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DIAGNOSTIC INNOVATION FOR INFECTIOUS DISEASES: A COMPARATIVE STUDY OF INDIA AND BRAZIL

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ABSTRACT

Achieving SDG 3 (Good Health and Well-Being) requires ensuring healthy lives and promoting well-being for all at all ages, with Target 3.3 calling for ending the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases. Diagnostic innovation, the development and deployment of rapid, accurate, affordable, and accessible diagnostic tests, is a critical determinant of infectious disease control, enabling early detection, appropriate treatment, transmission reduction, and antimicrobial resistance surveillance. However, diagnostic capacity varies dramatically across countries, shaped by health system infrastructure, research and development

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investment, regulatory pathways, intellectual property regimes, manufacturing capability, and public-private partnerships.

This study conducts a comparative analysis of diagnostic innovation for infectious diseases in India and Brazil, two large middle-income countries with contrasting health systems, strong pharmaceutical and diagnostic industries, and leadership in global health diplomacy. India has emerged as the "pharmacy of the developing world" for generic medicines and is rapidly expanding diagnostic capacity through major manufacturers, public sector diagnostic networks, and a strong cost-innovation model. Brazil has a universal public health system (SUS) serving 150 million people, with strong diagnostic infrastructure including Fiocruz (Oswaldo Cruz Foundation), Instituto Butantan, and a decentralized network of public health laboratories (LACEN). Brazil has pioneered molecular testing integration for multiple pathogens and led a brain infections intervention study (Lancet 2025) that increased syndromic diagnosis from 77 percent to 86 percent and microbiological diagnosis from 22 percent to 30 percent across 13 hospitals in Brazil, India, and Malawi.

Using a qualitative comparative case study methodology, the study analyzes secondary data from government reports, international databases, peer-reviewed literature, and program evaluations over the period 2000 to 2025. The study finds that both countries have built robust diagnostic innovation systems but face common challenges including regional disparities, point-of-care testing gaps, antimicrobial resistance diagnostics lagging, supply chain fragility, and regulatory harmonization needs.

The study concludes that diagnostic innovation requires sustained public investment, regulatory agility, local manufacturing, quality assurance, and integration with surveillance. Recommendations for both countries and the international community are provided.

Keywords: Diagnostic innovation; infectious diseases; India; Brazil; SDG 3; tuberculosis; molecular diagnostics; point-of-care testing; Fiocruz; ICMR

RÉSUMÉ

Atteindre l'ODD 3 nécessite de mettre fin aux épidémies de sida, tuberculose, paludisme et maladies tropicales négligées (cible 3.3). L'innovation diagnostique est un déterminant essentiel de la lutte contre les maladies infectieuses. Cette étude analyse l'innovation diagnostique pour les maladies infectieuses en Inde et au Brésil. L'Inde a développé une capacité de diagnostic importante avec des fabricants majeurs (Tulip, Meril, Transasia), un réseau de diagnostic moléculaire pour la tuberculose (NTEP), et une capacité de test COVID-19 d'un million par jour. Le Brésil dispose d'un système de santé universel (SUS) avec une infrastructure diagnostique solide incluant Fiocruz (production de vaccins et diagnostics) et un réseau de laboratoires de santé publique (LACEN). Une étude brésilienne sur les infections cérébrales (Lancet 2025) a démontré qu'une intervention simple a augmenté le diagnostic syndromique de 77 pour cent à 86 pour cent et le diagnostic microbiologique de 22 pour cent à 30 pour cent. L'étude conclut que l'innovation diagnostique nécessite un investissement public soutenu, une fabrication locale, une assurance qualité et une intégration à la surveillance. Des recommandations sont fournies pour les deux pays et la communauté internationale.

Mots-clés : innovation diagnostique, maladies infectieuses, Inde, Brésil, ODD 3, tuberculose, diagnostics moléculaires, tests de diagnostic rapide, Fiocruz, ICMR

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1. INTRODUCTION

Achieving SDG 3 (Good Health and Well-Being) requires ensuring healthy lives and promoting well-being for all at all ages, with Target 3.3 calling for ending the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases. Diagnostic innovation, the development and deployment of rapid, accurate, affordable, and accessible diagnostic tests, is a critical determinant

of infectious disease control, enabling early detection, appropriate treatment initiation, transmission reduction, antimicrobial resistance (AMR) surveillance, and outbreak response.

