An Evaluation of Chemical Screening Test Kits for Lead in Paint

A RESEARCH PROJECT
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MASTER

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Abstract

AN EVALUATION OF CHEMICAL SCREENING TEST KITS FOR LEAD IN PAINT.

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The Residential Lead-Based Paint Hazard Reduction Act (Title X) requires abatement and management of lead-based paint. Lead in paint may be determined by laboratory analysis, X-ray fluorescence survey instruments, and chemical screening test kits. The performance of chemical screening test kits has been evaluated in two previous studies using different materials and methods and yielding conflicting statistical results. The purpose of this study was to evaluate three chemical screening test kits common to both previous studies using materials and methods from one study and subjecting the results to the statistical analysis of the other.

The three kits were used to predict the presence of lead in paint at ten weight concentrations (0.04, 0.48, 0.91, 1.35, 1.79, 2.22, 2.66, 3.10, 3.53, 3.97%) formulated by adding lead carbonate to oil-based paint. Paint containing lead at the ten concentrations was applied to four wood boards yielding a sample size of 40. Four boards were painted with lead-free paint and used as blanks. All of the boards were tested with the three test kits by an untrained individual having no knowledge of the actual lead content. Sensitivity, specificity, and false positive and negative rates were calculated for the test kit results (negative or positive) and the known concentrations using 2 X 2 tables. The manufacturers' detection limits and the Federal threshold of 0.5% were used as critical values. At the manufacturers' detection limits, the observed sensitivity ranged from 1.00 to 0.80, specificity ranged from 1.00 to 0.42, false positives ranged from 0 to 58%, and false negatives ranged from 0 to 20%. At the 0.5% Federal threshold level, the observed sensitivity ranged from 1.00 to 0.94, specificity ranged from 1.00 to 0.5, false positives ranged from 0 to 11.1%, and false negatives ranged from 0 to 20%. The observed false positive and false negative rates for all three kits were found to be significantly lower than those reported in a previous study. These results indicate that the kits perform very well at the Federal threshold, with two of the kits having false negative rates below 12.5% and false positive rates of 3.13%. These results indicate that these two kits would probably be acceptable screening tests for lead in paint.

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I. Introduction

Lead background

Chemical and Physical Properties

Lead is a soft, malleable, bluish-gray naturally occurring heavy metal characterized by high density and corrosion resistance. Lead is considered to be one of the seven metals of antiquity. The periodic table of the elements symbolizes lead as Pb, from the Latin word for the metal, *plumbum*. The atomic weight of lead is 207 (1,2).

The desirable properties of lead have improved the overall quality of products to which it has been added. Properties of lead include its ability to impart resistance to acids and moisture, attenuation of sound and vibration, shielding of radioactivity, and addition of brilliance and hardness to ceramics (1). Lead is durable, malleable, easy to work with, and does not rust. Lead pipes expand when water within them freezes (2).

Sources and Manufacture

Lead occurs in many ores in concentrations of 1-11% (1). The predominant lead ore is a combination of lead and sulfur called galena (PbS). Other ores of lead include angelesite (PbSO_4); cerussite, also known as lead carbonate or "white lead" (PbCO_3); mimetite [$(\text{PbCl}_2 \cdot 3\text{Pb}_3\text{AsO}_4)_2$], and pyromorphite [$\text{PbCl}_2 \cdot 3\text{Pb}_3(\text{PO}_4)_2$] (2). The lead ores of commercial interest are primarily galena, cerussite, and angelesite (1). Lead consists of a mixture of four stable isotopes, with atomic weights of 204, 206, 207, and 208. The last three are the end products of the decay of three natural radioactive elements, i.e., uranium 238, uranium 235, and thorium 232 (3).

Lead is concentrated from its ores through wet grinding and flotation prior to smelting. The three-step process of smelting involves blending, sintering, and blast furnace reduction. The lead bullion and slag are further refined through pyrometallurgic or electrolytic processes to remove copper, arsenic, antimony, zinc, tin, bismuth, and other metal contaminants. Over one-third of the lead produced in the United States is recovered from secondary sources of lead scrap (2).

