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FDA Broadens Access to Lead Screening Test That Gives Immediate Results

Waiver Allows Community-Based Testing

The U.S. Food and Drug Administration (FDA) today expanded the availability of the first simple and portable lead test system to more than 115,000 certified point-of-care locations nationwide, including healthcare clinics, mobile health units and schools. This will allow children and adults to be tested and treated for lead poisoning much easier and faster.

"Broader availability and easier access to this test means healthcare providers will have more opportunities to test for lead exposure in the community and detect and treat people earlier, before the damaging effects of lead poisoning occur," said Andrew von Eschenbach, M.D., acting commissioner, Food and Drugs. "FDA's expansion of the test's availability bolsters ongoing efforts to reach populations at greatest risk for lead poisoning and to expand testing inside communities. This may be particularly true for young children and inner city residents who may face obstacles accessing healthcare."

The test, called the LeadCare II Blood Lead Test System and made by ESA Biosciences of Chelmsford, Mass., is used to screen children and adults for harmful levels of lead using a finger stick or venous whole blood sample. It is performed while the patient is present, in as little as three minutes. The rapid result means a second sample for further testing can be obtained quickly if needed, reducing the need for a follow-up visit.

FDA broadened access to the test system by granting an application to categorize the test as waived under the Clinical Laboratory Improvement Amendment (CLIA). This permits widespread distribution to nontraditional laboratory sites that have a CLIA waiver certificate. A test can be performed at a laboratory with a waiver certificate if it is proven to be simple, accurate and reasonably free of harm.

Currently, the test is only available at certain hospitals, private and public health laboratories, and other testing facilities with the capability of performing moderate- and high-complexity testing. Patients whose results are borderline or positive must make a second appointment with their doctor for follow-up testing. However, some patients fail to do so, and doctors sometimes have difficulty reaching patients to give them their results or to discuss treatment options.

Lead poisoning in children typically results from ingesting dust from deteriorating lead-based paint or drinking water from corroding plumbing. Lead poisoning may have no symptoms, but symptoms can include headaches, stomach cramps, fatigue, memory loss, high blood pressure, and seizures. Lead poisoning in children has been linked to learning disabilities and developmental delays.

According to the Centers for Disease Control and Prevention (CDC), more than 300,000 children under age six each year have blood levels that exceed 10 milligrams per deciliter, the threshold used to indicate lead poisoning. The U.S. Department of Housing and Urban Development estimates that 24 million homes in the United States have significant lead-

based paint hazards. The American Academy of Pediatrics (AAP) estimates one out of four homes with children under age six has lead contamination. The CDC and AAP have issued recommendations for screening children at ages one and two who live in high-risk homes.

The test will also aid adults exposed to lead in occupational settings where the availability of immediate lead test results will help to identify problems early.

The ease and accuracy of the test system was evaluated by testing 516 blood samples over a two-month period at 11 sites. The test instrument applies an electrical current to the patient's blood sample, causing lead to collect on disposable sensors. Studies show nearly 98 percent of the values measured by the test instrument were within Occupational Safety and Health Administration's recommendations for blood lead proficiency testing. Blood lead values above 10 milligrams per deciliter need to be confirmed with another laboratory method.

For more information on lead, visit: www.cdc.gov/nceh/lead/; www.hud.gov/offices/lead/; and www.epa.gov/lead/. For more information on the LeadCare II Blood Lead Test System, go to www.fda.gov/cdrh/oivd/leadtest-qa.html.

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