

# Results of the Portuguese EQA program for molecular detection of SARS-CoV-2, 2020-2022



Helena Correia<sup>(1)</sup>, Susana Silva<sup>(2)</sup>, Catarina Ventura<sup>(1)</sup>, Aryse Melo<sup>(3)</sup>, Raquel Guiomar<sup>(3)</sup>, Ana Faria<sup>(1)</sup>

<sup>(1)</sup> Instituto Nacional de Saúde Dr. Ricardo Jorge – Departamento de Epidemiologia – Unidade de Avaliação Externa da Qualidade, Lisboa

<sup>(2)</sup> Instituto Nacional de Saúde Dr. Ricardo Jorge – Departamento de Epidemiologia

<sup>(3)</sup> Instituto Nacional de Saúde Dr. Ricardo Jorge – Departamento de Doenças infecciosas – Laboratório Nacional de Referência para o Vírus da Gripe e Outros Vírus Respiratórios

## Introduction and Objective

The initial strategy for containing the spread of SARS-CoV-2 was the prompt identification of COVID-19 cases. National Reference laboratory implemented the biomolecular assays to detect SARS-CoV-2.

In June 2020, the Portuguese National External Quality Assessment Program (PNAEQ) in collaboration with National Reference Laboratory for Influenza and Other Respiratory Viruses (NRL) organized the first National External Quality Assessment Program (EQA) for detection of SARS-CoV-2 virus by molecular methods. The majority of the rounds included extra-analytical questions. The aim of EQA programs is to evaluate the participant's performance and also estimate the overall detection rate of multiple national laboratories.

We aimed to evaluate the results of implementation of a national external quality assessment program for the molecular detection of SARS-CoV-2 virus during 2020 – 2022.

## Methods

The participants were national public, private hospitals and ambulatory/academic laboratories.

Twenty four samples from extracted nucleic acid or inactivated virus (propagated in cell culture) were distributed (15 positive and 9 negative) from extracted nucleic acid or inactivated virus (propagated in cell culture). Each round consisted of five 5 samples (500 µL) distributed twice a year, with exception on 2020 where only one round was available with four control samples (30µL).

The samples were prepared by the expert laboratory (NRL) who also conducted the homogeneity and stability tests according to ISO 13528:2015 and the shipment was made in compliance with the International Air Transport Association (IATA) regulations, without temperature control.

The program documentation was available online in REDCap platform (instructions and result form).

Qualitative results were evaluated according to the expected results and inconclusive results were considered discordant.

## Results

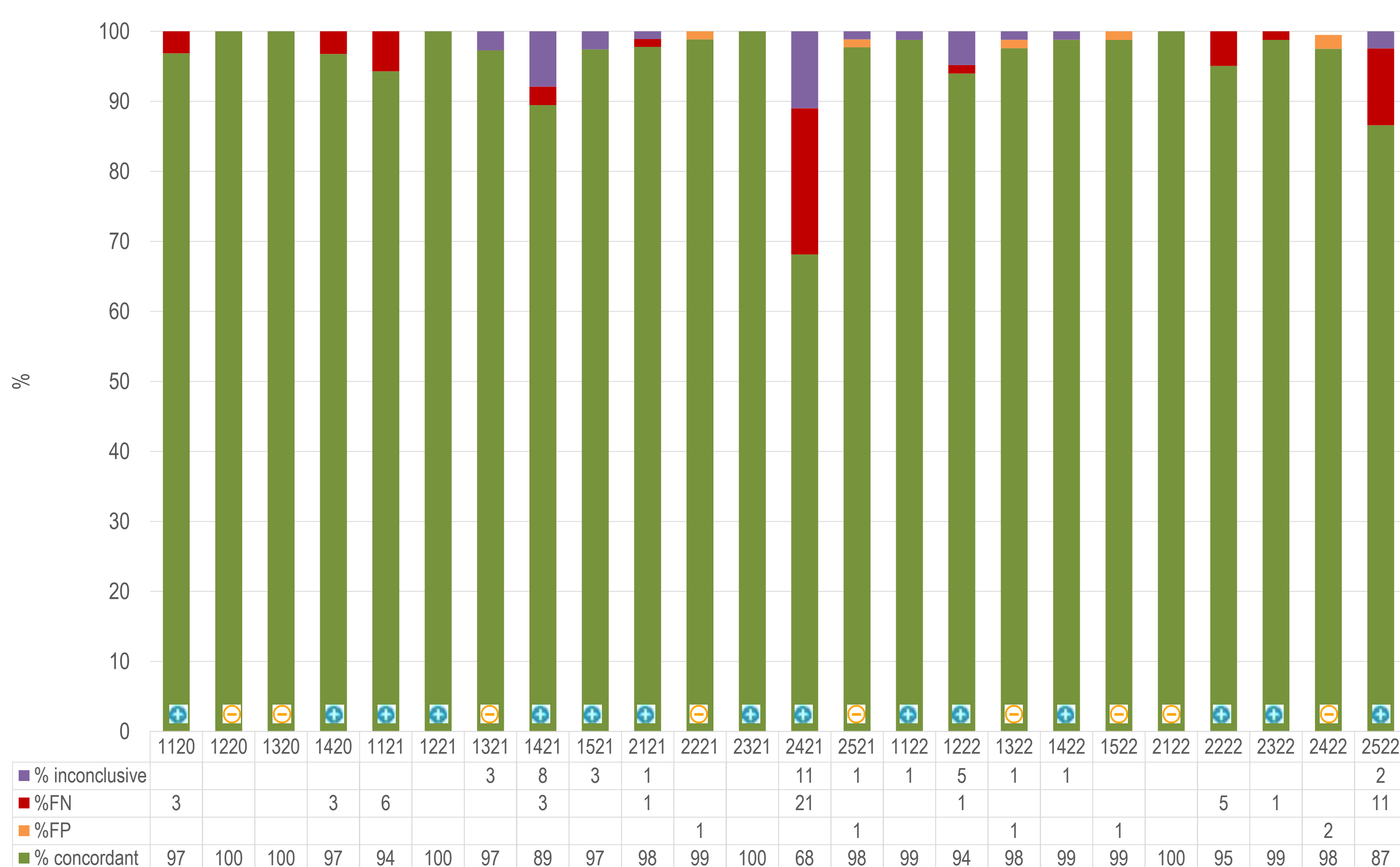
In the five rounds of molecular detection of SARS-CoV-2, 100 different laboratories participated. The mean participation rate for the molecular detection SARS-CoV-2 was 97% (89%-100%) – **Table 1**.