Uses

Lead was one of the first metals to be used by man. Throughout history it has been used as a preserving agent in food and wine, as colored decoration, in cosmetic face creams, and even as medicinal remedies (3). Today lead is primarily used in the manufacture of storage batteries. It is used in the chemical and building industry in pipes and cable sheathing. Tin-lead alloys are used in solder for electrical applications. Lead is used in construction and for shielding radioactivity. Lead is present in paint, ceramics, and children's toys. Other uses of lead include ammunition, bronze and brass, cosmetics, jewelry, colored newsprint, colored bread wrappers, wrapping paper, and temporary hair colorings (1,2). Tetraethyl and tetramethyl lead are antiknock agents in gasoline. In addition to its uses as pigments and stabilizers in paint, lead causes paint to adhere well and serves as a drier and extender. By virtue of lead's toxicity, it prevents the growth of mildew in paint (1).

Exposures

Lead is widespread in our environment as a consumer product and in our society's air, water, soil, and solid waste streams (2). Exposure pathways for adults and children include environmental, occupational, and non-occupational. Young children have a great potential for

lead exposures and are especially susceptible to its toxic effects. Therefore, gathering information about the major sources of lead contamination is essential to conduct childhood lead poisoning investigation. This information is also important in understanding how environmental sources of lead contamination can influence lead dust levels on abatement sites, at times making it difficult or impossible to achieve postabatement cleanup standards (2).

Environmental

The primary sources of environmental exposure to lead are paint, auto exhaust, food, and water (4).

Lead paint. Lead-based paint is the most common high dose source of lead exposure for children (5). The lead content of paint was not regulated until 1978 when the Consumer Product Safety Commission banned the manufacture of paint containing more than 0.06% lead by weight on interior and exterior residential surfaces, toys, and furniture (4). Unfortunately, about three million tons of lead remains in approximately 74% of the occupied private housing units built before 1980 (5).

Children can ingest loose paint as a result of pica, the repeated ingestion of nonfood items. The more common exposure pathways occur when children ingest dust and soil contaminated with lead from paint that has been distributed during home maintenance or renovation or which is peeling, flaking, or chipping due to aging (4,5).

Lead paint continues to be used on steel structures like bridges and expressways. Workers are at an obvious risk of lead exposure during the deleading or maintenance of such structures; increased lead absorption has been reported in children exposed to chips or dust during the performance of these tasks as well (5).

Soil and Dust. Deposition of lead from paint, gasoline, and industrial sources occurs in soil and dust (5). The lead from auto emissions is deposited in the soil and becomes available to children playing near roads and freeways (4). Lead deposited into the dust and soil becomes a long-term source of lead exposure due to the fact that lead does not decay in the environment. Ingestion of dust and soil during meals and playtime appears to be a more significant pathway of exposure than inhalation for young children (5).

Air. Airborne lead serves as a potential exposure pathway. The lead in auto emissions may be inhaled directly. Until the use of lead as a gasoline additive was completely prohibited, the combustion of leaded gasoline by motor vehicles was the predominant source of airborne lead in the United States. Airborne lead today is only a minor exposure pathway in the United States except around point sources like battery manufacturing plants and smelters (5). In most other countries the levels of lead allowed in gasoline have decreased. However, airborne lead from the combustion of leaded gasoline remains as a potential exposure pathway in some areas, including Mexico and the Middle East (3). Localized exposure to airborne lead could occur from other industrial activities including incineration and sandblasting or demolishing lead-painted metal structures (5).

Food. Lead from various sources may be present in food. The lead may be present from the environment or from food containers (4). Solder on aluminum cans may contain lead if imported from foreign countries where lead use is not restricted. Pesticides used on crops in the past such as lead arsenate still remain in the soil where new crops are grown. Food contamination can also occur from air and rain, food processing, and contact with lead dusts in

the home (5). Lead crystal glasses and decanters and lead containing glazes used on pattern and ceramics contribute to contamination of food by lead (2).

Water. Drinking water can be an exposure pathway for lead. The contamination of the water with lead usually occurs in the distribution system, not in reservoirs, aquifers, or other sources of water (5,2). Copper piping joined with lead solder is present in millions of homes. Plumbing fixtures made of brass and bronze (alloys of metals including lead) can leach lead into the water. Older water coolers and drinking fountains have been found to contain lead lined tanks and lead fixtures (2).

