



International  
Pandemic  
Preparedness  
Secretariat

**FIND**   
Diagnosis for all

# MAKING THE EXCEPTIONAL ROUTINE:

**Embedding diagnostic best practice to improve  
pandemic preparedness**

An independent report from the International Pandemic  
Preparedness Secretariat and FIND





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This report was authored by the International Pandemic Preparedness Secretariat (IPPS)'s 100 Days Mission Science and Technology Expert Group Diagnostics Subgroup in collaboration with FIND.

The IPPS is a wholly independent entity that serves to join up relevant states, the private sector, and global health institutions in support of the 100 Days Mission. The Secretariat works with the G7, G20, industry and the WHO as key partners. The 100DM Science and Technology Expert Group (STEG) provides technical input to the Secretariat. Reporting to the Steering Group, it delivers an assurance function for the annual report against the 100DM recommendations and galvanises support from the scientific community on pandemic preparedness.

FIND accelerates equitable access to reliable diagnosis around the world. We are working to close critical testing gaps that leave people at risk from preventable and treatable illnesses, enable effective disease surveillance, and build sustainable, resilient health systems. In partnership with countries, WHO and other global health agencies, we are driving progress towards global health security and universal health coverage. We are a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. For more information, please visit [www.finddx.org](http://www.finddx.org).



# Executive summary

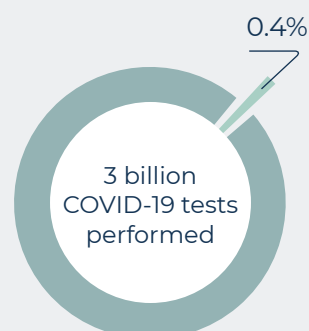
The first 100 days of an epidemic or pandemic threat are crucial to determining its course and preventing it from becoming a pandemic. In those 100 days, non-medical, public health interventions such as physical distancing, isolation, contact tracing and use of personal protective equipment are essential. But the best assets we have at our disposal to defeat a pathogen threat are **diagnostics, therapeutics and vaccines**, integrated into health systems. Together, they can save millions of lives.

The **100 Days Mission** (100DM) sets out the aspirational goal of preparing as much as possible, so that within the first 100 days of a pandemic threat being identified; safe, effective and affordable diagnostic tests, therapeutics and vaccines are ready to be produced at scale.<sup>1</sup>

**The COVID-19 pandemic highlighted the vital role that diagnostics play as the first line of defence in tempering the catastrophic impact of an epidemic or pandemic threat.**

Diagnostics were a crucial countermeasure to mitigate the spread of COVID-19, and by mid-2022, more than 3 billion SARS-CoV-2 tests had been conducted worldwide.<sup>1</sup> Once available, they empowered individuals and health workers alike to make informed decisions about healthcare and preventive behaviours, and provided the cornerstone of evidence-based, public health decision-making for policymakers and health workers alike. However, they were not available quickly or widely enough to prevent the rapid spread of disease: only 0.4% of the 3 billion COVID-19 tests performed through to mid-2022 were conducted in low-income regions.<sup>2</sup>

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Reverse transcription-polymerase chain reaction (RT-PCR) remains a mainstay for diagnosing COVID-19, and genomic sequencing has become vital for tracking variants. However, lateral flow tests (RDTs), while less sensitive than PCR, have enabled an unprecedented scale-up of global testing, including self-testing, owing to their simplicity, low cost, accessibility, rapid results and ability to detect infectiousness.<sup>2</sup> Nonetheless, during the COVID-19 pandemic, the first commercial antigen LFTs took five months after the first reported case to receive emergency use authorization. Effective diagnostics, coupled with strengthened regulatory systems for product development and surveillance, provide crucial information guiding local and regional actions, and initiate the development of vaccines and therapeutics to slow, treat and contain outbreaks. Unfortunately, we know that a future epidemic or pandemic threat is likely and potentially imminent. Thus, it is important to adopt a roadmap of co-ordinated actions to minimise both morbidity and mortality.

The original 100DM report highlighted the need to build prototypes libraries, strengthen R&D, normalise diagnostics within routine care, enhance surveillance and harmonise regulation.<sup>1</sup>

This report outlines  
**3 critical enablers**  
to meet these needs and examples of successful deployment

- 1 the use of multiplexed tests to enhance efficiency
- 2 digitally connected diagnostics
- 3 linking diagnostics to care and treatment

<sup>1</sup> International Pandemic Preparedness Secretariat. 100 DAYS MISSION to Respond to Future Pandemic Threats, June 2021, [d7npznm5zvw.cloudfront.net/prod/uploads/2023/01/100\\_Days\\_Mission\\_to\\_respond\\_to\\_future\\_pandemic\\_threats\\_3.pdf](https://d7npznm5zvw.cloudfront.net/prod/uploads/2023/01/100_Days_Mission_to_respond_to_future_pandemic_threats_3.pdf).

<sup>2</sup> Budd, Jobie, et al. "Lateral Flow Test Engineering and Lessons Learned from Covid-19." *Nature News*, Nature Publishing Group, Jan. 2023, [www.nature.com/articles/s44222-022-00007-3](https://www.nature.com/articles/s44222-022-00007-3).



**All three of these enablers will** effectively integrate diagnostics into wider healthcare systems globally to enhance diagnostics for both epidemic and endemic diseases. Embracing and embedding these enablers is essential for national, regional and global stakeholders, when designing and delivering strong healthcare systems with pandemic preparedness in mind. These enablers are also critical for funders of diagnostics procurement to consider when establishing requirements and developing initiatives.

The three critical enablers aim to make the **exceptional routine** by embedding best practice and preparation for diagnostics into business-as-usual activity, when the world is not battling a pandemic. We provide a summary of recommended actions for stakeholders to pursue regarding these three critical enablers, in order to make them, and the 100DM for pandemic preparedness, a reality.

