

  
**leadconfirm**™ professional  
lead level in body screening test

***Lead Level In Body Screening Test***  
***Determines Lead Level in Body (Laboratory-based)***

**INSTRUCTION BOOKLET**

***For in-vitro diagnostic use only***

***Before you Begin***

Read all the information in this instruction booklet before starting the sample collection procedure. First, make sure you are familiar with the sample collection kit contents shown on the following page. Do not use after the expiration date that is stamped on the package.

***Tests For:***

Body Lead level using Oral Fluids (Saliva)

***Kit Contents:***

- One Statsure Collection pad
- One Statsure Oral Specimen Vial
- One specimen ID Card
- One Clear Specimen Bag
- One instruction Booklet
- One mailer envelope

**IMPORTANT:** Do not open the pouch until ready to perform the procedure.

***Precautions***

- Follow the instructions exactly to obtain accurate results.
- Store the sample collection device in the sealed pouch until use.
- Do not use expired devices.
- Do not reuse the device.
- Do not use the device if you are color-blind.
- For in vitro diagnostic use only.

**WARNING:** Do not put the buffer fluid from the transport tube into mouth. If swallowed contact physician or poison control center.

***Storage:***

Store collection device at room temperatures (15C-30C or 59F – 86F) up to the expiration date shown on the pouch. Avoid direct exposure to sunlight.

### Salivary Diagnostics:

Saliva is a vital substance that carries molecules, many bio markers of disease, as well as many other indicators (known and unknown) of what is happening inside our body. Most compounds found in blood are also found in saliva. Its acceptance as a testing medium is now unquestioned.

Some of the advantages of using a saliva test over a blood test are that it is safe and less-expensive and, the sample is easier to collect and handle.

Positive results should be followed up with a physician for further analysis and treatment.

### Finding Lead in Saliva:

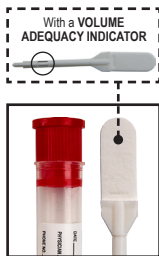
Until now the most accepted method to find lead in humans has been to test blood. A recent study, however, indicates that saliva can be as effective as blood as a medium through which body lead can be detected.

In that study, our patented methodology and process (LeadFinder™) was employed by our partner lab Western Slope Laboratory in Troy, Michigan to analyze the saliva of 100 children living in North Carolina. Concurrently, the blood of those children was analyzed at the Department of Health in North Carolina.

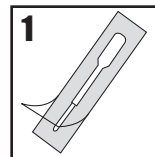
Results of the blood and saliva lead tests were compared. Without question, analyzing saliva is an effective means to establish body lead – especially if viewed as a “screen” with the recommendation of physician involvement in the event results exceed the cut off level.

### Collection Instructions

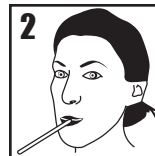
Our Saliva Collection Device (FDA Approved) has the highest standards and comes with a saliva collection indicator to assure that enough saliva has been collected. Once enough saliva is collected, the volume indicator will turn blue



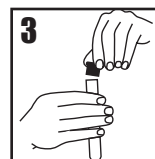
1. Peel open pad package and remove collector.



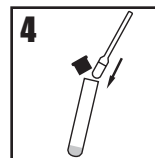
2. Place collector under the tongue. The collector should remain under tongue until indicator turns completely blue. DO NOT CHEW OR SUCK ON PAD! Do not move pad during collection. Blue color indicates collector is saturated with 1 ml of saliva. The collection time may take from 2 - 10 minutes. If the indicator has not turned blue within 15 minutes the pad should be removed from the mouth and discarded



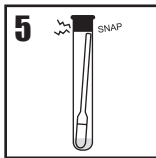
3. Uncap transport tube in upright position and old tube in hand. Do not stand tube on table.



4. Insert the saturated collector into the tube. Do not place collector into mouth after it has been in the buffer liquid.

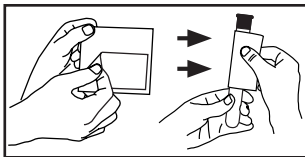


5. Carefully place cap over the top of the collector stem in tube. **FORCEFULLY PUSH CAP DOWNWARD UNTIL CAP “SNAPS” FLUSH WITH TOP OF TUBE**



### **Shipping Test and Getting Results**

1. Peel of the label from the specimen ID Card and apply on the tube. Keep the rest of the specimen id card in a safe place as you will need that number to get your results. Place the tube in the clear plastic bag and place all in prepaid shipping material. Ship saliva specimen to laboratory immediately.