The use of lead piping and solder in drinking water plumbing systems was prohibited in 1986 by the Federal Safe Drinking Water Act. However, much lead still remains from past usage. The EPA recalled lead containing water coolers and drinking devices and established a 15 part per billion "action level" for lead in drinking water for water supplies. The contribution of lead exposure from drinking water is expected to decrease substantially as EPA continues to implement Safe Drinking Water initiatives (2).

Occupational

More than one million workers in over 100 different occupations may be exposed to lead. Workers are exposed to lead by inhalation of lead dust and lead oxide fumes. They may also ingest lead by eating, drinking, and smoking in or around lead contaminated areas. Workers can bring lead dust home on their skin, shoes, and clothing, causing inadvertent exposure to family members (4). Some of the affected occupational categories are listed in Table I.

TABLE I.**Occupational Categories Affected by Lead Exposure (2)**

Battery manufacturing and repair	Fish sinker Manufacturing
Automobile Assembly	Jewelry making
Lead scrap melting/metal founding	Plastic manufacturing
Demolition/renovation activities	Pottery making
Auto body and radiator repair	Roofing
Secondary Lead Smelting	Glass and stained glass manufacturing
Inorganic chemical industries	Welding
Ammunition manufacturing	Law enforcement
Brick making	Plumbing
Cable making and splicing	Rubber manufacturing
Cutlery manufacturing	Ship building

Nonoccupational

Nonoccupational exposures can occur from such things as traditional medicines, cosmetics, and toys. Glazed pottery making, target shooting at indoor firing ranges, lead soldering, painting, art supplies, preparing lead shot or fishing sinkers, stained glass making, car or boat repair, and home remedies are all hobbies with potential lead exposure. Several folk remedies used in this country have been shown to contain large amounts of lead (4). A black cosmetic eyeliner called "surma" has been found to contain 85% lead. Antique toys and toys from other countries have been found to contain lead or lead-based paint and represent a high exposure potential for children that play with them (2).

Lead toxicity

Lead is ubiquitous in the human environment in spite of the known or anticipated health effects arising from incidental exposures to the lead. Lead serves no useful biologic function in humans (1,5). Children are particularly susceptible to lead's toxic effects. Most lead poisoned children have no symptoms due to the frightening silence of lead poisoning. Therefore, the vast majority of cases go undiagnosed and untreated (5). The specific concerns surrounding lead toxicity vary with the age and circumstances of the host, but the major risk is toxicity to the nervous system (6).

Routes of Exposure

The respiratory tract, gastrointestinal tract (GI tract), skin and placenta are potential routes of lead intake and absorption. At present, the major sources of human exposure to lead affecting the general population are food, drinking water and other beverages, while in the occupational exposure the main risk of lead absorption comes from inhalation of lead aerosols. The amount of lead entering the blood stream is influenced by the routes of intake, the amount of the element in the specific media, the physicochemical characteristics of the lead complex, and specific host factors such as age, sex, physical conditions and dietary deficiencies (3).

Respiratory tract. Lead may be present in the air, and thus available to the respiratory tract in the forms of vapors and aerosols (3). Lead vapors primarily consist of alkyl lead that has escaped by evaporation from automobile fuel systems (6). The mean life of lead vapors is extremely short, because these vapors rapidly undergo one of the following processes:

- a) Condensation nuclei, which are unstable and are eventually transformed into smoke
- b) Reaction with the oxygen contained in the air to form lead oxide fumes which consist

of solid submicron particles liable to gather into clusters or strings

c) Absorption on the surface of other dust particles found in the air.

Since lead vapors only remain in the air for an extremely short time, they in no way affect the risk of lead absorption by inhalation (3).

Lead aerosols may be derived from the condensation or sublimation of vapors created by heat, chemical reaction, or radiation, or from a fragmentation of solid masses by mechanical means. When lead aerosols are inhaled, particles are deposited at different sites of the respiratory tract and enter the bloodstream in different ways. The amounts of lead absorbed and the rates of absorption depend on the deposition and removal processes that are influenced by several factors including the physicochemical properties of the aerosol, the ventilatory activity of the lung, and the anatomic structure of the respiratory tract where the particles are deposited (3).

The respiratory tract is divided into three compartments. The first is the nasopharynx compartment which corresponds to the upper respiratory tract. The second is the tracheobronchial compartment which consists of the trachea and bronchial tree including the terminal bronchioles. The third is the pulmonary compartment which houses the respiratory bronchioles, alveolar ducts, atria, alveoli, and alveolar sacs (3).

