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Evaluation of In Vitro Diagnostic Technologies for Sars-Cov-2 Detection

Pragyaa Bajaj [1] *

1. M.Sc. in Biotechnology, B.I.M.R. College of Life Sciences, Gwalior, M.P., India
prgbjj26@gmail.com

Abstract: The World Health Organization's classification of SARS-CoV-2 as a pandemic on March 11, 2020, has had a lasting influence on global health systems, continuing until March 2025. This study evaluates in vitro diagnostic (IVD) technologies for SARS-CoV-2 detection, focusing on datasets from the Indian Council of Medical Research (ICMR) and the Web of Science (WoS) repository. Analysis covers 2,882 approved commercial devices and test kits manufactured by 1,257 companies, alongside 12,886 related research publications. Among assay categories, antigen-based kits dominated (44%), followed by antibody assays (31%) and nucleic acid-PCR tests (23%). Validation studies revealed Nucleic Acid-PCR as the gold standard, with clinical sensitivity of 98.6%±2.0% and specificity of 99.3%±1.2%, while antigen-based kits offered the fastest detection, returning results within 15–30 minutes. False result analysis showed antigen kits with lower false positives (2.3–4.1%) and antibody kits with slightly fewer false negatives (4.6%). Limit of detection (LOD) evaluation indicated that 90% of antigen kits and 80% of PCR kits successfully identified positives at 1,000 viral copies or higher. This study highlights India's significant role in diagnostic innovation during the pandemic and underscores the need for harmonized validation metrics, rapid testing platforms, and regulatory preparedness to strengthen global readiness for future outbreaks such as Disease X

Keywords: SARS-CoV-2, COVID-19, In Vitro Diagnostics (IVD), Antigen Tests, Antibody Tests, Nucleic Acid-PCR

X

INTRODUCTION

As of March 2025, the world's agenda has been profoundly affected by the World Health Organization's (WHO) announcement of SARS-CoV-2 as a worldwide pandemic on March 11, 2020. [1] The healthcare system, educational institutions, economic foundations, and social practices were all rocked by this extraordinary occurrence, which set in motion a wave of changes that seemed to be unstoppable. Although the immediate impact of the pandemic has faded, a reassessment of pre-pandemic standards has been necessitated by the damage it caused, which included extensive lockdowns, overcrowded healthcare facilities, and economic downturns. Now that organizations and society are adjusting to the new normal, they are trying to figure out what this means for the future and how to prevent health disasters. The World Health Organization (2024) and the World Economic Forum have begun thorough risk assessments to deal with the possible rise of a new epidemic disease, which is being tentatively called "Disease X." This continuous change is shown by the proactive actions being taken by these multinational organizations. These assessments, which rely significantly on the lessons learnt from the COVID-19 incident, seek to foresee and lessen the difficulties presented by such an unforeseen danger. Given that the SARS-CoV-2 pandemic's triumphs and failures will surely inform Disease X preparation tactics and plans, it is not only prudent but necessary to review the developments from 2020 to the current day. Together, we can better prepare for the unknown by using the results of this retrospective research as a springboard to create

systems that can endure future global health catastrophes. [2]

The COVID-19 pandemic sparked a scientific and technological innovation boom, with four key areas seeing an outpouring of resources: treating infected patients, finding effective therapeutic drugs, developing vaccines quickly, and making reliable diagnostic systems. War broke out in these spheres as people fought for command of the escalating health catastrophe. Among them, the seriousness of the problem was highlighted by the realization that the best immediate measures for treating the pandemic were early diagnosis and isolation, particularly until more sophisticated medical treatments like vaccinations and medications could be produced and used. [3]

Around the world, people were quick to react to this realization in two ways: first, by rushing to put strict lockdown measures in place to contain the virus; second, by racing to see who could create the most effective, efficient, and easily accessible diagnostic kits. Publication of the Wuhan-1 whole genome sequence in early 2020 was a watershed event since it gave scientists a road map to combat the virus. From more conventional methods like polymerase chain reaction (PCR) to more recent ones like CRISPR/Cas-based diagnostics and AI-supported tools, every tool in the scientific and technological toolbox has been refocused on developing detection methods since this breakthrough. These developments demonstrated a shared will to innovate faster than the virus, paving the way for a new generation of diagnostic tools that would be essential in the battle against COVID-19 and other viruses. [4]

