

APPROACH & OBJECTIVES

- The current global pandemic caused by Severe Acute Respiratory Syndrome 2 (SARS-CoV-2).
- In order to detect and diagnose the contagion of the virus, diagnostic methods have been developed.
- However, there is a deficiency in quality assurance and ease in assessing the performance of these tests.
- The correct application of metrological tools and qualitative analysis is extremely important to guarantee the quality and reliability of the results of any method.
- Therefore, the objective of this work is to review and evaluate these tools, highlighting the best practices for the diagnostic tests for SARS-CoV-2.

RESULTS & DISCUSSIONS

- Among these tools, the following stand out:



Figure 1. Different levels of quality validation categories for the analysis of diagnostic methods for SARS-CoV-2. Adapted⁷

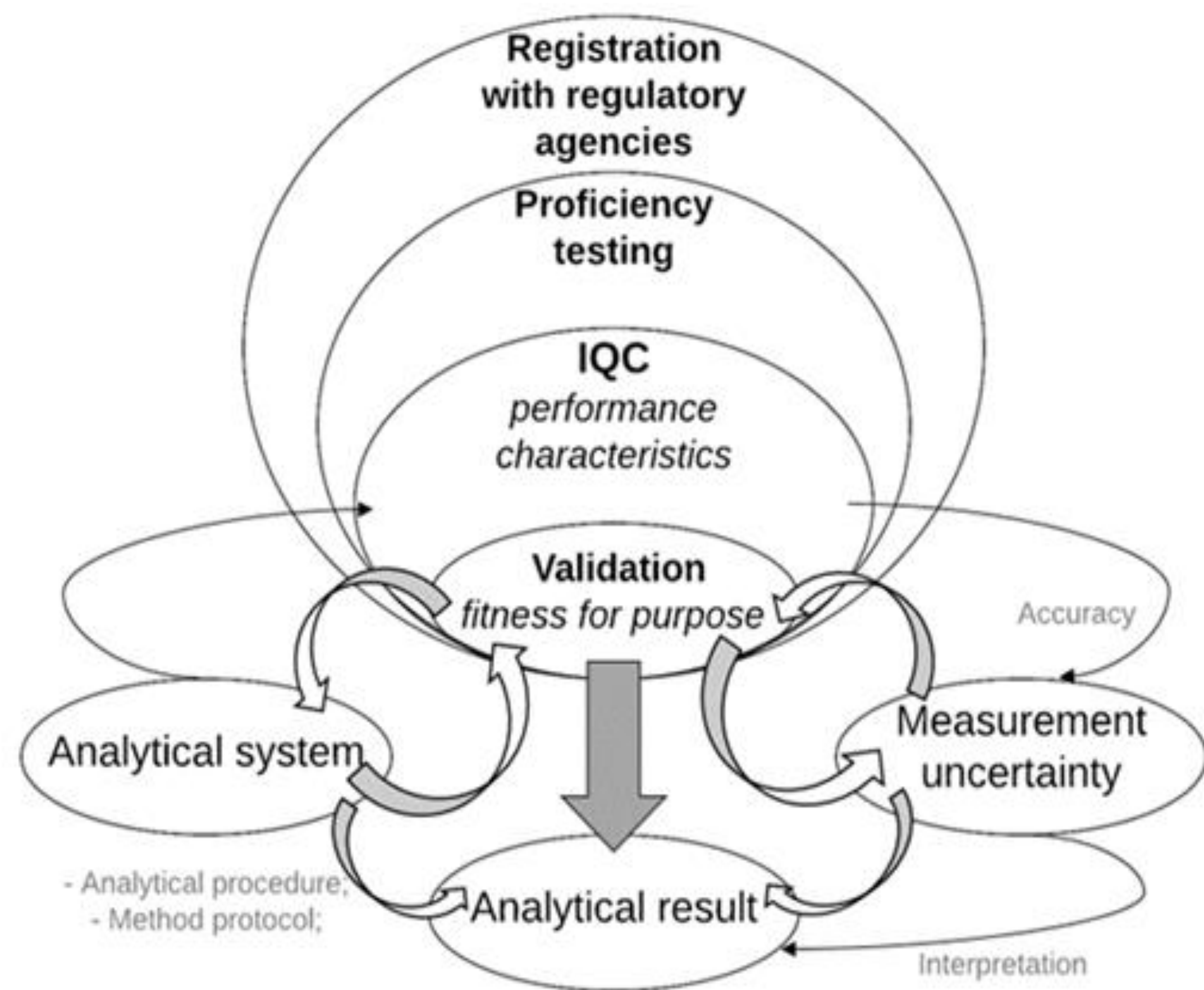
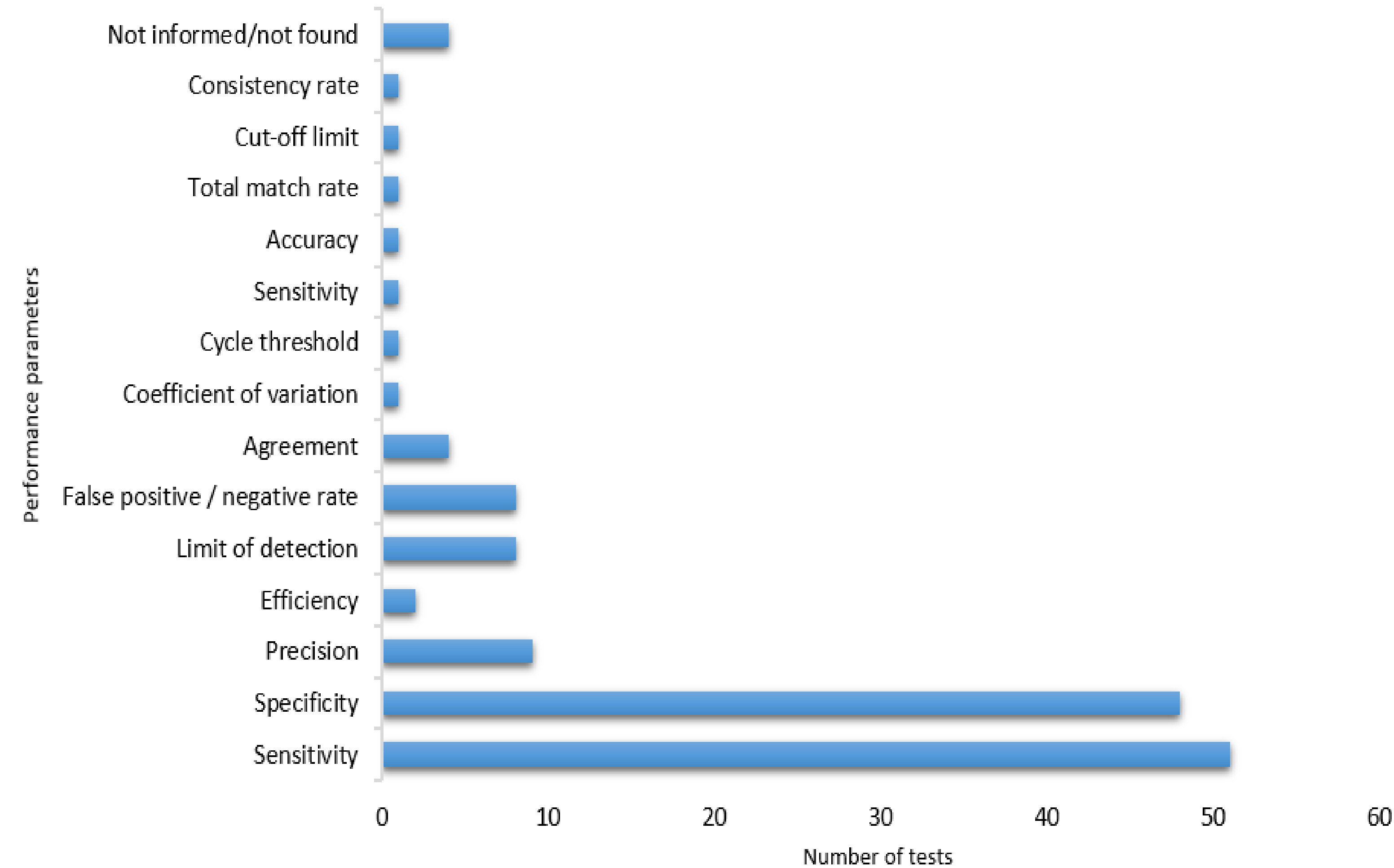


Table 1. Main parameters that must be addressed in the validation process based on the guides of EURACHEM, EC, and INMETRO.

