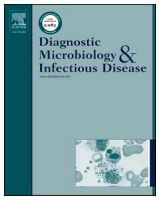
Diagnostic Microbiology & Infectious Disease 111 (2025) 116716

Contents lists available at ScienceDirect

Diagnostic Microbiology & Infectious Disease

journal homepage: www.elsevier.com/locate/diagmicrobio



Strengthening molecular testing capacity in Colombia: Challenges and opportunities

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ARTICLE INFO

Keywords:
Molecular Biology Techniques
One Health Approach
Testing Capacity
Pathogen Detection

ABSTRACT

The COVID-19 pandemic has accelerated efforts to enhance pathogen detection using molecular biology techniques. This study examines the expansion of molecular testing capacity in Colombia, identifying strengths and areas for improvement in the existing infrastructure. The study began with the creation of a database inventorying laboratories based on publicly available data from government entities and active web searches. Ten laboratories were selected for detailed characterization. Structured surveys assessed their testing capacity and progress in implementing molecular-based diagnostic tests for various infectious diseases. The strategy for identifying laboratories showed a total of 311 laboratories. Of these, 65 % ($n = 202$) are private and 21 % ($n = 65$) are state-owned, mainly public health laboratories, and the remaining 14 % ($n = 44$) are affiliated with academic institutions. The highest concentration of these labs is in Bogotá, Antioquia, and Valle del Cauca, primarily in urban areas. Key limitations affecting testing laboratories in Colombia include: i) infrastructure (26.2 %), highlighting the need for standardized facility guidelines; ii) quality and documentation (16.7 %), requiring stronger quality management systems; iii) biosafety (14.3 %), emphasizing the need for continuous waste management, especially in public labs; and iv) human talent (10.7 %), needing better policies for staff retention, particularly in government institutions. Strengthening laboratories can establish a comprehensive national molecular testing system. Integrating molecular tests into health system diagnostic algorithms and implementing sustainable laboratory strategies will address human health challenges and support the "One Health" approach for animal and environmental health.

1. Introduction

Infectious diseases remain a major cause of morbidity and mortality, significantly affecting global health and the economies worldwide [1]. Historically, these infections have triggered outbreaks, posing serious public health threats [2]. Due to the complexity of biological matrices, identifying these infections in clinical settings remains challenging [3]. Traditionally, pathogen detection relied on culture techniques, regarded as the gold standard. However, some microorganisms are challenging to detect using conventional methods [4]. Recent advances in molecular diagnostics, particularly Polymerase Chain Reaction (PCR), have revolutionized pathogen identification in public health [5].

PCR enables the amplification of specific DNA or RNA sequences, allowing the detection of even trace amounts of genetic material from clinical samples. Its high sensitivity and specificity overcome the limitations of traditional culture-based methods, which can be time-consuming and ineffective for certain pathogens [6]. PCR variants, including qPCR (Quantitative PCR), RT-PCR (Reverse Transcription PCR), digital PCR (dPCR), multiplex PCR, nested PCR, and reverse transcription-quantitative PCR (RT-qPCR), allow rapid identification and quantification of bacteria, viruses, fungi, and parasites, facilitating timely and accurate testing essential for effective treatment and improved prognosis [7,8].

The development of molecular techniques, along with complementary tools for microorganism characterization, has created new opportunities for pathogen detection and surveillance [9]. Among these,

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https://doi.org/10.1016/j.diagmicrobio.2025.116716
Received 11 November 2024; Received in revised form 21 January 2025; Accepted 27 January 2025
Available online 28 January 2025

next-generation sequencing (NGS) plays an increasingly prominent role in clinical microbiology, especially for infectious disease testing. As these technologies have become more practical and accessible, their adoption in clinical settings has surged, enabling faster, more comprehensive and accurate pathogen identification [9,10].

Recently, the World Health Organization (WHO) expanded its list of essential diagnostic tests to 219, including assays for Human Immunodeficiency Virus (HIV), tuberculosis, *Plasmodium*, Hepatitis B and C, Human Papillomavirus (HPV), and *Treponema* [11]. Similarly, the U.S. Food and Drug Administration (FDA) has approved 419 approved nucleic acid-based tests, primarily targeting respiratory/influenza viruses, *Chlamydia trachomatis/Neisseria gonorrhoeae, Streptococcus* species, *Clostridium difficile*, Herpes Simplex Virus, *Staphylococcus/*MRSA, and Hepatitis Virus [12].

In recent years, PCR-based tests have accounted for over 40 % of molecular diagnostics, followed by next-generation sequencing (NGS)-based tests at 10 % [13]. High-income countries, such as the United States and Canada, dominate this market due to advanced healthcare systems and early adoption of molecular technologies for infectious diseases detection. However, access remains limited in low- and middle-income countries, particularly in Africa and Latin America, highlighting disparities in diagnostic availability and the need for improved global healthcare infrastructure [11,14,15].

