June 20, 2005

CHDP Program Letter No.: 05-09
CLPP Program Letter No.: 2005-02

TO: ALL CHILD HEALTH AND DISABILITY PREVENTION (CHDP) PROGRAM DIRECTORS, DEPUTY DIRECTORS, STATE CHILDREN’S MEDICAL SERVICES (CMS) BRANCH STAFF, REGIONAL OFFICE STAFF, CHILDHOOD LEAD POISONING PREVENTION (CLPP) PROGRAMS, CLPP COORDINATORS, AND CLPP BRANCH STAFF

SUBJECT: CHDP PROVIDER INFORMATION NOTICE NO.: 05-07 AND CLPP PROGRAM LETTER NO.: 2005-02 ON LEADCARE BLOOD LEAD TESTING SYSTEM RECALL AND IMPACT ON CHDP PROVIDER REQUESTS FOR RETESTING FOR BLOOD LEAD

Enclosed are CHDP Provider Information Notice No.: 05-07 and CLPP Program Letter No.: 2005-02, advising CHDP Providers that ESA Biosciences (ESA), makers of the LeadCare Blood Lead Testing System, has issued a recall of specified test kits that have resulted in under reporting of blood lead levels (BLLs) by an average of 26 percent as compared to the graphite furnace atomic absorption spectroscopy method. ESA is voluntarily recalling and replacing test kits with specific lot numbers representing all lots shipped between September 2003 and April 2005.

This recall will impact those CHDP health assessment providers using laboratories that utilize the LeadCare Blood Lead Testing System for the analysis of blood lead levels. Any laboratories using the defective kits have been asked to stop doing so immediately and are being recommended to retest all patients that previously tested greater than or equal to six micrograms per deciliter (µg/dL) on one of the affected kits if their results were not confirmed by a method other than LeadCare.

Approximately 40 active laboratories, enrolled in CHDP as Clinical Laboratory (including Blood Lead) Provider Type 26, have indicated to the Environmental Health Laboratory Branch that they use the LeadCare Testing System. The Childhood Lead Poisoning Prevention Branch (CLPBB) is contacting these laboratories to verify the laboratory’s use of the LeadCare Testing System.
The CLPPB and the Occupational Lead Poisoning Prevention Program are asking the laboratories that use the LeadCare Blood Lead Testing System and the LeadCare Test Kit with a recalled lot number obtained between September 2003 and the present, to create a list of all individuals who were tested with one of the defective kits, had a blood lead result of ≥6 µg/dL, and were not retested using another method. The laboratories are being asked to send a letter to the patient’s healthcare provider advising the provider to have the test redone. Instructions for claiming this retest through CHDP are explained in the attached CHDP/CLPP Provider Information Notice.

Local CHDP programs please distribute this Provider Information Notice without any revisions to providers in your local health jurisdiction and complete and return a “Report of Distribution” (DHS 4504). The DHS 4504 can be found at www.dhs.ca.gov/chdp.

If you have any questions, please contact your Regional Consultant staff.

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Enclosure