Without accurate diagnostics, clinicians cannot distinguish between viral and bacterial infections, leading to antibiotic overuse and AMR. They cannot detect drug-resistant tuberculosis, leading to treatment failure and continued transmission. They cannot identify emerging pathogens, leading to delayed outbreak response. They cannot monitor treatment response, leading to poor outcomes. The COVID-19 pandemic demonstrated the centrality of diagnostics. Countries with robust molecular testing capacity (PCR) and rapid antigen tests were able to detect cases, isolate infected individuals, and target public health responses. Countries with weak diagnostic capacity suffered prolonged outbreaks, higher mortality, and economic disruption.

This study examines two countries that offer profound and contrasting insights into diagnostic innovation for infectious diseases: India and Brazil.

India, a lower-middle-income country with a population of 1.4 billion and a GDP per capita of $2,500, has emerged as the "pharmacy of the developing world" for generic medicines and is rapidly expanding diagnostic capacity. India has a fragmented health system with high private sector out-of-pocket spending, estimated at 65 percent of total health expenditure. Major diagnostic manufacturers include Tulip Diagnostics, Meril Life Sciences, Transasia Bio-Medicals, Agappe Diagnostics, and Span Diagnostic. Public sector diagnostic networks include the Indian Council of Medical Research (ICMR) through its National Institute of Virology, the National TB Elimination Programme (NTEP) with molecular diagnostics (CBNAAT and TrueNat), and COVID-19 testing capacity that reached over 1 million tests per day at its peak. India hosts the BRICS TB Research Network (inaugural meeting in 2026), focusing on next-generation diagnostics including rapid molecular testing, biomarker-based detection, and AI-driven screening. India's cost-innovation model has produced low-cost diagnostic tests, with pan-India TB testing using molecular platforms costing significantly less than Western counterparts.

Brazil, an upper-middle-income country with a population of 210 million and a GDP per capita of $9,000, has a universal public health system (Sistema Único de Saúde, SUS), established in 1988, serving 150 million people (75 percent of the population). Brazil has strong diagnostic

infrastructure, including Fiocruz (Oswaldo Cruz Foundation) in Rio de Janeiro, a leading public health research institution with vaccine and diagnostic production capabilities, 10 or more technical units, and WHO Collaborating Centre status for COVID-19, Chagas disease, and leishmaniasis. Instituto Butantan in São Paulo produces vaccines and sera. A decentralized network of public health laboratories (LACEN, Laboratórios Centrais de Saúde Pública) operates in each state (27 LACENs), plus municipal and regional laboratories. Brazil has pioneered molecular testing integration for multiple pathogens, including Zika, Chikungunya, Oropouche, and dengue, through its molecular testing network for infectious disease surveillance.

Brazil's brain infections intervention study (Singh et al., 2025, The Lancet) demonstrated that a multifaceted intervention including a diagnostic algorithm, lumbar puncture pack, testing panel, and staff training increased syndromic diagnosis from 77 percent to 86 percent (adjusted odds ratio of 1.81) and microbiological diagnosis from 22 percent to 30 percent (adjusted odds ratio of 1.46) across 13 hospitals in Brazil, India, and Malawi. The study was co-designed with policymakers, and the intervention is now being implemented by the World Health Organization as part of the Meningitis Roadmap and encephalitis control initiatives. Brazil faces challenges including regional disparities (north and northeast regions have lower diagnostic capacity than the south and southeast), supply chain fragility (reagent shortages and customs delays), and high dependence on imported diagnostics, though local production is increasing through Fiocruz and the private sector.

The contrast between India and Brazil illuminates critical questions for diagnostic innovation, infectious disease control, and SDG 3, which this study addresses.

2. LITERATURE REVIEW

The literature on diagnostic innovation for infectious diseases spans global health, public health, biomedical engineering, and health systems research.

2.1 Global Diagnostic Initiatives

Key global initiatives include FIND (Foundation for Innovative New Diagnostics) based in Geneva, WHO prequalification of diagnostics, Unitaid investments, and Global Fund diagnostic procurement. These organizations have played crucial roles in shaping diagnostic markets,

establishing quality standards, and funding diagnostic scale-up in low- and middle-income countries.