Before the COVID-19 pandemic, molecular assays were primarily focused on cancer and hereditary diseases, prioritizing precision over speed [14,16]. However, the pandemic, however, accelerated the widespread adoption of molecular tests for pathogen detection, shifting the focus to achieving both speed and accuracy [17].

The increasing importance of molecular diagnostics for identifying microorganisms has driven greater demand for these tools [18]. This points to substantial growth in both public and private laboratories, enhancing access for all population, especially in urban areas [14]. However, rural regions continue to face challenges, such as high equipment costs and a shortage of trained personnel, limiting the adoption of these technologies.

In recent decades, Colombia has faced significant public health challenges, highlighting the urgent need to enhance infection detection capabilities. Strengthening epidemiological surveillance through molecular tools and implementing a comprehensive modernization and training plan for diagnostic methods have become priorities. These initiatives are crucial for improving responses to infectious diseases and ensuring necessary infrastructure is in place to manage future outbreaks effectively [19].

The COVID-19 pandemic accelerated this process, prompting Colombia to allocate resources for the creation and strengthening of molecular testing laboratories through funding calls for research projects. This initiative led to the establishment of over 200 laboratories across 28 departments to enhance SARS-CoV-2 detection. Additionally, the country developed a genomic surveillance network, enabling robust genomic sequencing capabilities for monitoring circulating virus variants [20,21].

To strategically advance the molecular diagnosis capacity for pathogens, it is crucial to assess the existing resources and identify opportunities for improvement. This study aims to strategically advance Colombia's molecular diagnostic capacity for pathogens by conducting an inventory of resources and analyzing the expansion of molecular testing capabilities. By identifying strengths and areas for improvement in existing infrastructure, it provides essential baseline information to support the ongoing development of molecular-based diagnostic capacities in the country.

2. Methods

2.1. Defining a molecular diagnostic laboratory and laboratory search criteria in Colombia

A molecular diagnostic laboratory is equipped with the necessary infrastructure, advanced technology, and trained personnel to perform analyses using molecular biology techniques. These methods are applied to detect and study molecules such as DNA and RNA in tissue or fluid samples to identify infectious diseases and assess the risk of disease spread. Molecular diagnostics are essential for diagnosing infections, monitoring outbreaks, and guiding treatment strategies.

In this context, the strategy for identifying laboratories capable of performing molecular pathogen testing in Colombia was developed in several stages. Initially, search engines like Google and Safari were used to access a wide range of sources, including institutional, academic, and commercial sites. Spanish-language search terms such as "Cellular and molecular biology laboratory," "Applied molecular biology laboratory," "Microbial molecular biology laboratory," "Molecular diagnostic laboratory," "Molecular testing laboratory Colombia," and "Approved laboratories for molecular diagnosis" were employed to focus on specialized molecular diagnostics.

Additionally, the websites of governmental regulatory entities like the National Institute of Health, the Ministry of Health, and the Ministry of Science, Technology, and Innovation were reviewed. Official lists of laboratories with molecular diagnostic capabilities were requested via their customer service portals. This process included both private and public academic laboratories to ensure a comprehensive overview of the available resources. Identifying the locations and general capacities of these laboratories was essential for mapping Colombia's molecular testing landscape.

2.2. Laboratory characterization and structured survey application

Once the database was consolidated, an invitation strategy was implemented to encourage the identified laboratories to participate in a comprehensive study of their diagnostic capabilities. The laboratories that accepted the invitation were included in the sample, ensuring geographic diversity, institutional type (public or private), and experience in molecular diagnostics. This process resulted in the selection of 10 laboratories representing the country's testing capacity.

For characterization, structured surveys were administered (Table 1) to assess the equipment and trained human resources available for conducting molecular tests. The surveys also evaluated the status of test implementation, identifying strengths and areas for improvement. The questions were designed following international standards, including ISO Standard 17025, the WHO Laboratory Biosafety Manual (4th edition), and established guidelines in clinical microbiology and molecular diagnostics [22–26].

To address these questions, methodological guidelines were established, including a clear definition of the research purpose by the researchers to facilitate effective dialogue. Additionally, various forms of expression were incorporated, ensuring that each session allowed the interviewed staff to articulate their insights in different ways.

3. Results

3.1. Overview and geographical distribution of diagnosis laboratories in Colombia

A total of 311 laboratories capable of molecular diagnosis were identified through comprehensive database exploration and online searches. This diversity of laboratories reflects a broad spectrum of capabilities and geographic coverage but also highlights the need to generate a centralized platform with free access. Of these 311 laboratories, Bogotá and the Department of Valle del Cauca stand out for

Table 1
Description of some of the questions included in the survey.

