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Commentary

The emerging direct-to-consumer multiplex respiratory pathogen testing requires strengthened regulation

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Since November 2023, direct-to-customer (DTC) multiplex respiratory pathogen testing services have rapidly emerged in major Chinese cities, processing 460 000 samples within 6 months [1]. Using multiplex PCR technology, these services detect 12 to 16 common respiratory pathogens within 3 hours, offering symptomatic patients rapid insights prior to treatment initiation [2]. Although this model supports a shift from empirical to targeted antimicrobial therapy, it also raises significant concerns, including risks of overdiagnosis, inappropriate antibiotic use, and unverified laboratory accuracy [3]. This commentary debates the benefits and challenges of DTC respiratory pathogen testing and proposes regulatory and technical recommendations to ensure its safe implementation.

Background and current landscape

The COVID-19 pandemic familiarized the Chinese public with self-swabbing and accelerated the growth of independent clinical laboratories (ICLs). Facing reduced demand for SARS-CoV-2 testing postpandemic, ICLs have pivoted to new service models. In August 2023, the first DTC multiplex respiratory pathogen testing service was launched, quickly followed by two others. Services are now available in 15 major cities. Symptomatic users order via mobile apps and receive a kit from a courier, after which their self-collected oropharyngeal and nasal swabs are transported to accredited ICLs. Two pricing tiers are offered, including a basic package at RMB 99 (U.S. $14) covering 12 pathogens, and a premium option at RMB 159 (U.S. $22) covering 15 pathogens, with optional add-ons such as *Bordetella pertussis* and *Human metapneumovirus* available.

China's rapid development in DTC respiratory pathogen testing reflects a broader global shift toward consumer-driven diagnostics. The United Kingdom has seen 35 marketed tests for 20 biomarkers, including respiratory pathogens, yet these often face regulatory and evidence gaps [4]. Likewise, the United States offers DTC services for the influenza virus, SARS-CoV-2, and *Streptococcus pyogenes*, highlighting a parallel trend in the expansion of DTC testing.

Advantages of DTC respiratory pathogen testing

Comprehensive pathogen coverage

The primary advantage of multiplex PCR-based respiratory pathogen testing lies in its ability to provide comprehensive pathogen detection in a single assay, offering significant diagnostic improvements over traditional rapid antigen tests or bacterial cultures [5]. These panels enable simultaneous detection of multiple pathogens, covering common pathogens prevalent across different age groups. The panels can be rapidly adapted in response to evolving public health threats, such as resurgent scarlet fever or pertussis. This represents a significant upgrade over single or limited pathogen tests commonly used in hospitals based on clinician assessment. It also meets growing consumer demand for accessible and informative testing for influenza-like illnesses.

Diagnostic performance and quality assurance

The Infectious Diseases Society of America recommends nucleic acid amplification tests as the preferred diagnostic method for respiratory viruses, *Mycoplasma*, and *Chlamydia*, replacing traditional rapid antigen tests and viral cultures [6]. In China, 26 approved multiplex PCR assays (21 targeting viruses/mycoplasma/chlamydia and five focused on bacteria) cover the complete spectrum of common respiratory pathogens. Quality assurance is maintained through annual external quality assessment programmes administered by the Shanghai Center for Clinical Laboratory. These evaluations use standardized panels containing eight viruses and *Mycoplasma pneumoniae* at clinically relevant concentrations of cycle threshold ranging from 30 to 37, including simulated monoinfections and dual and triple combinations. Epidemiological results demonstrate comparable performance between ICLs and hospital-based testing facilities, with rigorous quality control systems ensuring reliable results throughout the testing process from sample collection to laboratory analysis [7].

Accessibility and convenience of service

This model has the potential to offer distinct advantages in Chinese urban settings. Express delivery combined with centralized laboratory testing could deliver test results within a relatively short time frame. The anticipated service turnaround time may be comparable with that of hospitals, while potentially being more cost-effective by reducing the need for in-person visits. In resource-constrained, densely populated urban areas, a mobile app-based service could help alleviate the burden on healthcare systems and lower the risk of cross-infection during outbreaks of infectious diseases such as influenza. Moreover, compared with rapid at-home antigen testing, nucleic acid testing offers higher sensitivity and accuracy, making it more reliable for clinical diagnosis [5].

Current limitations and regulatory challenges

Interpretation challenges of positive results

A key limitation of multiplex PCR testing is its inability to distinguish active infection from the incidental detection of either nonviable pathogens, asymptomatic colonisation or shedding of viable pathogens. A positive result may therefore indicate not only a past infection but also a state of colonisation or shedding that does not require therapeutic intervention [6]. This diagnostic challenge is particularly problematic given high baseline colonisation rates. Studies show 37.5% oropharyngeal gram-negative bacilli colonisation in the elderly with *Klebsiella pneumoniae* comprising 54.4% of isolates [8], and 60% pneumococcal carriage rates in young children with 52% cocolonisation with multiple respiratory pathogens [9]. Although quantitative values like cycle threshold values and copy numbers may offer clues, they correlate only moderately with culture-based quantification and cannot reliably distinguish infection from colonisation or shedding. Furthermore, consumers typically focus on a positive or negative result without the expertise to interpret its clinical meaning. Thus, standard reports can be misleading, as patients may misinterpret a positive result as definitive proof of an active infection requiring treatment. Regulatory oversight should address this gap by integrating interpretative guidance tailored to ordinary users.