The limitations of the newly developed CT scans and RT-PCR methods, which were initially considered complementary and adequate tools for detecting the SARS-CoV-2 virus and the pulmonary symptoms of the COVID-19 pandemic, became more apparent as the worldwide demand for testing increased. Diagnostic times and the ability to intervene quickly were both impacted by the tripartite bottlenecks that occurred during sample collection, transportation, and analysis. This problem underscored the need of finding substitutes for CT and RT-PCR tests performed in hospitals, especially when screening was necessary for millions of people throughout the globe. [5]

Substantial scientific and technical efforts were devoted to the development of the three main COVID-19 tests: molecular, antigen, and antibody testing. Engineers and researchers toiled away at these experiments, trying out different platforms, detecting technologies, and collection techniques (such as blood, saliva, and nose swabs) in an effort to find the sweet spot. In order to meet the pressing demands caused by the fast worsening of the pandemic, a careful equilibrium was sought between the testing turnaround time and the limit of detection, which is the lowest quantity of virus that can be successfully identified. Time was of the essence throughout this optimization process since public health choices, ranging from small scale confinement plans to massive quarantines, needed precise and quick answers. [6]

Decentralized, point-of-care (POC) testing options, supported by substantial technical advancements, were quickly developed and extensively used in response to the COVID-19 epidemic. While real-time polymerase chain reaction (RT-PCR) testing in a lab was formerly the gold standard for diagnostics, its limitations included long processing periods and dependence on centralized facilities. Nevertheless, isothermal amplification techniques like recombinase polymerase amplification (RPA) and reverse transcription loop-mediated isothermal amplification (RT-LAMP) [7] swiftly became standard practice in the field. These methods were perfect for use in settings with limited resources because of their portability

and the speed with which they produced results. The ultra-specific nucleic acid detection capabilities of CRISPR-based diagnostics have also brought them to the forefront, opening up new possibilities in precision medicine.

Regulatory agencies have granted Emergency Use Authorization (EUA) to a number of molecular and antigen-based tests, allowing testing to move out of institutionalized testing facilities and into community and residential settings. These tests include Abbott's ID NOW platform and the Cue COVID-19 Test. Regulatory stances differed by area when it came to the commercialization of these technologies.[8] For example, China's approach was more cautious and practical, with a focus on PCR-based kits (more than 60% of which were allowed for home use). On the other hand, European and American authorities were more nimble, quickly licensing hundreds of tests to suit varied demands; these included multiplex assays and diagnostics based on saliva. Despite these disparities on a regional level, there is a concerted effort worldwide to improve diagnostics, make testing more accessible, and prepare for future pandemics by investing in novel, fast, and scalable testing systems and simplifying regulatory routes. Not only did this new diagnostic technology solve the problems caused by COVID-19 right away, but it also put the globe in a better position to deal with future health crises. [9]

Numerous high-quality studies demonstrating the variety of detection strategies, technical characteristics, and detecting capacities created to counter SARS-CoV-2 are available in the scientific literature. [10] There is, nevertheless, a clear need for an in-depth evaluation of commercial detection kits, paying close attention to their procedures, technology, time required, and detection capacities. These kits are essential for technical verification procedures that include treatment regimens and quarantine measures determined by test findings; they have gone from bench research to field use. [11]

This work analyzes COVID-19 detection techniques and kits in depth to fill this knowledge gap and contributes to the larger conversation about biotechnological solutions to combat the virus. The study examines critical factors utilizing the ICMR COVID-19 IVD Devices and Test Methods dataset, such as the study's focal nations, certification status, detection-sample-target relationships, detection time, and sample limit distributions. With this work, we aim to assess readiness to respond to Disease X as of March 15, 2025, and use that information to inform future plans.

