Results of the Portuguese pilot EQA program in SARS-CoV-2, PCR

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Introduction

- Initial strategy for containing the spread of SARS-CoV-2 was the prompt identification of COVID-19 cases, as recommended by the World Health Organization. These recommendations demanded an expansion of the laboratory capacity to implement the testing procedures to detect SARS-CoV-2.
- In March 2020, the Portuguese National External Quality Assessment Program (PNAEQ) with the National Reference Laboratory (NRL) organized the 1st External Quality Assessment pilot program (EQA) for detection of SARS-CoV-2 virus by molecular methods.

Aim

- **Implementation** of a national external quality assessment program for the molecular detection of SARS-CoV-2 virus
- **Performance evaluation** and monitoring of the implemented PCR tests for SARS-CoV-2 detection in Portuguese Laboratory Network, and the differentiation between the new coronavirus and the seasonal coronavirus.

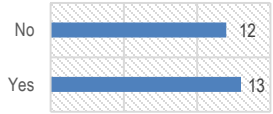
Methods

Four **control samples** (30µL each) were prepared from pools of extracted nucleic acids from positive SARS-CoV-2 and seasonal coronavirus samples.
The samples were selected according to the Cycle Threshold (CT): Two of the samples were SARS-CoV-2 positive, one was negative and the other contained seasonal coronavirus (hCoV HKU1); and preliminary tests for **homogeneity and stability** were performed.
Analysis: Descriptive analysis of results with comparison with expected results and interpretations. Each laboratory could send more than one answer or send results for only some samples. The participants reported CT's for the following genes: E, N1, Orf1a, RdRP1, N3, RdRP2 and S.

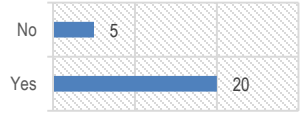
Results

Program accounted with 25 laboratories, that received samples which were considered stable and suitable according to stability analysis.

1. Extra analytical questions: 13 participants perform biologic product collection for SARS-CoV-2 *(graph 1)*, mainly in the upper respiratory tract (12); all mentioned the use of the recommended IPE; 20 receive samples from collection points and/or from other laboratories and implemented safety rules for the handling and transport of the samples *(graph 2)*.

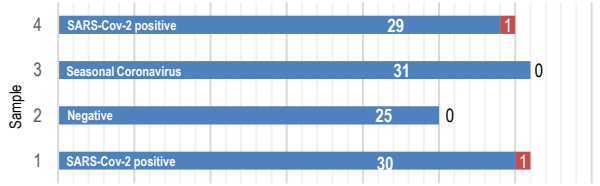


Graph 1 – SARS-CoV-2 product collection



Graph 2 – Reception of samples from collection points

2. Qualitative results: For the two SARS-CoV-2 negative samples we obtained 100% of correct results. No cross-reactivity was detected with seasonal coronavirus. It was reported a false negative for both SARS-CoV-2 samples (Graph 3).



Graph 3 – Results for molecular detection of SARS-Cov-2 (incorrect results represented in red)

3. Quantitative results: The expected CT's according to NRL were: for gene E 19,15 and 25,9 for sample 1 and 4 respectively. Results from labs varied between 19,3 and 25,3 and 25,3 and 34,36 for sample 1 and 4.

Conclusion

- The evaluation of the extra-analytical questions showed that the laboratories complied with the national guidelines.
- Generally, the analytical performance was good.
- The participation in EQA is one of the tools to evaluate the performance and result improvement.