# Global Commitment on Diagnostic Tests to Fight Antimicrobial Resistance

The development and spread of antimicrobial resistance (AMR) is a global public health crisis. Without action, AMR could cause 10 million deaths annually by 2050 accompanied by $100 trillion in lost global economic productivity.[1] The causes, extent and potential future impact of this health challenge have been well characterized by recent assessments and global leaders have made this issue a top priority.

It is essential that country-level action plans on AMR recognize the critical role of diagnostic tests in fighting this public health threat and promote adoption of existing tests as well as the development of new test technologies.

**This document is a statement of commitment by key global health stakeholders to optimize the use of diagnostic tests globally to fight AMR. This commitment will serve as a framework for collaborative action.**

## Diagnostic Tests are Essential Tools for Combating Antimicrobial Resistance

Diagnostics often can identify the organism causing the infection and also can provide insight into the host's immune response, thereby enabling health care providers to distinguish between infections requiring antimicrobial treatment and those that do not. Once the infectious organism has been identified, diagnostic tests also can determine which specific antimicrobials are effective and can guide the physician in appropriate therapeutic choice and dosage. The value of diagnostic test results is highly dependent on the right tests being ordered by the provider, performed on the correct sample at the right time and in the correct manner. The test results must also be communicated in a timely manner and interpreted appropriately, so that health care decisions are fully informed by test results.

Fully leveraging existing diagnostic tests would:

- Reduce inappropriate antibiotic use by identifying non-bacterial infections prior to prescribing;
- Expedite diagnosis and treatment decisions through either enhanced connectivity allowing the dissemination of results from laboratories to healthcare providers faster, or through the use of point-of-care tests that provide rapid results in doctors' offices and other care settings;
- Support early detection and diagnosis of drug-resistant infections;
- Enable effective disease surveillance and outbreak monitoring;
- Guide antimicrobial treatment selection through the use of antimicrobial susceptibility tests; and
- Help prevent the spread of resistant organisms and support hospital infection control programs.

## Diagnostic Tests are Underutilized

In order to optimize use of currently available diagnostics as well as encourage development of next generation technologies, the current barriers around access and uptake must be addressed.

1. Access to antimicrobials for patients who need them is essential, yet the use of diagnostics prior to prescribing varies widely across the globe.[2]
   - Most infections in developing countries are treated empirically without the benefit of diagnostic tests, contributing to unnecessary antibiotic use.
   - Even in developed countries many infections are treated empirically without utilization of available diagnostics.
   - In some countries, patients have over-the-counter access to antimicrobials, which removes diagnostics from the treatment equation altogether.
2. Antimicrobials often are prescribed before the organism causing the infection has been accurately identified and the antimicrobial therapy is not adjusted once the identification is known. This practice leads to significant improper, inappropriate or unnecessary use.
   - Individuals with viral infections commonly and inappropriately are treated with antibacterials, even though viruses do not respond to antibacterial therapy.
   - At least 30% of antibiotics prescribed in the United States are unnecessary,[3] and the percentage of antibiotics unnecessarily prescribed in the rest of the world is estimated to be even higher.
3. Diagnostics are not consistently used to confirm or modify treatment plans.
   - Antimicrobial susceptibility testing is important to determine whether the selected antimicrobial agent is effective or is associated with resistance,[4] but this testing is uncommon in most developing countries[5] and under-utilized in other health care settings.
   - In the poorest countries, $< 1\%$ of patients are treated at clinical facilities that have diagnostic microbiology laboratories.[6]
4. Diagnostics often are undervalued by health care systems relative to their essential role in providing quality care, and therefore may seem expensive or burdensome when compared to the simple practice of giving an antimicrobial agent.
   - Failure to appreciate the true value of diagnostics—in curtailing inappropriate antibiotic use, reducing antibiotic-related adverse events, and decreasing antibiotic resistance—limits effective adoption and appropriate reimbursement.
   - There is a lack of recognition that the cost of utilizing diagnostic tests is very small compared to the costs of infections, hospitalization, readmission and the long-term negative impact of antimicrobial resistance.
   - These are system failures that occur around the world in all income settings.