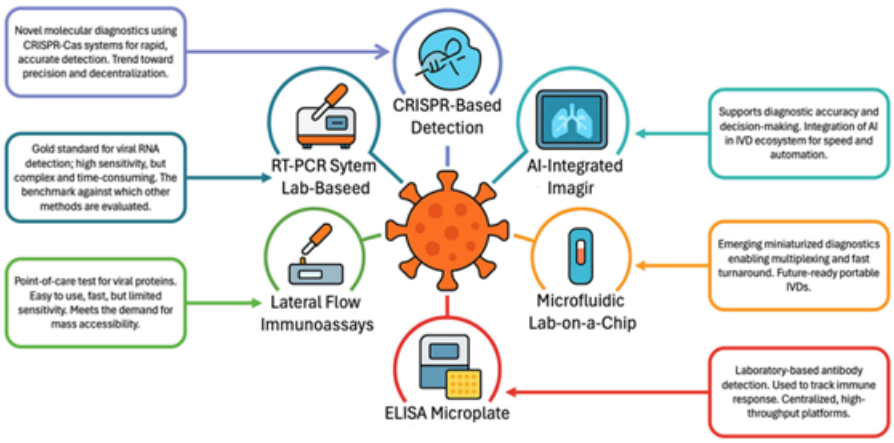


Figure 1: The diagnostic tool spectrum for SARS-CoV-2.

METHODOLOGY

Two separate data sets were analyzed in order to carry out this investigation. In order to uncover the COVID-19 detection and diagnostic efforts in scientific literature, the Web of Science (WoS) database was examined. World Health Organization (WHO) categories (for health-related category selection), and meso and micro citation subjects were the factors used to create the database findings. [12]

The 'ICMR COVID-19 IVD Devices and Test Methods' data collection, which is publicly accessible on the official website of the Indian Council of Medical Research (ICMR), is the second and primary database analyzed. The ICMR database included information on 2,882 COVID-19 IVD devices and test kits manufactured by 1,257 different companies

Out of the 34 metrics included in a typical commercial product, 19 satisfied the criteria for data quality and were thus included in our study. Regional and national approvals for the use of in-vitro diagnostics (IVDs) and test kits were issued across India during the pandemic by the Indian Council of Medical Research (ICMR) and the Central Drugs Standard Control Organisation (CDSCO). In the Indian context, emergency authorizations were granted primarily for RT-PCR-based molecular tests and rapid antigen test kits, with more than 400 products approved for use at different stages of the outbreak. Centralized RT-PCR laboratories and rapid antigen-based point-of-care testing were widely adopted across the country to enable large-scale screening, particularly in high-burden states such as Maharashtra, Delhi, and Karnataka. The IVDs approved under the Indian regulatory framework, however, do not provide the same volume of publicly accessible technical and scientific data as international repositories. Therefore, the ICMR database is taken as the major reference for this research due to its relevance in the Indian context and the availability of structured information on approved commercial products. The following analyses were conducted using Power BI version 2.120 with the Sankey 3.1.2 visualization patch and other standard data visualization techniques, including concatenation, tabulation, geographical mapping, and descriptive statistics.

RESULTS AND DISCUSSION

There were 12,886 articles published with commercial test kits that dealt with the topics of COVID-19 and detection when an initial online search was conducted. Research spanning the March 2022– March 2025 reveals that the United States and China will continue to dominate the development of diagnostic kits. Emerging alternatives to PCR that have been highlighted by citation analysis include biosensors and aptamers technologies. The United Kingdom and the United States lag behind China's three leading publishing houses.

Table 1: The quantity of research publications pertaining to the detection of COVID-19 organized by nation

Country	Articles
USA	2628

China	2212
India	1225
Italy	815
UK	762
Germany	622
S. Arabia	587
Spain	535
Canada	502
S. Korea	459

Table 2: Companies making intravenous diagnostics and test kits registered in the EU database and their locations

Country	**Firms**
China	384
USA	66
Germany	64
S. Korea	53
France	48
Italy	46
UK	34

Canada	29
Spain	23

The concentration of publications in China is likely due to the country's wealth of researchers, favorable technical environment, and widespread belief that the illness originated there. In the second database we examined, which deals with the distribution of commercial intravenous diagnostic equipment and kits by country, this pattern of distribution is more pronounced. China has more companies making IVD devices and test kits than the other four countries put together since the country prioritized meeting domestic demand before turning its attention to exports. There are 2,882 IVD devices and kits in the database, made in 51 different countries. We discovered that 86% of the intravenous drug devices and kits that were considered had CE certification.

