



MAGELLAN BIOSCIENCES

LeadCare® II WAIVED

Accurate, on-the-spot lead testing.

More children screened! Improve the impact of your outreach program.

At last! There's a fast, accurate, and inexpensive way to perform on-the-spot blood-lead measurements at community health centers, WIC and mobile clinics, health fairs, or home visits. CLIA-waived LeadCare II removes all the complications formerly associated with blood-lead testing.

LeadCare II improves patient care by providing instant results, so you can provide in one visit important health information on the dangers of lead, initiate immediate treatment when necessary, and offer peace of mind when it's not.

Public health departments and community-outreach programs are shouldering an ever-increasing burden in the battle against childhood lead poisoning. Reaching at-risk children even once to collect a blood sample is challenging enough. Reaching them a second time to initiate treatment can sometimes be impossible.

LeadCare II allows you to screen more at-risk children because it cuts time spent on paperwork, tracking, and follow up, and qualifies for reimbursement as a quantitative blood-lead test. And the cost per test is actually less than you would pay an outside laboratory, freeing resources so you can establish a sustainable program to help cover your uninsured population.

No more waiting days for expensive lab results, or spending precious time trying to locate families for critical follow-up care. Compact and easy-to-use, LeadCare II delivers quantitative blood-lead results in just *three minutes*, so you never have to worry about losing track of a child that needs treatment.

Developed with funding from the CDC, LeadCare II is an improved, waived version of the blood-lead testing system used by pediatricians, family practitioners, public health, and military clinics worldwide. It is the latest innovation from the name that has become synonymous with blood-lead measurement – ESA Biosciences.



LeadCare II
WAIVED

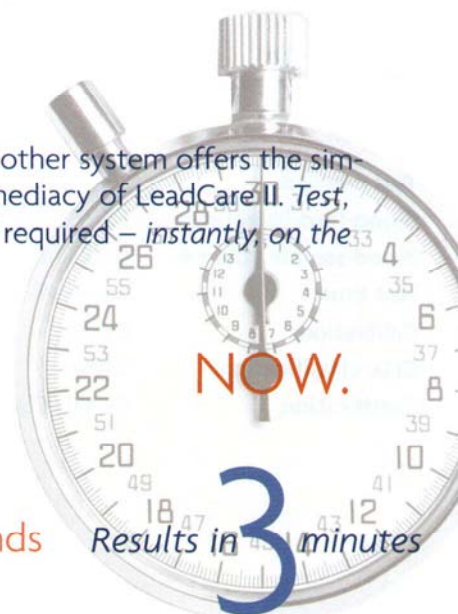
Portable and simple to use – waived test means no special training or advanced laboratory certification required

Results in three minutes with the accuracy and sensitivity of a reference-lab test – from capillary or venous blood sample

Two-drop sample size requires only a finger stick, and allows you to combine LeadCare II with other waived blood tests – so much easier, and less stressful for patient, parent, and staff

Reimbursable test – CPT code: 83655

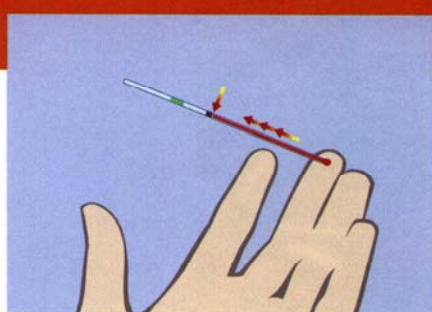
Timing is everything! No other system offers the simplicity, accuracy, and immediacy of LeadCare II. *Test, educate, and intervene* if required – *instantly, on the spot, and all in one visit.*



NOW.

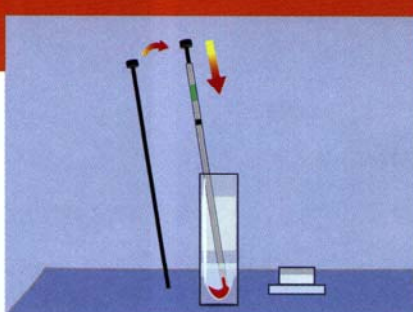
Results in **3** minutes

early detection + early intervention = healthy bodies + sharp minds



Collect Blood

Fill capillary to black line.



Treat Blood

Dispense blood into a treatment reagent tube and mix.



Analyze

Place one drop of sample on sensor. Read results from screen in just 3 minutes.

Portable

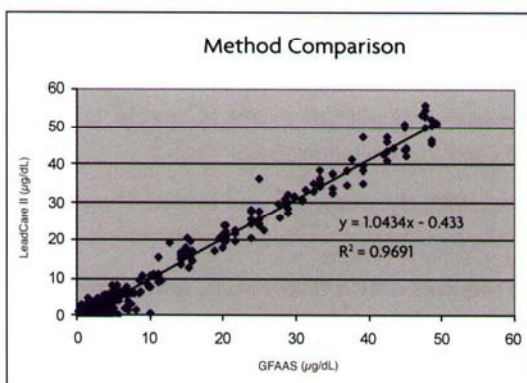
Power source: 4-AA batteries or AC adapter

Dimensions: 9.0 in x 6.5 in x 3.5 in (23 cm x 17 cm x 9 cm)

Weight: 2.4 lbs (1.1 kg)

Accurate

The accuracy of the LeadCare II system was determined by a method-comparison study in which 431 human samples (111 spiked with lead) were tested by untrained users at 11 different sites. These LeadCare II results were compared to graphite furnace atomic absorption spectroscopy (GFAAS) results generated in a reference laboratory.



Number of Samples: 431

Slope: 1.04

Intercept: -0.4

Correlation coefficient (R^2): 0.97

Specifications

Test method:	Electrochemical with disposable sensors
Blood-lead-level range:	3.3 - 65 µg/dl
Blood-sample volume:	50 µl
Test time:	3 minutes
Calibration:	Electronic calibration button
CLIA classification:	Waived
Certification:	CE, UL, CSA

Committed to customers

Approximately 60 percent of the laboratories performing blood-lead analysis use ESA products. With more than 30 years experience, we have a proven record of excellent service and support.

Ordering information:

The LeadCare II System is for the determination of lead in whole blood.

Product Description

Analyzer Kit

The kit contains the analyzer, power cord, and instructions.

Test kits must be ordered separately.

Test Kit

Contains reagents for 48 tests

Control Kit

Contains Level 1 and Level 2 quality controls

Label printer

Part No.

70-6760

70-6762

70-3440

70-3447



MAGELLAN BIOSCIENCES

Improving outcomes from discovery to diagnostics

Distributed by:

Ryan Diagnostics, Inc.
710 E. Ogden Ave. Suite 120
Naperville IL, 60563
(800) 352-3252

Specifications subject to change without notice. LeadCare II is covered by patent: US 5,468,366. LeadCare II and ESA are registered trademarks of ESA Biosciences, Inc. ESA Biosciences is a subsidiary of Magellan Biosciences, Inc., Chelmsford, MA.
70-7054 Rev A