

August 14, 2015

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director, NIH

Subject: NOT-OD-15-117

Dear Dr. Tabak:

The American Association for Clinical Chemistry welcomes the opportunity to comment on the NIH Environmental influences on Child Health Outcomes Program. We look forward to working with NIH on this initiative. We suggest four issues for NIH consideration as it develops its plan:

Improve pediatric reference intervals: As part of its efforts, NIH should focus on improving pediatric reference intervals. Nearly all future studies that emerge from this project will rely on these data points to define disorders in the pediatric population.

Consider pre-analytic issues: Analytical results are heavily influenced by pre-analytical factors. Collection, transport and storage practices need to be standardized to ensure the integrity of the specimens and the laboratory test values used to make decisions about the studies. Furthermore, new technologies are emerging that allow reasonable point-of-care or field analysis that may suit the needs of these studies. We suggest that NIH work closely with laboratory professionals who are well versed on these issues.

Consult with laboratory experts: The need to collaborate with laboratory specialists in the field of pediatric, maternal and fetal disorders is critical. The knowledge required to differentiate disease entities affected by environmental factors from confounding metabolic/genetic conditions is substantial. NIH should consult laboratory professionals on these matters.

Ensure the harmonization of clinical laboratory results: NIH is proposing a series of longitudinal studies that will collect data from many different research institutions and laboratories. The agency should ensure that the laboratory instruments or methods utilized by research facilities provide 'harmonized' test results so that researchers can make accurate, evidence-based recommendations.

If you have any questions, please email Vince Stine, PhD, AACC Director of Government Affairs, at ystine@aacc.org.

Sincerely,



David D. Koch, PhD, DABCC

President, AACCC