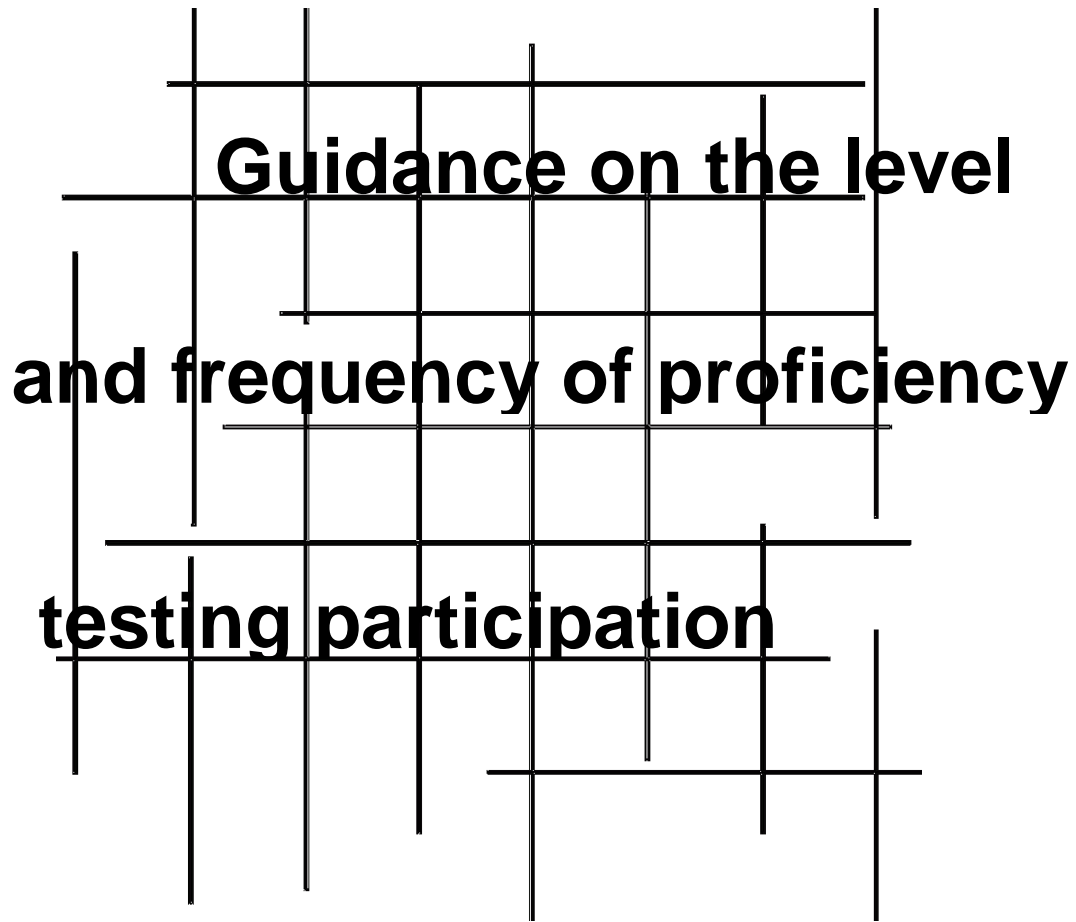

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Guidance on the level and frequency of proficiency testing participation

PURPOSE

The aim of this paper is to promote harmonization between Accreditation Bodies on how the level and frequency of participation in PT is evaluated and to assist laboratories in determining their own levels and frequency of participation.

Authorship

The publication has been written by the EEE-PT Working Group “Proficiency Testing in Accreditation”.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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1. Introduction

The standard ISO/IEC 17025:2005 *General Requirements for the competence of testing and calibration laboratories* (sub-clause 5.9) establishes that the *laboratory shall have quality control procedures for monitoring the validity of tests results and that this monitoring shall be planned*. Among others, the standard refers to participation in Proficiency Testing (PT) as one of the tools laboratories may use to achieve this objective.¹

ISO/IEC 17011:2004 *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*, the standard to which ILAC MLA Signatories are required to operate, requires that “*The accreditation body shall ensure that its accredited laboratories participate in proficiency testing or other comparison programmes, where available and appropriate, and that corrective actions are carried out when necessary. The minimum amount of proficiency testing and the frequency of participation shall be specified in cooperation with interested parties and shall be appropriate in relation to other surveillance activities.*”²

In addition EA³ and ILAC⁴ have established specific policies regarding participation of laboratories in PT activities. This paper, which has been prepared by the joint stakeholder working group, EEE-PT, on Proficiency Testing is the result of extensive discussions and helps the accreditation bodies in their implementation of these policies. The paper also aims to promote harmonization between accreditation bodies on how the level and frequency of participation in PT is evaluated and to assist laboratories in determining their own levels and frequency of participation.