## Diagnostics recommendations for the 100 Days Mission

Central to the 100DM is a need to strengthen research and development (R&D) to fill the gaps in the pipeline for medical countermeasures and ensure that products can be developed and delivered rapidly wherever an outbreak may occur. Alongside increasing the speed of product development and delivery, there is a need to 'make the exceptional routine'.

Upon the inception of the 100DM, 25 original recommendations were made for implementation partners and policymakers. A number are aimed at creating a holistic ecosystem for diagnostics and ensuring effective preparedness.

**The original recommendations were developed in 2021 and are reviewed on an annual basis by the International Pandemic Preparedness Secretariat.**

### Evolving them as necessary with real-world developments:



Build prototype vaccines and **diagnostic** libraries applicable to representative pathogens of pandemic potential



Strengthen the role of the international system in R&D capability and coordination for therapeutics and **diagnostics**



Governments should normalise the use of accurate **diagnostics** for coronavirus and influenza in point-of-care and nonclinical settings<sup>3</sup>



WHO should support an enhanced role for **diagnostics** in the surveillance of pandemic threats



Develop a common regulatory framework that better defines criteria and standards for effectiveness, quality and use cases for **diagnostics**



The IPPS and 100DM Science and Technology Expert Group (STEG)<sup>4</sup> have been established to track progress against the 25 recommendations, publishing an annual implementation report.<sup>5</sup>

A specific subgroup of the STEG focuses on addressing key policy and technical challenges for diagnostics – including via the publication of this report.

<sup>3</sup> While this original recommendation was specific to coronavirus and influenza, routine use of diagnostics should be embedded into clinical and non-clinical settings for all regionally relevant pathogens.

<sup>4</sup> International Pandemic Preparedness Secretariat – About Us <https://ippsecretariat.org/about-us/>

<sup>5</sup> International Pandemic Preparedness Secretariat – Publications <https://ippsecretariat.org/publications/>

# Summary of recommendations

Through an in-depth analysis of the diagnostics landscape by FIND, IPPS and key experts, we highlight three critical enablers where effective and routine use of diagnostics can improve the resilience of health systems and propose a series of recommendations to stakeholders to address the gaps and limitations.

By taking onboard the following recommendations, the world will be better equipped with the appropriate diagnostic tools to respond effectively to the next pandemic:

1

## The use of multiplexed tests to enhance efficiency

**Multiplex diagnostics for priority pathogens<sup>6</sup> should be embraced and delivered to enhance surveillance of priority pathogens.**

**Policymakers** should incorporate multiplex devices, which can detect multiple biomarkers in a single test, into healthcare systems.

**Research funders** and **health innovators** should appropriately fund and prioritise research into multiplex approaches.

**Regulatory authorities** should ensure that systems are designed to embrace and promote multiplex approaches.

**World Health Organization (WHO)** should recommend the use of multiplex approaches to member states as part of the *Model List of Essential In Vitro Diagnostics*, the WHO's evidence-based reference point for countries to develop national lists to guide how they choose and use *in vitro* diagnostics.<sup>7</sup>

2

## Digitally connected diagnostics

**Data connectivity must be prioritised in the delivery of diagnostics for patient care and enhanced surveillance.**

**Research funders** and the **private sector** should prioritise R&D for innovative diagnostic tools optimised for digital connectivity and data capture.

**Policymakers** and **governments** should invest in appropriate digital infrastructure to allow for integration with patient care and surveillance systems, real-time geospatial information, as well as strengthening digitalised infrastructure for connected diagnostics through both laboratory-based and decentralized testing, at the primary health care and community levels.

**WHO** should ensure that appropriate agreements are in place to promote ethical use of various diagnostic data across the value chain.

3

## Linking diagnostics to care and treatment

**Diagnostics should be linked to care and treatment wherever possible.**

Despite progress, diagnostics are still not routinely used, risking treatments being prescribed inappropriately and drug-resistance.

**Policymakers** should increase and optimise the use of test-to-treat for endemic diseases.

**Research funders** should appropriately fund and prioritise research to assess the benefits of test-to-treat.

**Government and international procurers** should provide demand signals for joint packages of tests and treatments to be developed and delivered.

<sup>6</sup> WHO priority list of pathogens of epidemic potential which could be included in future multiplexed tests: WHO. "Prioritizing Diseases for Research and Development in Emergency Contexts." *World Health Organization*, World Health Organization, [www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts](https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts). Accessed Nov. 2023.

<sup>7</sup> WHO. "The Selection and Use of Essential In Vitro Diagnostics - TRS 1031." *World Health Organization*, World Health Organization, [www.who.int/publications/item/9789240019102](https://www.who.int/publications/item/9789240019102). Accessed Nov. 2023.





# • Introduction: • The diagnostics • ecosystem

While essential for the success of the 100DM, these three enablers can only operate within an efficient product development ecosystem, building upon a foundation of fundamental investment in R&D ecosystems, regulatory capacity building across all regions, health system strengthening and investment in regional manufacturing capacity for diagnostics. All these investments should be situated within the context of broader health system strengthening.

Strengthening diagnostic capacity makes health systems better prepared and more resilient when monitoring diseases, responding to outbreaks and implementing targeted public health interventions.

For this to happen there are fundamental underpinning success factors that policymakers should consider:

**Ensuring sufficient funding and collaboration for diagnostics research and development, including for building prototype libraries and regulatory capacity, and improving manufacturing resilience.**

Despite the criticality of diagnostics, and the ongoing efforts of several countries and global financing initiatives, financial and political support for diagnostics R&D and better integration of diagnostics into health systems has never reached the levels of attention required. This was evidenced during COVID-19 by the lack of investment in the diagnostics pillar of the Access to COVID-19 Tools Accelerator (ACT-A) to which, as of June 2023, donor contributions totalled just US\$1.4bn,<sup>8</sup> compared with US\$16.4bn for vaccines. Furthermore, the funding available is almost exclusively oriented toward enhancing surveillance systems – a critical aspect, but often neglecting the vital steps of R&D, regulatory harmonization, distributed manufacturing, and resilient pipelines. FIND has set out a clear framework to achieve the 100DM for diagnostics globally (See Figure 1 below), estimating that an initial investment of US\$80–\$100 million seed funding will catalyse the full investment required to ensure the availability of optimal diagnostics; and

when used to leverage private finance, will be sufficient to build a prototype library of diagnostics for the priority pathogens of pandemic potential. Substantial long-term investment will then be needed to implement and maintain a fit-for-purpose diagnostics pandemic preparedness system. It is also vital that collaborative partnerships are built, including with industry and academia, to share information, mechanisms and know-how. Only with proportionate and sustained R&D investment will the necessary diagnostics products reach market and innovative, next-generation technologies will emerge.