2.2 Tuberculosis Diagnostics

The tuberculosis diagnostics literature is extensive. WHO endorsed CBNAAT (GeneXpert) in 2010 and TrueNat in 2017, and continues to evaluate new technologies. India's NTEP has one of the world's largest molecular diagnostic networks. The cost-effectiveness of TB diagnostic technologies in India and Brazil has been evaluated by Bashir et al. (2024, PLOS Global Public Health). Their study found that Diaskintest (a skin test) is more cost-effective at 41.00 *per correctly diagnosed case in India and* 22.60 per correctly diagnosed case in Brazil than TST-PPD. TSPOT.TB (an IGRA) has higher effectiveness with an incremental cost-effectiveness ratio (ICER) of 74 *for India and* 55 for Brazil (Bashir et al., 2024).

2.3 Brain Infections Intervention

Brazil's brain infections intervention study (Singh et al., 2025, The Lancet) is the first study to report the positive effect of an intervention package for central nervous system (CNS) infections that is generalizable across low- and middle-income countries (Singh et al., 2025). The Brazilian and Indian contributions to this study demonstrate successful South-South collaboration in implementation research.

2.4 Research Institutions and South-South Cooperation

Brazil's Fiocruz and India's ICMR are both WHO Collaborating Centres. The BRICS TB Research Network, with its inaugural meeting hosted by India in 2026, signals growing South-South cooperation in diagnostic innovation (Medgate Today, 2026). The network focuses on next-generation diagnostics including rapid molecular testing, biomarker-based detection, and AI-driven screening.

2.5 Comparative Studies

Comparative analyses of India and Brazil's diagnostic innovation systems are rare. Most studies focus on either Asian or Latin American contexts separately. This study fills that gap by providing a structured comparison of diagnostic innovation for infectious diseases in India and Brazil.

3. RESEARCH QUESTIONS

This study addresses the following research questions:

1. What are the diagnostic innovation systems, including research and development, manufacturing, procurement, and deployment, for infectious diseases in India and Brazil?
2. How do health system structures, with India's fragmented system versus Brazil's universal SUS, affect diagnostic access and equity?
3. What can each country learn from the other about diagnostic innovation and infectious disease control?

4. METHODOLOGY

This study employs a qualitative comparative case study methodology to examine diagnostic innovation for infectious diseases in India and Brazil. The comparative approach is appropriate for examining how different health system structures, research and development investments, and regulatory pathways shape diagnostic outcomes. India and Brazil were selected as cases offering meaningful comparison. Both are large middle-income countries and members of the BRICS group. Both have strong public health research institutions (ICMR in India and Fiocruz in Brazil). Both have local diagnostic manufacturing capabilities (Tulip, Meril, and Transasia in India; Bio-Manguinhos and private sector in Brazil). Both face regional disparities in diagnostic access, and both engage in South-South cooperation through the BRICS TB Research Network and Fiocruz-Africa partnerships. The research design integrates secondary analysis of multiple data sources spanning the period 2000 to 2025. Government sources include, for India, the Ministry of Health and Family Welfare, the Indian Council of Medical Research (ICMR), the National TB Elimination Programme (NTEP), the Department of Biotechnology, and the Central Drugs Standard Control Organization (CDSCO); for Brazil, the Ministry of Health (MS), Fiocruz, ANVISA (Agência Nacional de Vigilância Sanitária), and the Ministry of Science, Technology and Innovation (MCTI). International databases include the WHO Global Health Observatory, the

FIND diagnostics pipeline, the Global Fund, Unitaid, and the World Bank. Peer-reviewed literature from journals including PLOS Global Public Health and The Lancet, as well as program evaluations, were also analyzed. The analytical framework examines five dimensions: research and development institutions (ICMR, Fiocruz, and other research bodies); diagnostic manufacturing (major manufacturers and production capacity); molecular diagnostic scale-up (TB in India, arboviruses in Brazil, COVID-19 in both); cost-effectiveness research (India-Brazil collaboration on TB diagnostics); and regulatory pathways (CDSCO in India, ANVISA in Brazil). The study has several limitations, including reliance on secondary data constrained by availability, quality, and comparability. India's decentralized health system data are less uniform than Brazil's SUS data. The comparative case study design cannot establish causality as rigorously as experimental methods. No primary data collection, such as interviews with scientists, diagnostic manufacturers, or policymakers, was conducted. The study period (2000 to 2025) captures recent trends but does not fully explore longer-term historical dynamics. Despite these limitations, the comparative analysis provides valuable insights for policy and future research.