Samples were considered homogeneous, stable and suitable for laboratory performance assessment.

For the 9 negative samples the mean percentage of concordant results was 99% (97%-100%) with a total of 7 false positive results and 5 inconclusive results, corresponding to a mean average of 1% discordant results (0%-3%) – **Graph 1**.

For the 15 positive samples the mean percentage of concordant results was 94% (68%-100%) with a total of 55 false negative results reported and 27 inconclusive results corresponding to a mean average of 6% discordant (0%-32%) - **Graph 1**.

**Graph 1** – Percentage of Concordant results, False positive (FP); False negative (FN) and inconclusive results for each sample



**Table 1** – Target value, number of orders, number of returned results and respective percentage of returned results for each sample .

Sample	Target	No. of PT orders	N PT return results	% PT Return results
1120	SARS-CoV-2 NAT Positive	25	25	100%
1220	SARS-CoV-2 NAT Negative	25	25	100%
1320	SARS-CoV-2 NAT Negative	25	25	100%
1420	SARS-CoV-2 NAT Positive	25	25	100%
1121	SARS-CoV-2 NAT Positive	38	34	89%
1221	SARS-CoV-2 NAT Positive	38	34	89%
1321	SARS-CoV-2 NAT Negative	38	34	89%
1421	SARS-CoV-2 NAT Positive	38	34	89%
1521	SARS-CoV-2 NAT Positive	38	34	89%
2121	SARS-CoV-2 NAT Positive	77	73	95%
2221	SARS-CoV-2 NAT Negative	77	73	95%
2321	SARS-CoV-2 NAT Positive	77	73	95%
2421	SARS-CoV-2 NAT Positive	77	73	95%
2521	SARS-CoV-2 NAT Negative	77	73	95%
1122	SARS-CoV-2 NAT Positive	71	71	100%
1222	SARS-CoV-2 NAT Positive	71	71	100%
1322	SARS CoV-2 NAT Negative	71	71	100%
1422	SARS-CoV-2 NAT Positive	71	71	100%
1522	SARS CoV-2 NAT Negative	71	71	100%
2122	SARS-CoV-2 NAT Negative	70	70	100%
2222	SARS-CoV-2 NAT Positive	70	70	100%
2322	SARS-CoV-2 NAT Positive	70	70	100%
2422	SARS CoV-2 NAT Negative	70	70	100%
2522	SARS-CoV-2 NAT Positive	70	70	100%

## Discussion and Conclusion

It was observed a high percentage of returned results. The performance was better for the negative samples.

Overall, the program results indicate a good performance of the Portuguese Laboratories participating in EQA. To improve inconclusive results, education regarding interpretation must be performed.

At times when official surveillance is suspended, EQA schemes are the only way to recognize the performance of testing facilities and test systems[1].

### References:

[1] Christoph Buchta, Heinz Zeichhardt, Andrea Griesmacher, Ingo Schellenberg, Martin Kammel, Ignoring SARS-CoV-2 testing performance during COVID-19. Lancet Microbe 2023

