EGAC Policy on Implementation and Use of Proficiency Testing
PB14G

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Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (old/new, added, cancelled)
1.1/Feb 2019	Q G.M	8/26	Clause 8.1
1.2/Mar 2019	Q G.M	4/26, 11/26, 12/26 & 13/26	- Adding some definitions - Adding general policy for FSP laboratories
Annual Doc. Revision Jan 2021	Quality Manager	All Pages	Annual revision for this document, Conducted by Ashraf Saif Quality General Manager. And no changes needed.
Annual Doc. Revision Jan 2022	Quality Manager	All Pages	Annual revision for this document,
1.3/Mar 2022 Annual Doc. Revision	Quality Manager	5&6/33	Adding statement in clause 4 , clause 5-1 and Clause5-2
1.3/Mar 2022	Cal. Manager	5/33	Modification for clarification
1.4/oct2022	Quality Manager	6,14/35	Add new form related toAccredited laboratories participation in PT programs. Form F1PB14I G Issue No 1/ Oct 2022
1.٥ / Jan 2023 & Annual Doc. Revision	Quality representative	14/35	Canceled Form F1PB14I G and added to WI5M ,WI4TCL & WI12FP
2/Dec 2023	Quality Manager	5/34	Modification for clarificationn clause 4
2.1/ Nov.2024	Quality representative	10to 18/34	Modification for clarificationn clause 10,11 and 12

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SCOPE.

This document defines the policy for EGAC's implementation of Proficiency Testing, It is applied for the assessment of all accredited testing, calibration, medical laboratories and forensic service providers.

Note (1): According to ISO/IEC 17025.

The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:
a) participation in proficiency testing;
b) participation in interlaboratory comparisons other than proficiency testing.

2. Definitions

2.1. **Proficiency Testing (PT):**
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons
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Note (2):
Some providers of proficiency testing in the medical area use the term "External Quality Assessment (EQA)"

2.2. Proficiency Testing Scheme:
Proficiency testing designed and operated in one or more rounds for a specific area of testing, measurement, calibration or inspection.

2.3. Inter-laboratory Comparison (ILC):
Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

3. POLICY

EGAC considers proficiency testing as an important tool in assessment of the laboratory's performance. It provides a basis for improving the quality of laboratories.

EGAC requires its applicant(s) / accredited laboratories to develop a plan for "Four years of" participation in Proficiency Testing schemes, relevant to their scope. EGAC will review this plan and its implementation by the Laboratory

It is EGAC's policy to encourage Laboratories to participate in PT schemes that are being operated in their areas, also encouraging the formation of a new proficiency testing scheme was considered necessary for the laboratories.

Regionally, EGAC also encourages its accredited laboratories for achieving some proficiency testing schemes by subscribing to these CABs in the framework of cooperation with the regional accreditation bodies (AFRAC, ARAC, APAC, ……) in the fields of calibration , testing and medical laboratories, EGAC nominates the required number of required accredited CABs and send the nomination to the region and then receives the samples to be distributed on the selected CABs, EGAC follow the process for the participated CABs until it is completed with its results.

4. Types of accepted proficiency testing (for ISO/IEC 17025):

For the accreditation process: the acceptable types of proficiency testing in the following order according to availability are:

1. **Accredited Proficiency testing** provider according to (ISO/IEC 17043).
2. **Intralaboratory Comparison** designed primarily by EGAC after reviewing and accepting the programs from the accreditation manager relevant to the Scheme and technical assessor relevant to the activity.
3. **Measurement audit**: in case of impossibility implementing with any of the above, by EGAC after review and accept the programs from accreditation manager relevant to Scope and technical assessor relevant to activity.
4. **Unaccredited PT** provider but after review and accept the programs from accreditation manager relevant of Scheme.

* If not found Accredited Proficiency testing the CAB shall take approval from EGAC before implementing alternatives in item 2 or item 3 or last one item 4.

5.1 PT requirements for applicant (for ISO/IEC 17025).

a) Applicant Lab shall provide proficiency testing, at least one PT in sub-Discipline for Each Group within the same code (Annex 1) according to EGAC scope of accreditation for the (testing / calibration) laboratory.

b) The applicant also shall **provide a plan** of proficiency testing to cover the rest of the CAB accredited scope (testing / calibration) according to EGAC Sub-Discipline activities for Each Group within the same code (Annex 1) to implement it during its accreditation cycle (four years)

c) The required frequency of participation in the proficiency testing should be relevant to the technical scope as will be assessed by EGAC however it should not less than the frequent time explained in clause (9) below (within the period between two subsequent reassessments) for each sub- discipline of the laboratory's scope of accreditation.

d) Disciplines may need to be divided into more sub disciplines to clarify their PT schemes; this will be advised by EGAC assessors / experts. Disciplines and sub disciplines as illustrated in (Annex I) and are published on EGAC's website.

e) For calibration laboratories.

- At initial assessment visit the date of issue PT Report **not exceed 18 months** during submit application.
- At extension or re-assessment visit the PT Report must be valid **one year before** conduct the visit

5.2 PT requirements during the Document review and preliminary assessment (for ISO/IEC 17025)

The assessment and the system documentation allow for a correct evaluation of the proficiency testing report.

Assessors shall check the following before starting the assessment:

- The plan for the participation of the laboratory in the PT schemes, along with its justifications.
- The successful execution of this plan, according to the laboratory's success report.
- The results achieved in proficiency tests are adequately documented in the laboratories before they can be considered as part of an accreditation procedure.
- Accredited laboratories are maintaining their own records of performance in all types of proficiency testing, including the outcomes of investigations of any unsatisfactory results and any subsequent corrective actions, If the CABs have PT Report with all unsatisfactory results the CAB must re-participate in new proficiency testing.
- The period for keeping the records of proficiency testing results and other documentation is at least (Previous and Current) accreditation cycle, to establish the competence and stability of the accredited laboratory.
- Accredited laboratories shall have a written procedure covering participation in proficiency testing, including how the performance in proficiency testing is used to demonstrate the laboratory's competence and procedures followed in the event of unsatisfactory performance.
- Assessors shall check the conformity of the frequency and regularity of the laboratory's participation in the proficiency testing with regard to EGAC policy.

5.3 PT requirements during the assessment process

- During the assessment, the assessment team will obtain the laboratory's plan which participation in the proficiency testing schemes and a report on the participation of the laboratory in proficiency tests.

- This report of proficiency tests shall always be part of the documentation of the laboratory's accreditation or sequential assessment procedure. Such a report should contain:

- Plan for the participation of the laboratory in the PT schemes.
- Reporting the success of this plan.
- Dates of proficiency tests already carried out.

- Organizer of PT scheme.
- Test materials, measured quantities, parameters, artifacts and calibration equipment.
- Matrices (where applicable).
- Acceptability criteria.
- Results (satisfactory/questionable/unsatisfactory)
- Corrective actions and follow -ups, where required.

-If the laboratory submits a greater number of proficiency tests, then the assessment team should limit its assessment to a sufficient number chosen in a representative way.
- From the survey on proficiency tests and considering the above-mentioned main points, proficiency tests that are to be checked on-site are to be selected by the assessment team

-The laboratory shall be prepared to justify non-participation in readily available proficiency testing schemes, where one or more appropriate schemes exist.