5. RESULTS

Table 1: Comparative Summary – Diagnostic Innovation for Infectious Diseases

Dimension	**India**
Population	1.4 billion
GDP per capita (USD)	$2,500 (lower-middle)
Health system	Fragmented (public + private); high out-of-pocket (65%)
Public health research institutions	ICMR (26 institutes), NIV (Pune), NCDC (Delhi)
Major diagnostic manufacturers	Tulip Diagnostics, Meril Life Sciences, Transasia Bio-Medicals, Agappe, Span Diagnostic

Molecular diagnostic scale-up	TB: CBNAAT/TrueNat at 7,000+ sites (NTEP); COVID-19: 1 million+ tests/day
Cost-effectiveness research (TB diagnostics)	Diaskintest: 41.0percorrectlydiagnosedcase;TSPOT.TBICER41.0*percorrectlydiagnosedcase*; *TSPOT.TBICER*74 (Bashir et al., 2024)
Brain infections intervention (2025)	Participating site; intervention increased syndromic diagnosis (77% to 86%, aOR 1.81) and microbiological diagnosis (22% to 30%, aOR 1.46) (Singh et al., 2025)
BRICS TB Research Network	Hosted inaugural meeting (2026); focus on next-generation diagnostics (Medgate Today, 2026)
Regional disparities	High-performing states (Kerala, Tamil Nadu) vs lower (Bihar, UP)
Regulatory authority	CDSCO (Central Drugs Standard Control Organization)
Source	ICMR (2025); NTEP (2025)

Table 2: India – Diagnostic Innovation System

Element	**Description**
ICMR (Indian Council of Medical Research)	Apex body for biomedical research (1911, reorganized 1949). 26 institutes: National Institute of Virology (NIV, Pune – arboviruses, influenza, COVID-19), National Institute of Epidemiology (NIE, Chennai), National Institute of Malaria Research (NIMR, Delhi), National Institute of Cholera and Enteric Diseases (NICED, Kolkata), National Institute of TB Research (NITR, Chennai), Regional Medical Research Centres (RMRCs).

National TB Elimination Programme (NTEP)	Molecular diagnostic scale-up: CBNAAT (Cartridge-Based Nucleic Acid Amplification Test – GeneXpert) and TrueNat deployed at 7,000+ sites (district hospitals, medical colleges, some PHCs). Line-probe assay (LPA) for drug resistance (first-line, second-line). Capacity: 10 million+ TB tests/year.
COVID-19 testing capacity	Peak capacity 1 million tests/day (RT-PCR, TrueNat, CBNAAT, Rapid Antigen Tests). ICMR-approved labs: 3,000+ (public + private). India developed indigenous RT-PCR kits (Mylab, TATA MD CHECK, etc.).
Diagnostic manufacturers	Tulip Diagnostics (Goa – ELISA, rapid tests (HIV, HBsAg, HCV, Dengue, Malaria, Syphilis), molecular). Meril Life Sciences (Vapi – molecular diagnostics (RT-PCR, RNA extraction), point-of-care). Transasia Bio-Medicals (Mumbai – haematology, chemistry, coagulation, molecular). Agappe Diagnostics (Kerala – clinical chemistry, immunoturbidimetry). Span Diagnostic (Surat – rapid tests). Other startups.
Cost-innovation	India's "frugal innovation" model produces diagnostic tests at 30-50% of Western costs. Generic rapid tests (HIV, malaria) at $0.50-2.00. Molecular TB tests (TrueNat) developed in India, lower cost than GeneXpert.
BRICS TB Research Network	Inaugural meeting hosted by India (2026). Focus on next-generation diagnostics: rapid molecular testing (including CRISPR-based), biomarker-based detection (including transcriptomic), AI-driven screening. Participating countries: Brazil, Russia, India, China, South Africa. Objectives: collaborative research, joint clinical trials, data sharing, technology transfer (Medgate Today, 2026).
Regulatory pathway	CDSCO (Central Drugs Standard Control Organization) under DCGI (Drugs Controller General of India). Diagnostic devices regulated under Medical Devices Rules (2017). Classes A (low risk) to D (high risk). Fast-track approval for priority pathogens (COVID-19 emergency use authorization).
Challenges	Regional disparities (Bihar, UP, Jharkhand, Chhattisgarh have lower diagnostic capacity than Kerala, Tamil Nadu, Maharashtra). Fragmentation: public vs private sector coordination weak. Point-of-care gap: rural areas lack basic diagnostics

	(microscopy, rapid tests). AMR diagnostics lagging (rapid susceptibility testing not widely available).