The top three nations in terms of IVD production by origin are Italy (95%), Turkey (94%), & Spain (92%), with the United States (53%), India (79%), and the United Kingdom (84%). No data is provided for the other countries. So far, no European nation has been reported as having developed IVD equipment and test kits specifically for COVID-19. [13]

According to the data, the United States and China will most likely spearhead future initiatives to combat Disease X, thanks to their fast technological advancements and efficient mass manufacturing, while Europe could be left behind when it comes to commercialization. Nevertheless, as COVID-19 shown, it is still difficult to supply the worldwide need for inexpensive kits, particularly in an era when international cooperation is giving way to rivalry and regional division. [14]

Due to database inadequacies, extensive comparisons were not possible for SARS-CoV-2 IVD products, despite the adoption of several physical supports and detection techniques. Standardization and evaluation of detection limits were impeded by a lack of scientific data on materials, detection methods, and the uneven usage of units peculiar to manufacturers, especially in immunoassays. Policy choices should be made to enhance supply chains, research, trained individuals, and technological platforms in order to better prepare for future pandemics, as these shortcomings are brought to light.

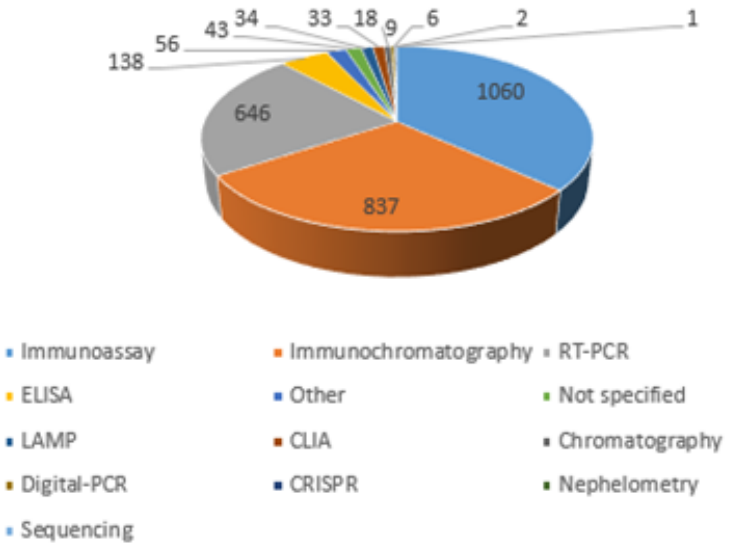
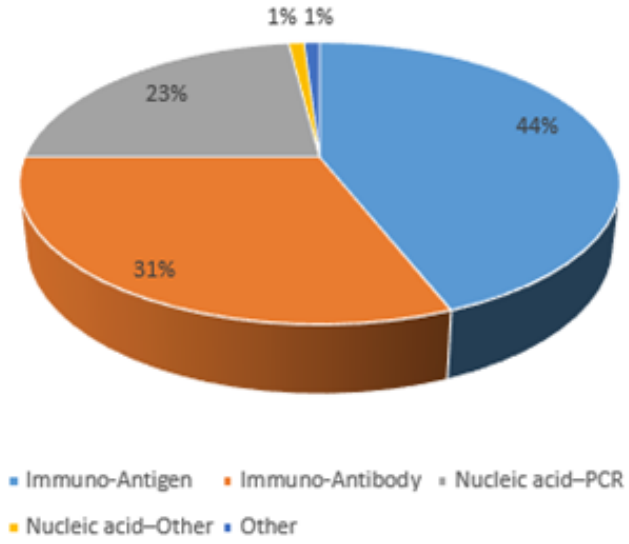


