



OHIO DEPARTMENT OF HEALTH

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John R. Kasich / Governor

Theodore E. Wymyslo, M.D. / Director of Health

To: LeadCare ® II Blood Lead Analyzer users
From: David Holston, Environmental Abatement Section Chief
Re: Clinical Lead Laboratory Approval Requirements
Date: February 12, 2013 *DH 2/12/13*

A facility must be approved as a Clinical Lead Laboratory if it provides information on the diagnosis, prevention or treatment of lead poisoning by examining substances from the human body for lead. Facilities that test or intend to test the blood of Ohio children who are under the age of sixteen by using technology contained in the CLIA Certificate of Waiver category, such as the LeadCare II Analyzer, manufactured by ESA Biosciences, Inc. must be approved as a Clinical Lead Laboratory in Ohio.

To become approved as a Clinical Lead Laboratory in Ohio, a facility must:

1. Coordinate with the Childhood Lead Poisoning Prevention Program to establish the required electronic reporting capabilities described in O.A.C. 3701-30-05, 3701-32-14 and 3701-82-02;
2. Provide a completed Application for Clinical Lead Laboratory Approval form HEA5808.
3. Provide a copy of the facility's current, valid CLIA (Waiver, Registration, Compliance of Accreditation);
4. Provide the \$300 annual application fee. and,
5. To maintain Clinical Lead Laboratory Approval status, a laboratory using a CLIA waived procedure for blood lead analysis must perform blood lead proficiency testing as described below, and provide a copy of the results to the Ohio Department of Health, DQA Lead Poisoning Prevention Program within five (5) days of receiving the results.

Facilities using the LeadCare II instrument will be permitted to use either the standard CLIA regulatory three (3) sets of five (5) annual samples testing protocol, or one of the the alternative (less costly) QA options of: two (2) sets of three (3) annual samples, or (3) sets of (2) annual samples, testing protocols for proficiency testing. The alternate option QA test protocols are the absolute minimum proficiency testing protocols for LeadCare II instruments used by approved Clinical Lead Laboratories for Ohio. If one of the less costly options is utilized, each Clinical Laboratory shall maintain proficiency testing result of three (3) out of three (3) correct samples, or (2) out of (2) correct samples for each testing round. If a laboratory fails to meet acceptable test results then the laboratory must provide an explanation of corrective actions to maintain satisfactory performance.

If you have any questions or concerns regarding Clinical Lead Laboratory approval, please call contact the DQA Lead Poisoning Prevention Program at 1-877-NOT LEAD (877-668-5323).