Table 3: Brazil – Diagnostic Innovation System

Element	Description
Fiocruz (Oswaldo Cruz Foundation)	Public health research institution (1900, renamed 1970). Headquarters in Rio de Janeiro, with 10+ technical units: Instituto Oswaldo Cruz (IOC) – diagnostics R&D, reference lab; Instituto de Tecnologia em Imunobiológicos (Bio-Manguinhos) – vaccine and diagnostic production; Instituto Carlos Chagas (ICC – Paraná, molecular biology); Instituto Gonçalo Moniz (IGM – Salvador, infectious diseases). WHO Collaborating Centre (COVID-19, Chagas, leishmaniasis, etc.) (Fiocruz, 2025).
Sistema Único de Saúde (SUS)	Universal public health system (1988). Covers 150 million people (75% of population). Diagnostic services provided at municipal, state, and federal levels. Laboratory network: Central Public Health Laboratories (LACEN) in each state (27 LACENs), plus regional and municipal labs (Ministério da Saúde, 2025).
Molecular diagnostic scale-up (arboviruses)	Brazil pioneered molecular testing integration for multiple pathogens: Zika, Chikungunya, Dengue, Oropouche, Mayaro, Yellow Fever. National arbovirus surveillance network uses RT-PCR (real-time polymerase chain reaction) for detection, genotyping, and outbreak monitoring. LACENs equipped with PCR platforms. Fiocruz produces molecular diagnostic kits (Zika, Dengue, Chikungunya multiplex).
Brain infections intervention (Lancet 2025)	Multifaceted intervention co-designed with clinicians, policymakers: diagnostic and management algorithm, lumbar puncture pack, testing panel (molecular, serological, CSF analysis), staff training. Across 13 hospitals (Brazil, India, Malawi): syndromic diagnosis increased from 77% to 86% (aOR 1.81, $p<0.0001$); microbiological diagnosis increased from 22% to 30% (aOR 1.46, $p=0.00040$) (Singh et al., 2025). Results fed into WHO Meningitis Roadmap and encephalitis control initiatives (Franca, 2025; Brain Infections Global, 2025).

Diagnostic manufacturing	Bio-Manguinhos (Fiocruz): produces immunobiologicals (vaccines, diagnostics) – ELISA kits for HIV, hepatitis, Chagas, leishmaniasis; molecular kits (Zika, Dengue, Chikungunya, COVID-19). Butantan (São Paulo): vaccines, sera. Private sector: multinational (Abbott, Roche, Siemens, Biomérieux – Brazil subsidiaries). Local manufacturers (small and medium).
Regulatory authority	ANVISA (Agência Nacional de Vigilância Sanitária, 1999). Regulates diagnostic devices (risk classification I to IV). Fast-track pathways for priority pathogens (COVID-19 emergency use). Harmonization with international bodies (IMDRF, WHO).
Genomic surveillance	Brazil established genomic surveillance network for SARS-CoV-2 (Fiocruz, Butantan, USP, UNESP, many others). Now expanded to influenza, arboviruses, and emerging pathogens. Real-time sequencing (Oxford Nanopore, Illumina) for variant detection, outbreak tracking.
Challenges	Regional disparities: north (Amazon region) and northeast have lower laboratory density, equipment, trained personnel than south and southeast (Rio, São Paulo, Porto Alegre). Supply chain fragility: reagent shortages, customs delays for imported supplies, distribution bottlenecks (Amazon). Import dependence: despite Fiocruz production, many high-end diagnostics (automated platforms, specialized reagents) imported.

Table 4: Comparative Diagnostic Outcomes

Indicator	**India**	**Brazil**
TB diagnostic coverage (molecular)	7,000+ CBNAAT/TrueNat sites	Molecular testing for TB available at reference labs (not decentralized to PHC level as India)
COVID-19 peak testing capacity	1 million+ tests/day	200,000+ tests/day (population difference)
HIV testing (annual)	30 million+ (ICMR, NACO)	10 million+ (Ministry of Health)

Public health laboratories (central)	ICMR-NIV (Pune) + 25 other ICMR institutes	Fiocruz (Rio) + 8 other Fiocruz units + 27 LACENs
Diagnostic manufacturing (local)	Tulip, Meril, Transasia, Agappe, Span (strong)	Bio-Manguinhos (public), private subsidiaries (weaker than India)
Regulatory approval time (priority)	30-60 days (emergency use)	30-90 days (emergency use)
Point-of-care testing (rural)	Limited (microscopy, some rapid tests)	Limited (some primary care rapid tests)
Genomic surveillance capacity	Moderate (INSACOG – Indian SARS-CoV-2 Genomics Consortium)	Strong (Fiocruz, Butantan, USP genomic network)
Source	ICMR (2025); NTEP (2025); INSACOG (2025)	Fiocruz (2025); Ministério da Saúde (2025)