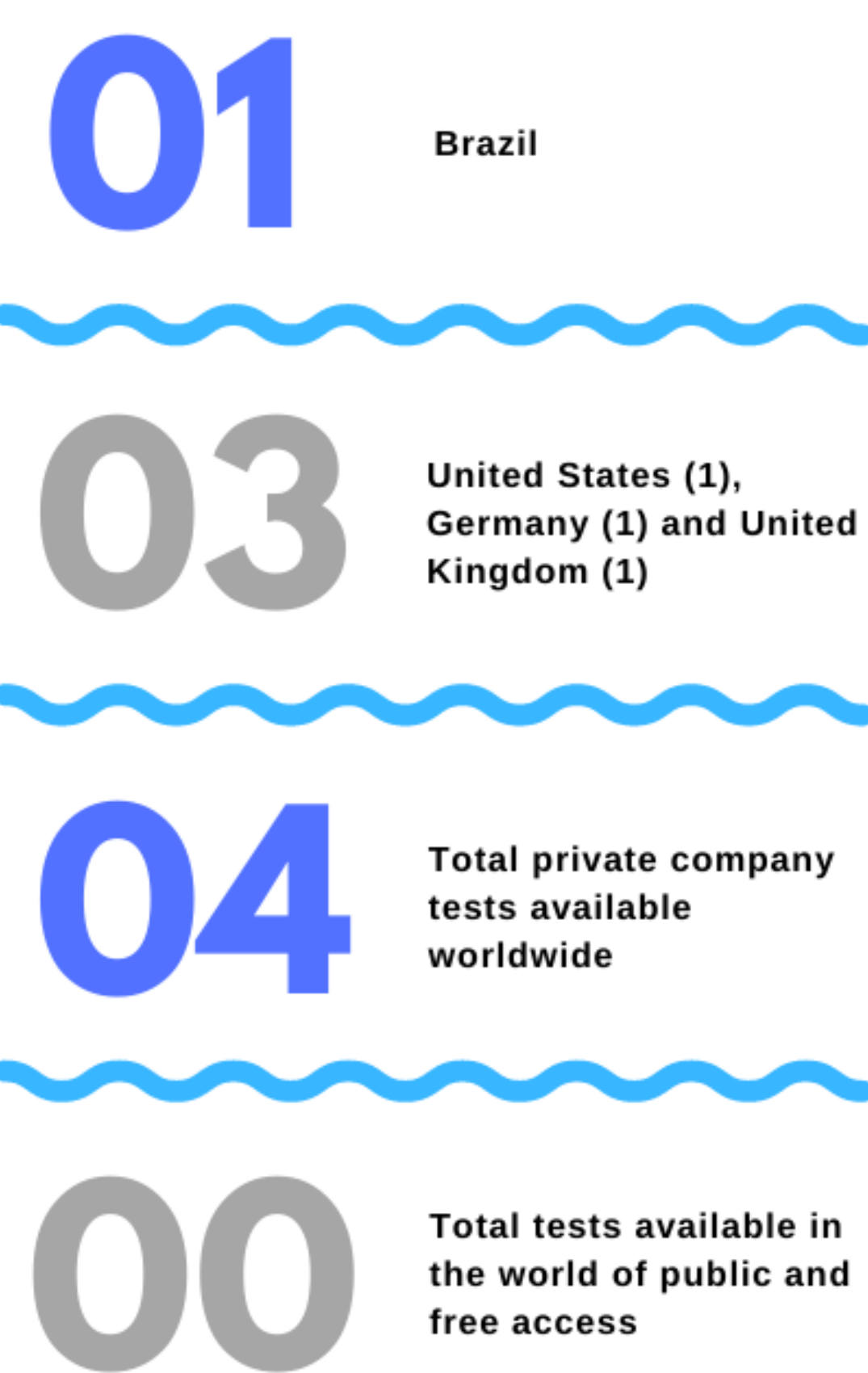
	EURACHEM ³	EUROPEAN COMISSION ⁷	INMETRO ^{1,2}
Accuracy: trueness, precision	✓	✓	✓
Cut-off limit	✓	✗	✗
Limit of detection (LOD)	✓	✓	✓
False positive and negative rates	✓	✗	✓
Ruggedness or robustness	✗	✓	✓
Sensitivity and specificity	✓	✓	✓
Selectivity/Confirmation of identity	✓	✗	✓
Unreliability region	✗	✓	✓

Table 2. Variation in the parameters approached by the test manufacturers for the detection of SARS-CoV-2 in Brazil, according to ANVISA.³



NUMBER OF PROFICIENCY TESTS FOR SARS-COV-2 CURRENTLY AVAILABLE

MAY, 2021.



CONCLUSIONS

- The lack of a complete and specific validation protocol for qualitative analyzes;
- There is a great divergence between the parameters used to validate the method by the manufacturer, and there is no specific document to regulate this;
- The lack of a complete and available proficiency test with free access to society;
- Despite the great importance of applying these methods for the detection of SARS-CoV-2, according to the data presented, there is still no standardization for this. This reveals the importance of applying a set of qualitative analysis checks to the method using different metrological tools to ensure that the tests must be compliant and suitable for their application.

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