Inhaled lead particles deposited in the respiratory tract can be removed from the lung by mucociliary clearance or alveolar clearance. The mucociliary activity takes place in the nasopharynx and tracheobronchial compartments (3). The particles are carried up the airways on mucous from the upper respiratory tract. The mucous is either swallowed, thereby allowing the lead particles to be absorbed by the gastrointestinal tract, or expectorated (7). Alveolar clearance occurs in the pulmonary compartments (3). Almost all the lead that is deposited in the lower

respiratory tract where the exchange of gases takes place will be rapidly absorbed into the body (7).

A large number of variables influence the amount of lead deposited in the respiratory tract. Studies suggest that the rate of deposition is about 30-50 percent for adults and is determined by factors such as particle size and ventilatory rates. However, little is known about the rates of deposition in children (7).

Gastrointestinal Tract. Lead-contaminated air and water may enter the biologic cycle through incorporation into plants and animals that form part of the human dietary intake. Traces of the metal may also be present in drinking water, milk, and other beverages consumed by humans. In addition, lead is contained in numerous materials which, although inedible, may be ingested. The risk is particularly serious for infants between six and 24 months because of oral exploration. Children from six months to five years may be affected by pica, a compulsive habit of ingesting nonfood items. This can be linked to psychological and socioeconomic factors and is often associated with inadequate diets with iron and calcium deficiencies. Lead-containing dusts can also be cleared from the lung by mucociliary activity and transported to the esophagus and GI tract by swallowing (3).

Biological variability, the subject's age, fasting conditions, GI emptying, the chemical form of different lead compounds, and nutritional deficiencies affect GI lead uptake and absorption. Intestinal absorption of lead occurs in the small intestine. The lead transport system is stimulated by an iron deficiency. The presence of bile in the duodenum enhances the transport of Pb^{++} cations across the intestinal mucosal epithelial cells. The absorption of lead may be modified by certain dietary constituents; some substances are thought to enhance the solubility of

lead, while certain bivalent cations (e.g., Ca^{++} and Fe^{++}) may compete with lead for absorption sites in the intestinal mucosa. It has also been shown that an increase of dietary fat increased GI lead absorption (3).

Research on laboratory animals and humans has shown that intestinal lead absorption is higher in newborns and during the early stage of life than it is in young and adult subjects. The available data demonstrated that the ingestion of lead during fasting considerably enhances its uptake (3). Smaller particles of lead tend to be absorbed more efficiently by the GI tract than large particles due to the higher surface area of smaller particles. This suggests that particle size influences lead absorption in the GI tract, as well as in the respiratory tract (7). The factors controlling lead absorption by the GI tract are complex and continue to be studied.

Skin. Skin absorption of inorganic lead is not usually considered a significant route of entry of lead into the body. However, it is generally assumed that organic lead compounds (e.g., alkyl lead) can be easily absorbed through the skin and represent a real potential hazard. The level of lead absorption seems to be influenced by the physicochemical characteristics of the lead compound, the amount of skin surface in contact with the compound, the length of time during which contact occurs, and by whether or not the skin is intact (3).

Placenta. The placenta has historically been thought of as a "barrier" that protects the fetus against the passage of noxious substances from the mother. However, the placenta should be thought of as a lipid membrane that permits bidirectional transfer of substances between maternal and fetal compartments rather than a "barrier". It provides nutrition for the conceptus, exchanges maternal and fetal blood gases, disposes of fetal excretory material, and maintains pregnancy by a complex hormonal regulation (6). By the end of the third month of pregnancy,

the placenta has already developed. It is gradually modified during the course of the pregnancy (3).

The placenta plays an important role in fetal lead intake, which occurs by means of maternal and umbilical cord blood. Substances can pass through the placenta by simple diffusion, facilitated diffusion, active transport, and carrier-mediated transfer. The movement of xenobiotics from maternal to fetal circulation occurs primarily by diffusion. Facilitated diffusion, active transport, and carrier-mediated transfer are important for endogenous materials, but seem to play a much more limited role for xenobiotics. Little is known about the lead transport mechanism. However, a balance is known to exist between lead concentrations in maternal and fetal blood. These concentrations are closely correlated with a coefficient ranging from 0.73 to 0.92 (3).

