

## LeadCare® II Blood Lead Testing System (For use with capillary puncture only)

Lead is a potent poison and is commonly found in the environment. Lead poisoning is a common pediatric health problem in the United States and the rest of the world. This harmful condition can be prevented, but it must first be identified. Children are especially sensitive to the effects of lead. Most poisoned children go undiagnosed and untreated.

Lead affects nearly every part of the body. It is particularly harmful to the developing central nervous systems of young children. Early detection of children with high blood lead and their follow-up treatment is important. Treatment can reduce or eliminate the harm of lead poisoning. It can also prevent future lead poisoning.



### PRINCIPLE

Most lead is carried in red blood cells. When a sample of whole blood is mixed with Treatment Reagent, the red blood cells are lysed and the lead is made available for detection. When the test is performed, the analyzer supplies a current that causes the lead to collect on the LeadCare® II sensor. The analyzer measures the amount of lead collected on the sensor and displays the result in  $\mu\text{g}/\text{dL}$ .

Universal Safety Precautions are required for all laboratory testing

- **PREPARATION AND LABELING**All reagents are labeled by the manufacturer and require no further labeling
- All laboratory supplies must be labeled with both the received and opened dates.

### Storage and Handling:

The test kit has an expiration date assigned. The end of the box shows the printed expiration date. Do not use the kit past the expiration date. Discard any remaining Controls and Treatment Reagent when opening a new Test Kit.

**NOTE:** The Treatment Reagent, blood lead controls and the sensors have separate expiration dates. Observe the earliest expiration date to set the test kits expiration date.

- Store in a cool, dry place. Storage temperature should be between 60-80°F (15-27°C). Do not freeze or refrigerate.
- Store away from direct sunlight
- Keep sensors sealed in their container until the sample is prepared until the test is performed. The container is lined with desiccant to keep the sensors fresh.

- Use the treatment reagent immediately after opening the tube.
- Do not place any object in the treatment reagent tube other than the capillary and dropper provided with this test kit. Contamination could occur.
- Do not use sensors, blood lead controls, and treatment reagent past their expiration dates.
- Blood lead controls should be kept at room temperature: 60-80°F (15-27°C). Do not refrigerate.

## **CALIBRATION**

Calibration is required for each new lot of test kits. Use the calibration button in the test kit. Use only the button packaged with the kit you are using. Failure to use the correct calibration button with the test kit could cause false results. Always make sure that the lot number on the sensor container and calibration button match the SENSOR LOT number on the analyzer display.

## **CALIBRATION BUTTON**

Each LeadCare® II test kit comes with 48 sensors and a calibration button. The button transfers calibration and expiration information to the analyzer. When you touch the calibration button to the reader, an audible tone will sound. The lot number from the calibration button appears on the screen to verify the button was read properly. The CALIBRATION SUCCESSFUL message flashes for 2 seconds.

## **CALIBRATING THE ANALYZER**

1. Turn on the analyzer. The analyzer is ready when the **“Prepare Sample”** message appears. **NOTE:** The first time you turn on the analyzer the **PLEASE CALIBRATE** message will appear.
2. Locate the calibration button for the test kit you are going to use.
3. Remove the calibration button from the test kit package.
4. Match the lot number on the sensor container with the calibration code on the button.
5. Hold the calibration button to the button reader until you hear the beep. The button must touch both the center and metal side of the button reader.
6. When calibration is complete the screen reads: **CALIBRATION SUCCESSFUL.**
7. Make sure the number of the button matches the display.

## **Quality Control:**

ESA Biosciences, Inc. provides the LeadCare® II Controls in the test kit for quality control. The Level 1 and Level 2 controls are used to verify system performance and accuracy. The Level 1 consists of a normal lead level and the Level 2 consists of an abnormal lead level. Each is assigned a target lead value with an associated acceptable

range. Controls should only be used with sensors of the same lot number. Discard remaining control solutions when the sensors from the kit are gone. Failure to do so may result in inaccurate patient results.

Quality control is performed: on each new test kit lot and each new shipment of test kits received.

Perform quality control on each new test kit, on each new shipments of test kits received, and any time to verify system performance.