6- Corrective actions and additional measures

According to :

- Data from monitoring activities shall be analyzed and used to control and, improve the laboratory's activities if applicable.
- If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported. **(ISO/IEC 17025)**
- CAB should make analysis for PT report results (Satisfactory/ questionable / Unsatisfactory), EGAC will accept the PT provider's acceptance criteria if available based on Laboratory analysis, otherwise it will set one according to the PT results presented to the laboratory.
- The laboratories are required to make the results available to be analyzed by EGAC. These results should be adequately documented in the laboratories before they can be considered as part of an accreditation process.
- The laboratories are required to demonstrate their ability to take the necessary corrective action when appropriate.
- Records of proficiency testing results should be analyzed and kept, to establish the competence and stability of the accredited laboratory.
- The general conclusions that have been drawn by the laboratory from the participation in proficiency tests concerning their work and corrective actions, if necessary, that have been taken, shall be studied by the assessment team.

If the laboratory doesn't have satisfactory results, then, the explanations and corrective actions shall be checked for sufficiency and suitability. The assessment team shall study these actions to gain information about a laboratory's competence. These actions may include the following internal

and/or external quality measures:

- Calibration of measuring devices.
- Use of quality control charts.
- Performance of duplicate/multiple determinations/measurements and appropriate statistical methods.
- Use of standard methods for calibration/ testing.

➢ **For testing laboratories:**

- Regular use of certified reference materials, where appropriate use of purchasable or in-house calibration and control materials.
- Introduction of "blind" test materials into the laboratory (e.g. by the Quality Manager).

➢ **For calibration laboratories:**

-Regular use of cross checks methods, where appropriate and the use of higher-level calibrations.

-All kinds of proficiency tests already carried out on the laboratory's own initiative.

In any case, if there are doubts concerning the competence after studying the corrective actions, the technical assessor should find out - in agreement with the laboratory - whether interlaboratory comparisons with other laboratories or the participation in existing interlaboratory comparison schemes should be performed. The extent, selected type, the way of performing and evaluating the proficiency tests shall be explained to the laboratory by the assessment. Other internal as well as external quality measures may be considered, e.g.:

- To repeat the PT.
- To check internal quality assurance measures.
- To ask for detailed reports on corrective actions.
- To make an on-site surveillance

7. Additional proficiency tests may be required when:

a. A significant Change of personnel / main used std. operating in the accredited scope, which may affect the technical competence of the laboratory,
b. External quality measures taken for the test methods/types of tests applied in the scope of accreditation are not sufficient, regarding, e.g.:
   - Number of proficiency tests performed in specific scopes
   - Extension of the scope of accreditation
   - Insufficiently validated and documented in-house methods
   - Procedural steps deviating from the test standard
c. A significant ratio result of the proficiency tests submitted by the laboratory is unsatisfactory as defined by the acceptability criteria.
d. The conclusions drawn and the necessary corrective actions of the laboratory have not been carried out or documented, or are in-sufficient

e. Assistance in detecting systematic errors in the laboratory is needed ~~and~~ if the laboratory has no other means to provide evidence of its technical competence and quality of measurement.

8. Determination of acceptability criteria

8.1General rules

Generally, the assessment team should use the criteria stated by the organizer of the proficiency testing scheme.
If the organizer of inter-laboratory comparisons does not provide any criteria for acceptance of results (e.g. inter-laboratory comparisons for validation of procedures and/or certification of reference substances), then the laboratory, under assessment, shall define its own acceptance limits. The assessment team will verify the criteria in use (defined either by PTP or by the laboratory) for suitability.

8.2 Regulatory authorities' criteria.

- If the laboratory is active in a mandatory area, the assessment team should use the criteria set by the regulatory authority.
- If the laboratory is not active in a mandatory area, but is taking part in the proficiency testing scheme established by regulatory authority for purposes of internal quality assurance, then the assessment team should use the criteria defined for the intended use by the laboratory, after checking the ability of the laboratory to set criteria and their suitability.

Note (3) : The criteria set by the authority or customer should normally have precedence over the criteria given by the accreditation body.

9. Proficiency Testing frequency

- **For Calibration laboratories fields:**

EGAC accept PT for its calibration laboratories activities according to each of its Sub-discipline to be renewed each accreditation cycle (four years) unless there is no change at the laboratory scope. (Back to Annex 1).

- **For Testing laboratories fields:**

a) EGAC accept PT for its testing laboratories activities according to its each Sub-discipline

As defined in (Annex I).to be renewed each accreditation cycle unless there is no change at the laboratory scope

b) For critical sub-discipline (field/s):

- Biological Testing.
- Environmental Tests.
- Food Tests.

To be renewed each (2 years/Cycle) unless there is no change at the laboratory scope

10. Proficiency Testing Requirements for Medical Laboratories:-

For the Medical laboratories discipline (Tests), its frequency is dictated by the PT provider scheme.

- ISO 15189:2022, clause 7.3.7.3, requires that the laboratory participates in an EQA program appropriate to the examination and interpretation of examination results, including POCT (Point of care testing) examination methods. When an EQA programme is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination method performance, including ILCs other than PT;

Note (1): *Participation in PT and/or ILCs other than PT, organized by competent providers is, for an accredited CAB, an integral part of the monitoring of the validity of its results.*

- The period for keeping the records of proficiency testing results and other documentation is at least (Previous and Current) accreditation cycle, to establish the competence and stability of the accredited laboratory.

10.1. Types of accepted proficiency testing:

For the accreditation process: the acceptable types of proficiency testing are in the following order according to availability:

a) Accredited PT providers that meet requirements of ISO/IEC 17043.

b) Unaccredited PT providers, approved by the accreditation manager and director following review of the PT provider plan, homogeneity, stability, traceability of PT samples, and previous work.

c) According to ILAC P9 and ISO 15189:2022, clause 7.3.7.3, it is required that the laboratory participates in an EQA program appropriate to the examination and interpretation of examination results, including POCT (Point of care testing) examination methods. When an EQA program is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination method performance, including ILCs other than PT, if either (a) or (b) is not available or not suitable, the CAB (CAB; is the conformity assessment body that performs medical testing) shall propose a suitable alternative and get approval from the EGAC accreditation manager and director following discussion and approval by at a technical assessor subcontracted by EGAC in the related

activity. A written approval will be provided to the CAB before implementing the alternatives, the acceptable types of alternatives are in the following order according to availability:

1. Interlaboratory comparison programs comparing the laboratory daily internal quality control with peer group using the same quality control materials;
2. Participation in sample exchanges with other accredited laboratories accepted by the EGAC accreditation manager and director following discussion and approval by the technical assessor(s) relevant to the activity;
   Note (2): *The accredited laboratories shall successfully participate in the same period and the reports of their results shall be reviewed by EGAC.*
3. When appropriate the medical laboratory use analysis of reference materials under EGAC supervision;
4. Depending on the scope of medical laboratory they can use participation in sample exchanges with another more than two competent and accepted labs by the EGAC accreditation manager and director following discussion and approval with the technical assessor(s) relevant to the activity.

The laboratory shall have a documented procedure for alternative methodologies and for exchange of samples with other accredited laboratories including frequency, number of samples and acceptable performance criteria. Storage, **stability and transport conditions of samples shall be considered to ensure valid results. Results are documented, reviewed** and corrective action is taken in case of unsatisfactory results.

