El futuro es de todos

Gobierno de Colombia

Industria y Comercio

SUPERINTENDENCIA

LEGAL METROLOGY

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How has the consumer been protected from legal metrology during the pandemic?

- Verification of scales in commercial establishments and postal services.
- Verification of liquid fuel dispensers.
- Technical regulation of measuring instruments and prepackaged products.
- Verification of prepackaged products: alcohol, gloves, among others.
- Awareness to employers to resolve specific doubts about the different topics of Legal Metrology.

VERIFICATIONS DURING THE HEALTH EMERGENCY - OAVM

VERIFIED INSTRUMENT	2020	2021	TOTAL
Truck scales	271	53	324
Commercial scales	8840	4301	13141
Liquid fuel dispensers	8246	4015	13465
TOTAL	17357	8369	25726

31 DEPARTMENTS - 637 MUNICIPALITIES

PERSONALIZED AWARENESS

TOPIC	2020	2021	TOTAL
Demonstration of conformity - SIMEL VUCE	1	0	1
Evidential breath analyzers	0	1	1
Metrological control approach	77	38	115
Non-automatic weighing instruments	19	1	20
Volume magnitude	7	0	7
Magnitude: Mass - Volume	3	0	3
Prepackaged Products	23	39	62
SIMEL	149	0	149
Liquid fuel dispensers	74	6	80
Total	**353**	**85**	**438**

CURRENT CHALLENGES METROLOGICAL CONTROL APPROACH

- Exchange of theoretical and practical knowlwdge with other countries.
- New regulation based on international standars.
- Metrological culture: Trainings, Repairs, post-repair checks, consumer instruments status identification (labels).

- **Strengthen control actions on some measuring instruments:** → **Evidential breath analyzers**
- **New technical regulation** → **Electric energy meters**

The Colombian experience in metrology for health in 2020

Edwin A. Cristancho-Pinilla, PhD
General Director

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Instituto Nacional de Metrología de Colombia

Topics

1. Supporting the assessment of pulmonary ventilators

2. Proficiency testing: SARS-CoV-2 virus RNA detection

1. Supporting the assessment of pulmonary ventilators

Purpose

To support the National Institute of Food and Drug Surveillance – INVIMA with the authorization process for the approval of low-cost alternative mechanical ventilators produced by national institutions (Cooperation between Universities, private companies and governmental agencies)

- In order to avoid the risk of shortages critical medical devices in the national territory, the medical devices required for the care of patients were declared as VITAL NOT AVAILABLE.
- This allows a faster approval procedure for the production of low-cost alternative mechanical ventilators by national institutions.
- The team that leads the approval process included experts in: pneumology, bioengineering, epidemiology, clinical research, metrology, among others.

invima
Instituto Nacional de Vigilancia de Medicamentos y Alimentos.

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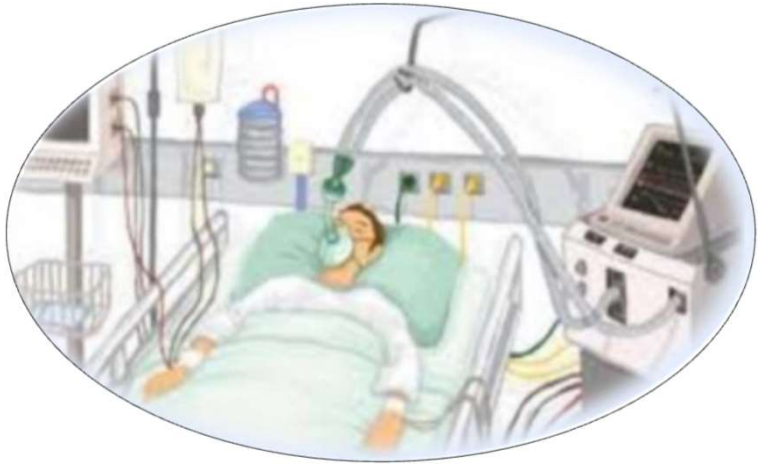
INM Instituto Nacional de Metrología de Colombia

1. Supporting the assessment of pulmonary ventilators

To accelerate the approval of mechanical ventilators projects, some administrative requirements that delayed authorization were removed, however there was **no flexibility** that directly affected technical requirements, safety or efficacy, of the devices.



- The INM support was focused in:
  - To analyze measurement results and their metrological compatibility
  - To analyze measurement results and if they were satisfactory to the required regulations
  - To verify the suitability of the tests carried out
  - To verify the conformity of the tests providers (measurement systems, personnel, equipment, methods)
- Six approval process were supported
- Three were approved for human test.

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Note: The NMI rol was advisory only

Instituto Nacional de Metrología de Colombia

1. Supporting the development of pulmonary ventilators

The process was lead by INVIMA.
INVIMA had the support of invited experts from national institutions.