*Note: This document is also applicable to medical laboratories and when used in such instances reference to ISO/IEC 17025 should be read as ISO 15189.*⁵

¹ ISO/IEC 17025:2005 General Requirements for the competence of testing and calibration laboratories

² ISO/IEC 17011:2004 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies

³ EA-2/10 (Current Version) - EA policy for participation in national and international proficiency testing activities

⁴ ILAC-P9 (Current Version) - ILAC Policy for Participation in National and International Proficiency Testing Activities

⁵ ISO/IEC 15189:2007 Medical laboratories. Particular requirements for quality and competence

2. Terms and Definitions

Proficiency Testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons⁶

Interlaboratory Comparison: organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions⁶

Measurement Technique: The process of testing/calibrating/identifying the property, including any pre-treatment required to present the sample, as received by the laboratory, to the measuring device. (e.g. ICP-MS, Rockwell Hardness, PCR, Microscopy, Force Measurement)

Property: The quantity being measured (e.g. Arsenic, Fat, Creatinine, Length, Hardness, Force)

Product: The item that the measurement technique is being applied. (e.g. Soil, Vegetables, Serum, Polystyrene, Concrete)

Level of Participation: The number of sub-disciplines that an organisation identifies within its scope, and therefore the number of specific proficiency tests that should be considered for participation

Frequency of Participation: This is how often a laboratory determines that it needs to participate in PT for a given sub-discipline, this may vary from sub-discipline to sub-discipline within a laboratory and between laboratories with the same sub-disciplines

Sub-discipline: An area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related. (e.g. Determination of Arsenic in soil by ICP-MS)

3. General Aspects

The following aspects should be taken into consideration by accreditation bodies when determining the suitability of a laboratory's "frequency" and "level" of participation in proficiency testing:

- (1) The laboratory should define its level and frequency of participation after careful analysis of its other QA measures (especially those that are able to disclose, quantify and follow the development of bias of a stated magnitude). The participation should be made dependent on the extent to which other measures have been taken. Other types of QA include, but are not limited to:
 - Regular use of (certified) reference materials
 - Comparison of analysis by independent techniques
 - Participation in method development/validation and/or reference material characterisation studies
 - Use of internal quality control measures
 - Other Inter/Intra – Laboratory Comparisons e.g. Analysis on blind samples within the laboratory

⁶ ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing

- (2) The level of risk presented by the laboratory, the sector in which they operate or the methodology they are using. This can be determined, for example, by considering:
 - Number of tests/calibrations/measurements undertaken
 - Turnover of technical staff
 - Experience and knowledge of technical staff
 - Source of Traceability (e.g. availability of reference materials, national standards, etc.)
 - Known stability/instability of the measurement technique
 - Significance and final use of testing/calibration data (e.g. forensic science represents an area requiring a high level of assurance)
- (3) Different types of PT that can be used by laboratories and should be accepted by accreditation bodies, include:
 - PT organised by other independent organisations such as accreditation bodies or organisations such as ILAC, EA, APLAC and IRMM
 - ILC organised by a sufficient number of laboratories as a one off or continual exercise
 - Submission of an internal sample or object to another or more external laboratories for the purposes of data comparison
- (4) It must be recognised that there are sectors where participation in PT may be difficult, due to the technical characteristics of the measurement, the lack of PT schemes, the low number of existing laboratories in the sector, etc. For some fields PT may only be possible or economically feasible for parts of the test/calibration undertaken (i.e. EMC tests on simple objects for a limited number of quantities to be measured). In these areas the suitability of other QA/QC measures is paramount.
- (5) Any legislative requirements for frequency of type of PT participation.

4. Level and Frequency of Participation

The first step for the laboratories should be to identify the sub-disciplines that apply to them for the tests/calibrations for which they are accredited.

Ideally a laboratory would participate in a specific PT for every measurement technique it uses and for every property measured in every product. However it is acknowledged that this is unlikely to be feasible, both logistically and economically. Therefore accreditation bodies should expect laboratories to identify groups of sets of measurement techniques, properties and products on which the outcome of a PT for one of these sets can be directly correlated to the others sets of measurement techniques, properties and products contained within the group. These groups of sets of measurement techniques, properties and products are termed a sub-discipline.