## **STORAGE AND HANDLING**

The control material is supplied in liquid form and ready to use. It should be stored at room temperature and should not be used beyond its expiration date.

## **QUALITY CONTROL PROCEDURE Prepare the Sample**

1. Label a treatment reagent tube, Level 1
2. Gently swirl control vial.
3. Remove cap from the Level 1 control and place it top down on a clean surface.
4. Fill one capillary tube with the control you are testing. Tilt control vial, insert the capillary tube into the liquid while holding the green end of the capillary tube almost horizontally. Capillary action will fill the tube to the black line.
5. Use a clean wipe to remove excess control material from the outside of the capillary tube.
6. Repeat this process for Level 2 control.

## **Mix with Treatment Reagent**

1. Remove cap from the treatment reagent tube and place it top down on a clean surface.
2. Drop the full capillary tube into the treatment reagent and insert plunger.
3. Dispense the control by pushing down on the plunger.
4. Remove the empty capillary tube and recap the treatment reagent.
5. Invert treatment reagent tube 8-10 times to thoroughly mix the two. The resulting mixture will be red.
6. Repeat this process with Level 2 control.

## **Test**

1. Insert a fresh sensor into the LeadCare® II analyzer.
2. Ensure the lot number on the display matches the sensor lot number that is being used. It must also match the lot number on the control vial.
3. Invert the sample to ensure the sample is well mixed, then remove the cap.
4. Using the dropper supplied, transfer a drop of the mixture to the X on the sensor.
5. When the three-minute countdown is complete, record your lead result in  $\mu\text{g}/\text{dL}$ .
6. Repeat this process for the Level 2 control.

7. Be careful to remove the cap from Level 1 and replace it before removing the cap from Level 2.

**INTERPRETING CONTROL TEST RESULTS** The target values are printed on the control vials. The blood lead level that appears on the LeadCare® II analyzer should be within the acceptable range provided for that control. If the reported value is within the acceptable limits for the Level 1 and Level 2 controls, the LeadCare® system is operating properly.

If the reported blood lead level is not within the acceptable range for the control:

- Rerun the control, using another sample from the Treatment Reagent/control mixture.
- Check all procedures/techniques to make sure the test is being performed correctly.
- Check the expiration date and storage of the controls and reagents; check calibration code; check the humidity and temperature requirements.
- Prepare a new Treatment Reagent/control sample mixture

If at any time the new value is within the upper and lower limits during any of these checks proceed to client testing. If the new value is outside the upper and lower limits after all of the above contact ESA Technical Support at 1-800-275-0102.

Do NOT proceed to patient samples unless both the Level 1 and Level 2 control results are within the acceptable ranges.

## **PATIENT TESTING**

The system is intended to test fresh whole blood (collected in either EDTA or Heparin). Add blood to the treatment reagent within 24 hours of collection. Blood older than 24 hours may produce false negative results. Use only fresh, unrefrigerated, whole blood with the LeadCare® treatment reagent. Blood must be stored at 50°-90°F (10°-32°C) prior to mixing with treatment reagent. Make sure the whole blood is free of clots, which can cause inaccurate results.

### **Required Materials:**

- Powder-free Gloves
- Alcohol Wipes, Gauze pads
- Lancets
- Biohazard Waste Container
- Container with Heparin capillary tubes/plungers provided with test kit.
- Treatment reagent tube
- Sensor container (lot number must match the number on the analyzer display)
- Dropper for depositing sample on sensor

### **SAMPLE HANDLING**

- Use only the heparin capillary tubes provided with the LeadCare® II test kit.
- Use only fresh, unrefrigerated blood, whole blood with the LeadCare® II treatment reagent. Do not refrigerate blood prior to mixing the reagent. Blood must be stored at 50-90°F (10-32°C).
- Add blood sample to the treatment reagent within 24 hours of collection. Blood older than 24 hours may produce false negative results.
- Any visual impairment, such as color blindness may affect the operator's ability to detect the sample color change. Operators with vision deficiencies should invert the tube 8 to 10 times to ensure that the sample is properly mixed.