10.2. PT Requirements for Applicant (Labs).

a) The applicant Medical Laboratory provides proficiency testing reports, at least one successful shipment for each parameter that is updated within **the last 6 months** from the date of submitting a new application or expanding the scope before final approval of laboratory application by EGAC;

b) **Provides a plan** of proficiency testing to cover the CAB accredited scope to be implemented during its accreditation cycle (four years). These plans shall be relevant to its scope of tests, matched with the PT provider programs and the frequency of proficiency testing shall be at least annually, also the planning is to take into account the risks and opportunities of the laboratory activity. This includes an evaluation of the level and frequency of participation in PT and/or ILCs other than PT;

c) The required frequency of participation in the proficiency testing should be relevant to PT suppliers with a final report provided at the end of the cycle;

d) **For special scopes** that include preparation, examination, and interpretation processes (e.g., pathology, cytogenetic, microbiology, etc.) the lab shall participate in PT program(s) that

cover(s) all steps of testing processes till reporting of results (whenever available/ possible). In the situation where the Lab's PT participation plan is considered not suitable in relation to the scope of accreditation such as when the examination process is not included in PT/ILC program the Lab will arrange for another alternative accepted approach from **(10.1)**;

e) The Medical Laboratory shall treat the PT samples in the same manner as the patient samples and as mentioned in the PT scheme protocol;

f) The applicant Medical Laboratory shall deliver reports that were provided by PT providers and prove successful participation to EGAC relevant department. Also, during the assessment visit the technical assessor shall review raw results or printout of the lab results that were submitted to PT provider;

g) Proficiency testing / ILC reports shall be clear and comprehensive and include at least the following minimum information:

- Identification of the participants;
- Measurement protocol;
- Measurement results;
- The reference value/s and how these were established;
- Evaluation of the measurement results;
- An indication of the performance of individual participants;
- Minimum acceptance criteria;
- Conclusion.

h) If the lab performs the same test on two or more identical equipment and the PT program provides only one report for one equipment, the lab can use the PT samples for comparison with the other equipment, and comparability studies between equipment should be done at **least every six months.**

i) The lab shall formulate and implement a policy and procedures related to its participation in proficiency tests/inter-laboratory comparison programs (ILCs), alternatives when used, and analyze their results. EGAC Periodicity will consider the risks and opportunities of the laboratory activity. This includes evaluating the level and frequency of participation in PT and/or ILCs other than PT.

j) The lab shall review all related policies and procedures periodically, provided that this review includes all the technical and organizational issues.

10.3. Successful Participation Requirements:

a) For monthly or biweekly provided samples, the lab shall pass at least **75%** of a whole PT annual cycle including acceptable alternative for those shipments that were not received by the lab. For any unsatisfactory result the lab shall investigate the root cause and take a corrective action.

b) For programs providing three shipments per year with five samples per shipment, the lab shall pass at least 75% of a whole PT annual cycle including acceptable alternative for those

shipments that were not received by the lab. For any unsatisfactory result the lab shall be investigate the root cause and take a corrective action.

c) For programs providing three shipments per year (with less than 5 samples per shipment), the lab shall pass successfully in two shipments, and for the unsatisfactory shipment the lab shall investigate the root cause and take a corrective action. An alternative is required for any shipment not received by the lab.

d) For programs with two shipments per year, the lab shall pass successfully one of the two shipments, and for the unsatisfactory shipment, the lab shall investigate the root cause and take a corrective action. An alternative is required for any shipment not received by the lab.

10.4. Maintenance of accreditation:

a) The lab shall maintain continuous participation and fulfill the previous successful participation requirements as explained in **(10.3)**;
b) The lab shall send reports of all PT results **every 6 months** for EGAC medical department;
c) The lab shall send a self-assessment report that includes the lab performance through the past six months, the root causes, and corrective actions/justifications for **failed** or **unreported/Late** test results. The accepted corrective action is taken in case of unsatisfactory results/delayed/undelivered PT samples. Actions shall be at the same time as the PT calendar plan and
d) **Failing to regularly send the above-mentioned reports will result in suspension of the lab scope in this particular sub-discipline/analyte.**
e) For an accredited medical laboratory, it will be **suspended or partially suspended for six months at most if there is no evidence of successful participation at the end of the PT cycle.** The lab shall send evidence of satisfactory PT result(s) before the end of the six-month suspension period, and the lab will be subjected to a reduction of its scope or withdrawal according to EGAC's procedures and regulations.

11. General policy for Forensic Services Provider Laboratories

11.1. On Application for Accreditation:

11.1.1 All applicant for forensic testing laboratories and inspection body are required to participate in appropriate proficiency testing or Inter-laboratory comparisons for the scope of accreditation required and provide EGAC with the relevant proof on application of participation and satisfactory performance.

'Appropriate' participation can be described as that level of participation which will result in an acceptable level of risk, i.e. risk that the laboratory may issue reports with results falling outside of the specified measurement uncertainty stated on the report. The EGAC policy requires that laboratories undertake proficiency testing or ILC for all items or parameters listed on their proposed schedule of accreditation covering examination and post

examination report.

11.1.2. **Proficiency Testing:**

Forensic testing laboratories and inspection body shall perform proficiency testing in order to verify the laboratory's performance. The frequency of proficiency testing shall be at least annually, in at least one parameter or different matrix and at least one of these PT should be from a recognized PT provider external to laboratory.

Proficiency –test samples should be representative of the laboratory's normal casework.

Methodology required to perform proficiency tests should be relevant to the normal practice in the laboratory.

11.1.3. Proficiency testing activities may include:

i) An external proficiency testing scheme, preferably operated in accordance with ISO/IEC 17043;
ii) An Inter-laboratory comparison scheme (where two or more laboratories are used);
iii) Suitable alternative to PT/ILC, as agreed to by EGAC, where PT schemes are not available or are not practical.

11.1.4. For Maintenance the Accreditation

11.1.4.1. All accredited forensic service laboratories should preferably participate in proficiency testing scheme, in at least one parameter or different matrix, at least once annually that have been independently shown to comply with the requirements of ISO/IEC 17043. The laboratory shall satisfy itself on the competence of the PT providers in whose schemes it voluntarily participates.

11.1.4.2. Where available and appropriate, forensic agencies are expected to select PT providers accredited to ISO/IEC 17043 by EGAC, if available, or another accreditation body that is recognized by ILAC.

11.1.4.3. The Forensic testing laboratories and inspection body shall review their own performance and investigate all measurement results that fail to meet the minimum acceptance criteria, including where there is evidence of consistent poor performance, and record the root cause analysis conducted and all corrective and preventative action(s) taken.

11.1.5. PT/ILC Activity Plan

11.1.5.1. All accredited Forensic service provider shall have available PT / ILC plans for at least 2 years, i.e. the activities conducted for the past years (where possible) and the plan for the subsequent years.

11.1.5.2. The plan shall cover all activities as specified above and shall be accomplished in a period not exceeding 1 accreditation cycle.

Note(3): The frequency and extent of participation shall be justified by the laboratory to EGAC for each accredited method and shall be at least once annually, in at least one

parameter or different matrix, and included in the plan.

11.1.5.3. The PT / ILC plan shall be subject to review in response to changes in staff, methodology or instrumentation, revision and approval as described.

11.1.5.4. Forensic testing laboratories and inspection body may incorporate in the plan participation in any other organized PT or other comparison programs organized nationally, regionally or internationally.