Figure 2: Product categorization according to the selected testing methodologies



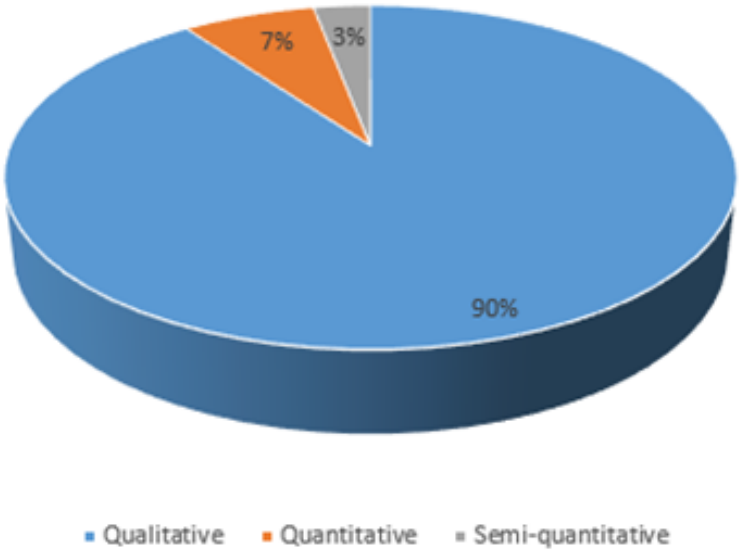
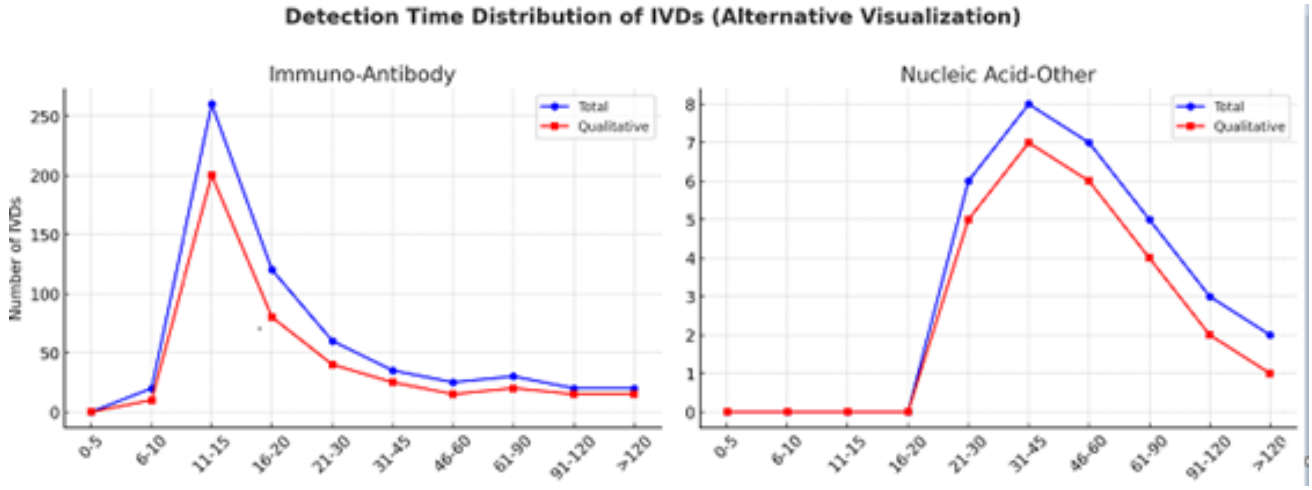


Figure 3: Distribution of Intravenous Diagnostic Devices by Assay Type and Measurement

"The 'assay category' dataset categorized tests into five groups: immuno-antigen, immune antibody, nucleic acid-PCR, nucleic acid-other, and unspecified.". Primarily used for the detection of present or previous infections, 44% of these kits were antigen-based, 23% were PCR-based, and 31% were antibody assays. Despite PCR's continued superiority, commercial kits were severely constrained in their variety due to the method's over-reliance. With 90% of the market, qualitative diagnostics were the most popular, and protein detection technologies helped with recovery after the lockdown. There is potential for adaptable and creative approaches to future epidemics in light of the lessons that emerging alternatives to conventional immunoassay, PCR, and ELISA may teach us about the strengths and limits of present diagnostic methods.

Pathogen kind, infection location, and patient symptoms impacted decisions about recognition molecules, sampling sites, and target molecules, which in turn impacted product trajectories in technical and commercial R&D. Data analysis shows that new dangers, such as Disease X, may be tackled using a combination of approaches, even if COVID-19 shown the value of simple sampling. The most important component for commercial success and real-world use was product validation, which was a major emphasis. The 'assay category' provided the most transparent assessment statistic, revealing patterns in validation and test diversity. The main requirement for validation was detection time. Antigen-based tests typically returned findings in 15 minutes, but quantitative and lab-based antibody-based tests might take up to 2 hours.