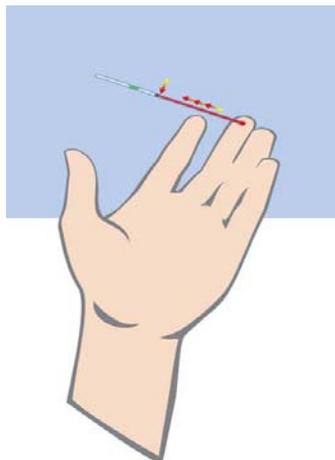
### **SAMPLE COLLECTION**

- Remove a LeadCare® II Blood collection capillary tube from the package and set it aside on a clean gauze pad or Kim Wipe.
- Open the lancet, alcohol swabs, gauze, bandage, and other items.
- Wash patient's hands with soap and allow to air dry. Do not allow patient's finger to touch any surface. Do not use recycled paper towels.
- Put on powder free gloves
- Massage the patient's hand and lower part of the finger to increase blood flow. Turn the hand down.
- Use a sterile disposable lancet to perform a swift clean puncture in a position slightly lateral of the center of the fingertip.
- Apply slight pressure to start blood flow. Wipe away the first drop of blood with a clean gauze or Kim Wipe.
- Keep the finger in a downward position to maintain blood flow. Hold the micro collection tube at an angle of 10 degrees below the collection site and touch the tapered end of the tube into the droplet of blood. Do not touch the skin with the tube. Fill the micro-collection vial with the appropriate amount of blood as defined by the micro collection container being used.
- Once a sufficient amount of blood has been collected, apply slight pressure to the finger to stop the bleeding.
- Apply sterile adhesive bandage over the puncture site.
- Seal the specimen container, and invert immediately to mix. Gently invert the container 7-10 times to prevent clots from forming.

### **PATIENT TEST PROCEDURE**

1. Label a treatment reagent tube with the patient ID using the label provided.
2. Holding the heparinized capillary tube almost horizontally with the green band on top, fill to the 50µL black line. Filling stops when the sample reaches the black line.

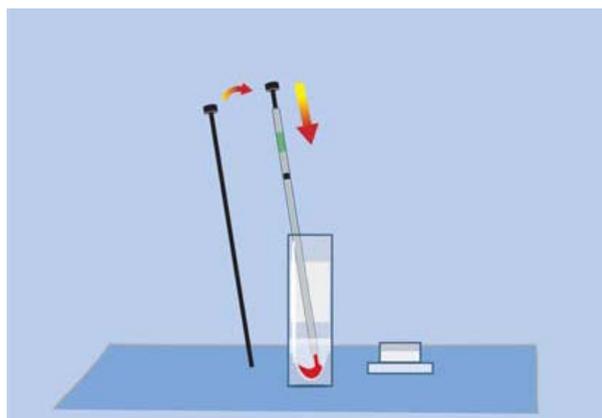
3. If using venous sample hold the capillary tube almost horizontally with the green band on top, fill the capillary tube to the 50 $\mu$ L black line.



4. Remove excess blood from the outside of the tube with a clean wipe or gauze pad. Use a downward motion to wipe excess blood from the capillary tube.
5. Inspect the capillary for proper filling. Make sure there are no gaps or bubbles, or any excess blood on the outside of the capillary.

#### **PREPARE SAMPLE**

1. Remove the treatment cap from the tube and place it face up on a clean gauze pad. Do not allow the inside of the cap to touch anything as this could contaminate the sample.
2. Place the full capillary tube in the treatment reagent tube. Insert a plunger into the top of the capillary tube. Dispense the entire volume into the treatment reagent.



3. Replace the tube cap.
4. Invert the tube 8-10 times to mix the sample completely.

- The test sample is ready when the mixture turns brown. Repeat sample collection and preparation for each sample to be tested.

### STORING SAMPLES

You do not need to test the prepared sample immediately. The mixture of blood and treatment reagent is stable for up to 48 hours at room temperature and 7 days refrigerated. Bring to room temperature before testing.