National Institute of Food and Drug Surveillance - INVIMA

National University of Colombia

Colombian Institute of Technical Standards and Certification

National Metrology Institute of Colombia - INM

The INM identified research and training opportunities for universities and research centers.

2. Proficiency testing: SARS-CoV-2 virus RNA detection

Purpose

To evaluate the performance of the laboratories authorized in Colombia for detecting SARS-CoV-2 virus by RT-qPCR.

Item description

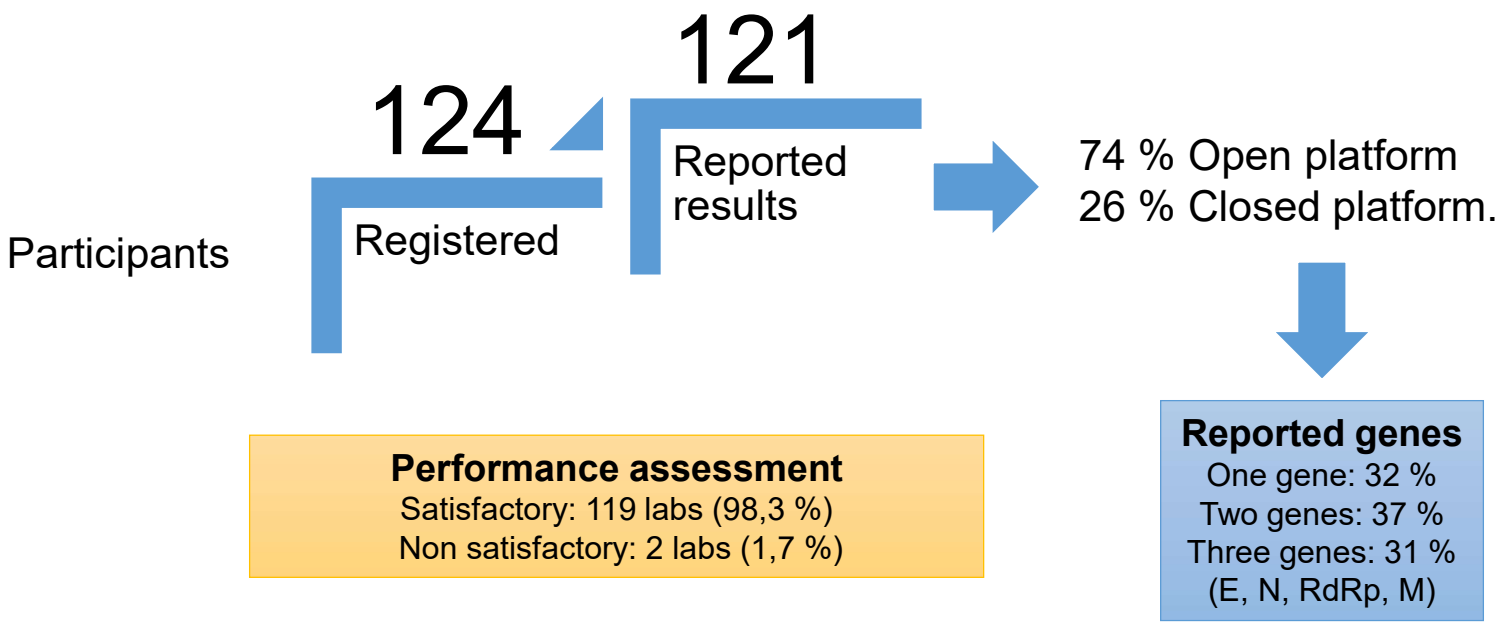
Five solutions including positive and negative samples.

Positive samples were gravimetrically prepared from RGTM10169 reference produced by NIST containing synthetic fragments of SARS-CoV-2 virus RNA.

Evaluation criteria

Positive / Negative

2. Proficiency testing: SARS-CoV-2 virus RNA detection



2. Proficiency testing: SARS-CoV-2 virus RNA detection

Conclusions

The performance of the authorized Colombian laboratories for SARS-CoV-2 virus RNA detection was evaluated. 98,3 % of them showed satisfactory results.

In Colombia, several genes are used for the SARS-CoV-2 virus diagnosis, the most commonly evaluated are E, N and RdRp.

The results of this PT provide confidence in the competence of the Colombian laboratories for detecting SARS-CoV-2.

In the future, we hope to carry out trials, in coordination with the INS, that include other genes associated with more diseases.

2. Proficiency testing: SARS-CoV-2 virus RNA detection

Acknowledges

National Institute of Technology and Standards - NIST

United Nations Industrial Development Organization – UNIDO

National Health Institute of Colombia – INS

National Metrology Institute of Colombia - INM

Thank you

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CONFIANZA QUE CONSTRUYE PROGRESO