**Building up regulatory capacity and regulatory pathways for diagnostics in all regions, particularly during emergencies.**

Diagnostics face many regulatory challenges and barriers that can delay or prevent their introduction and use in different settings, particularly in countries with less developed regulatory systems. Regulatory capacity and specific regulatory pathways for diagnostics should be strengthened in all regions to facilitate the timely approval, quality assurance, and post-market surveillance of diagnostic products.

**Strengthening health systems, utilising community healthcare workers and digital health systems.**

Diagnostics alone are not enough to improve health outcomes; they need to be integrated into strong and resilient health systems that can deliver effective and equitable care. Health

system strengthening and effective use of data, digital systems and improving data interoperability standards are key components of a holistic approach to diagnostics delivery, which can enhance access, utilisation, quality, and the impact of diagnostic services. Crucially, laboratory diagnostics nationally and regionally need to be linked to surveillance systems. Moreover, community health workers play a vital role in healthcare systems by acting as a bridge between the community and formal healthcare services. Their unique position allows them to perform on-the-spot assessments and screenings, enabling early detection. Equipping these workers with high-quality diagnostic tools and technologies has the potential to prevent disease progression and reduce the burden on healthcare facilities in underserved communities.

**Reinforcing diagnostic manufacturing in low- and middle-income countries as a key enabler of affordability and access.**

Production in high-income countries (HICs) can increase the cost and limit availability in low- and middle-income countries (LMICs). Diagnostic production in LMICs may reduce costs and improve access to products. Despite significant development during COVID-19, there remain a number of barriers to ensuring that regional manufacturing centres can effectively function, particularly in an emergency context.

<sup>8</sup> ACT-Accelerator Commitment Tracker: <https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker>.





Looking to the future

By making routine the exceptional utilisation and integration of diagnostics that was seen during COVID-19, we will not only build strengthened healthcare and surveillance systems that are prepared to withstand and respond to a pandemic threat, but also improve the standard of care for routine endemic diseases. Embedding the use of diagnostics for epidemic and pandemic threats within routine health services and public health practice is crucial for ensuring that patients and healthcare professionals are familiar with testing as a foundation for public health interventions.

Advocacy for evidence-based policy, equitable access and universal health coverage

Accelerate product Research & Development	Streamline evidence generation and regulatory approval	Strengthen surveillance and community-based testing infrastructure	Establish warm base for manufacturing and reliable pull mechanism
1 Develop novel diagnostic platforms	4 Integrated global biobanking network	7 Strengthen global disease surveillance	10 Support development of regional manufacturing hubs
2 Build prototype diagnostic library for 10 pathogens	5 Establish global clinical trial and product evaluation network	8 Normalise point-of-care testing programmes	11 Institute reliable pull mechanism
3 Establish clinical reference standards	6 Formalize pathway to enable collaborative product registration	9 Support digital connectivity and diagnostic network optimisation	

Figure 1 FIND's 5-year Initiative to Enable the 100 Days Mission for Diagnostics

This approach complements the IPPS' 100DM plan for strengthening diagnostics R&D based on set milestones outlined in the 100DM Annual Implementation report, which highlights the urgent need to develop accurate diagnostics to strengthen surveillance coverage for 8–10 virus families.



# Using multiplex diagnostics to enhance efficiency

Multiplexing is an approach whereby multiple biomarkers and conditions can be detected through a single diagnostic test or sample collection procedure.

Whereas traditional testing often follows a serial, monoplex approach (i.e. testing for one pathogen at a time) – most often revealing what a patient *does not* have – broader multiplex testing focuses more directly on finding out what a patient *does* have. Moreover, multiplexed diagnostic tests provide a key opportunity to enhance surveillance for priority pathogens (8–10 viral families) of epidemic potential, thereby strengthening pandemic preparedness.

Multiplex approaches have the potential to benefit both healthcare systems and patients; particularly in low-resource settings where patient to health worker ratios are often low and can cause diagnosis to be delayed. Having a single multiplex assay rather than a series of monoplex tests reduces the burden on patients, healthcare professionals and laboratories, allowing for more efficient use of limited testing supplies such as pipettes, swabs and reagents. Multiplex devices are often more costly, but given the advantages they confer in terms of care quality and diagnostic excellence, they are still a worthwhile investment and may additionally help to minimize environmental waste. R&D breakthroughs in the field of robust molecular multiplex platforms, which are gradually becoming less costly, hold particular promise.

While it is acknowledged that in some settings even monoplex diagnostic devices are often scarce, multiplex testing at the laboratory level is well-established. Point-of-care (POC)

ensuring that  
diagnostic tools used are  
**digitally  
connected**  
is vital

multiplex testing is less widespread, particularly in low-resource settings, despite the significant benefits it can provide. With the aim to expand the availability, affordability and use of multiplex devices, the recommendations set out in this report are geared towards expanding their use everywhere. Nonetheless, high-quality, monoplex diagnostic tools should continue to be used where available. Indeed, the digital connectivity of diagnostic tests may be the most important factor at play and ensuring that diagnostic tools used are digitally connected as a first priority is vital.





