

10/13/2006

LeadCare II Portable Blood Lead Instrument

LeadCare II Instrument approved for use in clinics, schools and other healthcare settings

Scientists at the Centers for Disease Control and Prevention (CDC), in collaboration with ESA Biosciences, a supplier of medical analytical instruments, have developed the first portable blood lead testing device approved for use in WIC clinics, healthcare clinics, schools and in the field. The LeadCare II Blood Lead Test System is a quick, uncomplicated way for healthcare providers to detect blood lead levels in patients.

- The LeadCare II is CLIA “Waived” for the additional access to ~160,000 CLIA waived labs
- CLIA “waived” labs include physician office labs, WIC clinics, etc.
- The LeadCare II works by taking a finger-stick blood sample from the patient
- Results in three minutes (the patient’s blood lead level)
- Allows for immediate venous blood draw for confirmation of elevated lead levels by a certified laboratory
- Previously, physicians collected blood from patients, sent the samples to an off-site laboratory for analysis and notified the patients of their results – delaying the time between diagnosis, confirmation of elevated lead levels and treatment.
- LeadCare II brings us closer to CDC’s goal of eliminating elevated blood lead levels in children by 2010
- Developed through a CDC/NCEH/DLS contract to ESA Biosciences in 2001
- Software for reporting blood lead results to state and local health departments available from ESA Biosciences at no cost.
- Very important to ensure complete reporting of blood lead results to CLPPPs. Software will facilitate surveillance and enables users to electronically report results to CLPPPs
- Many state CLPPPs require blood lead test results to be reported to a state registry. LeadCare II users should contact their CLPPPs for information on state-specific reporting requirements. CLPPP contact information can be obtained at:
<http://www.cdc.gov/nceh/lead/grants/contacts/CLPPP%20Map.htm>
- The previous LeadCare instrument was only available at certain hospitals, health laboratories and other testing facilities with the capability of conducting complex testing.
- The U.S. Food and Drug Administration waived LeadCare II under the Clinical Laboratory Improvement Amendments (CLIA), which allows the instrument to be used at nontraditional laboratory sites that have a CLIA waiver certificate – such as WIC clinics, schools and mobile health units – thereby moving the detection method closer to the communities that need it.
- LeadCare II makes it possible to reach those children who may not receive routine, preventive healthcare, such as blood lead testing
- Reimbursable test from CPT code (83655)
- This is a major milestone from the 2000 Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards, President’s Task Force on Environmental Health Risks and Safety Risks to Children
- The device will be distributed by ESA Biosciences www.esainc.com