

# Results of Portuguese Extra-Analytical Evaluation on SARS-CoV-2 in 2020 schemes

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## Background and Objectives

The Portuguese National External Quality Assessment Program (PNAEQ) assembles 3 schemes of extra-analytical issues since 2007 (Pre and Post-Analytical) and 2010 (Laboratory Safety). In 2020, due to the new Coronavirus (SARS-CoV-2), PNAEQ introduced a new SARS-CoV-2 molecular detection scheme with two rounds (May and November). In addition, were included questions in the 3 extra-analytical schemes concerning SARS-CoV-2 and added questions in the 2nd round of molecular detection in collaboration of the World Health Organization. The purpose was checking if laboratories implemented the biological safety recommendations at the entire examination process, including pre- and post-examination procedures. This study aims to evaluate PNAEQ participants in their ability to be aware to the laboratory diagnosis of SARS-CoV-2 in all extra-analytical areas.

## Methods

Participants came from public, private, social and academic laboratories. Several tools were used to evaluate extra-analytical issue (Figure 1):

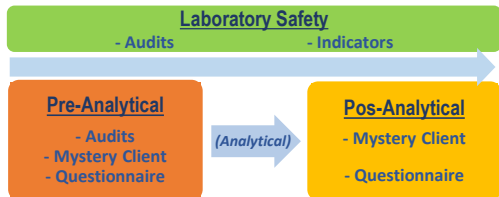


Figure 1: Tools included in 2020 EQA extra-analytical schemes, with items related to SARS-CoV-2

The items were focused on

- Compliance with national recommendations
- Contingency plan
- Quarantine measures applied to the staff
- Information on the safety manual
- Use of BSL2 or BSL3
- Education on the use of IPE
- Sample collection
- Specimen type and source
- Packaging and transport
- Result turnaround time and delivery mode

Results were analysed and issued a global and individual reports.

## Results

Participation rate was 100% in tools where PNAEQ had an active participation (questionnaire with mandatory answer and mystery client). On the remaining tools, participation rate varied from 24% to 57%.

In Figure 2 are the main results of the items included in the tools used to evaluate extra-analytical issue.

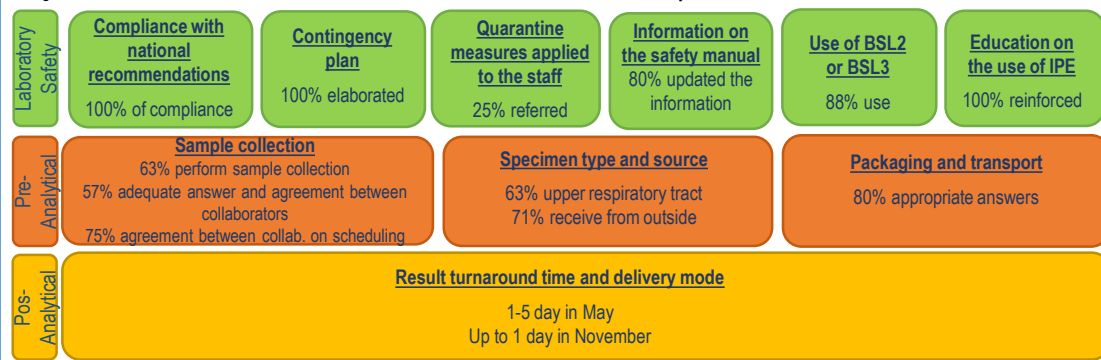


Figure 2: Main results obtained for each item included in the tools used in Laboratory Safety, Pre and Post-analytics 2020 EQA schemes, related with SARS-Cov-2

## Conclusion

Tools performed directly by PNAEQ or with mandatory response were the only with 100% of participation rate. We believe that PNAEQ should encourage participation in all exercises.

The topics evaluated in the **Laboratory Safety** 2020 EQA scheme had very satisfactory responses.

Concerning **Pre-Analytical** Phase 2020 EQA scheme, the focus goes to only 57% adequate answer and agreement between collaborators (Mystery Client tool) that may have been due to the period in which it took place (May 2020): there might have been insufficient training at that time and sparse issuance of national guidelines for professionals.

In the evaluation of the **Post-analytical** Phase 2020 EQA scheme, it is considered that there was a good evolution in the result turnaround time from May to November 2020.

In general, PNAEQ participants showed good performance in extra-analytical issues.

We consider essential to monitor extra-analytical topics in all the laboratory process using different tools, with an emphasis on issues involving laboratory safety related to the collection and analysis of samples for the diagnosis of COVID-19.

## References:

NP EN ISO. 15189:2014; Laboratory Biosafety Manual 4<sup>th</sup> Ed 2020 (WHO)