MAIN TOPIC	QUESTION TO ADDRESS
Scientific-technical aspects for characterization of physical resources	- The construction of the Molecular Biology Laboratory (LBM) adhered to the specifications outlined in Law 400 of 1997 regarding earthquake resistance? - Does the LBM have a restricted access system, authorized only for personnel responsible for molecular biology activities? - Are the LBM facilities designed with effective physical separation to conduct different activities and prevent cross-contamination of nucleic acids? - How many hermetically sealed areas does the LBM have? - Are the doors and windows fully airtight and washable? - Are the walls completely smooth and painted with epoxy, anti-fungal, and washable paint? - Are the floors non-slip, aseptic, and free of joints? - Does the LBM have a designated area for weighing reagents, located in a nucleic acid clean zone? - Does the LBM monitor and control environmental conditions such as temperature and humidity as required by procedures or equipment specifications? How frequently is this monitoring conducted? - Is there adequate lighting throughout all sections of the LBM as stipulated by procedures? - Does the LBM have documented and implemented exclusive cleaning protocols? How often are these performed? - Does the LBM have a clearly defined area for washing materials from sections that require this function? - Do the sections and technical areas of the LBM have a mechanical ventilation system that introduces outside air without recirculation or openable windows, ideally equipped with mosquito nets? - Do the air outlet windows have HEPA filters, similar to those in the biosafety cabinets? - Does the LBM have appropriate storage spaces to maintain the integrity of all types of samples that require storage?
Characterization of documentary resources for procedures	- Does the LBM document and implement its processes and procedures through manuals, formats, and standard operating procedures (SOPs)? - Is there an SOP (documented, implemented, and communicated) that outlines the workflow of all areas of the LBM, supported by architectural plans? - Is there a manual (documented, implemented, and communicated) detailing how to send and transport samples to the LBM for each type of test performed? - Is there a technical work route document (documented, implemented, and communicated) outlining procedures related to each test conducted at the LBM? - Is there a work route document (documented, implemented, and communicated) that specifies the management of documents associated with each test performed at the LBM? - Is there an SOP (documented, implemented, and communicated) for each test conducted at the LBM? - Does the SOP include a sample reception format for each test performed at the LBM? - Does the SOP specify the procedure and format for unpacking samples for each test conducted at the LBM? - Does the SOP provide formats for verifying the traceability of all procedures performed for each test? - Does the SOP include a format for issuing results for each test conducted at the LBM? - Do the SOPs specify the turnaround times and quality conditions related to the issuance of test results? - Is there an external alliance for carrying out reference and counter-reference processes for tests performed at the LBM? - Does the LBM have a protocol (documented, implemented, and communicated) for its reference and counter-reference processes for each test? - Are roles for issuing and validating each result established, documented, and implemented at the LBM?
Characterization of resources for biosecurity and waste management	- Does the LBM have an approved, implemented, and disclosed biosafety manual or procedure? - Does the biosafety manual describe the types of samples handled in the LBM, adjusted to their specificity and complexity? - Are primary protective elements easily accessible for personnel to enter the LBM? - Do the unpacking and nucleic acid extraction areas include the necessary personal protective equipment (gown, gloves, mask, face shield, and/or glasses) for handling infectious agents? - Is there a Type A2 biosafety cabinet in the unpacking area for handling and processing infectious samples? - Does the LBM have a manual or plan for the comprehensive management of waste generated across its various sections and work areas? - Does the waste management plan address the handling of infectious agents? - Is the waste management plan aligned with current regulatory guidelines? - Are wide-mouth plastic containers (guardian type) available for waste collection in all areas and cabinets of the LBM? - Do the plastic waste collection containers have labeling and pictograms in accordance with Resolution 1164 of 2002? - Does the LBM adopt the correct color code for waste containers and ensure proper waste segregation with clear signage at each waste collection point?

having the largest number of laboratories, with >50 each (Fig. 1). They are followed by the departments of Atlántico and Antioquia, with 18 and 20 laboratories respectively. Finally, it was found that the departments of Guaviare and Vichada have the lowest number of laboratories. Regarding the nature of these laboratories, it was found that approximately 65 % ($n = 202$) correspond to private initiatives, 21 % ($n = 65$) are state-owned, and 14 % ($n = 44$) are linked to university institutions. Fig. 2 illustrates the distribution of laboratories by department, and their ownership, showing a concentration of these facilities in urban areas.