A sub-discipline, as defined above, may contain more than one measurement technique, property or product as long as equivalence and comparability can be demonstrated. The first consideration for a laboratory, when determining a sub-discipline, is that it should generally not contain different technical competences. Different technical competences can usually be identified by the need for different qualifications, training, and use of different equipment, knowledge or experience.

When determining a sub-discipline it may be helpful to consider a stepwise approach working up from measurement technique through properties to products. This is because it is more likely that there will be several products and/or properties associated with one measurement technique within a given sub-discipline than vice versa:

- (i) With reference to the **measurement technique**: It is possible but not common to include different measurement techniques in the same sub-discipline.
- (ii) With reference to the **property** to be measured, determined or identified: It may be possible to include more than one property (parameter) in the same sub-discipline.
- (iii) With reference to **products** to be tested: It may be possible to include different products in the same sub-discipline provided that the matrices, objects or materials included, are of equivalent nature.

When a laboratory determines that more than one measurement technique, property or product is classified under the same sub-discipline, accreditation bodies should evaluate whether a laboratory can justify and demonstrate equivalence. This can usually be done by e.g.:

- The method validation data, or,
- Use of the same standard method

Once the laboratory has defined its sub-disciplines the “level of participation” can be deemed to have been defined. Accreditation bodies will also need to evaluate the suitability of a laboratories “frequency” of participation, based on level of risk and should expect a minimum frequency of participation for each sub-discipline to be set by the laboratory.

It should also be considered that according to ISO/IEC 17025:2005 (5.9.1) the laboratory should have quality control procedures (of which PT is one) and that these should be planned. Therefore, once the “level” and “frequency” of participation is established, laboratories should be expected to develop a proficiency testing strategy which takes into account those factors highlighted in “General Aspects” points 1-5. The extent and content of this strategy will depend upon the circumstances and scope of the individual laboratory. This should form part of the laboratory’s overall quality control strategy.

It is recommended that the strategy covers, at least, one accreditation cycle (period between full reassessments), and that this strategy is reviewed by the laboratory for its suitability on an annual basis, usually during the formal management review.

The classification of sub-disciplines may be different for every laboratory. For this reason, accreditation bodies should expect laboratories to be able to justify the technical arguments that have led to the laboratories decision on the “level” and “frequency” of participation in PT. It is recommended that laboratories document this justification.

5. Case Studies

It is for each individual laboratory to consider how many sub-disciplines will adequately cover the scope of their work and thus define their “level” and “frequency” of participation in PT, which should be detailed in their PT strategy. A number of case studies have been provided to illustrate how a laboratory might review their scope of work and thus derive the number of sub-disciplines. However, these case studies are only examples of how this could be approached and should not be regarded as strict and definitive; it is for the accreditation body to discuss with each individual laboratory their PT strategy, on a case by case basis.

Case Study 1 – Environmental Chemistry Testing Laboratory

Accredited testing activities performed by the laboratory:

- Polychlorinated Biphenyls (PCB) by GC-MS in Soils and Sewage Sludge
- Polyaromatic Hydrocarbons (PAH) by GC-MS in Soils and Sewage Sludge
- Volatile Organic Compounds (VOC) by Purge and Trap GC-MS in Waters
- Metals by ICP-MS in Soils, Sewage Sludge and Waters
- pH in Soils, Sewage Sludge and Waters

Considerations for determinations of sub-disciplines:

For pH the laboratory identifies that it utilises the same standard ISO Method for all three matrices (Soils, Waters and Sewage Sludges). This ISO Method has been validated against all three matrices and therefore the laboratory identifies this as one sub-discipline

For the analysis of metals the laboratory identifies that it uses the same measurement technique (ICP-MS) for all three matrices (Soils, Waters and Sewage Sludge). However, the preparation of Water samples compared to Soils and Sewage Sludges is significantly different. As such the laboratory identifies that it cannot declare this as one sub-discipline, but as the methodologies for soils and sewage sludge are demonstrably comparable they can be. Therefore the laboratory identifies two more sub-disciplines

For PAH and PCB analysis the laboratory identifies that it uses the same measurement technique (GC-MS) and the extraction of the matrices (Soils and Sewage Sludge) is identical for both matrices. However, via its initial validation of the methods it is apparent that PCB and PAH are effected in different ways by variations in the methodology and therefore acceptable performance or problematic performance on PCB would not necessarily mean the same for PAH (and vice versa). Therefore the laboratory identifies two more sub-disciplines

For its VOC method the laboratory only has one matrix (water) to consider. However the laboratory is aware that the method analyses several different properties that could potentially react in different ways to problems with the method. Through its method validation data the laboratory has demonstrated that the differing properties react in comparable ways to variations in the method. Therefore the laboratory identifies one more sub-discipline.

