PROCEDURE: LEAD ESA LEADCARE II® / HEALTHY KIDS EXPRESS

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PRINCIPLE:

The LEADCARE II System relies on electrochemistry and a unique sensor to detect lead in whole blood. Most lead is carried in red blood cells. When a sample of whole blood is mixed with Treatment Reagent lead in red blood cells is removed and made available for detection. When a test is run, the analyzer causes the lead to collect on the LEADCARE sensor. After a period of time, the Analyzer removes this lead, measures it and converts the result into a displayed blood lead result.

CLINICAL SIGNIFICANCE:

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. Children are especially sensitive to the effects of lead. 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 is important.

SPECIMENS:

Patient preparation: No special instructions.

Type: Use only heparin or EDTA as anticoagulant in the blood collection tubes. If using blood collection tubes containing EDTA, make sure the volume collected is at *least* one quarter of the designated fill volume of that particular tube. Collecting less may lead to falsely lower blood lead results.
Obtain specimens of whole blood from either a fingerstick. Only capillary specimens are acceptable. No venous specimens.
Follow the procedures of SLCH for specimen collection.
When using the fingerstick method for the whole blood collection, wash, rinse and dry the hands thoroughly with lead free materials wiping the target finger with an alcohol wipe. Similarly when collecting a venous sample of blood, wipe the target area with an alcohol wipe before inserting the needle. Wash, rinse and dry the target area when the area is visibly dirty.

Handling: Use only *fresh, unrefrigerated* (10-32°C), *whole blood* less than 24 hours after collection.

False negatives could be obtained by using blood older than 24 hours or if stored refrigerated.

Make sure that the blood sample does not contain clots, which can lead to an inaccurate blood lead result.

EQUIPMENT:

1. LEADCARE II Blood Lead Testing System, ESA, Inc., Chelmsford, MA.
2. LEADCARE II User's Guide

REAGENTS:

LEADCARE® Blood Lead Test Kit (Part No. 70-6762)

Kit Contains:

- 48 Sensors

The active electrode area in each sensor contains a small amount of gold particles in an inert matrix.

- 48 Treatment Reagent Tubes

The treatment reagent contains 250 microliters of a dilute hydrochloric acid solution in water (0.34).

- 50 Capillaries and Plungers
- 50 Droppers
- 1 Calibration Button
- Blood Lead Control Composition

Lead salt in buffered aqueous solution with bovine serum albumin (BSA). Two levels of quality control material are provided with the test kit, designated "Level 1 and Level 2. The actual target values are specified on the vial and in the kit.

Storage and Stability

Store all of the above equipment and reagents at Room Temperature. Room Temp: 60-80 F.
Store away from direct sunlight. Store in a cold dry place. Do not freeze or refrigerate.
The Treatment Reagent tubes, Sensors and Capillaries are good until the expiration date on the package
The sensors have an active electrode area in each sensor that contains a small amount of gold particles in an inert matrix. Keep sensors sealed in their container until the sample is prepared and you are ready to perform the test. The container is lined with desiccant to keep the sensors fresh.

Treatment Reagent contains 250ul of a dilute Hydrochloric acid solution in water (0.34m). Dispose of in Biohazard after use. 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 in the kit, contamination could occur.

The test kit has an expiration date assigned. It is printed on the exterior of the box. Do NOT use the test kit past the expiration date. NOTE: The treatment reagent, blood lead controls and the sensors have separate expiration dates. The earliest expiring component is used to set the test kit's expiration date.

Do not mix components from separate Lead Care Kit Lot numbers.

QUALITY CONTROL:

Two levels of LEADCARE® controls, low (Level 1), and high (Level 2) are used (LEADCARE® Blood lead Control Kit Part No. 70-6762). Level 1 and Level 2 are stable, liquid, ready to use lead controls. They are in the LeadCare II test kit. Controls are stored at room temperature and discarded when you finish the test kit,

or 90 days. The controls have the same lot number as the sensors and the target values are provided right on the control vials. *Both levels are measured at the beginning of each day the analyzer is used for patient testing. analysis*. Record all control values obtained on a quality control log. Control limits are ±2 SD's of the mean and are in the kit and are to be recorded on the worksheet. Values exceeding these limits are to be treated in accordance with the guidelines set in the Quality Assurance Manual. When Quality Control does not fall within established limits, repeat first and if the Quality Control still fails make new Quality Control and repeat. If Quality Control still does not fall within established limits, contact the Point of Care, Core Lab SLCH. Do not continue with patient testing.