## Steps to Drive Adoption and Innovation of Diagnostic Tests

1. Embed the use of diagnostic tests into prescribing practices on a global basis in order to decrease reliance on empiric antibiotic utilization.
   - Establish and promote clearer guidelines for doctors to address cultural biases regarding prescribing diagnostics.
   - Ensure that antibiotic prescriptions are informed by test results.
   - Implement antibiotic stewardship programs in hospital and health care facilities.
   - Utilize diagnostic test protocols to identify and confirm the type of infection.
   - Deploy antimicrobial susceptibility tests to inform escalation or de-escalation of therapy.
2. Enhance access to diagnostic tests and testing facilities in all countries.
   - Strengthen initiatives to boost national, regional, and local laboratory capacity—including expansion of laboratory technician workforces and greater access to easy-to-use cost-effective rapid diagnostic tests in remote areas—funded and supported by governments, public health agencies, foundations and the private sector.
   - Align financial incentives with public health goals to drive more timely and accurate diagnosis of infectious diseases.
   - Provide support to low-resource settings and health care facilities to increase access to and use of cost-effective diagnostic tests.
3. Establish predictable incentives for innovation in the full range of infectious disease diagnostic tools from laboratory systems to point-of-care diagnostics and informatics.
   - Foster research and development into new technologies to detect and diagnose infections, particularly those due to antimicrobial resistance organisms.
   - Foster efficient regulatory review of rapid and point-of-care diagnostics that can accelerate identification of infection and the causative organisms.
   - Develop appropriate funding models to support the optimal use of technologies that diagnose infections and guide treatment.
   - Support development of predictable processes for health technology assessment (HTA) for evaluating diagnostic tests with the potential to positively impact the healthcare system. HTAs should be designed in line with local and regional decision-makers' needs, and adequate reimbursement policies that reflect the true value of diagnostics.

## Stakeholder Commitments

To ensure availability of access to innovative diagnostic solutions to combat the spread of AMR, the signatories below commit to partnering to advance the steps outlined in this document, including:

- Building the **long-term economic case** for diagnostics as a public good in the fight against drug-resistant infections.
- Establishing **public-private partnerships** to develop health systems and create wide scale access to diagnostics for all people.
- Working to ensure **effective global utilization of diagnostics**, taking into account country specific resources.
- Advocating for **R&D investments, funding to strengthen lab systems, transparent and harmonized regulatory processes, and sustainable reimbursement policies** to encourage development, support efficient registration and approval processes, and bolster appropriate utilization of diagnostic tests.

ENDNOTES


1 Tackling Drug-Resistant Infections Globally: Final Report and Recommendations, Review on Antimicrobial Resistance Report, (2016).

2 Caliendo AM, Gilbert DN, Ginocchio CC, et al. Better tests, better care: improved diagnostics for infectious diseases. *Clinical Infectious Diseases*. 2013;57(suppl 3):S139–S170. doi:10.1093/cid/cit578.

3 Fleming-Dutra KE, Hersh AL, Shapiro DJ, et al. Prevalence of inappropriate antibiotic prescriptions among US ambulatory care visits, 2010–2011. *JAMA*. 2016;315(17):1864. doi:10.1001/jama.2016.4151.

4 Jorgensen JH, Ferraro MJ. Antimicrobial susceptibility testing: A review of general principles and contemporary practices. *Clinical Infectious Diseases*. 2009;49(11):1749–1755. doi:10.1086/647952.

5 Jamison D, Breman J, Measham A, et al., eds. *Disease control priorities in developing countries*. 2nd ed. New York, NY: World Bank/Oxford University Press; 2006.

6 de J. Sosa A, Byarugaba D, Amabile C, Hsueh P, Kariuki S, Okeke I, eds. *Antimicrobial resistance in developing countries*. New York, NY: Springer-Verlag New York; 2010.


## CURRENT LIST OF COMMITTED SIGNATURES

### DIAGNOSTIC COMPANIES

- Abbott
- Alere
- Amplex Diagnostics GmbH
- BD
- Beckman Coulter
- bioMerieux
- Bio-Rad
- Cambridge Life Sciences
- Cepheid
- CIGA Healthcare
- Erba Molecular
- Hologic
- Mast Group Ltd
- Micronics
- Mologic
- Momentum Bioscience
- OLM Diagnostics
- Oxford Impedance Diagnostics
- Philips Healthcare
- QIAGEN
- QuantumDx Group Ltd
- Roche
- Thermo Fisher Scientific

### DIAGNOSTIC ASSOCIATIONS

- AdvaMedDx
- British In Vitro Diagnostics Association
- CBDL—The Brazilian Chamber of In Vitro Diagnostics
- IVD Australia
- MedTech Europe

### KEY GLOBAL STAKEHOLDERS

- Africa Centers for Disease Control and Prevention
- ALADDIV—The Latin American Alliance for the Development of In Vitro Diagnostics
- FIND
- London School of Hygiene and Tropical Medicine
- Stop TB Partnership