July 19, 2019

The Honorable Roy Blunt
Chair
Appropriations Subcommittee on
Labor, Health and Human Services,
Education, and Related Agencies
United States Senate
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
Appropriations Subcommittee on
Labor, Health and Human Services,
Education, and Related Agencies
United States Senate
Washington, D.C. 20510

Dear Chairman Blunt and Ranking Member Murray:

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 pediatricians with objective data for evaluating the health status of their young patients.

When making a diagnosis, the pediatrician 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 pediatrician 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.

The good news is that 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 ranges for chronic disease biomarkers in adults and NHANES has the infrastructure and expertise to collect the requisite specimens from healthy children. In order to advance this important initiative, we recommend that Congress provide the CDC Environmental Health Laboratory with an additional $10 million in FY 2020 to initiate and coordinate 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 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
Clinical Laboratory Management Association
COLA
College of American Pathologists
Endocrine Society
Laboratory Corporation of America Holdings
Pediatric Endocrine Society
Quest Diagnostics
Seattle Children's Hospital
Siemens Healthineers
The Association of Genetic Technologists
Thermo Fisher Scientific