## Why are multiplex diagnostics important for the 100DM?



### Faster Diagnosis

Infections from diverse pathogens often cause similar disease symptoms. With multiplex diagnostics, healthcare professionals can expedite the diagnostic process since they do not need to perform separate tests for each individual pathogen. For example, infection with SARS-CoV-2, influenza A, influenza B and respiratory syncytial viruses all classically present with non-specific symptoms of fever, cough, and malaise. Typically, clinicians would order a battery of monoplex diagnostic assays for the suspected pathogens – an approach that is generally slow, laborious, and costly. However, multiplex assays can rapidly distinguish between various pathogens, rapidly providing patients and healthcare providers with the information they need for an accurate treatment plan.



### Disease Surveillance

Multiplex diagnostics can transform outbreak surveillance by integrating routine testing for endemic diseases with detection of less common diseases that pose epidemic or pandemic threats, as well as identifying individuals infected with highly transmissible and/or lethal pathogens, for whom isolation or other specialized measures may be indicated. Multiplex assays that can rapidly distinguish between various viruses are now deployed in high-income country health systems, having become more common following the COVID-19 pandemic. Lastly, recognising the potential of zoonotic infections and the need for a One Health approach, many multiplex modalities hold the potential for enhanced surveillance to track outbreaks in animals and the environment. Pathogen surveillance via multiplex testing of human or animal wastewater is emerging as a powerful public health tool to complement and strengthen clinical surveillance.



### Antimicrobial Susceptibility

In addition to identifying the pathogen responsible for disease, multiplexing can provide specific information regarding antimicrobial susceptibility. This assists health workers in rapidly selecting the most effective treatment plan, minimizing unnecessary antibiotic prescriptions, and promoting the responsible antimicrobial use that is critical for tackling antimicrobial resistance (see box on page 16). For example, the multiplex GeneXpert MTB/RIF test – endorsed by the WHO in 2010 – provides a simultaneous diagnosis of tuberculosis and information on sensitivity to the antibiotic rifampin in less than two hours. Rapid assessment of rifampin sensitivity allows patients to start on effective treatment much sooner than waiting for results from other types of drug susceptibility testing. Several other rapid diagnostic tests are available that test for multiple biomarkers that indicate an infection with specific antibiotic resistance profiles.



### Cost-Effectiveness

Despite the initial investment, multiplex diagnostic tools can be cost-effective in the long run, by reducing the need for repeated testing and hospitalization, ultimately lowering healthcare costs while improving patient outcomes.

## Common Types of Diagnostic Tests



### Polymerase Chain Reaction (PCR)

PCR is a widely used molecular test that amplifies and detects DNA sequences. It is valuable for identifying infectious diseases, such as COVID-19 (requiring respiratory swabs) and genetic disorders (requiring blood or tissue samples).

NOTE: PCR tests exist within a range between tens of dollars (USD) up to a few hundred dollars (USD). These tests are relatively affordable, the reagents are affordable, the equipment is in the low to mid-range and they are carried out within minutes by skilled professionals.



### Antigen Rapid Diagnostic Tests

Antigen tests, also known as lateral flow tests, became synonymous with rapid diagnostic screening for COVID-19. These tests are affordable to produce and yield a result within minutes. Lateral flow tests work by detecting specific proteins or antigens on the surface of the pathogen, rather than its genetic material. They are less sensitive than molecular diagnostic tests, but are faster and easier to use, making them valuable tools for rapid screening and point-of-care testing.

NOTE: These tests are highly affordable, the reagents used are accessible and no complex equipment is required to produce or analyze the result.



### Antibody Diagnostic Tests

Antibody diagnostic tests, also known as serological tests, play a crucial role in identifying the presence of antibodies in an individual's blood, indicative of a past or current infection. These tests can assess an individual's immune response to pathogens, aiding in the diagnosis of various infectious diseases or monitoring vaccine effectiveness. Requiring a blood sample, antibody tests detect specific antibodies produced by the immune system in response to a particular pathogen. While they may not provide immediate results like rapid antigen tests, antibody diagnostic tests offer valuable insights into an individual's immune status.

NOTE: The cost of antibody tests varies, ranging from moderate to relatively high, depending on the complexity and specificity of the test. The reagents used can be moderately priced, and the equipment required falls within a mid-range cost. These tests are usually performed in clinical settings by trained professionals, contributing to their accuracy and reliability.



### Loop-Mediated Isothermal Amplification (LAMP)

LAMP rapidly amplifies DNA or RNA at a constant temperature. These tests are suitable for point-of-care diagnostics and detecting infectious agents like tuberculosis (requiring sputum samples) and Zika virus (requiring blood or urine samples).

NOTE: LAMP tests, specifically for POC diagnostics are designed to be affordable to use.





## • Multiplex • in practice

## Multiplex testing of wastewater pathogens

Wastewater surveillance is emerging as a powerful public health tool to track multiplexed pathogens in populations and is intended to complement and strengthen clinical surveillance.

Wastewater testing of fragments of COVID-19 RNA has become routine in many countries and has identified poliovirus in sewage in London and New York, triggering immunisation programmes.

The WHO recommends wastewater testing as an additional objective indicator of virus circulation at the population level, with the advantage that it is not susceptible to biases inherent in clinical testing. If carried out ethically, wastewater environmental surveillance can provide community-level data that is not reliant on clinical testing. It should be a complementary activity that is not a substitute for clinical surveillance based on demonstrated use cases for SARS-CoV-2.



# The future of multiplex

## Enhanced surveillance for both endemic and epidemic threats.

Multiplex diagnostics hold the potential to drastically transform outbreak surveillance. Central to this approach is using multiplex formats that integrate testing for routine endemic diseases with testing for less common diseases that are considered epidemic or potential pandemic threats.



As pathogens that cause outbreaks are generally rare, vertical surveillance approaches, i.e. focused on a single, specific pathogen, are costly and thus often unsustainable in terms of financial and human resources. In contrast, surveillance approaches that provide everyday, actionable information pertinent to guiding patient and provider treatment and that can also detect rare diseases are most likely to be sustained. For example, in any given area in West or Central Africa, tens or even hundreds of thousands of patients with acute febrile illness might need to be routinely tested in order to pick up the first case of Ebola virus infection that initiates an outbreak.

