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LeadCare® II Blood-Lead Testing System is Critical Tool in the International Response to the Nigerian Lead Poisoning Crisis

Medical crisis response team including the U.S. Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and the Blacksmith Institute, is working with the Nigerian Ministry of Health in Zamfara State, where contamination from gold-mining activities have caused an estimated 200 deaths and put 10,000 villagers at significant risk of lead poisoning

CHELMSFORD, Massachusetts, U.S. and Zamfara State, Nigeria (September 28, 2010) – As part of the international response to the lead-poisoning crisis linked to small-scale gold-mining activities in this northwestern region of Nigeria, a medical crisis team is deploying Magellan's three-minute LeadCare II blood-lead test in the triage, assessment, and clinical follow-up of thousands of villagers who have been exposed to extremely high levels of lead in the soil and water. Of 113 children initially tested in two villages, 84 percent had dangerously high blood-lead levels greater than 65 µg/dl. The CDC recommends public health actions at 10 µg/dl and studies have documented neurological effects, speech and hearing deficits, hyperactivity, behavior, learning, and other problems with blood-lead levels as low as five µg/dL. Subsequent LeadCare II testing has helped to identify approximately 1,000 children with significantly elevated blood-lead levels and a CDC team will travel back to Nigeria in October to determine if lead poisoning is also the cause of severe illness in 180 other villages.

"The FDA approved the LeadCare II system as a CLIA-waived device four years ago this month," said Magellan President and Chief Executive Officer Hiroshi Uchida, Ph.D., "It's very gratifying to see that when results really matter, LeadCare II is the system of choice among international health experts. The CDC reports that the system is exceeding expectations, even under the extraordinarily difficult and contaminated conditions on the ground in Zamfara."

The LeadCare II system provides blood-lead results from two drops of blood in three minutes, reporting blood-lead levels greater than 65 µg/dl as "High." Since the vast majority of the Nigerian patients have had blood-lead levels exceeding 65 µg/dl, in order to determine the actual quantitative blood-lead level for each patient, Magellan proposed employing a dilution method that scientists originally developed for a program to test the California condor population, which has also been suffering from extremely high blood-lead levels. The CDC verified the method in Atlanta using samples from Zamfara, with excellent correlation between LeadCare II and mass spectroscopy results. The team in Nigeria has adopted the testing protocol, which in many cases, is being carried out by local public health workers. Each patient receives LeadCare II tests seven times while undergoing chelation, a therapy to remove metals from the blood. Being able to measure the exact lead levels during treatment and follow-up is important in order to track the progress of therapy.

The lead poisoning is a consequence of pulverizing, sluicing, and drying lead-containing ore in a process to extract gold. This creates a tremendous amount of lead dust, which may be ingested inadvertently. The lead also leaches into soil and water. Since drying often takes place inside the villagers' huts, it increases the risk of lead poisoning in children. In one village, 30 percent of children under age five have died. Many others are ill, blind, deaf, or unable to walk or talk. Initially, the team was providing chelation therapy to 140 of the most vulnerable patients from two of the affected villages in specially established units within the general hospitals of Bukkuyum and Anka in Zamfara state. It is now thought that at least eight villages are contaminated and approximately 1,000 children and breast-feeding mothers are undergoing chelation therapy. The first priority has been to test and intervene with the approximately 2,000 children under age five who are most at risk of death and severe long-term impairment from high levels of lead exposure. Pregnant women are also being tested, since lead exposure *in utero* can have serious consequences for the developing fetus. At the same time, Blacksmith Institute, an international not-for-profit organization dedicated to solving life-threatening pollution issues in the developing world, is working closely with the Nigerian government to clean up the toxic sites so that villagers can return safely after treatment.

Blacksmith Institute has been using the LeadCare II system and its predecessor instrument since 2005. According to Executive Director, Meredith Block, “The LeadCare systems have been invaluable tools for Blacksmith. Not only have these instruments helped us identify the populations most in need of care, but they are also critical pieces of equipment that help track the progress of our efforts. Fortunately, Blacksmith has enjoyed considerable success in its lead-remediation work and the LeadCare machines have been right along with us for every step of the way. In addition to Nigeria, LeadCare systems are an integral part of our programs in Senegal, Kazakhstan, the Dominican Republic, Far Eastern Russia, Mexico, Jamaica, El Salvador, Guatemala, Philippines, and Indonesia. We have seen significant reductions in blood-lead levels of children in every active site in our care, greatly improving the quality of life in a number of impoverished and polluted countries across the world.”

About the world’s only CLIA-waived blood-lead testing system – LeadCare II

Approved by the FDA as a CLIA-waived device in 2006, the CDC funded development of the LeadCare II system because too many children fall through the cracks of prescription-based and send-out methods of blood-lead testing. The LeadCare II system removes all the complications associated with traditional lab-based testing – waiting days for results, or spending precious staff time and resources trying to contact patients for critical follow-up care, or tracking down lab results for record-keeping, reporting, or compliance purposes. An ideal complement to hemoglobin testing, its CLIA-waived status enables a paradigm shift in lead testing: practitioners can test, educate, and take action to confirm elevated results and treat if necessary – instantly, on the spot, and all in one visit during the routine well-child check-up. This approach is convenient and easy for the child, parent, and healthcare provider, and thus, it is the most-effective way to ensure those at greatest risk for lead poisoning actually receive mandated blood-lead tests.

To learn more about LeadCare II, visit www.WaivedLeadCare.com, or call 1 (800) 305-0197. For lead poisoning facts and links to recall information and important lead poisoning prevention resources, visit www.LeadPoisonInfo.com.

Better Dx = Better Rx – About Magellan (www.magellanbio.com)

Founded in 2004, Magellan’s innovative technologies make diagnostic testing easier, more cost-effective, and less labor intensive. The company’s products deliver the timely information that clinicians need to make appropriate treatment decisions and improve outcomes for patients. They include LeadCare[®]-brand rapid point-of-care systems to screen children and adults for lead poisoning; TREK-brand microbiology products for blood culture and susceptibility testing that help in the global effort to prevent MRSA and other drug-resistant infections; as well as Dynex[®]-brand automated ELISA processing systems for a wide variety of immunoassays – from infectious disease to autoimmune and food-safety testing. Magellan has approximately 290 employees worldwide.

About The Blacksmith Institute (www.blacksmithinstitute.org)

Blacksmith Institute is an international not-for-profit organization dedicated to solving life-threatening pollution issues in the developing world. A global leader in this field, Blacksmith addresses a critical need to identify and clean up the world’s worst polluted places, focusing on sites where pollution threatens human health, especially where children are most at risk. Based in New York, Blacksmith works cooperatively around the world in partnerships that include governments, the international community, non-governmental organizations (NGOs), and local agencies to design and implement innovative, low-cost solutions to save lives. Since 1999, Blacksmith has completed more than 30 projects; Blacksmith is currently engaged in over 40 projects in 19 countries. Visit <https://app.etapestry.com/hosted/BlacksmithInstitute/OnlineDonation.html> to support Blacksmith’s work.