Resulting sub-disciplines from this exercise:

- Polychlorinated Biphenyls (PCB) by GC-MS in Soils and Sewage Sludge
- Polyaromatic Hydrocarbons (PAH) by GC-MS in Soils and Sewage Sludge
- Volatile Organic Compounds (VOC) by Purge and Trap GC-MS in Waters
- Metals by ICP-MS in Soils and Sewage Sludge
- Metals by ICP-MS in Waters
- pH in Soils, Sewage Sludge and Waters

Case Study 2 – Microbiology Testing Laboratory

Accredited testing activities performed by the laboratory:

- Enumeration of *Escherichia coli* in meat
- Enumeration of *Salmonella* in meat
- Enumeration of *Escherichia coli* in vegetables
- Enumeration of *Salmonella* in vegetables
- Enumeration of *Escherichia coli* in dairy products
- Enumeration of *Escherichia coli* in drinking water
- Enumeration of *Escherichia coli* in swimming pool water

Considerations for determinations of sub-disciplines:

For the enumeration of *Escherichia coli*, the laboratory identifies that it uses the same method for the analysis of meat samples and for vegetable samples. This method has been validated for these two sample matrix types and therefore the laboratory identifies this as one sub-discipline. However, this method has not been validated for dairy products and the laboratory uses a different method for such sample types. Thus this is identified as an additional sub-discipline.

The laboratory uses a different method for the enumeration of *Salmonella*, from that which it uses for the enumeration of *Escherichia coli*. However, it has been validated for both meat and vegetable matrices, and thus the laboratory identifies this as one additional sub-discipline.

For the enumeration of *Escherichia coli* in water, although different sampling and pre-treatment techniques are used for the collection of the samples, the method used (which is different to that used for the food products) has been validated for both drinking water and swimming pool water, so this has been identified as one additional sub-discipline.

Resulting sub-disciplines from this exercise:

- Enumeration of *Escherichia coli* in meat and vegetables
- Enumeration of *Escherichia coli* in dairy products
- Enumeration of *Salmonella* in meat and vegetables
- Enumeration of *Escherichia coli* in drinking water and swimming pool water

Case Study 3 – Clinical Testing Laboratory

Accredited testing activities performed by the laboratory:

- Screening for drugs of abuse in blood by ELISA and Liquid EIA
- Screening for drugs of abuse in urine by ELISA and Liquid EIA
- Confirmation of Amphetamine in blood and urine by GC-MS
- Confirmation of Amphetamine in urine by GC-MS
- Confirmation of Codeine in blood by GC-MS
- Confirmation of Codeine in urine by GC-MS
- Confirmation of Diazepam in blood by LC-MS-MS
- Confirmation of Diazepam in urine by LC-MS-MS
- Confirmation of Cocaine in blood by LC-MS-MS
- Confirmation of Cocaine in urine by LC-MS-MS
- Confirmation of EDDP in blood by LC-MS-MS
- Confirmation of EDDP in urine by LC-MS-MS
- Confirmation of Buprenorphine in blood by GC-MS-MS
- Confirmation of Buprenorphine in urine by GC-MS-MS
- Confirmation of Tetrahydrocannabinol in blood by GC-MS-MS
- Confirmation of Tetrahydrocannabinol in urine by GC-MS-MS

Considerations for determinations of sub-disciplines:

The two methods used for the screening for drugs of abuse are different, however both have been validated for use with both blood and urine samples. Thus the laboratory identifies these as two sub-disciplines.

The three techniques used for the confirmation of various drugs of abuse are very different, although each has been validated for both blood and urine matrices. Furthermore each different detection system is considered to belonging to a separate sub-discipline. The drugs, although coming from different families of products, are considered as equivalent from a competence point of view. Thus the laboratory identifies that their confirmation tests consist of three additional sub-disciplines.