Rather than a vertical programme aimed at testing only for one pathogen of concern, a more sustainable approach would be to use a single multiplex assay that could diagnose more routine endemic febrile disease in Africa, such as malaria, typhoid fever, and dengue fever – as well as more rarely seen outbreak-prone diseases such as Ebola and yellow fever. Similar multiplex approaches could be envisioned for other clinical syndromes, such as respiratory disease or meningitis, or tests to rapidly differentiate bacterial from viral infection. Widespread deployment of these POC tests in primary healthcare clinics, emergency care centres and pharmacies could greatly speed detection and response to known as well as unknown pathogens.

Since the pathogens that cause disease vary by region, it will be essential to have flexible platforms that allow incorporation of varied primers and probes of importance to a given geographic region and context. This would also allow quick inclusion of targets relevant to emerging health threats, accelerating access to testing and outbreak control.

Emerging technologies are making this multiplexing vision a reality, with the promise of a dramatic and fundamental shift in surveillance capacity for both endemic and epidemic-prone diseases. However there remains much work to be done to make this approach multiplexing commercially viable and logistically implementable.

## Actions for stakeholders to make the 100 Days Mission for Diagnostics a reality



### Policymakers

focused on healthcare delivery for both high- and low-resource settings should **embrace the benefits of multiplex diagnostics** to capacitate health systems to rapidly detect diseases of pandemic potential, integrated into surveillance for endemic diseases.



### Research funders and policymakers

focused on health innovation should ensure that **R&D for multiplex technologies is prioritized, appropriately funded and incentivised**. Where market demand is the major driver for private sector R&D investment, health system policies (including well-defined target product profiles) should provide a strong demand signal to promote such investment.



### Regulatory authorities

should ensure that **regulatory pathways are designed to embrace the potential of multiplex diagnostics**, including lab based, POC and over-the-counter settings **and wastewater surveillance**. They should support the development of target product profiles which outline the benefits of multiplex testing and guide industry towards desired characteristics of such tests.



### The WHO

should consider multiplex diagnostics in their recommendations to Member States, particularly via reference to their benefits in the Model List of Essential *In Vitro* Diagnostics.



# Digitally connected diagnostics

Diagnostic devices that connect to electronic health record systems, laboratory surveillance networks, and other technology systems have the potential to improve the accuracy, efficiency and usability of testing data.<sup>9</sup>

Such digitally connected diagnostics have several advantages, including ensuring that timely, patient-level, diagnostic data is available and integrated into clinical and public health systems to enable emerging infectious disease threats to be identified rapidly and tracked in real-time.

Most importantly, such devices enable more rapid and efficient treatment for the patient and implementation of preventive behaviours and measures for the individual and population.



## Why are digitally connected diagnostics important for the 100DM?



### Faster Access

Digitally connected diagnostics enable the rapid transmission of diagnostic results to healthcare providers, reducing the time between diagnosis and treatment, reducing workload for healthcare professionals and improving quality control. This is particularly crucial during disease outbreaks, since early treatment can significantly improve patient outcomes and help prevent further transmission.



### Disease Surveillance

Digital connectivity allows for the seamless integration of diagnostic data into disease surveillance systems, aiding the early detection of dangerous pathogens and new variants, and enabling a proactive response before escalation into larger outbreaks or epidemics, a key objective of the 100DM.

Deployment of digitally-connected diagnostics can help progress towards achieving the 7-1-7 targets for detection, notification and response to public health threats, which is strongly linked to data and reporting systems.<sup>10,11</sup>



### Continuous Monitoring

Digitally connected diagnostics provide real-time data on the performance of diagnostics, vaccines, and treatments. This continuous monitoring ensures that healthcare systems can adapt quickly if a need to update diagnostics or interventions arises. This provides valuable insights into, for example, whether current diagnostic tests maintain their sensitivity in detecting new virus variants. This real-world data complements experimental laboratory-generated data, offering a more comprehensive understanding of how interventions perform in different environments.



### Informing Decisions

Informing decisions about what R&D to prioritise, for example, by detecting a variant virus which poses a risk of vaccine escape. Digital connectivity supports data-driven decision-making for R&D priorities.



### Providing Information

Digitally-connected diagnostics help inform decision-making around the need for non-pharmaceutical public health interventions, such as masking, physical distancing, school closures, and revised travel policies, as well as prioritisation of medical countermeasures to certain high-risk groups.

Despite these potential advantages, there is still a long way to go to achieve digitally connected diagnostics at scale. During the COVID-19 pandemic, more than 45% of countries were unable to report up-to-date testing data at least twice per week.<sup>12</sup> Even in countries with established health systems, it was often the responsibility of the individual to report their test results into national surveillance programmes (with little incentive to do so), and test results were rarely connected to personal electronic health records.

<sup>9</sup> PATH, 2023. Connected diagnostics and the future of global health. <https://www.path.org/articles/connected-diagnostics-and-the-future-of-global-health/>.

<sup>10</sup> Bochner, Aaron F., et al. "Implementation of the 7-1-7 target for detection, notification, and response to public health threats in five countries: a retrospective, observational study." *The Lancet Global Health* 11.6 (2023): e871-e879.

<sup>11</sup> Ongareello, Stefano, et al. "Current testing systems are a barrier to achieving the 7-1-7 target for detection, notification, and response to public health threats." *The Lancet Global Health* 11.9 (2023): e1340.

<sup>12</sup> FIND. An analysis of the frequency of reporting COVID-19 testing data. <https://www.finddx.org/data-and-impact/an-analysis-of-the-frequency-of-reporting-covid-19-testing-data/>.