6. DISCUSSION OF RESULTS

6.1. Explaining India's Diagnostic Innovation Model

India's diagnostic innovation model leverages several key advantages. First, a large domestic market of 1.4 billion people with a high disease burden of TB, HIV, malaria, dengue, hepatitis, and COVID-19 creates economies of scale. Second, a cost-innovation culture of "frugal innovation" produces diagnostics at 30 to 50 percent of Western costs, as demonstrated by the TrueNat TB test and indigenous RT-PCR kits. Third, a strong generic pharmaceutical sector has extended into diagnostics, with companies such as Tulip, Meril, Transasia, and Agappe leading the way. Fourth, public-private partnerships have been effective, with ICMR collaborating with private manufacturers for COVID-19 test development and scale-up. Fifth, BRICS leadership, including hosting the inaugural TB Research Network meeting in 2026, positions India as a global health player (Medgate Today, 2026).

6.2. Explaining Brazil's Diagnostic Innovation Model

Brazil's diagnostic innovation model leverages different but equally important advantages. First, a universal public health system (SUS) provides large-scale diagnostic procurement through public tenders, creating a predictable market. Second, strong public research institutions with integrated manufacturing, such as Fiocruz Bio-Manguinhos, produce diagnostics for SUS and reduce import dependence. Third, pioneering molecular testing for arboviruses was driven by Brazil's experience with Zika, Chikungunya, Dengue, and Oropouche outbreaks, which necessitated molecular surveillance. Fourth, genomic surveillance leadership through Fiocruz, Butantan, and the USP genomic network sequenced thousands of SARS-CoV-2 genomes in real time. Fifth, South-South cooperation through Fiocruz-Africa partnerships with Mozambique, Angola, Cape Verde, and Guinea-Bissau builds diagnostic capacity across continents. Sixth, the brain infections intervention (Singh et al., 2025; Franca, 2025) demonstrated that simple, scalable interventions including algorithms, lumbar puncture packs, testing panels, and training can improve diagnostic outcomes.

6.3. Molecular Diagnostics: TB in India versus Arboviruses in Brazil

India's molecular diagnostics strength lies in tuberculosis, with NTEP deploying CBNAAT and TrueNat at more than 7,000 sites. Brazil's molecular diagnostics strength lies in arboviruses, with the LACEN PCR network testing for Zika, Chikungunya, Dengue, and Oropouche. Both countries built significant COVID-19 molecular testing capacity, with India reaching over 1 million tests per day and Brazil reaching 200,000 tests per day.

India could learn from Brazil's integration of multiple pathogen testing (multiplex PCR for arboviruses) to expand its TB platforms to test for other respiratory pathogens such as COVID-19, influenza, and RSV. Brazil could learn from India's decentralized TB molecular networks at district hospitals, medical colleges, and even some primary health centres to decentralize arbovirus testing beyond state LACENs to the municipal level.

6.4. Cost-Effectiveness Research

The India-Brazil collaboration on TB diagnostic cost-effectiveness (Bashir et al., 2024) demonstrates successful South-South research cooperation. The study found that Diaskintest, a skin-based test, is more cost-effective than TST-PPD, costing 22.60inBraziland22.60*inBraziland*41.00 in India per correctly diagnosed case.

TSPOT.TB, an IGRA, has higher effectiveness with an incremental cost-effectiveness ratio (ICER) of 55inBraziland55*inBraziland*74 in India (Bashir et al., 2024). This evidence informs national policy for India's NTEP and Brazil's TB programme.

6.5. Brain Infections Intervention: Brazilian Leadership

Brazil's Fiocruz played a leading role in the brain infections intervention study (Singh et al., 2025). The study was co-designed with policymakers, ensuring translation into policy, and the intervention is now part of the WHO Meningitis Roadmap (Franca, 2025; Brain Infections Global, 2025). Brazil's Fiocruz is now adapting this approach to other infectious diseases, including surveillance for emerging threats and diagnostic workflow refinement (Franca, 2025). This demonstrates how implementation science can drive policy change. India's participation in the same study, with sites in India, shows its capacity to conduct multi-country implementation research.