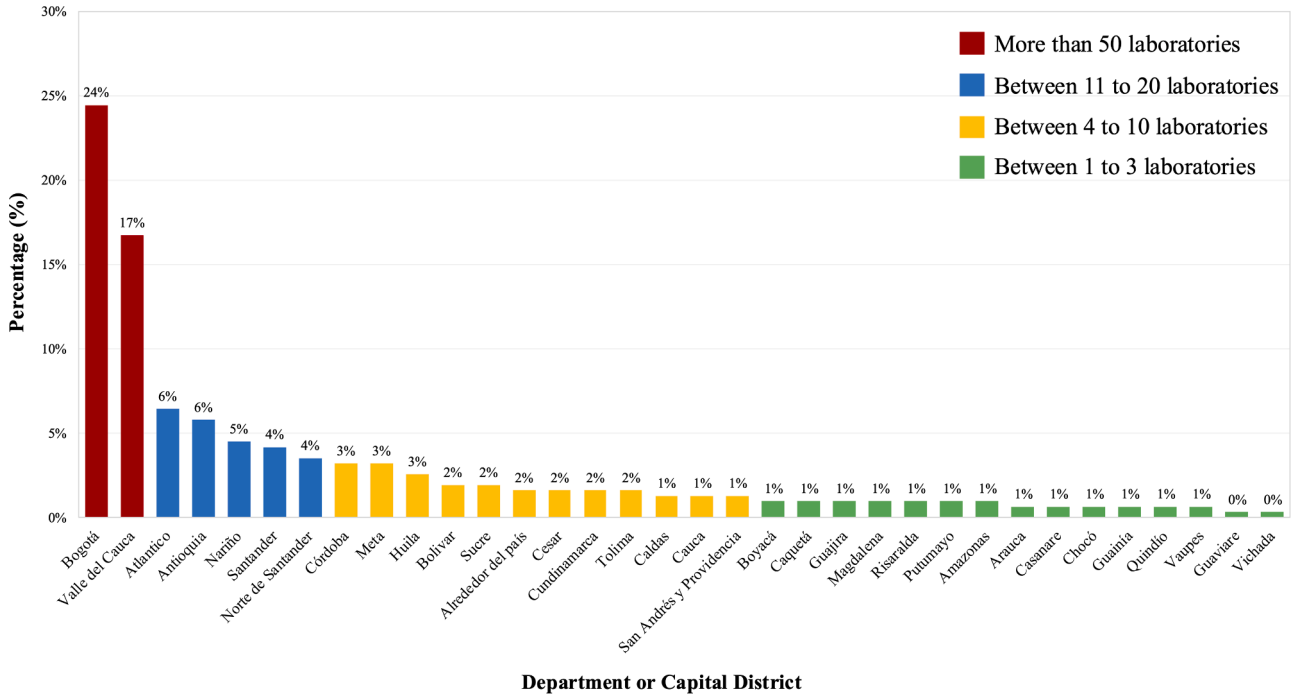

Fig. 1. Distribution of laboratories capable of molecular diagnosis of microorganisms by department.

3.2. Survey results and challenges and areas for improvement in laboratories

The survey results revealed several challenges hindering the advancement of testing laboratories in Colombia, with infrastructure cited as a significant issue by 26.2 % of laboratories (Supplementary Fig. S1). The need for standardized guidelines for infrastructure improvement is critical for enhancing market competitiveness. Opportunities for improvement were also identified in quality management systems and systematic documentation management, reported by 16.7 % of respondents.

Biosecurity and human resources emerged as critical areas requiring attention. Specifically, 14.3 % of laboratories, predominantly within public institutions, face substantial challenges in waste management This situation is exacerbated by the need for permanent employment contracts for waste management personnel, leading to disruptions, particularly when local and regional governments transition out of their legislative periods. Moreover, 10.7 % of laboratories indicated the need for more robust management and contracting policies to ensure the continuity of qualified personnel, especially in the public sector (Supplementary Fig. S1).

Training and availability of specialized personnel is another critical aspect, cited by 10.7 % of laboratories. Other factors, such as equipment and supply acquisition (7.1 %), strategic planning (6.0 %), and limited financial resources (4.8 %), were noted as lower-priority issues but are equally important for the optimal functioning of laboratories (Supplementary Fig. S1).

4. Discussion

Access to adequate diagnostic resources, particularly molecular diagnostics, is essential for strengthening health systems. However, this area receives less attention and funding compared to other health interventions, such as drug and vaccine development [15,27]. A major challenge in many countries is the inequitable distribution of diagnostic tools and limited access to basic testing methods, with low- and middle-income countries being the most affected. It is estimated that approximately 80 % of the population in these countries has restricted or no access to diagnostic resources at the primary care level [15].