Lead Distribution

The distribution and retention of lead in mammalian tissues have been widely studied and are now relatively well defined. When lead enters the bloodstream, it rapidly spreads out of the intravascular space in the interstitial fluids to penetrate the cells. Lead distribution in the body can be described by analyzing the blood, soft tissues and bone tissue (3).

Blood. Blood level concentrations are dependent upon the dose absorbed, the route of entry into the body, and the time elapsed since exposure. The lead present in peripheral blood is mainly bound to the erythrocytes (94-99%) with a small fraction retained in the plasma (1-6%) (3). An equilibrium exists between red cell and plasma lead, but the fraction is difficult to measure accurately. The half life of blood is approximately 36 days for adults, while the half life for a 2-year-old child may be as long as 10 months (7).

Soft Tissues. Lead is widely, but unevenly, distributed in all the soft tissues of the body. In early phases following lead exposure, the highest lead concentrations are found in the kidney and liver and, in decreasing order, in the other soft tissues: lungs, spleen, heart, muscular and cerebral tissues (3). The lead becomes readily exchangeable in these tissues. The concentrations in these tissues are highest with acute, high dose exposures (6). In spite of considerable interindividual variation in the absolute values of lead accumulation, the relative distribution of lead in various tissues proved to be fairly similar. In many soft tissues, lead concentrations decreased significantly with age (e.g., liver, kidney, pancreas) (3).

Cellular. The cellular distribution of lead has usually been examined in the liver and kidney. These study show that lead rapidly penetrates the cell membrane, diffuses into the cytosol, and binds to the intracellular organelles. The amount of lead content in the various subcellular fraction varies with the tissue examined. However, nuclei (kidney) and mitochondria (liver) contain the highest percentages of lead in cells (3).

Intracellularly, lead binds to sulfhydryl groups. The presence of lead in hair and nails is attributable to this binding. Lead interferes with numerous cellular enzymes, including those involved in heme synthesis. Lead also binds to mitochondrial membranes and interferes with protein and nucleic acid synthesis (6).

Bone. Bone constitutes the major site of deposition of absorbed lead, where it is incorporated into the bone matrix similar to calcium (1). The bone system seems to be much more sensitive to direct and indirect toxic lead effects in the early phases of skeletal development than when the skeleton is formed (3). The lead in dense bone is only slowly mobilized and

gradually increases with time (1). The absorbed lead is stored in bones with a half life of about 25 years (7).

The toxic effects of lead poisoning appear earlier in bone marrow than in the blood stream. The critical effects in bone marrow arise mainly from the interaction of Pb with some enzymatic systems responsible for heme synthesis. These interactions determine the inhibition of some enzymes and the variation in some metabolite concentrations (3).

Measuring Lead in the Body

The dose indices most frequently adopted for the measurement of lead in the body are lead in blood (PbB), lead in urine (PbU), urinary excretion of lead following introduction of EDTA (PbU-EDTA), lead in bone, lead in teeth, and lead in hair. Lead can also be measured in sweat, saliva, gastric juice, and bile. Some biochemical effects due to lead absorption are visible at low levels of exposure, when other signs and clinical symptoms of lead poisoning are not apparent. They indicate the critical concentration of lead in certain organs and tissues such as bone marrow, kidney, and the nervous system. Common effect indicators include the activity of delta-aminolevulinic acid dehydratase (ALA-D), urinary delta-aminolevulinic acid (ALA-U), urinary coproporphyrin (CP-U), and erythrocyte zinc-protoporphyrin (ZPP) (3).

Blood lead levels The most commonly used and widely accepted measure of internal lead exposure is the concentration of lead in the blood (PbB), denoted as micrograms of lead per deciliter of whole blood ($\mu\text{g}/\text{dl}$) or ($\mu\text{mol}/\text{l}$). Atomic absorption spectroscopy (AAS) is the method most widely used for lead determination in blood; Anodic stripping voltometry (ASV) is also used extensively for lead determination, but interference from EDTA used as an anticoagulant and with elevated concentrations of copper in the blood may occur. Blood lead

levels provide a "snapshot" of the most recent exposure. They do not reveal lifetime history of exposure. These levels indicate only the circulatory lead levels, not the levels stored in the bone and teeth. However, blood lead levels will be influenced by lead that is released from bone and other storage sites, so elevated blood lead levels may be measured even in the absence of recent lead exposure (3,7). The amount of lead released from the bone is influenced by nutritional and endocrine status, lactation, osteoporosis, renal disease, and other physiological and pathological conditions (3).