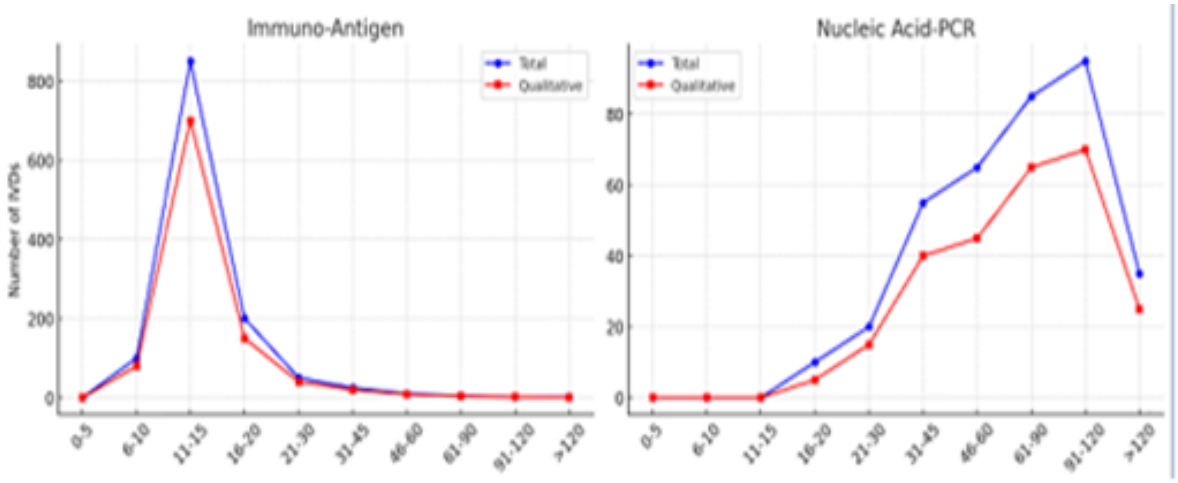


Figure 4: Time to detection histogram, expressed in minutes

Analysis of nucleic acid detection methods showed that PCR, the gold standard, clustered in the 61–90 minute range, while other methods were concentrated in the 21–45 minute range. Shortening diagnosis times for nucleic acid-based tests will be vital in tackling future threats like Disease X. A box–whisker plot revealed the narrowest detection time distribution for antigen-based kits and the widest for PCR-based kits. Future disease control will face hurdles such as reliance on advanced equipment, trained personnel, and variability in detection times across manufacturers and techniques.

Functionality validation of biotech products showed high performance across most criteria: 98% for cross-reactivity, 96% for precision, 94% for reproducibility, and 87% for robustness, though calibration was lower at 64%. This lower ratio may reflect limitations in calibrating certain technologies or the use of pre-purified samples in some methods.

Nevertheless, the overall number of IVDs underwent comparatively fewer robustness testing, which might prove to be vital when confronted with less-than-ideal real-life scenarios that test the IVDs' capabilities. Results showed that, when sorted by "assay category," “the Nucleic Acid-PCR group's results, which are also considered the gold standard, had the average maximum clinical sensitivity, with a standard deviation of 2.0%. Nucleic Acid-Other (97.3% ± 2.5%), Immuno-Antibody (95.7% ± 4.4%), and Immuno-Antigen (95.2% ± 4.3%), in that order, were the subsequent products. Biotechnological items belonging to the Nucleic-Acid PCR (99.3% ± 1.2%), Immuno-Antigen (99.2% ± 3.3%), Nucleic Acid-Other (98.9% ± 2.0%), and Immuno-Antibody (98.3% ± 1.9%) groups performed the best within the clinical specificity measure.”

This study assessed the accuracy, false result rates, and limit of detection (LOD) of SARS-CoV-2 in vitro diagnostic (IVD) devices, alongside their validation measures. Among the test categories evaluated, Nucleic Acid-PCR and Immuno-Antigen both showed high accuracy (97.9% ± 2.5% and 97.9% ± 3.4%, respectively), while Immuno-Antibody performed slightly lower at 96.6% ± 5.3%. False positive and false negative data were available only for antigen- and antibody-based kits. Antigen kits demonstrated lower false positive rates (2.3–4.1%), whereas antibody kits performed marginally better in terms of false negatives (4.6% vs. 4.9%). The persistence of false negatives highlights a major challenge for effective pandemic management.