6.6. Regional Disparities

Both countries face significant regional disparities in diagnostic capacity. In India, Kerala, Tamil Nadu, and Maharashtra have high capacity, while Bihar, Uttar Pradesh, Jharkhand, and Chhattisgarh have low capacity. In Brazil, the south and southeast regions have high capacity, while the north and northeast regions have low capacity. Both countries need targeted investment in infrastructure, equipment, and trained personnel for underserved regions.

6.7. Point-of-Care Testing Gap

Both countries have significant gaps in point-of-care (POC) testing for rural areas. India's rural primary health centres (PHCs) lack basic diagnostics including microscopy for malaria and TB, rapid tests for HIV and syphilis, glucometers, and urine dipsticks. Brazil's primary care units (Unidade Básica de Saúde, UBS) have variable POC capacity. Both countries need low-cost, portable, battery-operated devices; multiplex POC tests that can detect multiple pathogens from a single sample; and connectivity to transmit results to electronic medical records.

6.8. Regulatory Harmonization

CDSCO in India and ANVISA in Brazil both have regulatory pathways for diagnostics. However, approval times can be long, ranging from 6 to 12 months for novel devices. Fast-track pathways for priority pathogens, such as emergency use authorization, worked well for COVID-19. Both countries need alignment with WHO prequalification, mutual recognition agreements to reduce duplication, and strengthened regulatory science capacity to evaluate novel technologies.

6.9. Transferability: What India Can Learn from Brazil and What Brazil Can Learn from India

India can learn from Brazil in several areas:

- The universal health system (SUS) provides a model for India's fragmented system, where 65 percent of health spending is out-of-pocket, leading to inequitable diagnostic access.
- Brazil's public procurement through centralized tenders through SUS reduces prices. India could strengthen public procurement through the National Health Mission and state tenders.
- Genomic surveillance through Brazil's Fiocruz network is strong. India has INSACOG but it is less integrated into routine surveillance.

Brazil can learn from India in several areas:

- Decentralized molecular networks are well developed in India, with TB platforms at the district level (more than 7,000 sites). Brazil's arbovirus testing is mostly at state LACENs (27 sites) and could be decentralized to the municipal level.
- India's cost-innovation model for frugal diagnostics could stimulate local diagnostic manufacturing in Brazil beyond Bio-Manguinhos, using tax incentives and public-private partnerships.
- India's BRICS leadership could be complemented by Brazil co-leading with India on TB diagnostics research.

6.10. Implications for SDG 3

Diagnostic innovation is central to SDG Target 3.3, which aims to end the epidemics of TB, malaria, and neglected tropical diseases. India and Brazil demonstrate that middle-income

countries can build robust diagnostic capacity through strategic public investment, local manufacturing, and South-South cooperation. However, regional disparities, point-of-care gaps, and AMR diagnostics remain challenges.

The international community, including WHO, FIND, the Global Fund, Unitaid, and the World Bank, should fund diagnostic innovation hubs in middle-income countries such as India, Brazil, and South Africa; support point-of-care test development for low-resource settings including low-cost, multiplex, connected devices; harmonize regulatory pathways through WHO prequalification and Emergency Use Listing; promote South-South cooperation through the BRICS TB Research Network and Fiocruz-Africa partnerships; and invest in diagnostic supply chain resilience through local manufacturing and regional stockpiles.

7. CONCLUSION

This comparative analysis reveals that diagnostic innovation for infectious diseases in India and Brazil has achieved significant scale but faces persistent challenges.

India has developed a robust diagnostic innovation system. The ICMR research institutes, molecular TB diagnostics through NTEP with more than 7,000 CBNAAT and TrueNat sites, COVID-19 testing capacity exceeding 1 million tests per day, major diagnostic manufacturers including Tulip, Meril, Transasia, Agappe, and Span, a cost-innovation model for frugal diagnostics, and BRICS TB Research Network leadership, hosting the inaugural meeting in 2026 (Medgate Today, 2026), are all notable achievements.

Brazil has developed a universal public health system (SUS) with strong diagnostic infrastructure. Fiocruz provides research and manufacturing through Bio-Manguinhos. The LACEN network includes 27 state laboratories. Brazil has pioneered arbovirus molecular testing, genomic surveillance leadership, and the brain infections intervention (Singh et al., 2025; Franca, 2025), which is now being implemented by WHO (Brain Infections Global, 2025).

Both countries face common challenges. Regional disparities exist, with the north and northeast of Brazil and the states of Bihar and Uttar Pradesh in India having lower diagnostic capacity than the south and southeast. Point-of-care testing gaps persist in rural areas. Antimicrobial resistance

diagnostics are lagging. Supply chain fragility leads to reagent shortages. Regulatory harmonization is needed.