Resulting sub-disciplines from this exercise:

- Screening for drugs of abuse in blood and urine by ELISA
- Screening for drugs of abuse in blood and urine by Liquid EIA
- Confirmation of Amphetamine and Codeine in blood and urine by GC-MS*
- Confirmation of Diazepam, Cocaine and EDDP in blood and urine by LC-MS-MS*
- Confirmation of Buprenorphine and Tetrahydrocannabinol in blood and urine by GC-MS-MS*

*Note: although the different drugs have been combined into one sub-discipline for each detection system in terms of being equivalent from a competency point of view, this does not suggest that they are equivalent in terms of method and laboratory performance. Therefore, the laboratory would be expected to undertake such PTs specifically covering all the drugs in their scope on a periodic basis. This would be expected to be clearly detailed in their proficiency testing strategy.

Case Study 4 – Physical Testing Laboratory

Accredited testing activities performed by the laboratory:

- Fracture toughness and fatigue crack growth of metals and metal alloys (ASTM E 399)
- Tensile and compression testing of metals and metal alloys (example: EN 10002 part 1)
- Tensile and compression testing of plastics (ISO 527-1)
- Hardness test according to Brinell (ISO 6506), Vickers (ISO 6507), and Rockwell (ISO 6508)
- Charpy impact test according to ISO 148-1
- Determination of grain size (ISO 643)
- Optical emission spectrometry (Quantification of chemical elements in steel matrix, in house procedure)

Considerations for determinations of sub-disciplines:

Many accredited laboratories perform these named activities in the field of mechanical testing. ISO, EN or ASTM standards describe the test methods. The standards usually define the required equipment and other test related parameters. The named test activities are performed using the same or different types of equipment requiring a specific calibration status and specific knowledge of the staff performing these tests.

Fatigue crack growth and fracture toughness uses the same measurement technique and the method (ASTM E 399) has been validated for metals and metal alloys. Therefore, the laboratory identifies this as one sub-discipline.

Tensile testing and compression testing for metals and metal alloys are based on the same measurement technique. However, the testing of fatigue crack growth encompasses the measurement capability of tensile/compression testing and so the laboratory has identified no need to undertake additional PTs for metals and alloys. (Note: participation in a PT for tensile and compression testing would not be sufficient to cover the testing of fatigue crack growth). Usually specific testing machines with different load capacities are used for flat or round specimen. Basic requirements are on the load measurement, class 1 ($\pm 1\%$), and measurement of elongation ($\pm 1\%$). The calculation of the results of these test methods are actually done by computer systems, which are set up by the manufacturer of the machine or by the user who has access to the software. Basically, the strength and the elongation of steel are determined in this test. For specific materials, the machining of the specimen is critical for the behaviour of the material and the related results.

For tensile test on plastics a similar test system can be used, but usually a lower load capacity is necessary. The supplementary equipment is different because of the high ductility of plastics. Additionally, the definitions of the parameters which are determined are different in ISO 527. The equipment must be calibrated once a year, the use of reference material is limited to a small number of laboratories. Therefore, the laboratory identifies this as an additional sub-discipline since this uses a different method.

In the hardness tests according to Brinell (ISO 6506), Vickers (ISO 6507), a ball or a pyramid is used to make an indentation in a surface of a steel material. After this step, the diagonals of the indentation are measured and the hardness of the material is calculated. In the related ISO 6506-1 and 6507-1 series, the requirements on the direct calibration status of the equipment (load, indenter, length measurement device) are defined. They must be repeated once a year, and the use of certified reference material prior to a test is mandatory. Thus the laboratory identifies an additional sub-discipline for these two methods.

The Rockwell (ISO 6508-1) hardness test uses a different measurement procedure compared to Brinell and Vickers. According to ISO 6508 different types of indenters can be used to make an indentation on a metals surface under pre- defined loading conditions. In this test the depth of the indentation is measured using the specific test procedure. The ISO standard requires calibration and the use of certified reference material. Therefore this is identified as an additional sub-discipline by the laboratory

The Charpy impact test standard, ISO 148-1, defines the specimen dimensions. The test equipment is calibrated once a year, and the Standard requires additionally specific reference material for indirect calibration of the whole test setup. The impact energy is measured. Thus another sub-discipline is identified by the laboratory

For the determination of grain size (ISO 643), the surface of a steel is prepared in a specific way, grinding, polishing, etching to mark the grain boundaries of the material. After this preparation step, a microscope with calibrated magnification is used to measure the size of the grains and calculate the relevant parameters according to the standard. The laboratory identified this as another sub-discipline.

Optical emission spectrometry is used by many laboratories to identify steel alloys. Certified reference materials and secondary in-house standards are used to calibrate the equipment. This is identified by the laboratory as an additional sub-discipline.

