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# Quality Assurance Tools to Improve SARS-CoV-2 Detection in Colombia

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In partnership with UNIDO, NIST, and Colombia's National Institute of Health, INM deployed a proficiency testing scheme with over 98 % satisfactory results for over 120 national laboratories

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## The Challenge

In response to the COVID-19 pandemic, countries worldwide implemented contingency measures to control the outbreak, including the establishment of national laboratory networks to detect SARS-CoV-2. After approval from the national sanitary authority, laboratories began using the WHO protocols and available In Vitro Diagnostic (IVD) devices. Although each detection kit has its own positive and negative controls, not all protocols exhibit the same performance characteristics, leading to different results for the same sample and negative consequences for decision-making. In addition, during the COVID-19 pandemic, reference materials (RM), reagents, and molecular biology consumables were not widely available, and the transfer of biological samples between countries was restricted by national biosafety protocols. In this sense, the development of RMs as internal or external quality controls and proficiency testing (PT) schemes plays a key role in ensuring reliable results.

## The Solution

To strengthen the national network of public health laboratories responsible for SARS-CoV-2 detection in Colombia, the National Institute of Health (INS) and the National Metrology Institute (INM), with international support from the National Institute of Standards and Technology (NIST, US) and the United Nations Industrial Development Organization (UNIDO), developed a qualitative PT to evaluate the performance of authorized laboratories in detecting SARS-CoV-2 using a Reverse Transcription real Time Polymerase Chain Reaction - RT-qPCR as the reference method for SARS-CoV-2 detection. Accordingly, a proficiency test item (PTI) based on NIST reference material RGTM 10169 was developed (see **Figure 1**). The PTI consisted of a five 500  $\mu$ L vials panel, containing three positive samples with 80  $\mu$ L solution with nominal copy number concentrations of 1000, 100, and 10 copies/ $\mu$ L, and two negative samples with and without human RNA, to simulate real samples. They were packed in a plastic blister and in a previously coded aluminized bag. This PTI was distributed to more than 120 national laboratories as part of the Colombian Network for SARS-CoV-2 detection. Each laboratory then evaluated the PTI using its own implemented protocols. The technical performance of each laboratory was evaluated for each concentration level and each target sequence (E, N, M, RdRp) based on the reported results.



**Figure 1.** A proficiency test item (PTI) was developed by INM based on NIST reference material RGTM 10169 and characterized across a range of viral concentrations.

## A Quantifiable Impact

Reliable detection of SARS-CoV-2 infection is one of the first hurdles to controlling the spread of infection and depends on the availability of measurement assurance tools such as measurement methods, reference materials, inter-laboratory comparisons, and technical competence, among other factors of fundamental importance, especially in one country where none of these tools had been developed previously.

A qualitative Proficiency Test scheme for SARS-CoV-2 detection—the first of its kind in Colombia in molecular biology—was developed and sent to 124 testing laboratories [1].<sup>1</sup> Of these, 119 laboratories reported results, covering 27 of Colombia's 32 geographic areas. Compared to similar commercial external quality assessment programs that charge registration fees of at least USD 300 (not including sample shipping costs), this PT enabled the

<sup>1</sup> Proficiency test service provided by the INM Colombia: Programación EA - Instituto Nacional de Metrología – INM.  
<https://inm.gov.co/programacion-ea/>

Colombian healthcare system to save more than USD 36 000 through a timely evaluation of this laboratory network, given the restrictions on sample availability and shipping.

The participating laboratories used both open and closed PCR platforms, employing both commercial and in-house protocols to detect one to three SARS-CoV-2 DNA markers. Regarding laboratory results, 98.3 % were satisfactory, with 84 % at 100 % concordance, 7.6 % at 90 % concordance, and 8.4 % at 80 % concordance, indicating that most participating laboratories have the capacity to detect SARS-CoV-2 by PCR methods. Participation enabled the few laboratories that were not reporting satisfactory results to identify their areas of shortfall and implement corrective actions, including identifying or verifying test method performance parameters, to improve future comparability. Accordingly, the use of this PT has improved the quality of SARS-CoV-2 detection for public health surveillance in Colombia.

In addition to the direct benefits of laboratory comparability and assessment, this metrological intervention provided an opportunity to conduct an overview of the national inventory of measurement platforms, reagents, materials, and procedures used by laboratories for SARS-CoV-2 detection. A stakeholder and participant from the Virology Laboratory at the National Health Institute of Colombia attests:

*"This exercise provided us with important analytical tools to strengthen [the] technical capabilities of the network of laboratories dedicated to SARS-CoV-2 detection, which has helped build public confidence in testing efforts"*

This inventory can also be used to detect other pathogens of national interest and to strengthen national laboratories' capacity to perform PCR testing.

Finally, it is worth noting that the technical capabilities and coordination processes developed by both INM and INS, as Colombia's metrology and health institutes, remain relevant today. After vaccine development, SARS-CoV-2 is another one of the important respiratory viruses that must be surveilled by health authorities. In this sense, the development of similar exercises covering new respiratory viruses is the current challenge, as evidenced by the PT schemes developed in 2025 and 2026<sup>2</sup> for viruses such as SARS-CoV-2, Influenza A, Influenza B, Syncytial, and adenovirus, which contribute not only to providing an adequate and timely response, but also to national and regional preparedness for future pandemics.

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<sup>2</sup> Protocol for proficiency exercise (for 2026). [https://inm.gov.co/wp-content/uploads/2026/05/EA\\_virus\\_respiratorios-2\\_compressed.pdf](https://inm.gov.co/wp-content/uploads/2026/05/EA_virus_respiratorios-2_compressed.pdf)