February 27, 2020

The Honorable Roy Blunt The Honorable Patty Murray

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 Chairman Blunt, Chairwoman DeLauro, and Ranking Members Murray and Cole:

The undersigned groups are committed to ensuring that our nation’s children receive quality, appropriate healthcare. A key means of achieving this objective 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 evaluates a laboratory test value within the context of a reference interval – a range of numeric values that would be expected in a healthy child. If the test result falls outside of the reference interval – either higher or lower – the healthcare professional may order a medical intervention to address the condition. If the diagnosis is mistaken for any reason, including a faulty reference interval, the result could be harmful for the young patient. 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. 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 healthy children to develop their own accurate pediatric reference intervals (PRIs).

Fortunately, the Centers for Disease Control and Prevention (CDC) has the infrastructure in place to address this problem. Its Environmental Health Laboratory (EHL) could generate the needed reference intervals with clinical samples obtained from its National Health and Nutrition Examination Survey (NHANES). EHL has experience developing reference intervals for chronic disease biomarkers in adults and NHANES has the infrastructure and expertise to collect the requisite specimens from healthy children. Congress recognizes the critical role the CDC can play in addressing this issue.

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 identified improving pediatric reference intervals as a key priority, requesting that the CDC develop and

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submit a plan to Congress for improving PRIs. In order to advance this important initiative, we recommend that Congress provide the CDC Environmental Health Laboratory with an additional $10 million in FY 2021 to initiate and advance this vital work.

The undersigned groups stand ready to be an ongoing resource to members of Congress on improving pediatric reference intervals and ensuring 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

ARUP Laboratories

American Urological Association

Association of Pediatric Hematology/Oncology Nurses

Association of Public Health Laboratories

Children's Hospital Colorado/University of Colorado

Children’s Pathology Chiefs

Clinical Laboratory Management Association

COLA

College of American Pathologists

Endocrine Society

Laboratory Corporation of America Holdings

Lipoprotein(a) Foundation

National Association of Pediatric Nurse Practitioners

Quest Diagnostics

PCOS Challenge: The National Polycystic Ovary Syndrome Association

Pediatric Endocrine Society

Seattle Children’s Hospital

Siemens Healthineers

Thermo Fisher Scientific