Follow the instructions as described in the manufacturers package insert for control preparation, storage, and stability. This product as with all human based specimens should be handled with proper laboratory safety procedures to minimize the risk of infectious disease transmission.

Quality Control is reviewed and signed by Point of Care and the Medical Director. Results are faxed to Point of Care/SLCH, reviewed and faxed back to the Healthy Kids Express. Calls are made to the Healthy Kids Express when quality control issues are noted.

CALIBRATION:

Calibration must be done using each new Test Kit. Each Test Kit contains a Calibration Button. The information in this button must be read by the Analyzer to calibrate it.

1. Remove the Calibration Button from the new Test Kit.

2. Check the 3-digit number on each of the following:

   - The lot number on the end of the Test Kit box.
   - The code number on the Calibration Button
   - The lot number on all the bottles of the Sensors

   Make sure that all of these items have the same three-digit number. The Treatment Reagent lot number will be the only item that differs from these three items.

3. Check the expiration date on the end of the Test Kit box. Do **NOT** use if expired.

CAUTION
The Analyzer **MUST** be calibrated for each new or different Test Kit using the Calibration Button in that Test Kit before testing.

4. Turn on the analyzer using the Power switch, located at the back right hand of the device.

IMPORTANT NOTE:
- Analyzer automatically turns on when a new battery is inserted or the AC Adapter is connected (with no battery or a dead battery in the Analyzer).

5. After about one second, the Analyzer will beep and show an initial startup display and self test messages

IMPORTANT NOTE:
- If the **SELF TEST** fails, the Analyzer will not function and the window display will show **Er 1,** as shown in the figure below:

If your Analyzer shows this error code, refer to the LEADCARE® User's Guide section called CLEANING, TROUBLESHOOTING, DISPLAY CODES for help.

6. Turn on the Analyzer if necessary. The analyzer is ready when the "Prepare Sample" message appears. The first time you turn on the analyzer you will see the Please Calibrate message.

7. Press the round metallic end of the Calibration Button to the Calibration Reader. The Calibration Reader is on the right hand side of the Analyzer.

8. The Analyzer should beep and display **CALIBRATION** and the calibration code.

IMPORTANT NOTE:
- The Analyzer can be calibrated anytime **READY** is displayed.

9. Make sure that the calibration code on the Analyzer's display matches the calibration code printed on the Calibration Button.

   If the calibration code does not match the analyzer display, then repeat the process described in step 6 above. If a problem continues refer to the LEADCARE® User's Guide section called CLEANING, TROUBLESHOOTING, DISPLAY CODES for further help.

13. The Analyzer is now ready to analyze samples.

IMPORTANT NOTE:
- Only calibrate the Analyzer once for each Test Kit used. The Analyzer stores the calibration program even when it is off.
- Discard the Calibration Button after finishing a Test Kit.

PROCEDURE:

1. **Prepare the Analyzer**

Turn on the analyzer by the power switch on the back of the ESA Leadcare II.

- Wait for the **SELF TEST** to finish.

The Message display screen is designed to guide you through the testing process. Remember to read the display messages.

2. **Measure the Blood Sample**

- *Slowly and carefully* draw up *exactly* 50 µL of blood with the capillary tube provided in the collection kit.

- Wipe the outside of the capillary tube in a downward motion with a clean laboratory wipe. Be careful not to draw any blood *inside* the pipette tip by directly touching the tip opening. Verify there are no bubbles present in the blood in the tube.

3. **Mix the Blood Sample with the Treatment Reagent**

- Before using a tube of Treatment Reagent, gently tap it on a work surface to allow the liquid to collect at the bottom.

- Remove the cap and place the cap *upright* on a clean gauze pad.