Lead in Urine. The amount of urinary lead excretion (PbU) depends on exposure conditions, the extent of body burden and kidney function. In the past the determination of PbU was widely used however, the determination of lead concentrations in the blood has become the main internal dose index. Several factors contributed to this change: the wide fluctuation of specific gravity in urine, the frequent contamination of urine samples, the complexity of this biological matrix, the relatively low urinary lead concentration, etc. Two other factors, the daily and hourly variation in urinary lead excretion, and chronic renal insufficiency have the effect of considerably decreasing urinary lead concentration even when exposure is severe. Moreover, individual factors may interfere with urinary lead excretion including beverage intake and physical activity. PbU excretion has been shown to significantly decrease with water restriction and, vice versa, significantly increase with increased beverage intake. Physical activity is thought to play a primary role in the increase of urinary excretion (3).

Lead Mobilization Test (Pb-EDTA). PbU excretion following calcium-disodium ethylenediaminetetraacetate (EDTA) injection indicates the amount of lead that can be mobilized from the body stores (soft tissue and bone). Several hours after the administration of EDTA, 40-

50% of the total Pb-EDTA complex is excreted in urine. Since the Pb-EDTA test is invasive, it cannot be used as a screening tool. It should be carried out when other biochemical indices such as PbB and ZPP have indicated high lead exposure and/or body burden (3).

Lead in Bone. The most reliable index of cumulative lead absorption in long-term exposures is bone lead content. A number of physiological and pathological conditions, such as age, sex, nutritional and endocrine status, lactation, osteoporosis, and renal disease, can modify bone lead levels and lead release. Lead determination in bone can be carried out on biopsies by removing a sample of bone from the skeleton and conducting chemical analysis for lead by spectrophotometry of emission, AAS, or ASV. Recently, a nuclear technique (X-ray fluorescence) has been developed that enables the assessment of heavy metals in vivo (3).

Lead in Teeth. Lead accumulates in the mineralized tissues of the tooth where it is bound so firmly that it cannot be released. Little is known about the lead kinetics in teeth, which probably have the same characteristics as the kinetics of the inert bone compartment. However, milk teeth could be a better biological indicator of internal dose than other indices due to the fact that they are shed naturally with no need for any type of invasive procedure, and because they could provide an integrated historical record of lead exposure. AAS and ASV are the most frequently used methods for measuring lead in milk teeth. The lead content in permanent teeth in situ can also be measured using an X-ray fluorescence method. This method reveals less about cumulative exposure than measurement of milk teeth. However, multiple measurement with this method can be useful in showing the ongoing rate of increase in body lead burden (3).

Lead in Hair. Lead determination in hair can serve as a calendar of past exposure to the metal. Lead forms a stable complex with the numerous sulfhydryl groups that are present in

follicle proteins present in the hair structure. Hair is a noninvasive sampling source that can be stored for a long period of time without creating problems of stability. The measurement of lead in hair can be performed using different analytical techniques such as atomic absorption spectroscopy, XRF, etc. All methods are highly sensitive and capable of detecting even the smallest quantities of metal, however, a comparison of results is possible only by using reference standards which are currently not available. When using this measurement technique, one must take into account the numerous difficulties involved in interpreting results (3).

Indices of Biochemical Effects. At present, ZPP is the most promising biological indicator. Erythrocyte ZPP is the most frequently used effect index at the present time due to the data it can supply with regard to both current exposure and body stores, particularly for PbB levels ranging from 30-80 $\mu\text{g}/\text{dl}$ (3). It is blood measurement that provides information on the "total body burden" of lead. Protoporphyrin is a substance within the erythrocyte that forms heme (a compound of the hemoglobin molecule) with the addition of iron. Lead prevents iron from combining with the protoporphyrin, thus impairing the manufacture of hemoglobin. Protoporphyrin then accumulates in the erythrocyte. The erythrocyte protoporphyrin (EP) level in the blood begins to elevate, which may indicate a lead exposure. However, EP levels may be elevated by iron deficiencies and other illnesses. The ZPP test is not sensitive enough to identify children with elevated blood lead levels below about 25 $\mu\text{g}/\text{dl}$, so blood lead measurements are used as the screening test of choice (7).