For infectious diseases, molecular diagnostic tests are crucial for clinical management, monitoring, and prognosis in public health. In resource-limited settings, including parts of Colombia, clinical decision-making often relies on symptoms, complicating effective infection control [11,27,28]. Rapid and accurate tests, such as molecular diagnostics, improve clinical care and provide valuable information for targeted treatments. These measures can enhance epidemiological surveillance, enabling early outbreak detection and reducing disease transmission [29].

Although Colombia has an online application for recording laboratory information related to public health events [30], this study highlights the absence of a freely accessible, searchable repository that consolidates data on laboratories authorized for molecular testing of human pathogens. The lack of such a centralized resource represents challenges in assessing and accessing diagnostic capabilities nationwide.

The results show a concentration of laboratories in regions such as Bogotá and Valle del Cauca, in contrast to areas with a low number of laboratories (Fig. 1). This disparity indicates the robust infrastructure and resources available in some regions, which likely facilitate greater access to molecular diagnostic services for their populations, while underscoring the challenges faced in providing adequate healthcare resources in less developed areas. This variation in healthcare access reflects the differences in urban development and highlights the urgent need for targeted interventions to strengthen molecular diagnostic capabilities in regions with limited resources [31,32].

Additionally, the findings also indicate that laboratories capable of performing molecular diagnostics are predominantly located in urban areas (Fig. 2). Considering that nearly a quarter of Colombia's population resides in rural areas [33], this urban concentration reveals an unequal distribution of services that may hinder access to diagnostic testing in rural settings. The predominance of privately-operated laboratories in urban areas further exacerbates disparities in molecular testing availability, posing significant challenges in low-resource regions where access to testing is limited.

Population in these areas often face difficulties accessing reliable diagnostics and are required to travel long distances to obtain specialized medical services, restricting their ability to receive timely and