Resulting sub-disciplines from this exercise:

- Fracture toughness and fatigue crack growth of metals and metal alloys
- Tensile test on plastics
- Hardness test by Brinell or Vickers
- Hardness test by Rockwell
- Charpy impact test
- Determination of grain size
- Optical emission spectrometry

Case Study 5 – Matrix Approach (Clinical Chemistry)

Accredited testing activities performed by the laboratory:

- FSH by Chemiluminescence in blood
- LH by Chemiluminescence in blood
- Folic acid by Chemiluminescence in blood
- Calcium by Electrochemistry in blood and urine
- Potassium by Electrochemistry in blood and urine
- Cryoglobulins by Electrophoresis in blood
- Carbamazepine by Immunoassay in blood
- Ciclosporin by Immunoassay in blood
- Transferrin by Nephelometry in blood and urine
- α 2 Macroglobulin by Nephelometry in blood and urine
- ALAT by UV-Visible spectroscopy in blood
- ASAT by UV-Visible spectroscopy in blood
- Magnesium by UV-Visible spectroscopy in blood and urine

Considerations for determinations of sub-disciplines:

In order to determine its sub-disciplines, the laboratory should list all the measurement techniques it uses within its scope, all the properties, which can be individual parameters or groups of equivalent parameters, and all the products, as shown below.

Measurement techniques

Chemiluminescence
Electrochemistry
Electrophoresis
Immunoassay
Nephelometry
UV-Visible spectroscopy

Properties

Drugs (Carbamazepine, Ciclosporin)
Electrolytes (Calcium, Potassium, Magnesium)
Enzymes (ALAT, ASAT)
Hormones (FSH, LH)
Specific proteins (Cryoglobulin, Transferrin, α 2Macroglobulin)
Vitamins (Folic acid)

Products

Blood
Urine

List of analyses:

From the listed measurement techniques, properties and products, the laboratory should, for each individual parameter, link the parameter to one measurement technique, one property and one product, as shown in the table below.

Parameter	Measurement technique	Property	Product
FSH	Chemiluminescence	Hormones	Blood
LH	Chemiluminescence	Hormones	Blood
Folic acid	Chemiluminescence	Vitamins	Blood
Calcium	Electrochemistry	Electrolytes	Blood
Calcium	Electrochemistry	Electrolytes	Urine
Potassium	Electrochemistry	Electrolytes	Blood
Potassium	Electrochemistry	Electrolytes	Urine
Cryoglobulins	Electrophoresis	Specific Proteins	Blood
Carbamazepine	Immunoassay	Drugs	Blood
Ciclosporin	Immunoassay	Drugs	Blood
Transferrin	Nephelometry	Specific Proteins	Blood
Transferrin	Nephelometry	Specific Proteins	Urine
α 2 Macroglobulin	Nephelometry	Specific Proteins	Blood
α 2 Macroglobulin	Nephelometry	Specific Proteins	Urine
ALAT	UV-Visible spectroscopy	Enzymes	Blood
ASAT	UV-Visible spectroscopy	Enzymes	Blood
Magnesium	UV-Visible spectroscopy	Electrolytes	Blood
Magnesium	UV-Visible spectroscopy	Electrolytes	Urine

Resulting matrix:

From the list of analyses, the laboratory can then establish a matrix, which will highlight the sub-disciplines, as shown below. If the number of products is limited, they can be included in the matrix. If not the evaluation of the products can be treated separately.

Measurement technique	Property		Drugs		Electrolytes		Enzymes		Hormones		Specific proteins		Vitamins	
	B	U	B	U	B	U	B	U	B	U	B	U	B	U
Chemiluminescence									X				X	
Electrochemistry			X	X										
Electrophoresis											X			
Immunoassay	X													
Nephelometry											X	X		
UV-Visible Spectroscopy			X	X	X									

Resulting sub-disciplines from this exercise:

- Hormones by Chemiluminescence in blood
- Vitamins by Chemiluminescence in blood
- Electrolytes by Electrochemistry in blood and urine
- Specific proteins by Electrophoresis in blood
- Drugs by Immunoassay in blood
- Specific proteins by Nephelometry in blood and urine
- Electrolytes by UV-Visible spectroscopy in blood and urine
- Enzymes by UV-Visible spectroscopy in blood

Note: although the different products have been combined into one sub-discipline for each detection system in terms of being equivalent from a competency point of view, this does not suggest that they are equivalent in terms of method and laboratory performance.

Therefore, the laboratory would be expected to undertake such PTs specifically covering all the products in their scope on a periodic basis. This would be expected to be clearly detailed in their proficiency testing strategy.