# Examples of successful data connectivity for diagnostics

## COVID-19 diagnostic data integration in Rwanda through District Health Information Software version 2

The District Health Information Software version 2 (DHIS-2) system is the world's largest health information management system, covering 113 countries in Africa, Asia, and South and Central America.<sup>13</sup> During the COVID-19 pandemic, DHIS-2 was adapted to capture data on COVID-19 diagnoses in Rwanda. The data are integrated into electronic medical records to allow both patients and clinicians to access their COVID-19 test results through the online portal.<sup>14</sup>

## Deep learning of rapid diagnostic tests in low-resource settings (i-sense EPSRC IRC and m-Africa UCL-AHRI study<sup>15</sup>)

In 2017, a team from the UK and South Africa began to explore the use of mobile devices to capture and classify HIV rapid tests. This study<sup>16</sup> created the first real-world large image library of 11,374 LFTs for HIV acquired in field settings by health workers. A pilot field study of the deep learning algorithms deployed as a mobile application demonstrated high levels of sensitivity (97.8%) and specificity (100%) compared with traditional visual interpretation by humans (i.e. experienced nurses and newly trained community health workers) and reduced the number of false positives and false negatives. The findings lay the foundations for a new paradigm of deep learning-enabled diagnostics in LMICs. This provided a platform for workforce training, quality assurance, decision support and mobile connectivity to inform disease control strategies, strengthen healthcare system efficiency and improve patient outcomes and outbreak management in emerging infections.

## COVID-19 connected diagnostics in the United Kingdom for the REACT-2 study

In the UK, lateral flow antibody tests were used to estimate the prevalence of SARS-CoV-2 antibodies in the community through the REACT-2 (REal-time Assessment of Community Transmission-2) study<sup>17</sup>. This study of 207,000 people in 2021 demonstrated the impact of England's vaccination programme on population immunity, showing that 85–100% of people who received two doses of the COVID-19 vaccine had antibodies (varying by age and which vaccines they received, with those aged over 80 years having lower antibody prevalence). The data generated were invaluable for providing evidence on the success of vaccination, anticipating the spread of SARS-CoV-2, and planning next interventions.<sup>18</sup>

## Actions for stakeholders to make the 100 Days Mission for Diagnostics a reality

The following actions can achieve the goal of broadening access and availability of digitally connected diagnostics, ensuring that diagnostic devices and screening tests are developed from the early stage in a way that enables them to be digitally connected to data collection and integration systems that are trusted by the public, based on clear and transparent governance frameworks.



### Research funders

should increase R&D funding targeted to developing innovative, effective and accessible digitally connected diagnostic and screening tests.



### Private-sector players

should prioritise product development for technological advances to develop novel approaches geared towards ensuring infrastructure that allows test results to be automatically captured digitally.



### Policymakers

should ensure that, where available, systems are in place to allow for direct integration of these into routine care and public health surveillance systems. These approaches should leverage and build upon existing clinical and public health information systems, and should be developed in advance of a pandemic.



### The WHO

and health governing bodies should ensure pre-agreed, equitable and trustworthy data sharing commitments and mechanisms that ensure that individual privacy is protected and patient consent is obtained.



### National governments

should invest in health systems strengthening to develop digitalised health systems for connected diagnostics. Investments in tools and devices should be supported by broader funding of digital clinical and public health systems (including laboratory networks) for the data to be utilised effectively. Such investments are likely to ultimately pay dividends in quality and efficiency of care, value for money, and lives saved. Appropriate frameworks should also be put in place to ensure the careful management of patient data, privacy concerns and ethical implications of widespread diagnostic data collection and sharing. Moreover, it is noted that in national settings where data sharing is closely monitored, it is important that anonymised data is made available to appropriate authorities and health enforcing bodies.

<sup>13</sup> Kinkade C, et al. 2022. Extending and Strengthening Routine DHIS2 Surveillance Systems for COVID-19 Responses in Sierra Leone, Sri Lanka, and Uganda. *Emerg Infect Dis.* 28(13):S42-S48. doi: 10.3201/eid2813.220711. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9745217/>.

<sup>14</sup> ACT-A Dx Knowledge Hub. Using digital tools data science to strengthen COVID-19 management – case study Rwanda. <https://www.dxkhub.org/2023/04/21/using-digital-tools-data-science-to-strengthen-covid-19-management-case-study-rwanda/>.

<sup>15</sup> i-sense EPSRC IRC in Early Warning Sensing Systems for Infectious Diseases and AMR ([www.i-sense.org.uk](http://www.i-sense.org.uk)) EP/K031953/1; EP/R00529X/1

<sup>16</sup> Turbe V. et al. Deep Learning of HIV field-based rapid tests. *Nature Medicine* 27, 1165–1170 (2021).

<sup>17</sup> Wong NCK, et al. 2022. Machine learning to support visual auditing of home-based lateral flow immunoassay self-test results for SARS-CoV-2 antibodies. *Commun Med (Lond)*. 6:2:78. doi: 10.1038/s43856-022-00146-z. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9259560/>.

<sup>18</sup> Moshe M, Daunt A, Flower B, Simmons B, Brown J C, Frise R et al. SARS-CoV-2 lateral flow assays for possible use in national covid-19 seroprevalence surveys (React 2): diagnostic accuracy study *BMJ* 2021; 372:n423 doi:10.1136/bmj.n423 <https://www.bmj.com/content/372/bmj.n423>.





## Linking rapid diagnostics to care and treatment

Diagnostics are the gateway to treatment. But all too often, they are under-valued and under-used, risking missed opportunities for interventions and increased onwards transmission.

facilitates  
**rapid access**  
to appropriate  
treatment

The inappropriate prescribing of some treatments without an accurate test can also fuel drug resistance. Moreover, gold-standard tests typically require sending samples to centralised laboratories, resulting in delays and the need for follow-up appointments.

This highlights the need for a new generation of accurate rapid tests for use in decentralised community settings to support test-and-treat programmes, ensuring that infected individuals receive rapid access to appropriate treatment. This facilitates early guidance and appropriate treatment in an outpatient or home setting, which may reduce disease progression and onward transmission.

