**WHO-WIPO-WTO Workshop**
**Innovation and Access to diagnostics for COVID-19 and beyond**
28 October 2022

## Objectives of the Workshop

This practical capacity-building workshop jointly organized by the WHO, WIPO and WTO Secretariats will look at diagnostics with a focus on in vitro diagnostics (IVD). The workshop aims to:

- Strengthen members' capacity to assess medical device, diagnostic therapeutic technologies to respond to COVID-19;
- help to better understand the concept and particularities of all diagnostics (including in vitro and in-vivo);
- understand the importance of regulatory processes for ensuring timely access to safe, efficacious and quality in vitro diagnostics;
- review the landscape for in vitro diagnostics for COVID-19 and explore the following issues: key products, lead manufacturers, manufacturing data, main production locations, and trade flows;
- look at information resources, including those made available by WHO, WIPO or WTO;
- consider relevant IP issues, including the role of IP and licensing as part of the enabling environment for innovation, local production and access;
- review trade-related issues that impact on access to vitro diagnostics, as well as ingredients or components;
- provide a forum for exchange of experiences and views that can help the Secretariats of WHO, WIPO and WTO to better respond to capacity-building needs of their members.

## A significant role for in vitro diagnostics for COVID-19 and beyond

Innovation and access to diagnostics are fundamental to strengthening health systems so that they are resilient enough to withstand the global health challenges of the 21st century. Experiences gained from the COVID-19 pandemic can inform considerations about facilitating diagnostic innovation and access. As stated in the 2021 report of The Lancet Commission on Diagnostics, three major global health priorities—universal health coverage, antimicrobial resistance, and global health security—all require access to diagnostics.[1]

Diagnostics are an essential component of healthcare. Early diagnosis is linked to improved health outcomes and reduced out-of-pocket spending, while disease surveillance provides critical data to inform public health decision makers. However, in vitro diagnostic testing is the weakest link in the healthcare cascade.[2] No in vitro diagnostic tests exist for 60% of the pathogens identified by the WHO as having the greatest outbreak potential.[3]

IVD testing is considered essential at every stage of a pandemic response. IVDs are needed for an early identification of those who are infected to break the chain of transmission and to liberate healed persons from isolation. Massive testing that is implemented as early as possible, and sustained over time can help contain a virus, even in the absence of vaccines and dedicated treatments. IVDs are also needed to inform development and deployment of vaccines, as well as assess vaccine efficacy. When

[1] Fleming, K. A. *et al* (2021). The Lancet Commission on diagnostics: transforming access to diagnostics. Lancet, 398(10315), 1997-2050. doi:10.1016/s0140-6736(21)00673-5. Available at https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(21)00673-5.pdf.
[2] https://www.finddx.org/newsroom/75th-world-health-assembly/
[3] FIND Strategy 2021, available at https://www.finddx.org/wp-content/uploads/2021/05/FIND-strategy-2021_FINAL.pdf

treatment is, or becomes available, diagnostics are crucial to allow healthcare professionals to rapidly implement a "test-and-treat" approach. The pandemic is helping us to understand that diagnostics are necessary to put in place the right conditions for effective testing strategies for COVID-19 to avoid obstacles to the rapid roll out of approved therapeutics and vaccines.

The COVID-19 pandemic has driven innovation in the development and deployment of IVDs and other diagnostics. For example, the diagnostics pillar of the Access to COVID-19 Tools (ACT) Accelerator helped to condense development timelines for rapid antigen tests into just 8 months (compared with 5 years for HIV rapid tests).[4]

Despite the progress achieved, the COVID-19 pandemic highlighted the challenges that already existed in the in vitro diagnostics field: underinvestment in research and development, manufacturing, laboratory systems, supply chain bottlenecks, and the need to further streamline regulatory frameworks including surveillance. Furthermore, there are huge inequities in testing levels – high-income countries COVID tests were used at 10–100 times the rate of low- and middle-income countries (LMICs).[5] As of August 2022, only 21.2% of tests administered worldwide have been used in low and lower middle-income countries, despite these countries comprising 50.8% of the global population.[6]

Supporting local production of affordable diagnostics would help to address many supply shortages and promote timely access. Barriers to local production are not limited to lack of equipment, funds, supply chain issues, but are also caused by lack of technical assistance with design and production challenges and compliance with applicable regulatory requirements. The necessary information regarding intellectual property, technology transfer licenses as well as market exclusivities for some products or production processes is not always easily available. Lack of access to this type of information may ultimately hinder the wide-spread use of technologies and negatively impact the use of open-source information. In addition, LMICs with existing manufacturing capability and knowledge may lack access to financing that would enable timely scale up of local production.

While most LMICs have national regulatory authorities for medicines, many are less likely to have a regulatory framework for medical devices. Where the authority exists, regulatory pathways are varied, expensive and lengthy. The cost to comply with duplicative and complex regulatory approval processes may result in increased pricing of diagnostics and may disincentivize investment in production. As a result, patients may face delays in access to diagnostics.

**Background on Trilateral Cooperation**

Within the existing collaboration framework, WHO, WIPO and WTO have decided to organize practical capacity-building workshops at technical level to enhance the flow of updated information on current developments in the pandemic and responses to achieve equitable access to COVID-19 health technologies. The aim of these workshops is to strengthen the capacity of policymakers and experts in member and observer governments to address the pandemic.

This third in the series of technical workshops is an effort by the collaborating agencies to make their expertise, as well as data and factual evidence, available to support Members to promote the development and access to safe, effective, quality, affordable in vitro diagnostics for COVID-19 and other pandemics.

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[4] FIND Strategy 2021, available at https://www.finddx.org/wp-content/uploads/2021/05/FIND-strategy-2021_FINAL.pdf

[5] FIND SARS-COV-2 test tracker. Available at https://www.finddx.org/covid-19/test-tracker/

[6] FIND SARS-COV-2 test tracker. Available at https://www.finddx.org/covid-19/test-tracker/

**Registration Info for Participants/ Attendees**

When: OCTOBER 28, 2022 at 14:00 (Geneva Time)

Topic: WHO-WIPO-WTO Workshop: Innovation and Access to diagnostics for COVID-19 and beyond

Register in advance for this Webinar:

https://who.zoom.us/webinar/register/WN_hixjjcZLS_iRHDdELrN50g

After registering, you will receive a confirmation email containing information about joining the Webinar.