11.1.5.5. Where no formal PT is practical or available, the Forensic testing laboratories and inspection body shall indicate suitable alternative means by which performance will be assessed and monitored. These may include activities such as intra-laboratory comparisons, the use of reference materials or other comparisons. EGAC will consider these alternative arrangements as part of the laboratory's planned activities. It is the responsibility of forencsic agency to provide the details of the plan and its justification to obtain approval from EGAC.

11.1.5.6. The PT activity plan should address:

- The parameters for which PT is conducted;
- Proficiency testing type (PT scheme; Inter-laboratory comparison; Intra-laboratory comparison; Use of a Reference material);
- Identification and number of participants, if available, and/or potential participants for ILC;
- The name/s and or identification of the PT schemes which the laboratory intends to participate;
- The minimum acceptance criteria, if available;
- Any issues expected with participating in PT, from previous experience;
- Frequency of participation per time period justified by the laboratory.

11.1.6. During an Assessment

11.1.6.1. Failure of Forensic testing laboratories and inspection body to show effective participation, or that the use of alternatives to PT has been agreed on by EGAC, according to the PT plan, could result in suspension of the tests concerned.

11.1.6.2. Forensic testing laboratories and inspection body shall make available to the assessment team all proficiency testing scheme and ILC reports.

11.1.6.3. Proficiency testing / ILC reports shall be clear and comprehensive and include at least the following minimum information:

- Identification of the participants;
- Measurement protocol;
- Measurement results;
- The reference value/s and how these were established;
- Evaluation of the measurement results;
- An indication of the performance of individual participants;
- Minimum acceptance criteria;
- Conclusion.

11.1.6.4. The effectiveness of corrective and preventative action taken will be evaluated during the assessment, and taken into consideration during the decision making process.

12. General Policy for ISO 20387:2018 Biotechnology Biobanking

12.1. On Application for Accreditation:

12.1.1 All applicant for biobanks is required to participate in appropriate proficiency testing or Inter-laboratory comparisons for the scope of accreditation required and provide EGAC with the relevant proof on application of participation and satisfactory performance.

The EGAC policy requires that laboratories undertake proficiency testing or ILC for all items or parameters listed on their proposed schedule of accreditation covering examination and post examination report.

12.1.2. **Proficiency Testing:**

Biobanks shall perform proficiency testing in order to verify the biobank performance. The frequency of proficiency testing shall be at least annually, in at least one parameter or different matrix and at least one of these PT should be from a recognized PT provider external to the biobank organization.

Proficiency test samples should be representative of the biobanks normal casework. Methodology required to perform proficiency tests should be relevant to the normal practice in the biobanks.

12.1.3. Types of accepted proficiency testing::

For the accreditation process: the acceptable types of proficiency testing are in the following order according to availability:

a. Accredited PT providers that meet requirements of ISO/IEC 17043.
b. Unaccredited PT schemes, agreed by the accreditation manager and director following review of the PT provider plan, homogeneity, stability, traceability of PT samples, and previous work.
c. If either a or b is not available or not suitable, the Biobank shall propose a suitable alternative and get approval from EGAC Accreditation manager and director following discussion and approval by the relevant technical assessor(s). A written approval will be provided to the CAB before implementing the alternatives which could be:
d. Interlaboratory comparison programs comparing the laboratory of biobank daily internal quality control with peer group using the same quality control materials when appropriate.
e. Depending on the scope of biobanks they can use participation in sample exchanges

with another more than two competent and accepted biobanks by the EGAC accreditation manager and director following consultation with the technical assessor(s) relevant to the activity.

The biobank shall have a documented procedure for exchange of samples with other accredited/ competent competent including frequency, number of samples and acceptable performance criteria.Storage, stability and transport conditions of samples shall be considered to ensure valid results. Results are documented, reviewed and corrective action is taken in case of unsatisfactory results.

f. When appropriate biobank use analysis of reference materials under EGAC supervision.

12.1.4. For Maintenance the Accreditation

12.1.4.1. All accredited biobanks participate in proficiency testing scheme, in at least one parameter or different matrix, at least once annually that have been independently shown to comply with the requirements of ISO/IEC 17043. The biobanks shall satisfy itself on the competence of the PT providers in whose schemes it voluntarily participates.

12.1.4.2. Where available and appropriate, biobanks organization are expected to select PT providers accredited to ISO/IEC 17043 by EGAC, if available, or another accreditation body that is recognized by ILAC.

12.1.4.3. The biobanks shall review their own performance and investigate all measurement results that fail to meet the minimum acceptance criteria, including where there is evidence of consistent poor performance, and record the root cause analysis conducted and all corrective and preventative action(s) taken.

12.1.4.4. According to ISO 20387:2018, clause 7.8.2.9, requires that approaches from the biobanks to provide objective evidence to demonstrate the comparability of biological material quality (the processing or testing output) are used, where such approaches are available and appropriate. Such approaches include EQA schemes, PT schemes and/or ILCs other than PT;

12.1.5. PT/ILC Activity Plan

12.1.5.1. All accredited biobanks shall have available PT / ILC plans for at least 2 years, i.e. the activities conducted for the past years and the plan for the subsequent years.

12.1.5.2. The plan shall cover all activities as specified above and shall be accomplished in a period not exceeding 1 accreditation cycle.

***Note(4)**:* The frequency and extent of participation shall be justified by the bibanks to EGAC for each accredited scope and shall be at least once annually, and included in the plan.

12.1.5.3. The PT / ILC plan shall be subject to review in response to changes in staff, methodology or instrumentation, revision and approval as described.

12.1.5.5. Where no formal PT is practical or available, the biobanks shall indicate suitable alternative

means by which performance will be assessed and monitored. These may include activities such as intra-laboratory comparisons, the use of reference materials or other comparisons. EGAC will consider these alternative arrangements as part of the laboratory's planned activities. It is the responsibility of biobank to provide the details of the plan and its justification to obtain approval from EGAC.

12.1.5.6. The PT activity plan should address:

- The parameters for which PT is conducted;
- Proficiency testing type (PT scheme; ILCs; Intra-laboratory comparison; Use of a Reference material);
- Identification and number of participants, if available, and/or potential participants for ILC;
- The name/s and or identification of the PT schemes which the laboratory intends to participate;
- The minimum acceptance criteria, if available;
- Any issues expected with participating in PT, from previous experience;
- Frequency of participation per time period justified by the biobank.

12.1.6. During an Assessment

12.1.6.1. Failure of the biobanks to show effective participation, or that the use of alternatives to PT has been agreed on by EGAC, according to the PT plan, could result in suspension of the tests concerned.

12.1.6.2. the biobanks shall make available to the assessment team all proficiency testing scheme and ILC reports during the visit.

12.1.6.3. Proficiency testing / ILC reports shall be clear and comprehensive and include at least the following minimum information:

- Identification of the participants;
- Measurement protocol;
- Measurement results;
- The reference value/s and how these were established;
- Evaluation of the measurement results;
- An indication of the performance of individual participants;
- Minimum acceptance criteria;
- Conclusion.

12.1.6.4. The effectiveness of corrective and preventative action taken will be evaluated during the assessment, and taken into consideration during the decision making process.

