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| CAB Ref. No |  |  |  |  |  |  |
| Visit Date |  | | | | | |

**III. Veretical AssessmentReport for Medical Laboratories**

**According to ISO 15189:2022**

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| Laboratory Name | | |  | | | | | | | | | |
| Organization Name | | |  | | | | | | | | | |
| Division / Dept. | | |  | | | | | | | | | |
| Lab. Representative | | | Name: |  | | | Position: | |  | | | |
| Laboratory Ref. No. | | |  | | | | | | | | | |
| Assessment Type | | | Pre-assessment | | Initial | AssessmentNo. ( ) | | | | | Follow up | |
| Re- Assessment | | Extension | | | | | | Un-Planned | |
| Team Leader (TL) Name | | |  | | | | | | | | | |
| Reporting Assessor(s) Name(s) | | |  | | | | | | | | | |
| **Report** *(Select one or more final at least the number, date and the accredited parameters, as on the Accreditation Schedule)and document details for it below:* | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| *Clause* | **REQUIREMENTS AND COMMENTS** *Compliance = C, Non-compliance = NC, Not applicable = NA*  ***NB: Indicate WHAT has been checked and HOW requirements have been implemented. The order of assessment need not follow the order of the checklist. Assessors are expected to know & have the standard, this checklist is designed as guidance to prompt detailed recording of the process.***  ***REFER TO ISO 15189:2022 FOR DETAIL AND FOR CLARIFICATION NOTES.*** | | | | | | | | | | | **C,**  **NC,**  **Cm,**  **NA** |
| **7.4.1** | Reporting of results | | | | | | | | | | |  |
| **7.4.1.1** | The report include all available information necessary for the interpretation of the results. | | | | | | | | | | |  |
|  | Record for notify users when examination results are delayed, based on the impact of the delay on the patient. | | | | | | | | | | |  |
| All information associated with issued reports shall be retained in accordance with management system requirements | | | | | | | | | | |  |
| **7.4.1.2** | Result review and release | | | | | | | | | | |  |
|  | Record ensure that Results are reviewed by authorized personnel prior to release. | | | | | | | | | | |  |
|  | Record ensure the autherized personnel evaluate examination results against IQC and, as appropriate, available clinical information and previous examination results. | | | | | | | | | | |  |
|  | Record for examination results are released for reporting, including by whom and to whom | | | | | | | | | | |  |
|  | | | | | | | | | | | | |
| **7.4.1.6** | Requirements for reports | | | | | | | | | | |  |
| ***Notes in Std.*** | The report include unique patient identification, the date of primary sample collection and the date of the issue of the report, on each page of the report; | | | | | | | | | | |  |
| The report include Identification of the laboratory issuing the report; | | | | | | | | | | |  |
| The report include Name or other unique identifier of the user; | | | | | | | | | | |  |
| The report include the type of primary sample and any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description); | | | | | | | | | | |  |
| The report include clear, unambiguous identification of the examinations performed; | | | | | | | | | | |  |
| The report include Identification of the examination method used, where relevant, including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle; | | | | | | | | | | |  |
| The report include Examination results with, where appropriate, the units of measurement, reported in SI units, units traceable to SI units, or other applicable units; | | | | | | | | | | |  |
| The report include the Biological reference intervals, clinical decision limits, likelihood ratios or diagrams/nomograms supporting clinical decision limits as necessary; | | | | | | | | | | |  |
| The report include Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available; | | | | | | | | | | |  |
| The report include Identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed); | | | | | | | | | | |  |
| The report include Identification of any results that need to be considered as preliminary; | | | | | | | | | | |  |
| The report include Indications of any critical results; | | | | | | | | | | |  |
| The report include unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end (e.g. page number to total number of pages). | | | | | | | | | | |  |
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| **7.4.1.7** | Additional information for reports | | | | | | | | | | |  |
|  | Record insure that the time of primary sample collection for patient care. | | | | | | | | | | |  |
| Record available for Time of report release, if not contained in the report electronically or other method of recording; | | | | | | | | | | |  |
| When applicable, a report include interpretation of results and comments on it. | | | | | | | | | | |  |
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| **6.2.2** | Check Competence requirements for personal perform laboratory activities for which they are responsible. | | | | | | | | | | |  |
| **6.2.5** | Personnel records of the persons performing the examination | | | | | | | | | | |  |