In the case of COVID-19, treatment with the oral antiviral nirmatrelvir/ritonavir has been shown in clinical trials to reduce the risk of hospitalization by 85% in high-risk groups, with the greatest impact observed when taken within 5 days of symptom onset.<sup>19</sup> This provides a real-world example of the value of connecting rapid diagnostics to treatment.

<sup>19</sup> ACT-Accelerator Facilitation Council Working Group Report on Diagnostics and Therapeutics <https://www.who.int/publications/m/item/act-accelerator-facilitation-council-working-group-report-on-diagnostics-and-therapeutics>





## Why is linking diagnostics to care and treatment important for the 100DM?

### Increased Testing Uptake

Establishing a clear connection between diagnostics and treatment encourages more individuals to get tested and provides a clear pathway to care, as exemplified by a survey of over 5,000 people across 22 countries, in which 81% of respondents stated they would be more willing to get tested for COVID-19 if it was linked to treatment.<sup>20</sup> This is an important outcome from a wider public health perspective, as increased diagnostics uptake may not only aid in the early detection and control of infectious diseases, but also contribute to better epidemiological tracking and informed decision-making by health authorities.

### Early Intervention

Timely diagnosis and treatment are essential for infectious diseases that can rapidly spread in communities. Linking diagnostics to treatment allows for swift interventions that can help contain outbreaks and prevent the spread of endemic or epidemic disease, an important dimension of global health security.

### Streamlined Patient Journey

Linking rapid diagnostics to treatment during a healthcare visit simplifies the patient journey, minimising the need for repeat visits and ensuring that scarce healthcare resources are used efficiently. This is especially significant in rural and low-resource settings, where patients often face long travel distances and financial constraints, using larger proportions of their income to access healthcare services.

### Patient and Community Support

Linking early testing to treatment allows community health workers to provide comprehensive support to patients. This includes contact tracing, assistance with safe isolation, identifying vaccination candidates, and detecting transmission hotspots.

### Protecting the Right to Know

Ensuring access to diagnostics is vital to uphold individuals' fundamental right to know their infection status. Even when treatment is not available, where diagnostic capacity exists, individuals should be able to access it and make informed choices about their behaviour and healthcare options based on the fundamental right of the individual to know one's disease status (see box on page 28).

### Global Health Equity

Linking diagnostics to care is a fundamental principle of global health equity. It ensures that individuals, regardless of their geographic location or socioeconomic status, can be in a better position to receive prompt and appropriate care based on accurate diagnoses.

<sup>20</sup> COVID-19 Access to Testing survey conducted by the ACT-A Diagnostics Pillar <https://www.who.int/publications/m/item/act-accelerator-facilitation-council-working-group-report-on-diagnostics-and-therapeutics>.

## The right to know your status and self-testing



Diagnostic tools provide personal information about an individual's infection status. Although we must always advocate for the necessary R&D investments to produce treatments for a given condition – and for universal access once the treatment exists – access to testing should be independent of whether there are established treatment pathways in place. All patients should have a right to know their infection status: a principle that has been well-established in the case of HIV testing and self-testing,<sup>21</sup> where knowledge of one's status even before advanced antiretroviral treatments were widely available helped guide preventive behaviours, such as safer sex with condoms, and for which the collective epidemiologic data demonstrated the enormity of the problem, driving the R&D agenda for treatments and vaccines.<sup>22</sup> Moreover, self-testing for pregnancy has empowered women and families to make informed behavioural choices for decades, demonstrating the inherent value of equipping patients with knowledge of their health status.



One way of improving access to diagnostics and the right to know your status in any context, but particularly for those in low- and middle-income countries, is to increase rollout of self-testing, such as via LFTs for respiratory diseases, or through low-cost rapid multiplexed molecular tests. These tests can provide rapid results at home or in a clinical setting, significantly reducing the burden of testing on healthcare systems and reducing barriers to testing, such as the logistical challenges of seeing a healthcare professional or the stigma associated with testing for some diseases.



Self-tests do not need to be isolated from wider systems. Results can still be reported digitally to contribute to public health surveillance techniques (see 'The opportunities from digitally connected diagnostics' above), and the outcome of a self-test can still be effectively linked to a treatment pathway.



Despite the demonstrable benefits of self-testing, as of August 2022, most people in the lowest resource settings did not have any access to COVID-19 self-tests. This stands in contrast to many high-income countries, where these tests were available for free or at highly subsidised rates since early in the COVID-19 pandemic.<sup>23</sup>

<sup>21</sup> LSHTM, STAR. "Background of HIV Self-Testing." *STAR - HIV Self-Testing Africa Initiative – Research*, London School of Hygiene and Tropical Medicine, 10 Mar. 2020, [hivstar.lshtm.ac.uk/background-of-hiv-self-testing](https://hivstar.lshtm.ac.uk/background-of-hiv-self-testing).

<sup>22</sup> UNAIDS – Knowledge is Power – Know your status, Know your viral load [https://www.unaids.org/en/20181122\\_knowledge\\_is\\_power](https://www.unaids.org/en/20181122_knowledge_is_power).

<sup>23</sup> MAPPING COVID-19 ACCESS GAPS: Results from 14 Countries and Territories <https://itpcglobal.org/wp-content/uploads/2022/08/Mapping-Access-Gaps-in-COVID-19.pdf>.



# Examples of test-to-treat in practice

## COVID-19

The USA COVID-19 'test-to-treat' initiative mobilised thousands of locations (including pharmacy-based clinics, federally funded health centres, long-term care facilities, and community-based sites) across the country to offer a 'one-stop' service. At these sites, people with COVID-19 symptoms can be tested, and receive antivirals (nirmatrelvir/ritonavir) all in a single visit, offering a simplified alternative to the traditional multi-step and multi-provider approach to treatment. The drawback of this approach is that patients need to leave the home and potentially risk becoming infected or infecting others. To overcome this obstacle, such initiatives could be expanded to encompass home-based testing and treatment linked to telehealthcare systems that can prescribe medicines and have them delivered to their homes.