13. REFERENCES

ILAC-P9:01/ 2024
ISO/IEC 17043: 2023
ISO/IEC 17011: 2017
ISO/IEC 17025 :2017
ISO 15189 :2022
ISO 20387:2018
ISO 5725
EA-4/21 INF: 2018
EA-4/18 G: 2021
IAF/ILAC-A2
ASTM Designation E2327-15

Annex 1

EGAC Scope for Accreditation Schemes:

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
1	Calibration	A	Electrical - DC/ Low Frequency (≤ 1 MHz)	1	A1	Voltage
				2	A1	Current
				3	A1	Resistance
				4	A2	Capacitance
				5	A2	Inductance
				6	A3	Power
				7	A4	Energy
				8	A5	Impedance
				9	A6	Transformer's ratio
				10	A7	Oscilloscope Functions
				11	A8	Process calibrators
				12	A9	Logic State Analysis
				13	A10	High Voltage quantities
				14	A11	AC/DC transfer (voltage)
				15	A11	AC/DC transfer (current)
				16	A12	Voltage Ratio
				17	A13	Dissipation Factor
		B	Electrical - RF/Microwave & High Frequency (> 1 MHz)	1	B1	Modulation (AM)
				2	B1	Modulation (FM)
				3	B1	Modulation (PM)
				4	B2	Impedance (reflection coefficient)
				5	B3	Power
				6	B4	Attenuation
				7	B5	Adaptors
				8	B6	Antennas
				9	B7	Signal Generators
				10	B8	Spectrum Analysis
				11	B9	S-parameters
				12	B10	Noise
				13	B11	Electric/Magnetic Field quantities
				14	B12	Voltage Standing Wave Ratio (VSWR)
				15	B13	Electrostatic discharge Simulations (ESD)
				16	B14	Coupling/Decoupling Networks
				17	B15	Line impedance stabilization network
		C	Magnetism	1	C1	Magnetic Flux Density
				2	C2	Magnetic Material properties
		D	Time and Frequency	1	D1	Time Interval
				2	D1	Periodical time
				3	D2	Frequency
				4	D3	Rise Time
				5	D3	Fall Time

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
				6	D4	Phase Angle
				7	D5	Phase Shift
				8	D6	Acceleration
				9	D8	Rotational Speed (rpm)
		E	Dimensions - Laser	1	E1	Frequency stabilized laser vacuum (wavelength; optical frequency
		F	Dimensions - Length Instruments	1	F1	(Laser, length) interferometer (system, optics, refractometer)
				2	F2	EDM instrument
				3	F3	1-D measuring machine (ULM)
				4	F4	Height measuring instrument
				5	F5	1-D displacement transducer (LVDT)
				6	F6	Gauge block comparators
				7	F7	Dial-indicator tester
		G	Dimensions - End Standards	1	G1	Gauge block
				2	G1	Length bar (long gauge block)
				3	G1	[Plane] micrometer setting rod
				4	G2	[thread] micrometer setting rod
				5	G3	Step gauge
				6	G4	Feeler (thickness) gauge
		H	Dimensions - Line Standards	1	H1	Stage micrometer
				2	H2	(Surveyor, engineer, pi) tape, (geodetic) wire
				3	H3	Engineer or machinist scale, steel Rule
		I	Dimensions - Diameter Standards	1	I1	External cylinder (plug)
				2	I1	External cylinder (piston)
				3	I1	External cylinder (pin)
				4	I1	External cylinder (wire)
				5	I2	Internal cylinder (ring)
				6	I3	Sphere (ball)
		J	Dimensions - Angle	1	J1	Angle block gauges
				2	J1	90° (steel, granite, try) square
				3	J2	Cylinder square
				4	J3	Autocollimator
				5	J4	Electronic level
				6	J5	Clinometers
				7	J6	Spirit (bubble) level
				8	J7	Theodolite
				9	J8	(Bevel) protractor
				10	J9	Sine bar – Sine table
		K	Dimensions - Flatness Standards	1	K1	Optical flat
				2	K2	optical parallel
				3	K3	Surface Plate
		L	Dimensions - Roundness Standards	1	L1	External cylinder
				2	L1	Internal cylinder

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
				3	L2	Sphere – hemisphere
		M	Dimensions - Straightness Standards	1	L1	Straight edge
				2	L1	Cylindrical straightness standard
		N	Dimensions - Screw Thread	1	N1	Thread plug, plain & Tapered
				2	N1	Thread ring, plain & Tapered
				3	N1	Internal & External API screw thread gauge
		O	Dimensions - 2-D, 3-D Instruments	1	O1	Profile projector
				2	O2	Measuring microscope
				3	O3	Coordinate measuring Machine (CMM)
		P	Dimensions - Hand Instruments	1	P1	External micrometer
				2	P1	Micrometer head
				3	P1	Caliper
				4	P1	Snap gauge (internal, external)
				5	P2	Depth micrometer
				6	P2	Depth gauge
				7	P3	Internal two-point (bore) micrometer
				8	P3	Internal three-point (bore) micrometer
				9	P4	Dial gauge
		Q	Force	1	Q1	Universal Testing Machine (UTM)
				2	Q1	Tensile testing machine
				3	Q1	Compression Testing machine
				4	Q2	Shear Testing machine
				5	Q3	Bending testing machine
				6	Q4	Force proving Instrument (load Cell, Proving ring ….etc
		R	Torque	1	R1	Torque Wrench
				2	R2	Torque Transducer
				3	R3	Torque Multiplier
		S	Impact	1	S1	Impact machine calibrations
		T	Hardness	1	T1	Hardness calibration
		U	Pressure	1	U1	Dead weight testers
				2	U2	Gauge
				3	U3	transducer
				4	U4	Transmitter
		V	Vacuum	1	V1	Dead weight testers
				2	V2	Gauge
				3	V3	transducer
				4	V4	Transmitter
		W	Absolute Pressure	1	W4	Dead weight testers
				2	W4	Gauge
				3	W4	transducer
				4	W4	Transmitter
				5	W5	Data logger/ Recorder

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
		X	Differential pressure (ΔP) and Low pressure	1	W1	Dead weight testers
				2	W2	Gauge
				3	W3	transducer
				4	W4	Transmitter
		Y	Mass	1	Y1	Conventional Mass/ Weight
				2	Y2	True Mass/ Weight
				3	Y3	Density of solid
		Z	Weighing Instruments	1	Z1	Balances/Scales
				2	Z2	Mass Comparators
		AA	Acoustics	1	AA1	Microphones
				2	AA1	Sound Level
				3	AA2	Artificial Mastoids
				4	AA3	Noise Dosimeters
				5	AA4	Vibration
		AB	Fluid	1	AB1	Liquid Flow Rate
				2	AB2	Gas Flow Rate
				3	AB3	Quantity
				4	AB4	Velocity / Speed Flow
				5	AB5	Viscometers
				6	AB6	Viscosity
				7	AB7	Density
				8	AB7	Hydrometer
				9	AB7	Specific Gravity
		AC	Volumetric	1	AC1	Glass ware volumetric apparatus (One-mark) Pipette, Burette and flasks.
				2	AC1	Glass ware volumetric apparatus (Graduated) Pipette, Burette and flasks.
				3	AC2	Piston-operated volumetric apparatus (Single Volume) Micro Pipette
				4	AC2	Piston-operated volumetric apparatus (Variable volume) Micro Pipette
				5	AC3	Metal ware
		AD	Photometric	1	AD1	Luminous flux (lumen)
				2	AD2	Illuminance (Lux),
				3	AD3	Luminous intensity (Candela)
		AE	Radiometric	1	AE1	Power (watt)
				2	AE2	Irradiance (W/m^2)
				3	AE3	Spectral irradiance ($W/m^2/nm$)
				4	AE4	Detector sensitivity ($A/W/m^2$)
				5	AE5	Solar irradiance (W/m^2)

