July 20, 2022

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Patty Murray
Chair
Committee on Health, Education,
Labor and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education,
Labor and Pensions
United States Senate
833 Hart Senate Office Building
Washington, D.C. 20510

Dear Chairman Pallone, Chair Murray, and Ranking Members Rodgers and Burr:

We write on behalf of a diverse group of stakeholders, representing test manufacturers, laboratories, physicians, healthcare providers, patients, consumers, and public health groups, and we are united in a commitment to ensuring patients' access to accurate and reliable *in vitro* diagnostics. We appreciate your continuing efforts to deliver vital funding to the U.S. Food and Drug Administration (FDA), and we ask that as you reconcile differences between the user fee reauthorization legislation passed by the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions (HELP), you address an urgent public health issue by enacting the diagnostics reform provisions included in the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022 (S. 4348).

These provisions reflect years of continuous engagement and thoughtful collaboration among committee and congressional leaders and the stakeholder community. Our organizations deeply appreciate the careful balance the Senate HELP Committee struck in the diagnostics provisions it advanced to the markup on June 14th, referred to as the VALID Act of 2022. This approach not only enjoys broad support from the stakeholder community, it was approved by the Senate HELP Committee on a bipartisan basis and was largely developed under the leadership of Members from both sides of the aisle in both chambers of Congress.

As you are aware, the legislation addresses a longstanding issue that has been recognized by administrations of both parties. The current federal approach to oversight has fueled regulatory uncertainty that jeopardizes investment in the next generation of diagnostics that will provide for improved patient outcomes. As Congress finalizes a legislative package reauthorizing FDA's user fee programs, it can also seize this truly unique opportunity to advance a flexible, risk-based regulatory system for all *in vitro* clinical tests. We appreciate your continued support for meaningful diagnostics reform and we remain committed to working with you and the committees to advance these reforms into law this year.

Signed,

Abbott
AdvaMedDx
American Cancer Society Cancer Action Network (ACS-CAN)
American Society of Clinical Oncology (ASCO)
Arizona Bioindustry Association, Inc. (AZBio)
Ascensia Diabetes Care
BD (Beckton, Dickinson and Company)
Beckman Coulter Diagnostics
BioFlorida
bioMérieux Inc.
BioNebraska
BioOhio
Bio-Rad Laboratories
Center for Science in the Public Interest
Cepheid
College of American Pathologists (CAP)
Colorado BioScience Association
Danaher Diagnostics
Foundation Medicine
Friends of Cancer Research
Global Liver Institute
GRAIL, LLC
HealthCare Institute of New Jersey (HINJ)
Hologic
Indiana Health Industry Forum
Indiana Medical Device Manufacturers Council
LUNGevity
Lymphoma Research Institute
MassBio
MedTech (New York)
Michigan Biosciences Industry Association (MichBio)
Muscular Dystrophy Association
North Carolina Biosciences Organization (NCBIO)
Ovarian Cancer Research Alliance (OCRA)
PERSOWN, Inc.
Pew Charitable Trusts
QIAGEN
QuidelOrtho Corporation
Renalytix AI, Inc.
Renegade Bio
Roche Diagnostics
Sekisui Diagnostics
South Dakota Biotech
Triage Cancer
U.S. PIRG
Werfen