Guidance on test-to-treat for COVID-19 has also been issued by the Africa Centres for Disease Control and Prevention (Africa CDC), setting out best practice for African Union Member States and recommending that patients receive "one-stop-care for COVID-19 testing and treatment", linking a positive test result to immediate outpatient treatment where appropriate and available.<sup>24</sup> However, it should be noted that access to oral antivirals for COVID-19 has been limited on the African continent.<sup>25</sup>

In 2021, the ACT-Accelerator and seven implementation partners launched early test-to-treat pilot programmes across 22 LMICs, supported by US\$50 million from FIND and Unitaid.<sup>26</sup> In 2022 FIND and Unitaid further delivered a package of US\$2 million to support advocacy for COVID-19 testing.<sup>27</sup>

## HIV

In South Africa, a successful test-to-treat initiative found that early initiation of antiretroviral therapy within 7 days of HIV diagnosis reduced mortality by 57% compared with delayed treatment initiation.<sup>28</sup> In San Francisco, USA, a separate study demonstrated a 75% reduction in HIV transmission rates after implementing a test-and-treat strategy.<sup>29</sup>

## Malaria

In a WHO Test, Treat, Track study, the use of rapid diagnostic tests led to a significant reduction in malaria-related mortality.<sup>30,31</sup>

## Tuberculosis

In India, TB test-to-treat initiatives have been successful in reducing TB-related morbidity and mortality. The implementation of GeneXpert MTB/RIF testing and immediate treatment initiation resulted in a 90% reduction in the time to treatment initiation and a 40% reduction in mortality among people with TB.<sup>32</sup>

## Chlamydia

Digital, online clinical care pathways linking testing to treatment have been shown to be safe, feasible, acceptable and fast for people with chlamydia diagnosed through online and in person postal self-sampling services with preliminary evidence of similar treatment outcomes to those in traditional services (Estcourt et al 2017). Efficacy, cost-effectiveness, and impact on inequalities of this intervention are being investigated in a definitive trial.<sup>33</sup>

24 COVID-19 Test to Treat Guidelines for African Union Member States <https://africacdc.org/download/covid-19-test-to-treat-guidelines-for-african-union-member-states/>

25 Boro E and Stoll B (2022) Barriers to COVID-19 Health Products in Low- and Middle-Income Countries During the COVID-19 Pandemic: A Rapid Systematic Review and Evidence Synthesis. *Front. Public Health* 10:928065. doi:10.3389/fpubh.2022.928065.

26 FIND and Unitaid invest US\$ 50 million to speed lifesaving testing and treatment solutions to the COVID-19 pandemic's frontlines <https://unitaid.org/news-blog/find-and-unitaid-invest-50m-covid19-nov2021/#en>.

27 FIND and Unitaid invest US\$2 million to support advocacy for COVID-19 test-and-treat approaches in low- and middle-income countries <https://unitaid.org/news-blog/find-and-unitaid-invest-us2-million-to-support-advocacy-for-covid-19-test-and-treat-approaches-in-low-and-middle-income-countries/#en>.

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## Actions for stakeholders to make the 100 Days Mission for Diagnostics a reality



### Policymakers

should prioritise increasing and optimising the use of test-to-treat services in routine healthcare settings for endemic diseases. This will help capacitate healthcare systems to respond to these conditions, while also building facilities and infrastructure that have the potential to pivot for use in response to an emergent epidemic or pandemic threat.



### Research funders

should ensure that research demonstrating the value of linking testing to treatment is appropriately prioritised through funding and incentives.



### Policymakers working on test-to-treat initiatives

should ensure ongoing collaboration with local and international research institutions to ensure that robust evaluation metrics are in place, so that objective data can be collected to evidence the benefits of such an approach and useful learnings can be shared widely, and ultimately written into national policies.



### Governments and international procurers

of tests should provide clear demand signals based on projections and encouragement to industry partners to develop 'packages' of tests – ideally relying on rapid multiplex platforms – with treatments for existing diseases, while **industry** should in turn develop plans to produce these for pathogens of pandemic potential.





# Conclusion

The world cannot afford to lose its focus on pandemic preparedness, and within that, the importance of innovation and access to diagnostics.

The 100 Days Mission emphasizes the importance of the first 100 days in responding to epidemic and pandemic threats.

With regards to diagnostics, a crucial element of this is enacting preparedness for epidemic or pandemic threats by making the regular use of exceptional diagnostics a routine part of healthcare systems globally.

Strengthening research and development, building prototype libraries, and normalizing diagnostics within routine care have been identified as vital first steps towards effective pandemic preparedness.

To ensure global readiness, stakeholders must embrace and embed the enablers outlined in this report into routine healthcare systems. The report recommends a coordinated approach, involving governments, international organisations, research institutions, industry and regulatory bodies, to enhance diagnostics for both epidemic and endemic diseases.

Political and financial commitment to multiplexed testing, digitally connected diagnostics, and linking diagnostics to treatment, as well as the underlying framework for diagnostics R&D to meet the goals of the 100DM, are essential to keeping populations safe.

Despite the recent impacts of the COVID-19 pandemic and the ongoing global transmission of SARS-CoV-2, the impact of this pandemic seems to be rapidly fading from view. This is in part due to the many technological successes regarding R&D and implementation of medical countermeasures that tempered its impact compared with previous pandemics. However, despite the successes in fighting COVID-19, now is not the time to be complacent: the world is not prepared for another major infectious disease threat. Improving access to diagnostics is a vital step towards ensuring preparedness for all.





International  
Pandemic  
Preparedness  
Secretariat

**FIND** ➡➡  
Diagnosis for all

# MAKING THE EXCEPTIONAL ROUTINE:

**Embedding diagnostic best practice to  
improve pandemic preparedness**

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