Antimicrobial misuse risks from online drug sales

A critical concern of DTC testing is the systematic online promotion of antimicrobials alongside test results, regardless of clinical significance. This concern is substantiated by a meta-analysis of 56 diagnostic accuracy studies, which found that rapid molecular testing failed to reduce antibiotic use, treatment duration, or hospital admissions compared with conventional methods [10]. Even more alarmingly, the integration with online pharmacies that facilitates immediate antimicrobial prescriptions suggests a business model that prioritizes drug sales over clinical needs. This is indefensible when a positive PCR result is equated with a treatable infection, especially since such positivity is common in high-carriage populations. Nor does it consider patient-specific factors or account for local resistance patterns like inappropriate macrolide prescriptions in the context of high prevalence of macrolide-resistant *Mycoplasma pneumoniae*. Although Chinese regulations restrict online prescriptions to follow-up cases, users can easily claim to be returning patients and partnered internet hospitals frequently operate without proper antimicrobial oversight. Addressing these risks demands the immediate establishment of prescription review mechanisms and stronger regulatory control over internet hospital prescribing practices.

Diagnostic coverage gaps and clinical implications

Preconfigured test panels face inherent limitations in pathogen coverage that may delay diagnosis of specific infections. Early respiratory symptoms like influenza-like illnesses, sore throat or persistent cough pose diagnostic challenges. Selecting an appropriate test panel is therefore important to help consumers identify the target pathogenic agent. Standard panels exclude common bacterial pathogens such as *Streptococcus pyogenes* and *B. pertussis,* which may lead to underdiagnosis. Conversely, the inclusion of bacteria associated with frequent colonisation, such as *Streptococcus pneumoniae*, routinely leads to online antibiotic prescriptions following a positive result.

Recommendations and future perspectives

To mitigate these risks, we propose a three-part approach combining stringent regulatory oversight, technological advancement and diagnostic stewardship. First and foremost, regulatory measures should include a ban on online prescription of antimicrobials without physical consultation and the implementation of real-time prescription audit systems. Second, test panels should exclude organisms with high colonisation rates, such as *Streptococcus pneumoniae* and gram-negative bacteria in the nasopharyngeal site, to avoid overuse of antibiotics. Third, ICLs must undergo mandatory external quality assessment, with noncompliant labs facing immediate suspension. Technologically, test panels should be rationally designed and appropriately differentiated based on clinical syndromes such as influenza-like illness, sore throat or suspected pneumonia. Also, panels may incorporate resistance gene screening for macrolide-resistant *Mycoplasma pneumoniae* to guide appropriate antibiotic selection in high-resistance regions. Service innovations could include professional mobile sampling teams to ensure specimen quality. Furthermore, given the current scarcity of empirical outcome data on the downstream effects of DTC testing, we recommend establishing a dedicated national surveillance system to track clinical outcomes, prescribing behaviours, and patient safety metrics associated with DTC testing to inform evidence-based policy and practice.

Conclusion

China's DTC respiratory testing model is not an isolated development but a harbinger of global shifts in diagnostic services. Although these services offer considerable benefits, including speed, convenience, and potential reductions in health care burden. They also pose significant risks, particularly regarding antibiotic misuse and diagnostic inaccuracy. Policymakers must balance innovation with safety through robust regulatory frameworks that ensure quality, require clinical interpretation, and enforce antimicrobial stewardship. Parallel improvements in conventional diagnostic pathways in health care facilities are equally essential to ensure equitable and responsible access to accurate testing.

CRediT authorship contribution statement

Tianxing Feng: Conceptualization. Tianxing Feng, Yu Shi, and Kai Lin: Investigation. Tianxing Feng: Writing - Original draft preparation. Tianxing Feng and Mei Zeng: Revision. Tianxing Feng, Yu Shi, Kai Lin, Chouwen Zhu, and Mei Zeng: Reviewing and Editing. Yunlu Zhang: Illustrations. Mei Zeng and Chouwen Zhu, and Yunlu Zhang: Supervision and Project administration. Tianxing Feng, Yu Shi, Kai Lin, Yunlu Zhang, Chouwen Zhu, and Mei Zeng: Reviewing and Approval. Mei Zeng and Chouwen Zhu: Guarantors.

Transparency declaration

Potential conflict of interest

The authors declare that they have no conflicts of interest.

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