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| **6.3.1** | Records for environmental conditions at the time of examination | | | | | | | | | | |  |
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| **6.4.7** | Check the Status of the equipment performance records at the time of examination; | | | | | | | | | | |  |
|  | Check the maintenance activities performed by the laboratory carried out, and the programme for preventive maintenance; | | | | | | | | | | |  |
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| **6.5.2** | Check equipment calibration at the time of examination: | | | | | | | | | | |  |
|  | Record for the calibration of equipment that directly or indirectly affects examination results. And confirm the following at the time of examination: | | | | | | | | | | |  |
| Conditions of use and manufacturer's instructions for calibration; | | | | | | | | | | |  |
| Recording of the metrological traceability; | | | | | | | | | | |  |
| Verification of the required measurement accuracy and the functioning of the measuring system at specified intervals; | | | | | | | | | | |  |
| Recording the calibration status and date of re-calibration; | | | | | | | | | | |  |
| **6.5.3** | Check metrological traceability of measurement results | | | | | | | | | | |  |
|  | The record maintained metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. | | | | | | | | | | |  |
| 1. Ensure that measurement results are traceable to the highest possible level of traceability and to the International System of Units (SI) through:  * Calibration provided by a competent laboratory; or * Certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI * *Calibration laboratories fulfilling the requirements of ISO/IEC 17025 are considered competent for performing calibrations.* | | | | | | | | | | |  |
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| **6.6.7** | Reagents and consumables status at the time of examination — Records | | | | | | | | | | |  |
|  | Identity of the reagent or consumable; | | | | | | | | | | |  |
| Manufacturer's information, including instructions, name and batch code or lot number; | | | | | | | | | | |  |
| Date of receipt and condition when received, the expiry date, date of first use and, where applicable, the date the reagent or consumable was taken out of service; | | | | | | | | | | |  |
| Records that confirm the reagents or consumables initial and ongoing acceptance for use. | | | | | | | | | | |  |
| The records available reference to the person or persons undertaking the preparation of reagents, resuspended or combined in-house, as well as the dates of preparation and expiry. | | | | | | | | | | |  |
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| **7.2.3** | Requests for providing laboratory examinations | | | | | | | | | | |  |
| **7.2.3.1** | Request accepted by the laboratory for examination(s). | | | | | | | | | | |  |
|  | The examination request provide sufficient information to ensure:Unequivocal traceability of the patient to the request and sample;Identity and contact information of requester;Identification of the examination(s) requested;Informed clinical and technical advice, and clinical interpretation can be provided. | | | | | | | | | | |  |
| The examination request information appropriate by the laboratory and acceptable to the user. | | | | | | | | | | |  |
| **7.2.3.2** | Record for oral requests for examinations, if applicable includes documented confirmation of the examination request to the laboratory, within a given time. | | | | | | | | | | |  |
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| **7.2.4.4** | Record for collection activities for the case of the report examined checked for the following: | | | | | | | | | | |  |
|  | The identity of the patient from whom a primary sample is collected verified; | | | | | | | | | | |  |
| When relevant, recording that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals]; | | | | | | | | | | |  |
| Available descriptions of the primary sample containers and any necessary additives; | | | | | | | | | | |  |
| Labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected; | | | | | | | | | | |  |
| Recording of the identity of the person collecting the primary sample and the collection date, and, when relevant, recording of the collection time; | | | | | | | | | | |  |
| Record available when separating or dividing the primary sample; | | | | | | | | | | |  |
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| **7.3.7.2** | Record for checking the validity of internal quality control (IQC) on the date of selected report | | | | | | | | | | |  |
|  | IQC data shall be reviewed with defined acceptability criteria; | | | | | | | | | | |  |
| Record for that the laboratory prevent the release of patient results in the event that IQC fails the defined acceptability criteria; | | | | | | | | | | |  |
| When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error has been corrected (see 7.5). | | | | | | | | | | |  |
| The results from patient samples that were examined after the last successful IQC event shall be evaluated. | | | | | | | | | | |  |
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| Assessor Signature | |  | | | | | | Date | |  | | |