BIOMÉRIEUX

ADVANCING HEALTH THROUGH TRADE:
Eliminating Tariffs to Safeguard Diagnostic Access and Innovation

bioMérieux is a global leader in *in vitro* diagnostics (IVD), committed to serving public health by advancing patient care and supporting clinical decision-making for healthcare providers across more than 160 countries. In vitro diagnostics are tests performed on samples such as blood, tissue, or other bodily fluids to detect diseases, monitor health conditions, or guide treatment decisions without direct contact with the patient. The IVD industry is critical to healthcare systems worldwide, providing the diagnostic information that underpins over 70% of clinical decisions.[1] To meet global public health needs with high-quality bioMérieux maintains significant manufacturing operations in both the United States and Europe, while also relying on an international network for sourcing raw materials, components, and finished goods. However, tariffs and restrictive trade measures threaten the accessibility, affordability, and the pace of innovation of diagnostic technologies. These barriers undermine the sector's economic resilience and risk delaying provider, and ultimately patient, access to essential diagnostics.

With manufacturing hubs in both the U.S., Europe, and China bioMérieux advocates for a stable, flexible international trade environment that exempts IVD products and their constituent components from quotas or tariffs and streamlined regulatory pathways to enable agile supply chains.

Introduction

Since its founding in 1963, bioMérieux has been dedicated to improving global public health by providing diagnostic solutions (systems, reagents, software, services) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Our innovative technologies are primarily used for diagnosing infectious diseases and detecting microorganisms in agri-food or pharmaceutical products. The solutions our teams imagine, develop and manufacture are key to enabling healthcare professionals and industry partners to make confident decisions to improve patient outcomes and ensure consumer safety.

Today, bioMérieux is present in 45 countries, serves customers and patients in 160 countries, and employs more than 14,000 people worldwide. The company generates 93% of its revenue outside of France, reflecting its deeply international character. The footprint in the U.S. includes operations in 7 cities, 5 manufacturing plants in 4 states, and 6 R&D centers. This footprint includes its Global Center of Excellence for Molecular Diagnostics in Salt Lake City, which was established in 2014. bioMérieux also recently opened a new facility situated within the Philadelphia Navy Yard, a Life Sciences hub known for innovation and collaboration; this office houses the predictive diagnostics innovation center for food safety business. bioMérieux also has manufacturing sites in Europe, Australia, and China.

IVDs play a critical role in modern healthcare, providing information that influences over 70% of clinical decisions.[1] Despite their pivotal importance in diagnosing, monitoring, and managing diseases, IVDs represent only a small fraction of overall healthcare expenditures.[2] For instance, in the European Union, United Kingdom, and EFTA countries, IVDs represent just 1% of total healthcare spending.[3] Similarly, in the United States, IVDs constitute about 2.4% of the $3 trillion healthcare expenditure.[4] This disparity highlights the extraordinary value diagnostics deliver to healthcare systems — enabling better outcomes at relatively low cost — and underscores the need to protect access to these essential technologies.

Diagnostic tests are essential to modern healthcare, improving patient outcomes and delivering system-wide efficiencies. For example, by identifying pathogens and determining drug susceptibility, diagnostics enable targeted, more effective treatments, reduce inappropriate antibiotic use and subsequent harms, and help combat antimicrobial resistance (AMR). Beyond clinical benefits, diagnostics generate significant cost savings by streamlining care pathways and reducing unnecessary interventions. As healthcare costs rise, there is growing demand for evidence encompassing their full economic value. Demonstrating and appropriately recognizing the holistic impact of IVDs — from better patient management to healthcare system sustainability — is critical for building a more efficient, resilient healthcare future.

Global Supply Chain Vulnerabilities

The production of IVDs depends on highly complex, globally integrated supply chains that are critical to maintaining access to timely and accurate healthcare. Manufacturing a single diagnostic device can involve assembling over 1,000 individual components — including reagents, optical sensors, semiconductors, specialty plastics, and microfluidic systems — each sourced from a wide network of international suppliers. No single country can produce all the inputs required for modern diagnostics, making multi-national sourcing an operational necessity, not a choice.

This complexity makes the IVD sector's supply chains uniquely fragile. Tariffs, import and export controls, or other trade disruptions affecting even a single raw material or component can trigger cascading delays across the manufacturing process, jeopardizing the availability of critical diagnostic tests for hospitals, clinics, and patients. Compounding the challenge, IVDs are subject to stringent regulatory frameworks: any change in a supplier or component often requires re-validation and fresh approvals from regulatory agencies such as the FDA in the U.S., the EMA in Europe, and other national authorities. These processes are time-consuming, costly, and difficult to expedite — meaning manufacturers cannot simply substitute components in response to supply chain disruptions without risking compliance violations or market withdrawal.

Given these realities, policy measures that impose tariffs or restrict cross-border trade in medical components pose an immediate threat to public health. Protecting the flow of diagnostic materials across borders — and streamlining regulatory flexibility for validated components — must be prioritized to safeguard healthcare access, maintain innovation, and support global pandemic preparedness. Any failure to do so could lead to shortages, delayed diagnoses, higher healthcare costs, and worsen patient outcomes.

