February 17, 2021

The Honorable Patty Murray The Honorable Roy Blunt

Chair Ranking Member

Appropriations Subcommittee on Appropriations Subcommittee on

Labor, Health and Human Services, Labor, Health and Human Services,

Education, and Related Agencies Education, and Related Agencies

United States Senate United States Senate

Washington, D.C. 20510 Washington, D.C. 20510

The Honorable Rosa DeLauro The Honorable Tom Cole

Chair Ranking Member

Appropriations Subcommittee on Appropriations Subcommittee on

Labor, Health and Human Services, Labor, Health and Human Services

Education, and Related Agencies Education, and Related Agencies

United States House of Representatives United States House of Representatives

Washington, D.C. 20515 Washington, D.C. 20515

Dear Chairwomen Murray and DeLauro, and Ranking Members Blunt and Cole,

The undersigned groups are committed to ensuring that our nation’s children receive high-quality, appropriate, and equitable healthcare. A key means of achieving this goal is through laboratory tests that provide objective data to healthcare professionals for evaluating the health status of their young patients.

When making a diagnosis, the healthcare professional considers a laboratory test value within the context of a reference interval – a range of numeric values that would be expected in a healthy individual. If the test result falls outside of the reference interval – either higher or lower – the practitioner may order medical intervention to address the condition. If the diagnosis is incorrect for any reason, including a faulty reference interval, it could result in patient harm. Therefore, it is critical that reference intervals be correct.

Whereas reference intervals for adults are generally reliable, there is considerable inconsistency and large gaps in the ranges provided for children. It is imperative that reference intervals accurately reflect the physical development of patients from birth through adolescence to adulthood, including any variations due to race, ethnicity, or gender. Accurate and actionable reference intervals are particularly important for our youngest patients, who are often unable to verbally communicate their symptoms. Unfortunately, most laboratories are unable to obtain enough samples from a diverse, healthy population of children to develop their own accurate pediatric reference intervals (PRIs).

In December 2019, the House and Senate passed, and the President signed into law, the *Further Consolidated Appropriations Act of 2020*. In the accompanying report language, the two chambers requested that the Centers for Disease Control and Prevention (CDC) develop and submit to Congress a plan for improving PRIs. The agency outlined its plan in the Department of Health and Human Services fiscal year 2021 congressional justification to Congress.

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According to the CDC they already have the infrastructure in place to achieve this objective. The agency is proposing to:

* Collect clinical samples through its National Health and Nutrition Examination Survey (NHANES), which has the organization and expertise to collect the specimens from healthy children; and
* Utilize its Environmental Health Laboratory (EHL) to generate the reference intervals for children and disseminate the information to clinical laboratories. EHL has developed reference intervals in the past.

CDC projects that it would need an additional $10 million to initiate and advance this vital work.

The undersigned groups support CDC’s approach and urge Congress to provide the agency with the additional funding needed to improve pediatric reference intervals and ensure equitable and quality care for our country’s children. We appreciate your consideration on this matter.

Academy of Clinical Laboratory Physicians and Scientists

American Academy of Pediatrics

American Association for Clinical Chemistry

American Clinical Laboratory Association

American Medical Technologists

American Society for Bone and Mineral Research

American Society for Clinical Laboratory Science

American Society for Clinical Pathology

American Society of Hematology

American Society of Pediatric Hematology/Oncology

American Urological Association

ARUP Laboratories

Association of Pediatric Hematology/Oncology Nurses

Association of Public Health Laboratories

Children’s Healthcare of Atlanta

Children’s Hospital Association

Children’s Hospital of Philadelphia

Children’s National Hospital

Children’s Pathology Chiefs

Clinical Laboratory Management Association

COLA, Inc.

College of American Pathologists

Endocrine Society

Laboratory Corporation of America Holdings

Lipoprotein(a) Foundation

National Association of Pediatric Nurse Practitioners

PCOS Challenge: The National Polycystic Ovary Syndrome Association

Pediatric Endocrine Society

Quest Diagnostics

Seattle Children's Hospital

Siemens Healthineers

Society for Reproductive Investigation

Thermo Fisher Scientific