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
				6	AE6	Laser Power (W)
				7	AE7	Laser frequency (Hz)
				8	AE8	Laser wavelength (nm)
		AF	Spectrophotometric	1	AF1	Reflectance/ Transmittance/ Absorbance, Wavelength
		AG	Colorimetric	1	AG1	Gloss
				2	AG1	Opacity
				3	AG1	Whiteness
		AH	Thermometry-Resistance Thermometry	1	AH1	SPRTs / PRT Without Indicator
				2	AH1	RTD, Pt-100 Without Indicator
				3	AH2	Thermistors Without Indicator
			Thermometry-Thermocouples	1	AH2	Thermocouple Without Indicator
			Thermometry-Simulation	1	AH3	Temperature Indicators Without Sensors (Source/Measure Simulation)
			Thermometry-Temperature Sensor/Transducer/Transmitter with Indicator (Thermometer With Indicator)	1	AH4	PRT With Indicator (Secondary/Industrial)
				2	AH4	RTD / Pt-100 With Indicator
				3	AH5	Thermocouple With Indicator
				4	AH6	Dial Temperature Gauge (Filled Bulb / Bimetallic)
				5	AH7	Temperature Datalogger with External Sensor
				6	AH7	Temperature Recorder with External Sensor
				7	AH7	Temperature Datalogger with internal Sensor
		AI	Thermometry-Glass Thermometers	1	AI1	Liquid-In-Glass Thermometers
		AJ	Thermometry-Closed Volume	1	AJ1	Oven (Multi Sensors according to volume)
				2	AJ1	Muffle (Multi Sensors according to volume)
				3	AJ1	Incubator (Multi Sensors according to volume)
				4	AJ1	Temperature Chambers (Multi Sensors according to volume)
				5	AJ1	Autoclave (Multi Sensors according to volume)
				6	AJ1	Liquid Bath(Multi Sensors according to volume)
				7	AJ2	Refrigerator (Multi Sensors according to volume)

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
				8	AJ2	Freezer (Multi Sensors according to volume)
				9	AJ3	Cold Rooms (Multi Sensors according to volume)
				10	AJ4	Oven (Working location) (single Sensor)
				11	AJ4	Muffle (Working location) (single Sensor)
				12	AJ4	Incubator (Working location) (single Sensor)
				13	AJ4	Temperature Chambers (Working location) (single Sensor)
				14	AJ4	Autoclave (Working location) (single Sensor)
				15	AJ4	Liquid Bath (Working location) (single Sensor)
				16	AJ5	Refrigerator (Working location) (single Sensor)
				17	AJ5	Freezer (Working location) (single Sensor)
				18	AJ5	Cold Rooms (Working location) (single Sensor)
				19	AJ6	Thermal mapping
		AK	**Thermometry-Radiation Thermometry**	**1**	AK1	Infrared thermometers
				2	AK2	Radiation Thermometers
		AL	**Thermometry-Thermometer Calibration Equipment(Temperature Source)**	**1**	AL1	Dry Block
				2	AL1	Liquid Bath
				3	AL2	Black Body
		AM	**Thermometry-Humidity**	**1**	AM1	Humidity Sensor With Indicator
				2	AM1	Humidity Transducer With Indicator
				3	AM1	Humidity transmitter With Indicator
				4	AM2	Hygrometer/Thermohygrometer (Digital/Analog)
				5	AM2	Temperature/Humidity Datalogger
				6	AM3	Climatic Chambers (Temperature/Humidity)
		AN	**General - Equipment**	**1**	AN1	NIBP -Non Invasive Blood Pressure
				2	AN2	Defibrillator
				3	AN3	Electrical Safety Analyzer Measurements
				4	AN4	Electrosurgical Unit
				5	AN5	Infant Incubator (Temperature, Relative Humidity, Air Flow and Noise)
				6	AN6	Infusion Syringe Pum

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
				7	AN7	Ventilator
				8	AN8	Phototherapy
				9	AN9	Electrical properties: (Voltage, Earthlings, Leakage …) Medical safety tool
				10	AN10	Particle size analyzer
				11	AN11	Particle counter devices
				12	AN12	Gas analyzers
				13	AN13	Moisture analyzers
				14	AN14	PH meter
				15	AN15	Conductivity meter
				16	AN16	Automatic Micro Distillation Apparatus
				17	AN17	Automatic Freezing Point Meter
				18	AN18	Automatic Pour Point Meter
			Other Scope (please specify)			

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
2	Testing	A	Chemical	1	A1	Wet Chemistry
				2	A2	Spectroscopy
				3	A3	Chromatography
				4	A4	Surface Analysis Techniques
				5	A5	Electrochemical (pH)
				6	A6	Electrochemical (Conductivity)
				7	A7	Thermal Analysis
				8	A8	Fire and Combustion Tests
				9	A9	Corrosion
				10	A10	Microscopy (Optical)
				11	A11	Microscopy (Electron)
				12	A12	Microscopy (Atomic force)
				13	A13	Clinical Chemistry
		B	Physical	1	B1	Density
				2	B2	Viscosity
				3	B3	Particle size
				4	B4	Porosity
				5	B5	Colligative properties
				6	B6	Geometric Tests (Length measure)
				7	B7	Geometric Tests (dimension)
				8	B8	Geometric Tests (thickness)
				9	B9	Optical Properties (Luminance, Refract index, …)
				10	B10	Visual Characteristics (Color, …)
				11	B11	Washability
				12	B12	Fineness
				13	B13	Melting point
				14	B14	Flash point
				15	B15	Melt flow rate
				16	B16	Suspended Solids
				17	B17	Glow Wire
				18	B18	Non-Destructive Testing (NDT)
		C	Mechanical	1	C1	Tensile
				2	C2	Compression
				3	C3	Shear
				4	C4	Torsion
				5	C5	Fracture
				6	C6	Impact Resistance
				7	C7	Hardness
				8	C8	Material properties
				9	C9	Metallography
				10	C10	Fatigue
				11	C11	Pressure (Switches)
				12	C12	Pressure (Safety/relief valves)

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
				13	C12	Pressure (valves)
				14	C13	Pressure (Pumps)
				15	C14	Hydrostatic/Hydraulic Pressure (Hoes)
				16	C14	Hydrostatic/Hydraulic Pressure (vessels)
				17	C14	Hydrostatic/Hydraulic Pressure (pipes)
				18	C15	Bending
				19	C16	Friction
				20	C17	Coating Thickness
		D	**Electrical**	**1**	D1	Resistance
				2	D2	Current
				3	D3	Voltage
				4	D4	Electromagnetic Compatibility EMC
		E	**Environmental**	**1**	E1	Potable Water (organisms)
				2	E1	Potable Water (organic …)
				3	E2	Non-potable (Sea Water)
				4	E2	Non-potable (Irrigation …)
				5	E3	Mineral Water
				6	E4	Waste Water (industrial)
				7	E4	Waste Water (agricultural)
				8	E5	Water Sediments & Mussels
				9	E6	Solid/Hazardous Waste
				10	E7	Lead
				11	E8	Asbestos
				12	E9	Air [Chemical (content]
				13	E10	Air [Chemical (contamination)]
				14	E11	Air [Physical (particles)]
				15	E12	Air [Physical (color)]
				16	E13	Air [Physical (density)]
				17	E14	Air [Physical (dust)]
				18	E15	Light
				19	E16	Heat Stress
				10	E17	Acoustics
				11	E18	Vibration
		F	**Biological**	**1**	F1	Virology
				2	F2	Bacteriology
				3	F3	Biology
				4	F4	Immunology
				5	F5	Molecular Biology
				6	F6	Parasitology
				7	F7	Mycology
		G	**Radioactivity/ radiation**	**1**	G1	Radioactivity Analysis
				2	G2	Radiation Dose Measurement
		H		**1**	H1	Concrete

