Addressing the challenges of molecular diagnostics in infectious diseases by developing metrology tools in Colombia

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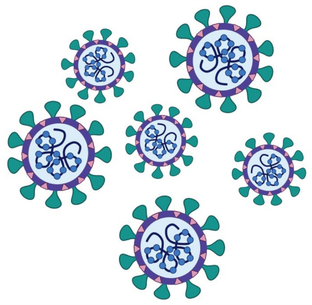
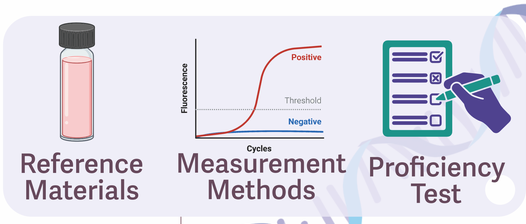
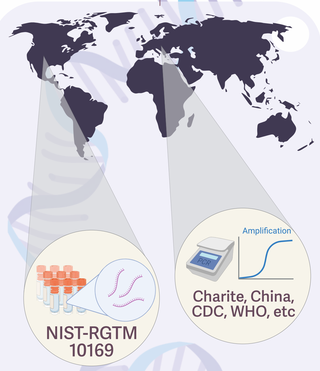
Metrology Challenge



In 2019, the emergence of the SARS-CoV-2 pandemic underscored the urgent need for **robust tools** to ensure the **reliability of results**.



Reference Materials | Measurement Methods | Proficiency Test

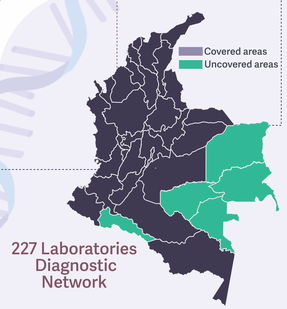


Initial tools were developed globally to **ensure** the **accuracy and reliability** of measurement results

The **rapid distribution** of **reference materials** was **challenging** due to international trade restrictions and **limited availability** of these **critical resources**

Current Progress

- **2024** — Genomic RNA Influenza A, B SARS CoV-2
- **2022** — SARS CoV-2 Genomic RNA
- **2020** — Syntethic RNA SARS CoV-2



227 Laboratories Diagnostic Network

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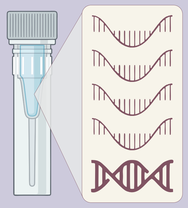
International coperation and support

Development of technical competencies across multiple levels:

1. **Strengthening** the network of clinical laboratories in molecular PCR assays
2. **Reference molecular methods development** Detection and quantification of nucleic acid by digital PCR
3. **Production and characterization of Reference Materials** at DNA/RNA for proficiency testing exercises.

CMC Development

Future Work



- SARS CoV-2
- Influenza A: H1 - H3
- Influenza B
- Sincytial
- Adenovirus

Reference material broad-spectrum coverage

Support and provide tools to stakeholders

Profeciency testing
Trainning programs

References
[1] V. M. Corman et al., "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR," Eurosurveillance, vol. 25, no. 3, Jan. 2020, doi: 10.2807/1560-7917.ES.2020.25.3.200004
[2] M. H. Cleveland et al., "Rapid production and free distribution of a synthetic RNA material to support SARS-CoV-2 molecular diagnostic testing," Biologicals, vol. 82, p. 101680, May 2023, doi: 10.1016/J.BIOLOGICALS.2023.101680.

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