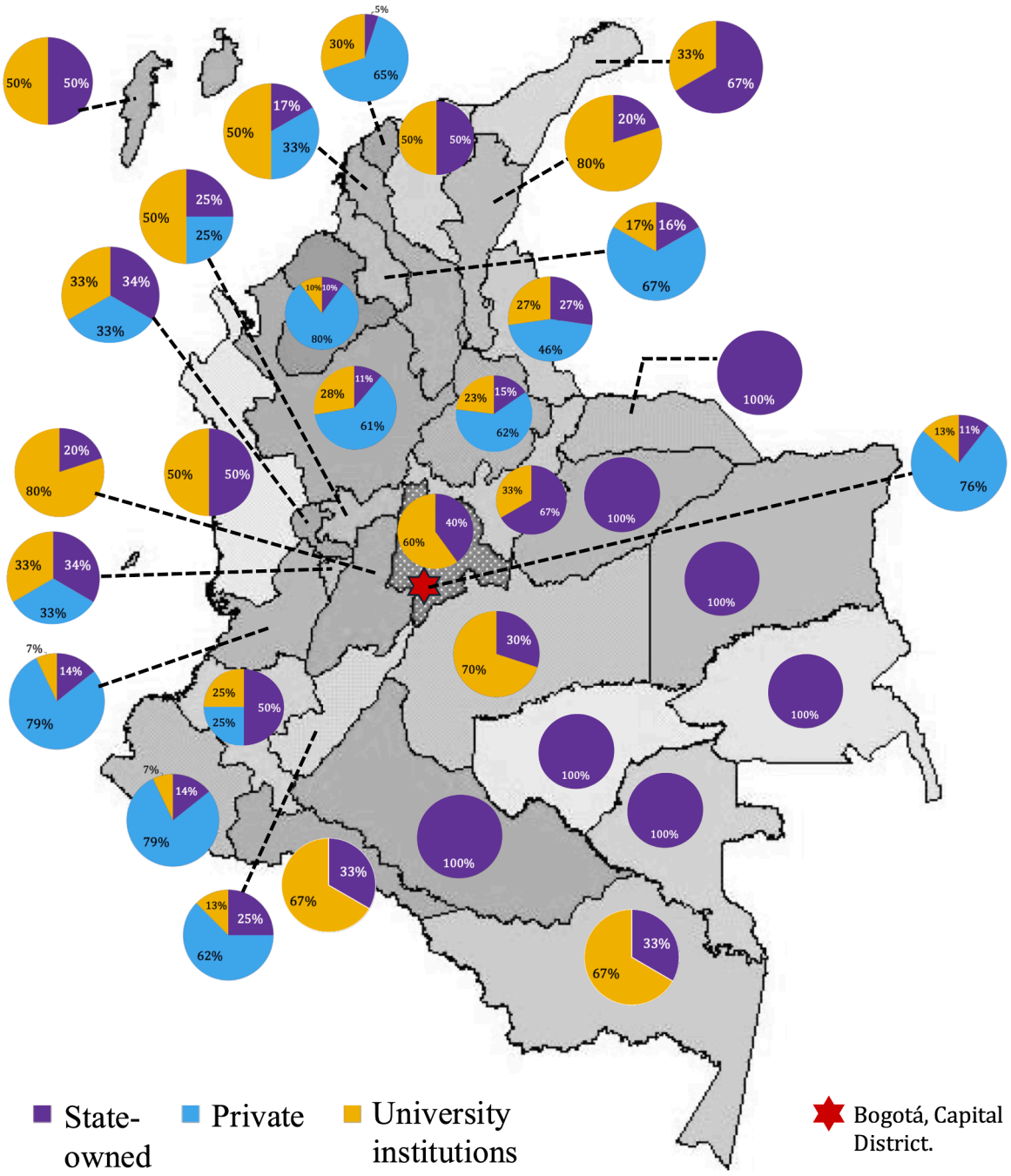

Fig. 2. Distribution of state, private, and university laboratories by department.

accurate healthcare. This issue has been documented for diseases of public health importance, such as cervical abnormalities related to HPV and cervical cancer [34], which remains one of the leading causes of cancer-related deaths among women in Colombia, with an estimated incidence rate of 12.7 per 100,000 women. Similar challenges have also been observed in the context of other infectious diseases, including Chagas disease, which affects >400,000 people in the country [35,36], and leishmaniasis, with Colombia being one of the countries reporting the most cases of the disease in the world, and the second-highest number of cases in the Americas, after Brazil [37]. These challenges underscore the need to improve molecular testing and develop innovative care models that enhance test applicability in non-conventional settings [38–40].

The findings also indicated that many laboratories, particularly state-run facilities, need to expand their service portfolios to include molecular biology-based testing. This update would not only enhance the competitiveness of these laboratories but also support their long-term sustainability. Additionally, the broader integration of molecular diagnostics would allow for better alignment with market demands, offering opportunities to implement more efficient business management strategies. Business management education could play a key role in this transformation, equipping laboratory managers with the skills to optimize resources, improve service quality, and maximize the impact on public Health [41].

The implementation of molecular diagnostics for infectious diseases varies significantly across countries, influenced by disparities in healthcare infrastructure, financial resources, and governmental policies. In high-income countries such as the United States and United Kingdom, the adoption of molecular diagnostic technologies has been rapid and widespread. This success stems from robust investment in

research and development, substantial government funding, and the availability of advanced laboratory infrastructure. These factors enable access to cutting-edge technologies, such as next-generation sequencing (NGS), which support precise and timely detection of infectious agents [42,43].

In contrast, low- and middle-income countries (LMICs) face considerable challenges in adopting molecular diagnostics. Limited financial resources, a lack of infrastructure, and difficulties in accessing advanced technologies have slowed the implementation process. For instance, laboratories in rural areas of many LMICs often lack the necessary equipment and trained personnel to perform complex molecular tests. This disparity highlights the need for innovative approaches tailored to resource-limited settings [43,44].

One promising solution has been the development of "lab-on-a-chip" technologies, which integrate multiple laboratory functions onto a single, portable chip. These devices are cost-effective, require minimal infrastructure, and allow for rapid, accurate diagnoses at the point of care. This innovation is particularly beneficial in remote or underserved areas, where access to centralized laboratories is limited. Additionally, international collaborations and investments in healthcare infrastructure have proven effective in enhancing molecular diagnostic capacity. For example, partnerships between laboratories and the establishment of diagnostic networks have strengthened the ability to respond to outbreaks of infectious diseases, improving both detection rates and response times [45–47].

Ultimately, addressing the challenges associated with molecular diagnostics for infectious diseases requires a combination of innovative technologies, international cooperation, and supportive government policies. Countries can benefit from sharing best practices and adapting successful methodologies to their specific contexts. For instance, the United States' investment in advanced diagnostic tools or the implementation of decentralized laboratory networks in Brazil can serve as models for other nations [48,49]. By leveraging these approaches, countries can enhance their diagnostic capabilities, improve public health outcomes, and build resilience against future health emergencies [50].

In Colombia, universal access to healthcare is a constitutional right; however, not all medical procedures are equally accessible to the population. The Health Benefits Plan, as defined by resolution 2366 of 2023 [51], regulates and includes a list of health services and technologies available to members of the General Health Social Security System (SGSSS). This list standardizes authorized medical procedures and includes molecular-level laboratory tests. Currently, 39 codes are assigned to molecular tests for the diagnosis of specific pathogens, such as Human Papillomavirus, HIV, Cytomegalovirus, *Toxoplasma gondii,* Varicella zoster virus, Epstein-Barr virus*, Mycobacterium tuberculosis*, and *Clostridium difficile* [52].