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
			Construction Material	2	H2	Cement
				3	H3	Masonry
				4	H4	Bituminous Materials
				5	H5	Asphalts, Road Oils, & Tars
				6	H6	Lime and Limestone
				7	H7	Marble
				8	H8	Soils
				9	H9	Doors & windows (Frames, Locks …)
				10	H10	Gypsum
				11	H11	Aggregate
				12	H12	Ceramics
		I	General Products	1	I1	Adhesives and sealants
				2	I2	Fasteners
				3	I3	Agricultural
				4	I4	Animal Products
				5	I5	Foods (animal)
				6	I6	Foods (vegetal food)
				7	I7	Foods (dietary)
				8	I8	Foods (beverages)
				9	I9	Animal Feeds
				10	I10	Additives & Supplements
				11	I11	Fertilizers
				12	I12	Residues in food and agricultural products
				13	I13	Herbicides, Insecticides, & Pesticides
				14	I14	Seeds & Grains
				15	I15	Soil and Plant Analysis
				16	I16	Fuels: (Gaseous)
				17	I17	Fuels: (Liquid)
				18	I18	Fuels: (Solid)
				19	I19	Petroleum Products
				20	I20	Coal
				21	I21	Lubricants
				22	I22	Soap & Detergents
				23	I23	Drugs
				24	I24	Ferrous Metals
				25	I25	Non Ferrous Metals
				26	I26	Polymers (Plastics, …)
				27	I27	Rubber
				28	I28	Leather
				29	I29	Paints and Varnishes
				30	I30	Textile, Fabrics
				31	I31	Floor Covering (Carpet, ….)
				32	I32	Pharmaceutics

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
				33	I33	Paper
				34	I34	Cigarettes & Tobacco
				35	I35	Wood
				36	I36	Glass
				37	I37	Ores
				38	I38	Coating
				39	I39	Cables (Electrical)
				40	I40	Cables (Telephone)
				41	I41	Cables (LAN)
				42	I42	Cables (Fiber Optics)
				43	I43	Insulations Cables
				44	I44	Car Spare parts
				45	I45	Home Appliances
				46	I46	Fire Protection Equipment
				47	I47	Telecommunication Equipment (TV & Radio)
				48	I48	Air Conditioners
				49	I49	Printing Material (Ink, Dye, …)
				50	I50	Foam & Packing Materials
				51	I51	Cosmetics
				52	I52	Fats & Oils
				53	I53	Toys
				54	I54	Precious Metals
				55	I55	Food Contact Materials
				56	I56	Meters (Electrical)
				57	I57	Meters (Water)
				58	I58	Meters (Gas)
				59	I59	Transformer
				60	I60	Tire & wheel
				61	I61	Drinking (Cups, Accessories, bottles, …..)
				62	I62	Batteries
				63	I63	House holding
				64	I64	Switches, plugs and Sockets
				65	I65	Lamps
				66	I66	Luminaires & Electrical components (Phototherapy, ….)
				67	I67	Circuit Breaker
				68	I68	Spark plug
				69	I69	Glow Plug
				70	I70	Filter (Oil)
				71	I71	Filter (Air)
				72	I72	Footwear
				73	I73	Motor
				74	I74	Magnet Wire
				75	I75	Gas Detectors

No	Field	Discipline		Sub- Discipline		
		Code	Name	Code	Group	Name
				76	I76	Cutlery and Table Houseware
				77	I77	Pressure cookers
			Other Scope (please specify)			

No	Fields	Major Discipline		Sub-Discipline	
		Code	Name	Code	Name
5	Medical Laboratories	A	Clinical Chemistry	1	Routine Chemistry
				2	Blood gases
				3	Hormones
				4	Vitamin assays
				5	Protein electrophoresis
				6	Special proteins
				7	amino acids
				8	Drug assay
				9	Clinical toxicology
				10	Toxic metals
				11	Tumor markers
				12	Emergency Clinical Chemistry
		B	Hematology	1	Routine hematology (CBC, HB, TLC.)
				2	Specialized Hematology (CBC with Film)
				3	Bone marrow examination
				4	Immunohematology
		C	Coagulation	1	Coagulation tests
				2	Platelet function tests
				3	Coagulation Factors
				4	Bleeding and clotting
		D	Specialized Hematology	1	Hemostasis and thrombosis
				2	Hemoglobin electrophoresis
				3	Thalassemia
				4	Hemoglobinopathies
				5	Hemoparasites
		E	Flow cytometry	1	Leukemia and Lymphoma Immunophenotyping
				2	Lymphocyte subsets
				3	Cell cycle analysis
				4	Flowcytometry tests (CDs count)
		F	Immunology	1	Routine Immunology
				2	Immunoglobulin and complement assay
				3	Autoantibodies assay
				4	Cellular function
				5	Immunofixation electrophoresis
				6	Isoelectric focusing
				7	Tissue typing (HLA)
				8	Hepatitis antibodies
5		G	Serology	1	Serology for infectious diseases
				2	Serology for parasitic diseases
				3	Antibodies to COVID-19
				4	Antibodies to Measles and mumps
				5	Hepatitis
				6	Mononucleosis
				7	Autoimmune
		H	Microbiology	1	Clinical Bacteriology
				2	Mycology
				3	Tuberculosis
				4	Mycobacteriology

				5	Virology (Culture)
		I	Molecular Biology	1	Molecular microbiology
				2	Molecular Chemistry
				3	Molecular Hematology
				4	Molecular Immunology
		J	Molecular Diagnostics	1	Microarray tests
				2	Next Generation Sequencing tests
				3	DNA sequencing tests
				4	Other tests
		K	Genetics	1	Molecular genetics
				2	Immunogenetics
				3	Metabolic Genetics
				4	General Genetics
				5	Pediatric Genetics
				6	Prenatal Genetics
		L	Anatomic Pathology	1	Histopathology (Processing, H&E stain)
				2	Histopathology (Special stains)
				3	Intraoperative frozen section
				4	Cytopathology
				5	Gynecologic
				6	Non-gynecologic
				7	Fine needle aspiration
				8	Immunohistochemistry
				9	Molecular Pathology
				10	Immuoflorescence
				11	Electron microscopic examination
5		M	Hematopathology	1	Routine (Processing, H&E stain)
				2	Special stains
				3	Immunohistochemistry
		N	Metabolic Disorders	1	Metabolite analysis
				2	Enzymology
				3	Newborn screening
				4	Phenylketonuria (PKU)
		O	Clinical Cytogenetic	1	Conventional Cytogenetic (on Blood sample)
				2	Conventional Cytogenetic (on Bone marrow sample)
				3	Conventional Cytogenetic (on Amniotic fluid sample)
				4	Fluorescent In-Situ Hybridisation (Amniotic fluid)
				5	Fluorescent In-Situ Hybridisation (Blood & Bone marrow)
				6	Pre-implantation genetic testing
				7	Chromosome breakage
		P	Clinical Toxicology	1	Drug assay (therapeutic drug monitoring ; TDM)
				2	Narcotic Testing (screening & confirmation)
				3	Pesticide screening
				4	Heavy Metal & Trace element assays