Validation parameters proved crucial during COVID-19, particularly as regulators sought to balance urgency with accuracy. Countries adopted varying emergency approval strategies: the U.S. Food and Drug Administration (FDA) employed Emergency Use Authorizations (EUAs), China's NMPA introduced a "green channel" with post-market reviews, Japan implemented Special Approval for Emergency (SAE), and South Korea followed the EUA model with rapid laboratory verification. These experiences underline the importance of robust post-market monitoring and the global standardization of validation metrics such as sensitivity, specificity, and LOD. [15]

He analysis of LOD revealed inconsistencies, as antigen and antibody kits often relied on manufacturer-defined arbitrary units, complicating direct comparisons. Standardized data showed that 88.5% of antigen-based products tested positive at or above 1,000 TCID50/mL, while 80.0% of PCR-based products tested positive at 1,000 copies/mL. Prior research indicates that false negative rates rise by 13% with every tenfold increase in LOD, emphasizing the urgent need to refine detection limits to ensure preparedness for future outbreaks

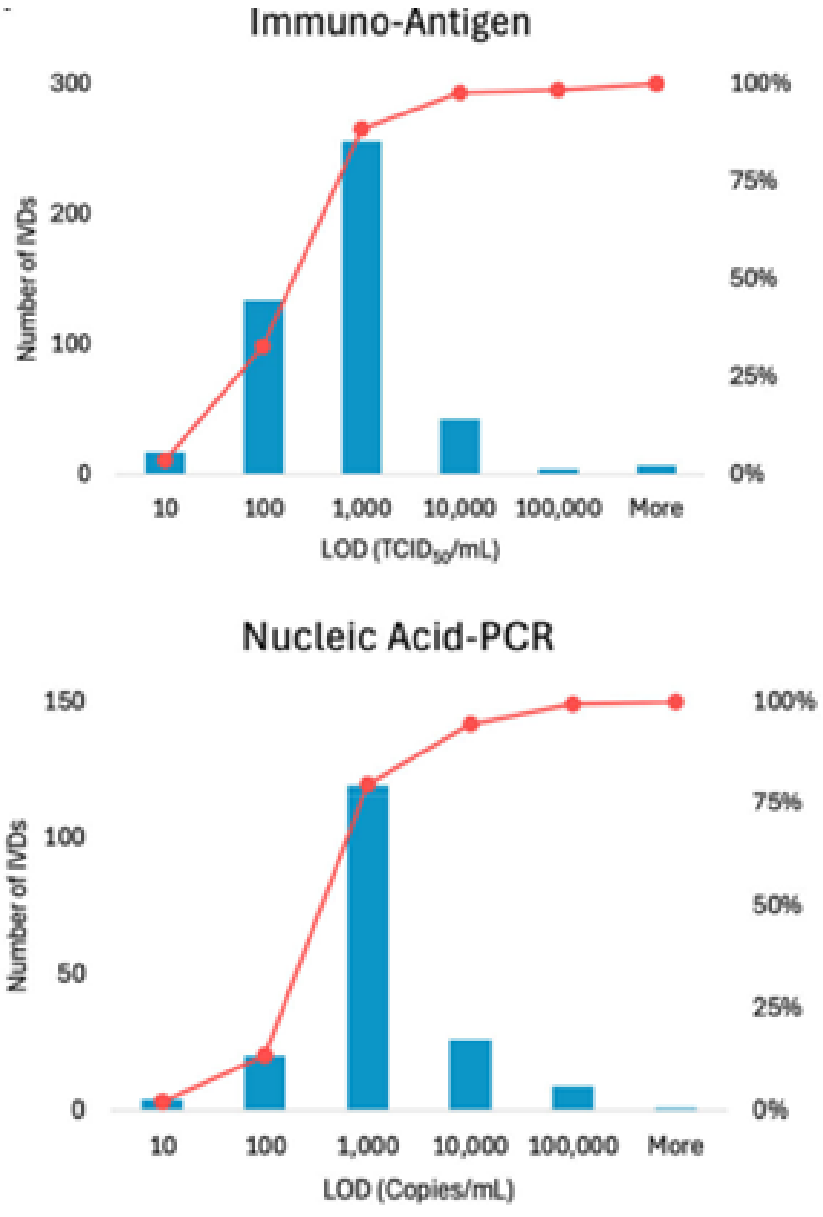


Figure 5: Distribution of LOD histogram for immune antigen test kits. (c) Distribution of LOD histogram for nucleic acid PCR test kits. The distribution's cumulative proportion is shown by the red lines.