2. Results will be available 5-6 business days after the sample is received by the laboratory. To get your results simply log on to [www.leadtestconfirm.com](http://www.leadtestconfirm.com). Use your specimen number and passcode to register your test and to view your results.

**Consult a doctor if the quantity of the lead reported in the body is a positive result (i.e. over 10).**

For questions or more information call **1-888-5-CONFIRM** or visit us on the web at [www.leadtestconfirm.com](http://www.leadtestconfirm.com)

### **Frequently Asked Questions**

#### **1. What is LeadConfirm**

Leadconfirm is a laboratory based test that will provide you information on whether a person has been exposed to lead – as measured in the saliva sample

you will send to the laboratory. The test is not definitive in terms of measuring exactly how much lead is present and does not tell you whether lead “poisoning” exists. The test is a “screening” test and will inform whether someone has had recent exposure to lead. If the result from this test confirms recent exposure, a visit to your physician for a follow-up blood test is highly suggested. Historically, lead exposure and/or toxicity have been measured by testing blood and, to this day, blood analysis is best. However, because of the cost of testing blood and all that is involved in getting a blood test done (visit to your doctor, doctors order, visit to lab, etc), there is value to a screening test. It is our pleasure to offer this service to you.

#### **2. What does LeadConfirm test for?**

LeadConfirm will inform whether someone has had recent exposure to lead by analyzing the saliva (oral fluids)

#### **3. What is a cut off level?**

The cut-off level is the specified concentration of lead in a saliva sample. Above that concentration the test is called positive, and below that concentration it is called negative

#### **4. What does Oral Fluid Screening mean?**

Commonly referred to as the “mirror of the body,” Saliva is a vital substance that carries molecules, many bio markers of disease, evidence of drug use and many other indicators (known and unknown) of what is happening inside the human body. The United States Food and Drug Administration long ago approved saliva to be used in testing for HIV-1 or HIV-2 infection. Hormones and other commonly measured compounds are typically analyzed from saliva as opposed to blood. Most compounds found in blood are also found in saliva. Its acceptance therefore as a testing medium is unquestioned as well as easier and cheaper to collect, since it doesn’t expose health-care workers to blood-borne diseases.

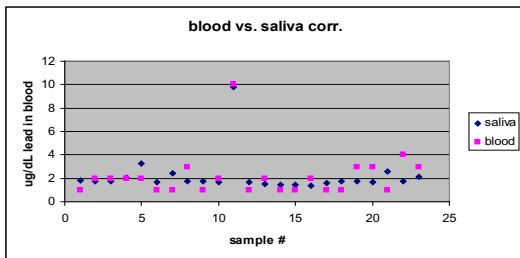
### 5. How accurate is the test?

Our studies have shown that saliva-based lead testing yields results that approximate blood testing with a high degree of correlation

Until now, the commonly accepted way to find lead in humans was to test blood. A recent study, however, clearly indicates that saliva can be an effective medium through which body lead can be detected (see graph below for correlation data.)

In this study, a patented methodology and process called “LeadFinder™” was employed at Confirm BioSciences’s partner lab Western Slope Laboratory in Troy, Michigan to analyze the saliva of 100 children living in North Carolina. At the same time, the blood of those children was analyzed by the Department of Health in North Carolina.

- By comparing the results of the two lead test studies it became apparent that:
- Analyzing saliva is an effective means to establish body lead – especially if this test is viewed as a “screening method” with the recommendation of a physician involved in the event results exceed a certain level.-
  - There was a 1.00 (100%) correlation between lead levels found in the saliva tests vs. blood tests



### 6. Does a positive screen mean that there’s excessive lead in the body?

The test is a “screening” test and will inform whether someone has had recent exposure to lead. If the result from this test confirms recent exposure, a visit to your physician for a follow-up blood test may be required.

