Comments to Lead Exposure and Prevention Advisory Committee, October 30, 2020

Re: Blood Lead Reference Level

Good Afternoon,

My name is Paul Moyer. I am the Chair of the Environmental Health Committee at the Association of Public Health Laboratories (APHL). APHL is a membership organization, comprised of state and local governmental public health, environmental, agricultural science and food safety laboratories. The Environmental Health Committee focuses on the assessment of potentially harmful environmental exposures to chemical contaminants. APHL appreciates the opportunity to provide comments regarding the National Center for Environmental Health (NCEH) Board of Scientific Counselors' recommendation to lower the blood lead reference level from 5.0 micrograms per deciliter (µg/dL) to 3.5 µg/dL.

Many of our laboratories perform confirmatory blood lead testing and work closely with public health lead programs on the ground. APHL members have long been involved in the fight against lead poisoning, striving to provide the best science to protect the most vulnerable. We strongly agree that no child should have to live with any elevation of blood lead. As blood levels come down nationally, we understand the desire to push the reference range lower. However, we are very concerned that these best intentions may cause inadvertent harm.

APHL is taking this opportunity to reiterate our concerns and recommend that CDC evaluate the resource needs and the real life clinical impact of the 3.5 µg/dL reference level, especially on under-resourced communities, prior to making a final decision.

Many blood lead tests, especially in rural and at risk areas are done with point of care instruments, that are not capable of producing a sufficiently accurate result at a lower 3.5 µg/dL reference value. At this extreme, close to their limit of detection, there is a huge amount of uncertainty. At lower values point of care instruments have inherent technological limitations, and sample contamination, through lead in the environment and even blood collection tubes, becomes a much more problematic issue.

It cannot be assumed that lowering the reference level will drive technology in point of care instruments to achieve a report level that is sufficiently low enough to account for the increased analytical variability inherent at these low levels. The analytical uncertainty associated with a lowered reference range will likely result in significantly more specimens that should have confirmatory testing. While this confirmatory testing will be even more important at a lower reference range, this is not always performed in clinical practice.

While the lowered reference range may detect a number of children with truly elevated blood levels that would not have been detected otherwise, there will be a concurrent rise in false positives, children that do not in fact have elevated blood lead levels. False positives tests lead to unnecessary additional blood tests and stress, often along with time and financial expenditures for families that are very real and need to be considered.

While states do not have to follow the new CDC recommendations, state and local Childhood Lead Poisoning Prevention Programs (CLPPP), responsible for environmental assessment and clinical case management, will realistically need to provide services to a larger number of children.

APHL requests that the ability of programs to continue serving those with the greatest exposure, while serving additional populations detected by this lower reference range, needs to be considered before the 3.5 µg/dL reference level is implemented.

If the new reference value is implemented:

APHL encourages the concurrent publication of materials that explain to parents, providers and laboratories what results based on a new reference value represent.

We urge that additional funding be provided to Childhood Lead Poisoning Prevention Programs. We must ensure that as resources are split between more families, children in most need are not left with fewer resources and that public health laboratories are funded to provide any additional testing capacity that will be required.

We ask that manufacturers consider certifying their blood collection materials as having below a set level of contamination so as not to interfere with blood lead testing.

We ask that point of care instrument manufacturers work under revised and more stringent CLIA and FDA oversight to improve the accuracy of their instruments to meet any new recommendations.