | | | | | |
| Agreements | | | | | |
| 6.7 Service agreements *(§ 4.4 et § 4.7 v.2012)* | | | | | |
|  | | | | | |
| A.2 Governance of Point-of-Care Testing (POCT)  *(non applicable v.2012)* | | | | | |
|  | | | | | |
| 6.8 Externally provided products and services *(§ 4.5 v.2012)* | | | | | |
|  | | | | | |
| Process requirements | | | | | |
| Vertical traceability audit  Please indicate the of assessed file(s) | | | | | |
|  | | | | | |
| 7.1 General / 8.5 Actions to address risks and opportunities for improvement / 5.6 Risk management *(§ 4.14.6 v.2012)* | | | | | |
|  | | | | | |
| 7.2 Pre-examination processes *(§ 5.4 v.2012)* | | | | | |
|  | | | | | |
| 7.3 Examination processes:  Selection, verification and validation of methods *(§ 5.5 v.2012)*  Documentation of examination procedures  OLAS annex [A011](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/a011-validation-methodes/A011-validation-methodes-en.pdf) | | | | | |
|  | | | | | |
| 7.3.4 Evaluation of measurement uncertainty *(§ 5.5.1.4 v.2012)*  7.3.5 Biological reference intervals and clinical decision limits | | | | | |
|  | | | | | |
| 7.3.7 Ensuring the validity of examination results: IQC and EQA *(§ 5.6 v.2012)*  Frequency of participation, results obtained, corrective actions and other proofs of their competence in case of non-participation  OLAS annex [A015](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/a015-comparaisons-interlaboratoires/a015-comparaisons-interlaboratoires-en.pdf)  ILAC document [P9](https://ilac.org/?ddownload=3259) | | | | | |
|  | | | | | |
| A.3 Quality assurance programme of Point-of-Care Testing (POCT)  *(not applicable v.2012)* | | | | | |
|  | | | | | |
| 7.4 Post-examination processes / Reporting and release of results *(§ 5.7, § 5.8 and § 5.9 v.2012)* | | | | | |
|  | | | | | |
| Respect of the guidelines for the use of the OLAS accreditation symbol  OLAS annex [A003](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/A003-regles-logo/A003-regles-logo-en.pdf) | | | | | |
|  | | | | | |
| 7.5 Nonconforming work & 8.7 Nonconformities and corrective actions *(§ 4.9 and § 4.10 v.2012)* | | | | | |
|  | | | | | |
| 7.6 Control of data and information management  (built-in software, data transfer, data protection and security, software version management …)  *(§ 5.10 v.2012)* | | | | | |
|  | | | | | |
| Management of the accreditation scope (fixed and/or flexible scope)  OLAS annex [A012](https://portail-qualite.public.lu/content/dam/qualite/fr/documentations/accreditation-notification/accreditation-olas/annexes/a012-portees-fixes-et-flexibles/A012-portees-fixes-et-flexibles-en.pdf)  EA document EA-[2/15](https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-15-m.pdf) | | | | | |
|  | | | | | |
| 5.3.3 Advisory activities | | | | | |
|  | | | | | |
| 5.6 Risk management | | | | | |
|  | | | | | |
| In case of a transition from a fixed to a flexible scope | | | | | |
|  | Monitoring of the competence of the technical personnel responsible for the concerned activities (stability of personnel, training, competency assessment).  Degree of understanding of the CAB in the rules and procedures for implementing and managing a flexible scope | | | | |
|  | | | | |
| Design and implementation process  Complexity and level of familiarity of the NAB with the conformity assessment activities  Robustness of the process (including extent of controls) designed by the CAB for  managing its flexible scope | | | | |
|  | | | | |
| Contract review and management of the List of accredited activities | | | | |
|  | | | | |
| Planned frequency with which the CAB intends to update the List of activities relating to the flexible scope | | | | |
|  | | | | |
| Control of corrective actions of the previous assessment  Please do also check the intermediary report of the CAB (F037) | | | | | |
|  | | | | | |
| Only mention those findings which have not been closed in the table below | | | | | |
| Identification n° of the finding from the previous assessment | | | Identification n° of the finding from the previous assessment | | Identification n° of the finding from the previous assessment |
|  | | |  | |  |
| Additional comments (if relevant): | | | | | |
|  | | | | | |
| Strong areas: | | | | | |
|  | | | | | |
| Sensitive areas: | | | | | |
|  | | | | | |
| **Final conclusion** of the technical assessor regarding the technical competencies of the audited body: | | | | | |
|  | | | | | |
| Persons encountered: | | | | | |
| Name – First name | | Function - Service | | Technical domain(s)  (see accreditation scope) | |
|  | |  | |  | |
|  | |  | |  | |
|  | |  | |  | |
|  | |  | |  | |
|  | |  | |  | |
|  | |  | |  | |

|  |  |
| --- | --- |
| **Finding n°: initials of the assessor + n° x/y** | |
| **Accreditation standard:** |  |

**Comment:** concerns a provision which requires further definition or detail.

**Non-conformity:** gap detected in the organization of the laboratory or body resulting from a requirement from the frame of reference which has not been dealt with or partially dealt with, but which does not have a direct impact on the reliability of results or decisions.

**Major non-conformity:** significant gap detected in the organization of the laboratory or body presenting a serious risk to the reliability of results or decisions.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| TECHNICAL OR QUALITY ASSESSOR | Finding: | - comment | | - non-conformity | - major non-conformity |
| Paragraph cited: | § | | | |
| This finding relates to: | - application | | - documentation |  |
| Description: | | | | |
|  | | | | |
| Motivation of the classification of the finding: *please describe the context associated with the finding* | | | | |
|  | | | | |
| Date: | | Assessor: | | Signature: |
|  | | | | | |
| assessed entity | Assessed entity approval: | | - yes | | - no |
| Remarks of the assessed entity: | | | | |
| Date: | | Assessed: | | Signature: |

**Remark: For major non-conformities, proof that corrective action has been implemented shall be sent by the CAB to the assessors and experts who issued the finding and to OLAS within 3 months of the assessment.**

|  |
| --- |
| **Corrective action sheet for finding n°: initials of the assessor + n° x/y** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| assessed entity | Analysis of the extent of the finding: | | | | |
|  | | | | |
| Analysis of the cause (e.g. root cause analysis) of the finding: | | | | |
|  | | | | |
| Corrective action: | | | | |
|  | | | | |
| Deadline for application (cannot exceed three months after the date of the assessment): | | |  | |
| Date: | Assessed: | | | |
|  | | | | | |
| QUALITY OR TECHNICAL ASSESSOR | Is the suggested corrective action appropriate? | | - yes | | - no |
| Remarks: | | | | |
| Date: | Assessor: | | | |
|  | | | | | |

**Remark: The recommended corrective action should be submitted by organizations to the appropriate Team Leader or Technical Assessor within 15 working days following the assessment.**

## Validated accreditation scope of a medical laboratory

| Medical Biology |
| --- |

| **Objects submitted for analysis** | **Characteristics or properties measured** | **Measurement principle and equipment** | **Analysis methods** |
| --- | --- | --- | --- |
| (e.g. products, materials, samples, matrices, equipment) |  | (e.g. manual or automatic measurement) | (e.g. published, adapted, checked internally) |
| **General domain:** | | | |
| **Technical domain:** | | | |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |