

# Compliance of the PNAEQ Preanalytical scheme with the ISO 15189:2012



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## Introduction and Aim

Since 2007, PNAEQ, the Portuguese External Quality Assessment Program, has implemented the EQA program to evaluate the preanalytical phase. PNAEQ established a consortium with Labquality and ECAT Foundation that allowed the evaluation of more items.

Although the accreditation of clinical laboratories by ISO 15189:2012 is not mandatory in Portugal, the implementation of good practices is essential to ensure that the collection, handling and transport of samples ensures correct analytical results. Laboratories must have tools to detect, monitor, reduce and eliminate errors in Preanalytical phase.

The participation in these schemes provided by PNAEQ allows the evaluation and information of the direct impact on the sample quality, technician safety, analytical results and thereafter on the patient health, providing schemes that allow the compliance with the management and technical requirements of ISO 15189:2012.

The aim of this work is to inform clinical laboratories that the participation on a EQA scheme on Preanalytical phase allows the compliance with the normative reference and evidence the good laboratory practices.

## Material and Methods

Since 2007 PNAEQ has distributed tools for the evaluation of Preanalytical phase. In 2018, these tools were the following:

- Monitoring Indicators:** It was sent a worksheet for monitoring 20 indicators. Participants were asked to register and return to PNAEQ the results four times per year. The evaluation of results was made by percentage of occurrences.
- Audits:** It was provided a checklist for auditing the blood sampling to identify errors. It was asked to participants to complete the checklist based on the observation of 5 blood draws per technician. The main topics were: sample identification, sample quality, safety practices and performance evaluation.
- Mystery Client:** Twice a year PNAEQ made anonymous phone calls based on a script. This procedure was repeated in different days and hours in order to verify the given information to the user and its consistence.
- Simulated cases:** Online cases in order to detect errors in Preanalytical phase were available for the participants.
- Sample quality:** Samples were sent to the participants to determinate serum interferers (Hemolysis / Icterus / Lipemia - HIL).
- Training actions:** It was organized a workshop to participants where there was a place for clarification of doubts, presentation of results, evaluation and monitoring of methodologies available by PNAEQ. The subjects were the following: Uncertainties Associated with Preanalytical Variability; Potassium and the Preanalytical phase; The Preanalytical phase in Microbiology; and Elaboration and interpretation of risk matrix for the Preanalytical phase.

## Results

The follow requirements of ISO 15189:2012 are reflected in the available tools on PNAEQ Preanalytical schemes (Table 1):

- Monitoring Indicators:**
  - ✓ 4.14.7. Quality indicators;
  - ✓ 5.4.2 Information for patients and users;
  - ✓ 5.4.3 Request form information;
  - ✓ 5.4.4 Primary sample collection & handling;
  - ✓ 5.4.5 Sample transportation;
  - ✓ 5.4.6 Sample reception.
- Audits:**
  - ✓ 4.14.6. Risk Management;
  - ✓ 5.1 Personnel;
  - ✓ 5.4.4 Primary sample collection & handling.
- Mystery Client:**
  - ✓ 5.1 Personnel;
  - ✓ 5.4.2 Information for patients and users.
- Simulated Cases:**
  - ✓ 5.4 Pre-examination procedures
- Sample Quality:**
  - ✓ 5.4.6 Sample reception
- Training Actions:**
  - ✓ 5.1 Personnel

PNAEQ Preanalytical Scheme	Requirements of ISO 15189:2012								
	4.14.6	4.14.7	5.1	5.4	5.4.2	5.4.3	5.4.4	5.4.5	5.4.6
Monitoring Indicators		✓			✓	✓	✓	✓	✓
Audits	✓		✓				✓		
Mystery Client			✓		✓				
Simulated Cases				✓					
Sample Quality									✓
Training Actions			✓						

Table 1 - PNAEQ Preanalytical scheme reflected on requirements of ISO 15189:2012.

## Conclusion

- ❖ PNAEQ provides tools that, when properly used in laboratory routine, evidence good laboratory practices and compliance with regulatory and almost all the total reference requirements, ensuring correct attendance, collection and handling of the patient and samples, leading to proper results for medical and health decisions.
- ❖ More tools will be included in the future in order to integrate other requirements of the ISO 15189:2012.
- ❖ PNAEQ meets annually with the participants to re-evaluate the tools, methodology of information collection and training needs, in order to promote good laboratory practices in a continuous improvement.

## References

ISO 15189:2012. Medical laboratories – Particular requirements for quality and competence.