March 18, 2024

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

The Honorable Robert Aderholt Chair Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies United States House of Representatives Washington, D.C. 20515 The Honorable Shelley Moore Capito Ranking Member Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies United States Senate Washington, D.C. 20510

The Honorable Rosa DeLauro Ranking Member Appropriations Subcommittee on Labor, Health and Human Services Education, and Related Agencies United States House of Representatives Washington, D.C. 20515

Dear Chair Baldwin, Ranking Member Moore Capito, Chair Aderholt, and Ranking Member DeLauro:

The undersigned organizations are committed to ensuring that our nation's children receive highquality, appropriate, and equitable healthcare. A key means of achieving these goals are laboratory tests that provide healthcare professionals with objective data to evaluate the health status of their young patients. Unfortunately, providers often do not have the most accurate information to interpret these data and ensure our children receive the best care possible.

Fortunately, the Centers for Disease Control and Prevention (CDC) can address this vital, but underappreciated issue, if Congress provides them with \$10 million to advance this initiative.

To make a diagnosis, healthcare professionals evaluate test results within the context of a normal range of values or reference intervals for the medical condition. If the value is outside of this range, the care team may order medical treatment to address the situation. Therefore, the normal range used to interpret the value must be precise, otherwise the patient could be misdiagnosed, and unnecessary or harmful interventions ordered. While reference intervals are widely available for adults, pediatric reference intervals (PRIs) are often of poor quality or nonexistent.

Many laboratories do not have the resources to obtain the necessary samples from healthy children to develop appropriate normal ranges. Therefore, they rely upon intervals derived from specimens from sick children, which distort the 'true' normal range. Alternatively, adult reference intervals may be used. However, adult ranges do not reflect the different growth and developmental stages of children and can lead to misdiagnosis and inappropriate care.

A national effort is needed to deal with this children's health issue.

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Congress recognized the importance of this issue when it asked CDC to develop and submit a plan outlining how PRIs can be improved in the fiscal year 2020 budget. In 2021, the agency addressed the issue in the Department of Health and Human Services congressional justification to Congress. CDC stated they 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 reference intervals for children and disseminate the information to clinical laboratories. EHL has developed reference intervals in the past through industry standards.

The House of Representatives included report language in its Fiscal Year 2022 Departments of Labor, Health and Human Services, Education, & Related Agencies appropriations bill encouraging CDC to begin working on this initiative. However, the agency projects that it will need an additional \$10 million to initiate and advance this vital work.

The undersigned organizations support the CDC's approach and urge Congress to provide the funding needed to improve PRIs and ensure quality and equitable care for our country's children. We are asking Congress to appropriate an additional \$10 million to CDC's FY 2025 budget for Environmental Health to fund this important initiative. We appreciate your consideration on this matter.

Academy of Clinical Laboratory Physicians and Scientists American Academy of Pediatrics American Association of Nurse Practitioners American Clinical Laboratory Association American College of Clinical Pharmacy American Medical Technologists American Society of Andrology 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 for Diagnostics & Laboratory Medicine Association of Maternal & Child Health Programs Association of Pathology Chairs Association of Pediatric Hematology/Oncology Nurses Association of Public Health Laboratories Association of Schools and Programs of Public Health Avalon Healthcare Solutions Children's Healthcare of Atlanta

Children's Hospital Association Children's Hospital Colorado Children's Hospital of Philadelphia Children's National Hospital Children's Pathology Chiefs COLA, Inc. College of American Pathologists **Endocrine Society** International Society of Andrology Laboratory Corporation of America Holdings National Association of Pediatric Nurse Practitioners National Hispanic Medical Association National Rural Health Association PCOS Challenge: The National Polycystic Ovary Syndrome Association Pediatric Endocrine Society **Quest Diagnostics** Seattle Children's Hospital Siemens Healthineers Society for Reproductive Investigation Society for Pediatric Pathology University of Pittsburgh Medical Center (UPMC) Health System