Three other indices of biochemical effects have been studied, ALA-D, ALA-U, and CP-U. ALA-D is found in mature erythrocytes. It is the first enzyme to be affected by a rise in PbB concentration. The response to lead increase in blood is immediate. ALA-U and CP-U are

capable of accurately predicting lead poisoning as they show significant increases even when PbB levels are very high (over $80\mu\text{g/dl}$) (3).

Target Organs

The critical effects or most sensitive effects of lead in infants and children involve the nervous system. For adults with excess occupational exposure, or even accidental exposure, the concerns are peripheral neuropathy and/or chronic neuropathy. The critical effect for adults in the general population through environmental exposure may be hypertension. Effects on the heme system provide biochemical indicators of lead exposure, but anemia due to lead exposure is uncommon without other detectable effects or other synergistic factors (6). Other target organs are the GI tract, the kidneys, and reproductive systems (6,7).

The Nervous System. The human nervous system is composed of the central nervous system (CNS), which includes the brain and spinal cord, and the peripheral nervous system (PNS), which comprises the nerves extending from the spinal cord. Lead is known to affect both the CNS and the PNS. Neither system has any apparent barrier nor protection from lead intake (7). The dramatic effects of lead include encephalopathies (diseases of the brain) and peripheral motor neuropathies (abnormal and usually degenerative state of the nerves). It has been suggested that lead plays a role in the etiopathogenesis of motor neuron diseases, particularly amyotrophic lateral sclerosis (ALS); however, none of the findings suggesting a link between lead exposure and ALS offer conclusive proof, and ALS cannot be considered one of the classic neurological manifestations of lead exposure. Neuropsychological and behavioral disturbances are consequences of lead exposure. Impaired response to sensory evoked potentials (SEP) and neurophysiological abnormalities in the peripheral nerves have been reported (3).

The mechanism of neurotoxicity of lead occurs in the absence of morphologic changes by producing deficits in neurotransmission through inhibition of cholinergic function, possibly by reduction of extracellular calcium. Other noted changes in neurotransmitter function include impairment of dopamine uptake by synaptosomes and impairment of the function of the inhibitory neurotransmitter gamma-aminobutyric acid. Also, studies of capillaries from children poisoned with lead and from experimental studies suggest that the immature endothelial cells forming the capillaries of the developing brain are less resistant to the effects of lead than capillaries from mature brains and permit fluid and cations including lead to reach newly formed components of the brain, particularly astrocytes and neurons (6).

The primary target organ for lead toxicity in children is the central nervous system. The predominant neurologic syndrome in children is acute encephalopathy. Lead exposures in the range of $80\mu\text{g}/\text{dl}$ and above can cause encephalopathy and convulsion (6). High lead concentrations may affect the CNS by causing irreversible mental retardation and seizures, comas, and even death. Children can be affected adversely by lead at blood lead levels of $10\text{--}25\mu\text{g}/\text{dl}$, usually with no overt sign or symptoms of lead poisoning. These effects can include subtle behavior changes such as irritability, suppression of appetite, sleep disturbances, hyperactivity, hearing impairment and reduction in short term memory. Moderate blood lead levels in children ($30\text{--}50\mu\text{g}/\text{dl}$) often effect reading comprehension, school dropout, and special education needs. Unfortunately, the majority of children with elevated blood lead levels are either mildly symptomatic or asymptomatic (7). Children with blood lead levels in the $50\text{--}70\mu\text{g}/\text{dl}$ range, but without clinical symptoms of lead poisoning may have decrements in expected cognitive abilities by as much as five or more IQ points (6).

In adults, acute encephalopathy is a less frequent neurologic consequence of acute lead poisoning. Most cases of acute encephalopathy in adults are the result of nonoccupational exposure to the metal. In the past 30 years the most frequent source has been the consumption of illegally distilled whisky (moonshine). The clinical onset of acute lead encephalopathy in adults is often characterized by warning signs including decreased alertness and loss of memory, orientation, and perception. At a later stage, convulsions and severe deterioration in the state of consciousness may occur. Anemia and basophilic stippling are almost always present, and increased urinary lead excretion has been reported in all cases. These clinical signs are usually associated with blood lead levels in excess of $120\text{ }\mu\text{g/dl}$. However, low PbB levels do not exclude a diagnosis of acute lead encephalopathy (3).