### ANALYZE SAMPLE

- Remove a sensor from the sensor container.
- Close the container immediately
- Grasp the sensor at the end without the black bars.  
**NOTE:** Keep the sensors in their container until use. Minimize handling to prevent contamination which could cause a false result.
- With the black bars facing up insert the sensor into the analyzer.  
When the sensor is inserted properly the analyzer beeps and displays the following message: ADD 1 DROP OF SAMPLE TO X ON SENSOR
- Make sure the sensor lot number matches the lot number on the display. If the number doesn't match recalibrate the analyzer and test controls.
- Make sure the sample is at room temperature and mixed uniformly
- Remove cap from tube
- Remove a transfer dropper from its container.
- Squeeze the walls of the dropper and insert the tip into the sample.
- Release pressure to draw the sample into the dropper.  
Make sure the following message is displayed: ADD 1 DROP OF SAMPLE TO X ON SENSOR
- Touch the dropper tip to the X on the sensor and squeeze the walls to dispense.



- The analyzer following SECONDS
- After 3 beep again to finished.

will beep and display the message: TESTING XXX TO GO  
minutes the analyzer will indicate the test is

- Record the result
- Remove the sensor
- Discard the materials in biohazard waste.
- The analyzer is ready to test the next sample when the following message appears: LAST TEST RESULT

If you do not run another test within 60 seconds the analyzer will automatically

go into "sleep" mode. If you have not recorded your result it will be lost. You will have to repeat the test.

### INTERPRETING PATIENT TEST RESULTS

- The analyzer's display window shows the blood lead result.
- The result is in micrograms ( $\mu\text{g}$ ) of lead per deciliter (dL) of whole blood.
- No calculation is needed.
- Results are displayed to one decimal place.
- The reportable range of the LeadCare II® system is 3.3-65  $\mu\text{g}/\text{dL}$ .

"Low" appearing in the display window indicates a blood lead result of less than 3.3  $\mu\text{g}/\text{dL}$ . When this occurs report the result as less than ( $<$ ) 3.3  $\mu\text{g}/\text{dL}$ .

"High" appearing in the display window indicates a blood lead result greater than 65.0  $\mu\text{g}/\text{dL}$ . Report the result as greater than ( $>$ ) 65  $\mu\text{g}/\text{dL}$ .

Blood lead levels less than 10  $\mu\text{g}/\text{dL}$  are below CDC's "level of concern".

Blood lead levels above 10  $\mu\text{g}/\text{dL}$  indicate possible lead poisoning, which is a serious medical condition. Patients with blood lead levels above 10  $\mu\text{g}/\text{dL}$  must be confirmed with a venous sample. The following table shows when to test patients again if the results is above the 10  $\mu\text{g}/\text{dL}$ .

<b>Retesting Guidelines</b>	
<b>If blood lead result of screening test is:</b>	<b>Perform diagnostic test on venous blood within:</b>
10 - 19 $\mu\text{g}/\text{dL}$	3 months
20 - 44 $\mu\text{g}/\text{dL}$	1 month to 1 week (the higher the result, the more urgent the need for follow-up testing)
45 - 59 $\mu\text{g}/\text{dL}$ 48 hours	48 hours
60 - 69 $\mu\text{g}/\text{dL}$ 24 hours	24 hours
Greater than or equal to 70 $\mu\text{g}/\text{dL}$	Immediately as an emergency lab test

When the LeadCare II® display reads "High", the analyzer has detected a blood lead level greater than 65  $\mu\text{g}/\text{dL}$ . "High" results on LeadCare II® should be followed up immediately as an emergency laboratory test.

### References

*Preventing Lead Poisoning in Young Children. Guidance for State and Local Public Health Officials.* Centers for Disease Control and Prevention 1997.  
[http://www.cdc.gov/nceh/lead/publications/pub\\_Reas.htm](http://www.cdc.gov/nceh/lead/publications/pub_Reas.htm)

*Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials.* Centers for Disease Control. 1997.

<http://www.cdc.gov/nceh/lead/guide/guide97.htm>

### **Document Retention**

The QC documents will be retained for a minimum of two years. The physical QC documents will be located in the county health department. Procedure changes will be retained for a minimum of two years after retirement and will be located in the county health department.