

OHIO DEPARTMENT OF HEALTH

246 North High Street Columbus, Ohio 43215 614/466-3543 www.odh.ohio.gov

John R. Kasich/Governor

JUL 1 5 2014

Barb Kirkley, Administrator Cleveland Clinic Foundation 9500 Euclid Ave., Clinical Pathology L23 Cleveland, OH 44195

RE: Clinical Lead Laboratory Approval Number C10007

Dear Barb Kirkley:

The Ohio Department of Health (ODH) Lead Poisoning Prevention Program has reviewed your Clinical Lead Laboratory application. Your laboratory has met all of the criteria for approval as specified in Chapter 3701-82 of the Ohio Administrative Code (O.A.C.). Your laboratory approval number is C10007. The approval will expire on 7/24/2015.

O.A.C. 3701-82-02 (G) requires you to notify ODH within twenty four hours if for any reason your Clinical Laboratory Improvement Amendment (CLIA) accreditation is denied, revoked, suspended or limited. Additionally, you shall notify ODH within five business days each time the laboratory's CLIA accreditation as a clinical laboratory is renewed or modified. O.A.C. 3701-32-14 (B) requires you to submit a copy of your tri-annual lead proficiency testing results to ODH within five business days of receiving the results.

Please submit the above required information by one of the following methods; first class mail to the address listed below, electronic mail at lead@odh.ohio.gov, or facsimile to 614-564-2479.

Ohio Department of Health DQA, Lead Poisoning Prevention Program 246 North High Street Columbus, OH 43215

In addition, you are required to comply with the electronic reporting requirements outlined in O.A.C. 3701-30-05. Questions regarding this reporting should be directed to the Surveillance Coordinator for the Childhood Lead Poisoning Prevention Program at (800) 532-3723.

In accordance with Chapter 119. of the Revised Code and O.A.C. 3701-82-02 (K), I may propose to refuse to issue or revoke the approval of any Clinical Lead Laboratory if at any time the laboratory does not meet the requirements of the O.A.C. or Chapter 3742. of the Revised Code.

If you have any questions about this approval letter, please contact David Holston at (877) 668-5323.

Sincerely,

Lance D. Himes

Interim Director of Health