However, Colombia lacks standardized national guidelines for molecular diagnostics. Therefore, efforts to expand the number and diversity of molecular tests covered by the Health Benefits Plan would strengthen microorganism surveillance systems and promote equitable access to accurate diagnostics and appropriate treatments. Such advancements would also encourage the full utilization of molecular biology laboratories across the country [31].

Colombian legislation regulating the provision of molecular diagnostic services is designed to ensure the quality, safety, and effectiveness of the services provided by laboratories involved in this field. Key regulations include Resolution 1619 of 2015 [53], Decree 780 of 2016 [54], Resolution 3100 of 2019 [55] and the Technical Standard ISO 15189:2022 (Supplementary Table S1) [56]. These regulations establish guidelines to ensure quality control processes and technical competence in medical laboratories, including those conducting molecular diagnostics. However, during the pandemic, infrastructure challenges became particularly evident. Many laboratories reported a pressing need for standardized guidelines tailored to the local context. Addressing this challenge requires the creation of a regulatory framework that meets these needs, coupled with a policy of sustained investment to improve the infrastructure of existing laboratories across the country.

During the pandemic, one of the most notable achievements was the establishment of an inter-institutional collaboration network that facilitated the joint use of resources, the exchange of information, and rapid data generation, significantly enhancing the response effectiveness. Testing capacity increased from zero to over 40,000 daily tests, peaking at nearly 92,000 tests per day (approximately 0.672 PCR tests per inhabitant per year in Colombia) by 2022 [57]. In various regions, expanded access to essential resources for the strengthening and adaptation of laboratories improved equity in testing services, as reflected in the surge in the number of tests conducted during this short observation period (Fig. 3) [21]. Additionally, the CoVIDA project, which implemented a Drive/Walk-through detection model, enabled free and large-scale testing in Bogotá and surrounding municipalities. This initiative demonstrated that Colombia's viral identification capabilities could be on par with those of high-income countries, such as the United States and South Korea [58].

This study faces several limitations. First, the reliance on online databases and search engines may have resulted in incomplete data regarding the total number of laboratories nationwide. Many facilities, particularly those in rural or underserved areas, may lack an online presence, which limits the accuracy and representativeness of the dataset used for this study. Second, the analysis focused on only ten laboratories, a small subset of the 311 laboratories registered in Colombia. This sample size represents a limited perspective and may not adequately capture the diversity in infrastructure, diagnostic capabilities, or operational challenges faced by laboratories across the country. Furthermore, laboratories without an online presence or those in less urbanized regions may exhibit distinct characteristics that were not accounted for in this study.

The small sample size limits the generalizability of the findings, particularly regarding the distribution and availability of molecular diagnostic tools. To overcome these limitations, future studies should prioritize a more comprehensive sampling strategy, incorporating a larger and more diverse range of laboratories, including those in remote areas. This approach would allow for a more accurate and equitable characterization of molecular diagnostic capabilities and inform the development of targeted strategies to strengthen the diagnostic landscape in Colombia. Following the pandemic, many laboratories faced significant challenges regarding the continuity of qualified personnel, particularly in public institutions. To ensure the sustainability of these laboratories, it is essential to develop more robust management and hiring policies that guarantee the retention of trained staff, as well as to provide ongoing training and support for health workers to maintain operations during emergencies. In response to the COVID-19 pandemic, laboratories expanded their capacities to meet the increasing demand for viral identification tests. This expansion not only provided valuable infrastructure and equipment but also presents an opportunity to refocus these resources on the implementation of tests for the identification of other pathogens of public health interest.

The pandemic highlighted disparities in molecular testing availability, particularly affecting rural populations in Colombia, where most laboratories are concentrated in urban areas. This urban-centric distribution limits access to accurate testing in less populated regions, emphasizing the need for strategies that enhance service coverage. Despite the existence of internationally validated molecular tests for various infections, their widespread implementation within the Colombian health system remains limited. Traditional diagnostic methods, such as culture and ELISA tests, continue to dominate, leading to underreporting and less accurate results, which complicate clinical management.