Complexity of Component Validation by Regulators

IVD devices are subject to some of the most stringent regulatory requirements in healthcare. Any change to a component — even a minor material or supplier change — often requires new validation and regulatory approval. In the U.S., this typically means filing a supplemental premarket submission (510(k)) or even a new premarket approval (PMA) with the FDA. Similarly, under Europe's *In Vitro* Diagnostic Regulation and China's National Medical Products Administration regulations, design, material, or manufacturing changes often trigger fresh conformity assessments by notified bodies.[6]

These regulatory processes are critical for ensuring patient safety, but they are lengthy and resource-intensive. Re-validation and re-approval can take anywhere from several months to multiple years, effectively locking manufacturers into their original supply chains. As a result, manufacturers cannot quickly adapt to supply disruptions, tariff impacts, or material shortages without risking non-compliance, product recalls, or market withdrawal.

This regulatory inflexibility creates significant vulnerabilities in the event of global trade disruptions. Policymakers must recognize that the diagnostics sector cannot easily shift suppliers or reconfigure manufacturing in response to tariffs or trade barriers. Protecting cross-border access to components and raw materials — and creating expedited regulatory pathways for validated supply chain changes — is critical to maintaining healthcare resilience and ensuring uninterrupted patient access to essential diagnostics.

Rising Costs and Fixed Reimbursement Structures

Trade barriers, including tariffs and regulatory misalignment, are driving up costs for IVD manufacturers — costs that are difficult to offset under existing healthcare payment systems.[7] Medicare, Medicaid in the United States, and similar social medical insurance schemes present other countries and private insurers issue reimbursement rates for diagnostic tests in two- to three-year cycles. These fixed structures make it particularly challenging for manufacturers to adjust pricing to reflect rising input costs caused by tariffs or supply chain disruptions. In other markets without a comprehensive public healthcare scheme, price increases due to tariffs would increase patients' out-of-pocket expenses which would make diagnostic tests unaffordable, hereby directly impacting patient outcomes. As a result, diagnostic companies often must absorb increased costs, threatening the financial viability of critical tests, particularly routine or high-volume diagnostics.

Impact on Small Businesses and Startups

Around 80% of MedTech companies are small businesses or startups, many focused on developing single diagnostic platforms. These firms operate with limited resources and are especially vulnerable to tariff-driven cost increases and regulatory burdens.[8] Unlike larger companies, they cannot easily reconfigure supply chains or weather financial shocks, risking reduced innovation, delayed market entry, and fewer diagnostic options for patients.

Additional Trade Barriers

Global trade barriers are increasingly disrupting the *in vitro* diagnostics industry.[9] Key challenges include high tariffs on diagnostic devices, import bans on refurbished equipment and spare parts, and the non-recognition of internationally accepted certifications such as the CE mark.[10-12] These measures force companies to navigate duplicative and costly regulatory processes, driving up the price of diagnostics and delaying the introduction of new technologies to patients.

In addition to tariff and certification issues, some procurement policies favor domestic suppliers at the expense of international competition. Local content requirements, which mandate sourcing or manufacturing a sizable portion of components domestically, further fragment global supply chains and can increase operational costs. Collectively, these trade barriers weaken the ability of diagnostic companies to innovate, expand globally, and deliver affordable, timely testing solutions critical to public health.

bioMérieux Policy Position: Eliminating Tariffs to Safeguard Diagnostic Access and Innovation

As a leading IVD company, bioMérieux strongly supports a zero-tariff policy for diagnostic products, spare parts, components, and raw materials. IVD technologies are critical to modern healthcare, informing the majority of clinical decisions while representing only a small portion of overall healthcare costs. Tariffs at any point in the supply chain — whether on a finished device, a critical component, or a raw material — add unnecessary cost burdens to public and private payers, delay patient access, and disrupt innovation. To maintain global health security, promote affordability, and strengthen supply chain resilience, it is essential that diagnostics are exempt from tariffs worldwide.

bioMérieux endorses the "zero-for-zero" approach advocated by AdvaMed and MedTech Europe, which calls for a mutual elimination of tariffs on all lifesaving and life-enhancing medical technologies.[13] Adopting this policy across major markets would ensure that patients everywhere can benefit from timely access to advanced diagnostics, while reinforcing the global competitiveness and stability of the diagnostics industry.

To facilitate the consistent tariff exemption of IVD, raw materials, components, and finished products, policymakers should implement a supplementary customs code specifically applicable to IVDs across all jurisdictions. Establishing a clear designation would enable efficient identification at the border, streamline trade procedures, and support uninterrupted access to critical diagnostic technologies worldwide. For example, the European Union uses a supplementary system under the Tarif Intégré de la Communauté (TARIC) to distinguish products for special tariff treatment. The United States could adopt a similar approach by creating a Harmonized System (HS) code classification for FDA 510(k)-approved IVDs.[14]

Historically, sectors with a strong public health mission—such as healthcare—have benefitted from reduced or exempted tariffs, recognizing the critical need for broad access to essential technologies.[15-16] The rationale is clear: tariffs on medical technologies increase healthcare costs, reduce access to care, and stifle innovation. Eliminating these barriers for diagnostics would strengthen global supply chain

resilience, ensure the timely availability of innovative testing technologies, lower overall healthcare system costs, and enhance the world's ability to respond to emerging health threats, including antimicrobial resistance. Zero-tariff policies are not only an economic imperative but also a public health necessity.

Conclusion

The IVD industry is central to healthcare outcomes and global health innovation. However, tariffs and uncoordinated trade restrictions expose the sector to vulnerabilities that risk harming patients, slowing scientific advancement, and undermining economic growth.

To protect patient care, safeguard innovation, and ensure resilience, governments must act decisively to:

- Eliminate tariffs on IVDs, spare parts, components, and raw materials;
- Implement global zero-for-zero trade policy for diagnostics;
- Establish IVD-specific customs codes to support tariff exemptions;
- Streamline regulatory pathways to enable agile supply chains.

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