Several cross-cutting insights emerge from this comparison:

1. Public investment in research institutions such as ICMR and Fiocruz and in manufacturing such as Bio-Manguinhos and India's private manufacturers creates diagnostic capacity.
2. South-South cooperation through the BRICS TB Research Network and Fiocruz-Africa partnerships accelerates innovation (Medgate Today, 2026).
3. Cost-effectiveness research informs policy, as demonstrated by the India-Brazil TB diagnostics study (Bashir et al., 2024).
4. Implementation research, as demonstrated by Brazil's brain infections intervention, shows that simple, scalable interventions improve outcomes and influence WHO policy (Singh et al., 2025; Franca, 2025).
5. Molecular diagnostics scale-up requires decentralized networks, as seen in India's TB model, and multiplex capacity, as seen in Brazil's arbovirus model.

For India, priorities include: expanding molecular diagnostic networks to primary health centres for TB, HIV, hepatitis, and AMR; strengthening antimicrobial resistance surveillance through AMR diagnostic networks and rapid susceptibility testing; scaling up point-of-care testing for rural areas using low-cost, portable, battery-operated devices; operationalizing the BRICS TB Research Network through joint clinical trials, technology transfer, and regulatory harmonization; integrating diagnostic data with the national digital health mission (Ayushman Bharat Digital Mission); and reducing regional disparities through targeted investment in Bihar, Uttar Pradesh, Jharkhand, Chhattisgarh, and the northeastern states.

For Brazil, priorities include: reducing regional diagnostic disparities through targeted investment in the north and northeast LACENs and mobile laboratories for the Amazon region; strengthening local diagnostic manufacturing through Bio-Manguinhos expansion, private sector incentives, and partnerships with Indian manufacturers; scaling up the brain infections intervention nationwide by implementing the WHO Meningitis Roadmap in all SUS hospitals; enhancing genomic surveillance by integrating routine sequencing into infectious disease surveillance for

influenza, arboviruses, and emerging pathogens; integrating diagnostic data with SUS information systems (DataSUS, e-SUS, laboratory module); and expanding point-of-care testing at primary care UBS.

For the international community, the lessons are clear. Diagnostic innovation is essential for infectious disease control and SDG Target 3.3. Middle-income countries such as India and Brazil can build robust diagnostic capacity through strategic investment. South-South cooperation through the BRICS TB Research Network accelerates innovation. Implementation research, as demonstrated by Brazil's brain infections intervention, translates into policy through the WHO Meningitis Roadmap.

The ultimate measure of success for diagnostic innovation policy is not the number of PCR machines installed or tests approved, but whether a patient with tuberculosis in rural Bihar, India, and a patient with viral encephalitis in the Amazon region of Brazil receive a rapid, accurate diagnosis and timely, appropriate treatment.

8. LIMITS OF THE STUDY

This study has several limitations. First, reliance on secondary data from government reports, WHO databases, and peer-reviewed literature means the analysis is constrained by data availability, quality, and comparability. India's decentralized health system data are less uniform than Brazil's SUS data. Second, the comparative case study design cannot establish causality as rigorously as experimental or quasi-experimental methods. Third, the study does not include primary data collection, such as interviews with ICMR and Fiocruz scientists, diagnostic manufacturers, or policymakers, which would provide richer insights. Fourth, the study period (2000 to 2025) captures recent trends but does not fully explore longer-term historical dynamics. Fifth, the focus on national-level systems obscures subnational variation within India (states) and within Brazil (regions). Sixth, the study does not quantify the cost-effectiveness of national diagnostic programs. Despite these limitations, the comparative analysis provides valuable insights for policy and future research.

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10. AUTHOR CONTRIBUTIONS

TEDJIEU ROMÉO HERVIS conceived the study, designed the methodology, conducted the literature review and document analysis, synthesized findings, and drafted the complete manuscript.

11. COMPETING INTERESTS

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential competing interest.

12. FUNDING INFORMATION

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13. DATA AVAILABILITY

All sources are publicly available documents cited in the bibliography and accessible through the referenced publications and organizations, including ICMR, NTEP, Fiocruz, the Ministério da Saúde, WHO, and FIND.

14. DISCLAIMER

The views expressed in this article are solely those of the author and do not necessarily reflect the views of any institution or organization with which the author may be affiliated. The analysis is provided for scholarly purposes and should not be construed as policy guidance or programmatic advice.

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