The Honorable *Jane Smith*

U.S. Senate / U.S. House of Representatives

*Address*

Washington, DC *zip code*

DATE

*Submitted electronically*

Dear [Senator, or Representative *Smith*],

[Insert info about company, district/state presence]

Diagnostic tests facilitate evidence-based medicine and are used to screen patients for diseases, guide informed treatment decisions, and monitor disease progression and treatment effectiveness. The ongoing COVID pandemic has further made clear tests are essential to public health preparedness and response efforts during infectious disease outbreaks and other public health emergencies.

Unfortunately, regulation of clinical diagnostics does not current apply to all tests and has not kept pace with advancements in the field, including those driving personalized medicine.

To better support patient care and public health, [company] strongly supports the establishment of a modernized, risk-based regulatory framework crafted with the unique attributes of diagnostic tests in mind, overseen by the Food and Drug Administration, but separate and distinct from the traditional medical device framework. Such an approach would increase the reach of cutting-edge diagnostics, allowing patients to benefit more rapidly and broadly. This approach would also increase the confidence of patients and providers in the latest diagnostic technologies as it would apply to all diagnostic tests, no matter where they are developed.

We are greatly appreciative of Senators Michael Bennet (D-CO) and Richard Burr (R-NC) and Reps. Diana DeGette (D-CO) and Larry Bucshon (R-IN) for their efforts to develop and introduce ***the Verifying Accurate Leading-Edge IVCT Development Act (VALID) Act of 2021***. [Company] believes the regulatory framework that VALID would establish is sound and we look forward to continuing to constructively engage with the sponsors and the Senate Health, Education, Labor, and Pension Committee, and House Energy and Commerce Committee to improve several components of the bill as the legislative process progresses.

With that in mind, [company] respectfully urges you to consider co-sponsoring S. 2209 / H.R. 4128, encouraging the Committees to prioritize the VALID Act this Congress. We would be happy to meet with you or your staff to provide additional insight and answer any questions you have.

Sincerely,