				5	Toxicological screen
		Q	Blood Transfusion	1	Immunohematology (ABO group and Rh type)
				2	Antibody Detection and identification
				3	Compatibility testing
				4	Nucleic acid testing (NAT)
				5	Molecular
		R	Parasitology	1	Semen tests
				2	Stool analysis
				3	Urine analysis
				4	Blood parasites
				5	Occult Blood Test (FOBT)
		S	Point of care testing	1	Blood gases
				2	Blood Glucose
				3	Urease
				4	Toxicological screen
				5	Urine strip tests
				6	Intra-arterial needle puncture
				7	Oxygen saturation tests
				8	Hemo-Screen test

No	Fields	Code	Major Discipline	Code	Sub- Discipline
10	**Forensic Examination**	**A**	**Controlled/non-controlled Substances**	1	Botanical material
				2	Controlled pharmaceutical and drugs
				3	Related chemicals and paraphernalia
		B	**Fingerprints**	1	Fingerprints and finger marks
				2	Palm prints
				3	Footprints
		C	**DNA Analysis**	1	Animal DNA profiling
				2	DNA profiling
				3	Parentage testing
				4	Body fluid identification
				5	Mitochondrial DNA profiling
		D	**Forensic Medicine**	1	Cause of death determination
				2	Examination of Injuries
				3	Odontology
				4	Crime Scene Investigators
				5	Violence clinic
		E	**Forensic Pathology**	1	Histopathology
				2	Immunohistochemical Examination
				3	Tissue Sample Selection
				4	Toxin- and – Drug Induced Pathologies
				5	Histopathology Special Intoxications
				6	Alcohol Related Histopathology
				7	Effect of Heat, Fire, Electricity, Lightning, Radiation and Gases
		F	**Autopsy**	1	Post Mortem Examination
				2	Characterize The Extent of Disease States
				3	Identify of Disease States
					Cause and Manner of Death
		G	**Toxicology**	1	Alcohol
				2	Pharmaceutical products
				3	Drugs
				4	Cigarettes & Tobacco
				5	Poisons
		H	**Trace Evidence**	1	Acids
				2	Alkalis
				3	Botanical material
				4	Components of technical or household appliance
				5	Dyes and pigments
				6	Feeding stuffs and ancillary items
				7	Fibers and hair

				8	Soils
				9	Plastics
				10	Corrosives
				11	Arson & fire evidence
				12	Corrosives Cosmetics
				13	Fertilizers
				14	Electrical devices and components
				15	Explosives and explosion debris
				16	Pyrotechnic devices
				17	Food
				18	Glass
				19	Lubricants and spermicidal agents
				20	Pyrotechnic devices
				21	Paints
				22	Lachrymatory chemicals
				23	Oils and greases
				24	Light filaments
				25	Hydrocarbon fuels
				26	Manufacturers marks
				27	Firearm discharge residues
				28	Clothing/garments
		I	**General Materials**	1	Adhesives and sealants
				2	Fasteners
				3	Agricultural
				4	Animal Products
				5	Soil and Plant Analysis
		J	**Food Toxicology**	1	Foods (animal & vegetal food, dietary, beverages)
				2	Animal Feeds
				3	Additives & Supplements
				4	Fertilizers
				5	Residues in food and agricultural products
				6	Herbicides, Insecticides, & Pesticides
				7	Mineral Water
				8	Seeds & Grains
		K	**Fuels**	1	Gaseous, Liquid, Solid
				2	Petroleum Products
				3	Coal
				4	Lubricants
				5	Oil & Soap
		L	**Metals**	1	Ferrous Metals
				2	Non Ferrous Metals
				3	Plastics & Polymers

				4	Rubber & rubber products
				5	Leather
				6	Paint
				7	Textile
				8	Carpet & Floor Covering
				9	Paper
		M	**General Materials**	1	Wood
				2	Glass
				3	Coating
				4	Electrical Cables & Insulations
				5	Car Spare parts
				6	Home Appliances
				7	Fire Protection Equipment
				8	Telecommunication Equipment (TV & Radio)
				9	Air Conditioners
				10	Lighting
				11	Foam & Packing Materials
		N	**Environmental Tests**	1	Potable Water (organisms, organic)
				2	Non-potable (Sea Water, Irrigation)
				3	Fertilisers Waste Water (industrial, agricultural)
				4	Water Sediments & Mussels
				5	Radiochemistry
				6	Solid/Hazardous Waste
				7	Lead
				8	Pyrotechnic devices
				9	Air [Chemical (content, contamination) & Physical (particles, color, density)
		O	**Scene Investigation**	1	Scene of crime investigation
				2	Fire investigation
				3	Blood pattern analysis
				4	Bullet trajectory
				5	Photography
				6	Chemical, Biological, Radioactive, Nuclear
		P	**Handwriting and Document Examination**	1	Copiers and copied material
				2	Handwriting
				3	Inks and printing materials
				4	Printers and other printed objects
				5	Security marks
				6	Embossing and embossed materials
				7	Indentations paper
				8	Rubber stamps
				9	Typewriters and typewritten material
		Q	**Firearms and ballistics**	1	Bullets and cartridges
				2	Gunshot residue

				3	Entomology, Botany, Archaeology, Anthropology
				4	Firearms
				5	Stun Guns
				6	Arson – Fire Investigation
				7	Distance determination
				8	Database (NIBIN, others)
				9	Serial number restoration
				10	Ammunition
		R	**Digital Analysis**	1	Speech, audio and video analysis Biometrics
				2	Computers (hardware and software)
				3	Image enhancement
				4	Recovery of information from electronic devices and media
				5	Automated skull reconstruction and aging simulation
				6	CCTV
				7	Facial Mapping
				8	Mobile computerized devices (including phone, GPS, PDA)
		S	**Marks and Impressions**	1	Damage examination
				2	Glove marks
				3	Shoe marks
				4	Tyre mark
				5	Fabric impression
				6	Non-friction ridge body marks Tool
				7	marks and impressions
		T	**Vehicles and Vehicle Accident Investigation**	1	Component failures including light bulbs
				2	Electrical failures
				3	Speed calculations
				4	Trajectory determination
				5	Car immobilizer systems
				6	Erased markings
				7	Tachograph charts
				8	Tyre examination
		W	**Entomology, Botany, Archaeology, Anthropology**	1	Entomology, Botany, Archaeology, Anthropology
		X	**Environment. Safety**	1	Environmental protection
				2	Wastes
				3	Air quality
				4	Water quality
				5	Soil quality
				6	Occupational safety

				7	Safety of machinery
				8	Domestic safety
				9	Noise
				10	Accident and disaster control
				11	Protection against fire
				12	Explosion protection
				13	Protection against pressure
				14	Protection against electric shock
				15	Radiation protection
				16	Prot. against dangerous goods
				17	Protection against crime
				18	Alarm and warning systems
				19	Protective equipment