To address these challenges, it is essential to establish government policies that ensure broad and timely access to molecular biology tests. Advanced diagnostic tools, supported by robust scientific evidence, offer superior performance characteristics, making them indispensable for

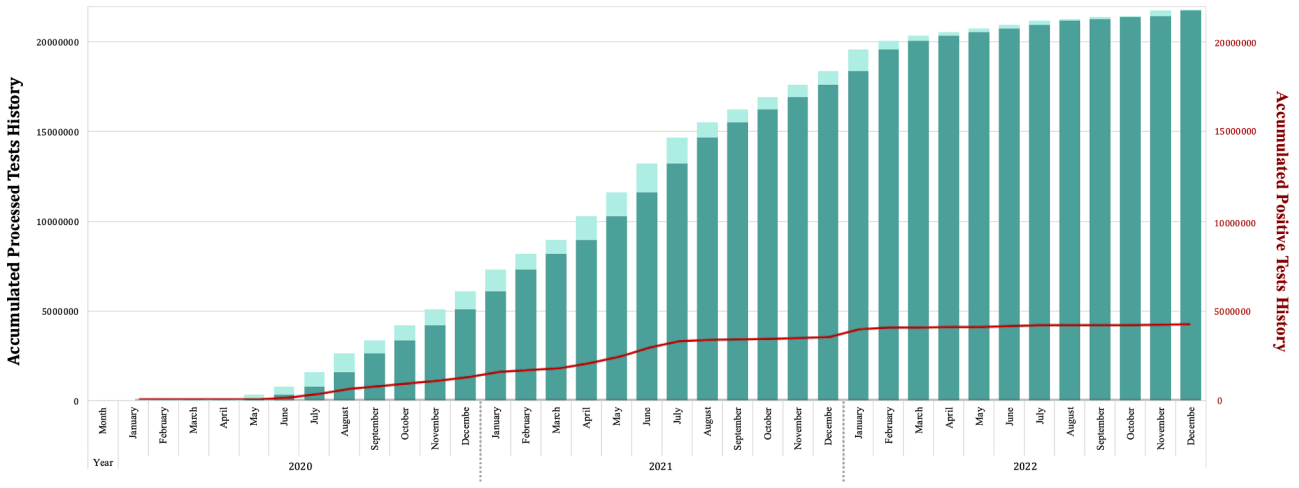

Fig. 3. Testing capacities for SARS-CoV-2 in Colombia between 2020 and 2022. The accumulated testing capacity is represented in dark green, while the monthly increase in testing capacity is shown in light green. The red line indicates the number of diagnosed COVID-19 cases over time.

detecting microorganisms of public health significance. Expanding and diversifying testing services rapidly is crucial not only for improving responses to health emergencies but also for ensuring the economic sustainability of laboratories. In addition, developing quality evaluation programs for molecular tests in Colombia is vital. These programs should establish biological standards for pathogen DNA identification and amplification, ensuring result accuracy and reliability. The creation of microorganism collections as reference banks would further standardize testing processes, facilitate professional training, and strengthen epidemiological surveillance systems, ultimately improving infectious disease management in the country [31,32].

Strengthening Colombia's molecular diagnostic capacity requires a comprehensive evolution of the legal framework to promote technological independence and ensure scientific autonomy. A Biotechnological Sovereignty Law could catalyze innovation and guarantee funding for research and development in diagnostic technologies, vaccines, and medicines [59,60]. Such measures would enable the country to reduce its dependence on external markets, enhance public health outcomes, and lower healthcare costs. Furthermore, the government should prioritize investments in infrastructure, continuous training for laboratory personnel, and the standardization of molecular tests to enhance diagnostic accuracy and cost-efficiency.

Given the limited number of laboratories equipped to perform sophisticated techniques like Next-Generation Sequencing (NGS), addressing the infrastructural and regulatory gaps is crucial. While the current legal framework provides a foundation for operational standards, the expansion of laboratory capabilities and adoption of new technologies will require additional regulatory support, sustained investment in education and infrastructure, and a focused effort to achieve biotechnological autonomy. The results of this study provide an overview of the molecular testing capacity in selected laboratories, offering preliminary insights into the status of these facilities. This foundational knowledge is essential for planning strategies that strengthen and expand diagnostic capabilities, ensuring their continuous and sustainable improvement.

The results of this characterization provide an overview of the molecular testing capacity in selected laboratories, essential for planning strategies to strengthen and expand diagnostic capabilities. This study generates preliminary insights into the current status of laboratories in Colombia, aiming to establish a foundation for the continuous and sustainable improvement of molecular diagnostic capabilities.

Data availability

All data analysed during this study are included in this article.

Funding

This research was funded by the Ministry of Science, Technology and Innovation of Colombia, AGORA project: "Alliance for the Generation of Evidence on COVID-19, its Response and Lessons Learned for the Post-pandemic and Future Epidemics" (Contract No 637-2022).

CRediT authorship contribution statement

Milena Camargo: Writing – original draft, Visualization, Validation, Resources, Methodology, Investigation, Formal analysis, Data curation. **Marina Muñoz:** Writing – original draft, Project administration, Funding acquisition, Formal analysis, Conceptualization. **Luz Helena Patiño:** Writing – review & editing, Resources, Project administration, Methodology, Investigation. **Juan David Ramírez:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.diagmicrobio.2025.116716.

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