### 7. What is Lead?

Lead is a metal found in the earth, and it is a poison. For years, lead was used in paint, gasoline, plumbing and many other items. Lead is practically everywhere in today’s environment. It enters our bodies from many sources including defective glazes (pottery), drinking water, contaminated soil, airborne particulate, leaded gasoline, paint and several other sources. There is no safe age to be exposed to lead. Adults can have problems from lead poisoning, but it is most harmful to children younger than age 6 (especially those younger than age 3) because it can permanently affect their growth and development. A pregnant woman who is exposed to lead can pass it to her unborn baby (fetus). Lead can also be passed to a baby through the mother’s breast milk.

### 8. What is lead poisoning?

Lead poisoning occurs when you absorb too much lead by breathing or swallowing a substance with lead in it, such as food, dust, paint, or water. Too much lead in the body can cause irreversible problems in growth and development in children, including:

- Behavior problems
- Learning problems
- Hearing problems
- Slowed growth

In adults, lead poisoning can cause serious health problems, including high blood pressure and damage to the brain, nervous system, stomach, and kidneys. Although it is not normal to have lead in your body, a small amount is present in most people. Lead can damage almost every organ system, with the most harm caused to the brain, nervous system, kidneys, and blood. The Centers for Disease Control considers lead to be the greatest environmental health risk to children as their immune systems are still in the developmental stages!

### **9. How is lead poisoning it treated?**

Treatment for lead poisoning includes removing the source of lead exposure and eating a balanced diet. Adequate nutrition, especially sufficient iron intake, helps prevent absorption of lead. Often this treatment approach is enough to reduce lead levels in the body. If this is not successful or if lead levels are very high, chelation therapy may be used. Chelation therapy involves taking medicines that bind to lead in the body and help speed its elimination through the kidneys. It is important to make sure that children are not exposed to lead. The most effective means of prevention is to keep children out of buildings and toys that contain lead-based paint until the lead has been either removed or sealed away and the environment is certified by professionals to be free of lead residues.

### **10. How is lead used in manufacturing?**

**Paint:** Lead may be found in the paint on toys. Lead paint was banned for use in house paint, on products marketed to children, and dishes or cookware in the United States in 1978; however, it is still widely used in other countries and therefore the reason it can be found in imported toys. It may also be found on older toys made in the United States before the ban in 1978.

**Plastic:** Lead may also be used in plastic toys to stabilize the plastic molecules from heat. It makes the plastic more flexible and softens the plastic so that it can go back to its original shape. The use of lead in plastics has not been banned. When the plastic is exposed to substances such as sunlight, air, and detergents the chemical bond between the lead and plastics breaks down and forms a dust

### **11. How can my child be exposed?**

Lead is invisible to the naked eye and has no smell. Children may be exposed to lead from consumer products through normal hand-to-mouth activity. As part of normal development, young children often place their toys, fingers, and other objects in their mouth, which puts them in contact with the lead paint or dust.

### **12. How Can I Limit My Child's Exposure to Lead in Toys?**

The Consumer Federation of America [www.consumerfederation.org](http://www.consumerfederation.org) recommends the following steps:

1. Identify whether you have a product in your home that has been recalled. Go to [www.cpsc.gov](http://www.cpsc.gov) to determine whether the products in your home are subject to the recall.
2. If you do have a recalled toy in your home:
  - Take it out of your children's hands immediately.
  - Follow the manufacturer's instructions for the recall; do not just throw out the product.
  - If the recalled toy contains lead, wipe down other toys that were near the recalled toy to catch lead dust.

3. Beware of young children's tendencies to put small toys in their mouths.

4. Beware of choking hazards, including small magnets. To determine if there are toys or parts of toys that may pose a choking hazard to a young child, use the inside of a toilet paper tube. If a toy or piece of a toy easily fits through, do not let children under three play with or have access to these toys.

### **13. Additional Resources**

- Centers for Disease Control and Prevention  
1-800-424-LEAD or visit [www.epa.gov/lead](http://www.epa.gov/lead)
- US Environmental Protection Agency Lead Awareness Program  
[www.epa.gov/lead](http://www.epa.gov/lead)
- National Institute for Occupational Safety and Health  
1-800-311-3435 or visit [www.cdc.gov](http://www.cdc.gov)
- Occupational Health and Safety Administration  
1-800- 321- 6742 or visit [www.osha.gov](http://www.osha.gov)



San Diego, CA 92111  
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**1-888-5-CONFIRM**

1-888-5-266-3476