Quick, scalable diagnostic solutions and flexible national policies are critical for managing epidemic outbreaks, as the COVID-19 pandemic demonstrated. In a way that might outstrip the pandemic's effect on mankind, artificial intelligence (AI), a game-changing instrument that was noticeably lacking during the crisis, is now in a position to reshape future public health responses. To effectively monitor, identify, and forecast the course of diseases in the future, it will be essential to include AI-driven surveillance and big data analytics into diagnostic frameworks. This will be especially important for upcoming outbreaks. In addition, flexible regulatory frameworks and national initiatives that guarantee fair access should enable point-of-care testing.

Harmonized data systems, responsive governance, and continuous diagnostic innovation will be key to curbing epidemic growth during potential resurgences. [16] Tracking pathogen spread considering factors like location, population, symptoms, and mutations will rely on integrating diverse diagnostic outcomes, likely encrypted data packets containing patient details, test locations, dates, sampling methods, technologies, and results. This integration will support agile, intelligent emergency management. While a simple "yes/no" patient status might lack sophistication, it offers a straightforward way to control disease spread. More importantly, the ability to merge various test results with health-related data such as socio-environmental conditions, medical histories, pathogen levels, current health metrics, and standardized symptoms will deepen our understanding of infectious diseases as dynamic public health challenges.

This analysis explores the technical preferences, challenges, and performance of in vitro diagnostic (IVD) tools and test kits developed in India to tackle future threats like Disease X. It draws on two key datasets: the Indian Council of Medical Research (ICMR) repository of approved COVID-19 diagnostics and the Web of Science (WoS) database. The findings position India as a leading hub in the Global South for diagnostic innovation, evidenced by a high volume of local research publications and ICMR/CDSCO-approved kits.

Among five molecular targeting categories for SARS-CoV-2 detection, rapid antigen kits dominate with a 44% share in India. Protein detection techniques are used in over 1,800 nationally approved IVD devices and kits. Key development factors test format, recognition molecule, sample source, and target molecule favor near point-of-care (POC) and manual formats for mass screening. Antigen, used in over 1,200 devices, varies in sample and target selections. Validation studies in India prioritize detection times (30 minutes to 2 hours), with Nucleic Acid-PCR kits leading at 98.6%±2.0% sensitivity and 99.3%±1.2% specificity, closely followed by immuno-antigen kits in accuracy. False positive/negative rates favor antigen kits for lower false positives. Limit of detection (LOD) analysis shows 90% of antigen kits and 80% of PCR kits detecting positives at 1,000 viral copies or higher.

This paper highlights India’s strides in IVD technology during COVID-19, emphasizing antigen kits for mass testing and PCR for precision. It offers vital guidance for future pandemic readiness, pinpointing technological gaps and opportunities for improved diagnostics.

ETHICAL CONSIDERATION

This study is based on secondary data obtained from publicly available and authorized sources, namely the ICMR COVID-19 IVD Devices and Test Methods database and the Web of Science (WoS) repository. Since no direct human participation was involved, issues of consent or privacy did not arise. However, ethical considerations were maintained by ensuring accuracy, transparency, and integrity in analyzing and reporting the data. Care was taken to avoid bias, misinterpretation, or overstatement of results, and due acknowledgment was given to all data sources. The study also upholds the ethical responsibility of promoting equitable access to reliable diagnostic technologies, particularly in the context of global health preparedness.

CONCLUSION

The study proposes enhancements for future pandemic preparedness. Firstly, standardizing validation metrics such as specificity, sensitivity, & LOD—is crucial to ensure consistent performance across diverse platforms and regions, especially as geopolitical tensions may disrupt supply chains. Secondly, fostering regulatory harmony and international cooperation is essential to streamline approval processes, ensuring widespread access to reliable diagnostics during crises. Confronting a borderless microscopic adversary demands a unified, large-scale standardization approach for safe clinical deployment. Lastly, post-market surveillance, informed by COVID-19 experiences, should evaluate in-field IVD performance, addressing optimal technology choices and establishing robust emergency monitoring systems to maintain accuracy. Together, these strategies emphasize the integration of cutting-edge technology, proactive regulation, and robust data systems to bolster global health security against emerging diseases.

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