July 18, 2023

The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Richard Hudson
Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chair McMorris Rodgers, Ranking Member Pallone, Representative Hudson, and Representative Eshoo,

Thank you for your continued efforts to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA). We particularly appreciate and urge the Committee to include Section 107 of H.R. 4421.

The Point of Care Testing Association (POCTA) seeks to facilitate access to safe, effective, and cost-effective patient testing at the point of care. Laboratory testing furnished at the point of care, such as in a physician's office, offers benefits to patients, the health care system and public health. Point of care testing better enables physicians to monitor chronic conditions, diagnose illnesses, and provide timely information to patients, which can stop transmission of infectious diseases.

When diagnostics are available at the point of care, physicians and patients receive the results in real time, which minimizes delays in starting or changing treatment and providing timely information on the patient's clinical needs. Point of care testing is frequently used to diagnose illnesses like COVID-19, flu and HIV, and to monitor chronic conditions like diabetes, instances where immediate results can make for significant clinical difference.

For these reasons, we want to express support for Section 107, Diagnostic Testing Preparedness Plan. Section 107 calls for the creation of a plan to help facilitate development and utilization of diagnostics during a public health emergency (PHE), including focus on rapid deployment, scaling, procurement, and distribution of clinical and diagnostic laboratory testing equipment. The language as currently written also describes the variety of diagnostics essential to pandemic preparedness, including high-throughput laboratory diagnostics, point-of-care diagnostics, and rapid at-home or point-of-use diagnostics. The bill further calls for public-private coordination and collaboration during a PHE.

Access to rapid, point of care testing was essential during the recent pandemic. Point-of-care tests allow for rapid results, which provide more effective contagion control because the infected individual can isolate that much sooner, and a healthcare practitioner can provide treatment advice while the patient is still present. Physicians' offices and clinic laboratories typically can turn results within an hour. We learned the high public health value of this access during the COVID-19 PHE and believe it is essential to carry forward as we evaluate lessons learned and better prepare for the future.

As you continue to move forward with this bill, we would like to encourage the Committee to make clear that at-home, point of care and point-of-use diagnostics can are all typically rapid and point of care and rapid point of use diagnostics may also be high-throughput testing. The language as currently written refers to high-throughput "laboratory diagnostic, point-of-care diagnostic, or rapid at-home or point-of-use diagnostic." It is our sense that the Committee may intend for "high-throughput" to be modifying three testing sites. We support that.

All three modalities can indeed provide the same patient outreach as high-throughput processing in a core laboratory. While a core lab running a large analyzer can process dozens of tests simultaneously, a point of care setting likewise can process many tests with speed. Same can be said for at home and point of use, which provide comparably quick results and reach out to test large numbers of patients in short periods of time. We saw in the PHE that CMS differentiated between core lab and point of care services when it sought to incentivize high-throughput capacity and only provided a payment incentive to high throughput core labs. Policies also should incentivize point of care and at home testing, which can meet similar volume and timing objectives. **The Committee should consider clarifying its intent behind this language to acknowledge this support for point of care, at home and point of use testing.**

Again, we support Section 107 in H.R. 4421 and encourage the Committee to include it in the final version of the bill. Should you have questions or would like more information, we are available to discuss this important matter further.

Thank you,

Members of the Point of Care Testing Association