

Results of the Portuguese EQA program for molecular detection of SARS-CoV-2, in 2020

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Background and Objective

The 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 (WHO). 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 collaboration of the National Reference Laboratory (NRL) implemented a pilot round of External Quality Assessment program (EQA) for detection of SARS-CoV-2 virus by molecular methods and with the WHO collaboration on the second round. The aim of this work is to report the results of the implementation of a national external quality assessment program for the molecular detection of SARS-CoV-2 virus.

Methods

The methods for rounds one and two are discriminated in Table 1.

Table 1: Methods description for rounds one and two for molecular detection of SARS-CoV-2 distributed in 2020

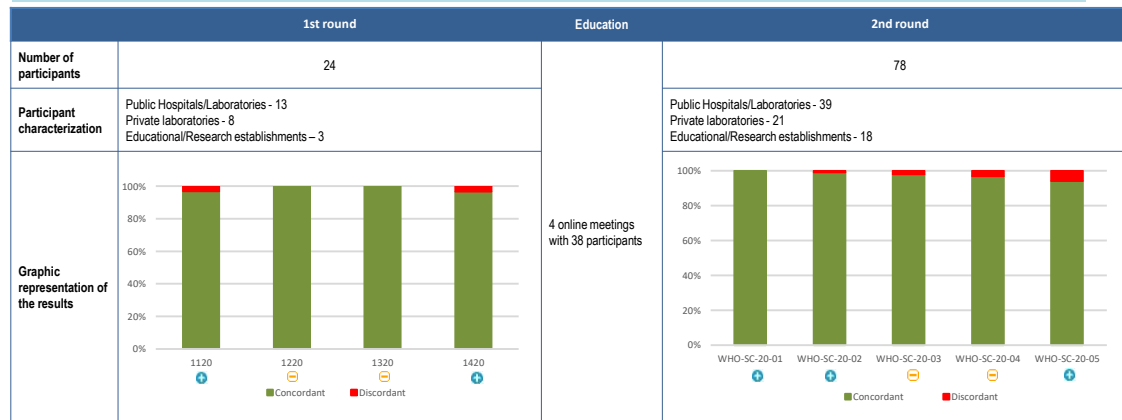
	1st round	2nd round
Sample characterization	4 samples (30 µL) – extracted nucleic acid 1120 – SARS-CoV-2 Positive + 1220 – SARS-CoV-2 Negative - 1320 – SARS-CoV-2 Negative - (Seasonal human coronavirus hCoV HKU1) 1420 – SARS-CoV-2 Positive +	5 samples (500 µL) – inactivated virus WHO-SC-20-01 – SARS-CoV-2 Positive + WHO-SC-20-02 – SARS-CoV-2 Positive + WHO-SC-20-03 – SARS-CoV-2 Negative - (Seasonal human coronavirus hCoV-OC43) WHO-SC-20-04 – SARS-CoV-2 Negative - WHO-SC-20-05 – SARS-CoV-2 Positive +
Collaboration	National Reference Laboratory	World Health Organization
Homogeneity and stability tests	Performed according to ISO17043:2010 – 4.4.3 and ISO13528:2015 – Annex B	
Participant characterization	Public Hospitals/Laboratories; Private laboratories; Educational/Research establishments	
Distribution	June 2020	November 2020
Statistical analysis	Qualitative results – Concordant/discordant results Quantitative results – Algorithm A	Qualitative results – Concordant/discordant results
Fee	No costs for the participants	

Education: PNAEQ made available, during August and September 2020, online sessions for External Quality assessment (EQA).

Results

The main results for both rounds are discriminated in Table 2.

Table 2: Results obtained for rounds one and two for molecular detection of SARS-CoV-2 distributed in 2020



Conclusion

- The 1st round did not include the genetic material extraction, and therefore this procedure could not be assessed.
- The 2nd round included Educational/Research establishments and private laboratories, that usually do not perform clinical analysis or did not have implemented in the past Molecular Biology techniques. Nonetheless these laboratories implemented this methodology in order to answer the demand of SARS-CoV-2 testing.
- The Training/Educational sessions held by PNAEQ contributed to the increase of the number of participants for the 2nd round, and to educate on external quality assessments the new participants in this area.
- Participation in EQA programs, allowed the estimation of the assays performance required for patient care, contributed for the harmonization of implemented methods and the improvement of the analytical quality.
- The program results indicate a good performance of the Portuguese Laboratories participating in the EQA's, although with room for improvement.

Acknowledgments: To the National Institute of Health Dr. Ricardo Jorge and World Health Organization for enabling the participation in both rounds free of charge. To Alina Guseinova for the cooperation and hard work.