- Place the capillary tube end inside the Treatment Reagent tube. The capillary tube should touch the bottom of the Treatment Reagent liquid. Next use the plunger provided to expel the blood sample in to the treatment reagent tube.

- Remove the capillary tube using a side or rotating motion. Re-cap the Treatment Reagent tube. Dispose of the capillary tube/plunger and all items used in the testing in a biohazard waste container.

- Mix the sample by gently rocking the tube. Thoroughly mix **the entire** Treatment Reagent with **the entire** blood sample. The color of the sample and reagent mixture should be brown. Coat the entire inside surface of the tube by inverting and rocking 8-10 times.

IMPORTANT NOTE:
- The blood and Treatment Reagent mixture is stable for up to 48 hours at room temperature and up to 7 days if refrigerated immediately.

4. **Apply Reagent Mixture to Sensor**

- Remove a Sensor from its package. Handle the Sensor at the end without the black bars. Place the Sensor into the Sensor Holder with the black bars facing up, completely into the analyzer. When the sensor is inserted properly the analyzer beeps and displays the message: ADD 1 DROP OF SAMPLE TO X ON SENSOR.
- Make sure the sample is thoroughly mixed.
- Remove the cap from the tube. Remove a Transfer dropper from its container. Squeeze the walls of the dropper and insert the tip into the sample. Release the pressure to draw the sample into the dropper.
- Make certain the above message is displayed on the screen before adding the sample.
- The analyzer will beep and display the message: TESTING XXXX SECONDS TO GO.
- After 3 minutes the analyzer will beep again to indicate that the test is completed.
- Record Results and discard the sensor in an appropriate biohazard container.

- The analyzer is ready for the next sample when the LAST TEST RESULT message appears on the screen.
- If you do not run another test within 60 minutes the analyzer will go into "sleep" mode.

- Draw a minimum of 35 µL for accurate test results. Be careful not to apply too much mixture or the liquid will spill. (**Note:** The amount of blood and reagent mixture measured is not critical for this step.)

CAUTION
- Do **NOT** use Sensors if broken, scratched, damaged or that have been dropped on the floor.
- Do **NOT** touch the active area on the Sensors, except for the dropper when applying the sample.

MAINTENANCE
Equipment is inspected by Clinical Engineering when put in service . No yearly p.m. is required. Instrument has a CE silver tag stating the equipment has been inspected by BJC Clinical Engineering.

Analyzer

- Clean with a cloth and warm soapy water.
- Disinfect with dilute bleach solution.
- Rinse thoroughly with clean water.
- Disinfect with a dilute bleach solution /Bleach wipe.

TROUBLESHOOTING
Contact the Point of Care at SLCH Core Lab when QC's fail or there are assay problems with the ESA LeadCare. The back-up is the other ESA LeadCare.

RESULTS:

HKE results are recorded on HKE Log sheets. They are not part of the SLCH Medical Record.

The results are in mcg/dL of Lead and are displayed to one decimal place. The reportable range of the test is 3.3 to 45 mcg/dL. Results displayed that are less than 3.3 mcg/dL are to be reported as less than (<) 3.3 mcg/dL. "**HI**" in the display window indicates a blood lead result greater than 45.0 mcg/dL. Report the blood lead result as greater than (>) 45 mcg/dL. The LeadCare II at SLCH has established linearity from 3.3 to 45 mcg/dL. Results 3.3 or Greater are compared to Mayo Medical labs and signed by the Medical Director every six months.

Blood lead levels 3.3 mcg/dLor greater must have confirmatory testing performed at Mayo Medical Laboratories. Blood levels above 5.0 as defined by the CDC guidelines in 2012 indicate a potentially serious medical condition and are considered physician alert values requiring intervention to reduce lead exposure.

REFERENCES:

1. ESA LEADCARE® Blood Lead Testing System User's guide.

Written By: Donna Walck Point of Care Coordinator

_____ _____
Technical Supervisor Date

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Medical Director Date

Annual Review: Medical Director/Designee Date

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Location of hard copy location(s): Core Lab Office
See Test Methods / Test Locations (POC.1.0002.0)
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