The most common clinical picture in adults after severe, prolonged lead exposure is peripheral motor neuropathy. Effects to the peripheral nervous system are more common occurrences with the nervous system. Lead causes a condition known as ankle or wrist drop. Nerve damage occurs and the ankle or wrist can no longer be supported. This frequently occurs from chronic exposure to lead (7).

Blood. Lead interferes with the production of hemoglobin and blood cells, resulting in anemia. The effects of anemia include fatigue, exhaustion, and pale coloring. Lead can also reduce hepatic heme resulting in a lowering of the body's ability to detoxify pollutants (7).

At blood lead levels of $15\text{-}20\mu\text{g/dl}$ in children, adverse impacts of the heme formation pathway on vitamin D and calcium metabolism have been documented. The effects on heme synthesis increase in number and severity at levels greater than $40\mu\text{g/dl}$ (7).

GI tract. The GI tract is one of the first target organs lead encounters since many lead exposures are a result of ingestion (7). Symptoms and signs of acute inorganic lead exposure through ingestion or inhalation tend to present themselves gastrointestinally with cramping, colicky abdominal pain, and constipation. Nausea, vomiting, and black tarry stool may also be present (1). These symptoms usually occur at blood lead levels greater than $80\mu\text{g/dl}$ (7).

Kidneys. The major function of the kidneys is to filter substances in the bloodstream that may prove harmful to the body. Impurities, such as lead, are absorbed by the organ as blood passes through the kidneys and is excreted in urine. Chronic exposure to lead eventually alters the metabolism of the kidney by interfering with the filtering process. Kidney damage is irreversible (7).

The existence of lead nephropathy (disease of the kidneys caused by lead exposure) was firmly established by the end of the 1800s. Several concurrent observations reinforced the documentation of the relationship between lead exposure and comprised renal function. Hundreds of occupational exposure situations have been identified and the compromising health effects of lead exposure have been fully established (7).

Other indicators. Gout became associated with lead exposure during the beginning of the 18th century. It was first recognized following an epidemic of lead poisoning that resulted from ingestion of lead contaminated cider (7). Recent studies show that gout patients with renal disease have a greater chelate-provoked lead excretion than do renal patients without gout. This lends support to the relationship between chronic lead exposure and gouty nephropathy (6).

Increase in blood pressure is probably the most sensitive adverse health effect from lead exposure occurring in the adult population. An estimated increase of about 1.5 to 3.0 mmHg in

systolic blood pressure occurs for every doubling of blood lead concentration in adult males, but less than 1.0 to 2.0 mmHg for adult females (6).

Lead is classified as a 2B "possible human" carcinogen by the International Agency for Research on Cancer (IARC). The Environmental Protection Agency (EPA) assigned lead and inorganic lead compounds as B2 substances-probable human carcinogen. The EPA classification was based on numerous scientific studies and was endorsed by the EPA's Science Advisory Board (7). The evidence for carcinogenicity is adequate for animals, but inadequate in humans (6).

Lead effects the reproductive organs of both men and women. Chronic lead poisoning in men may create abnormal sperm cells and/or decrease sperm mobility. It may also cause a reduction in sex drive. Toxic effects of lead in women include sterility, abortion, and neonatal mortality and morbidity. The greatest concern is for intrauterine effects on the unborn fetus. Because of greater sensitivity of the fetus, pregnancy must be regarded as a period of increased susceptibility of lead (6).

Lead Excretion

Excretion of lead is slow over time, primarily through the kidney in urine. Lead can also be excreted via fecal excretion, sweat, and epidermal exfoliation. The half life of lead is long, estimated at 5-10 years. This varies with the intensity and duration of exposure and the ultimate body burden accumulated (7).

Body Lead Burden

Epidemiologic and experimental studies have shown that a high proportion of lead absorbed from all sources of intake is retained in the body, particularly in the skeleton and to a

lessor degree in soft tissues. The cumulative lead retention in mammals clearly exceeds the total excretion of this metal, therefore, the body lead burden (BLB) represents the total content of lead in the whole body at time t (3). The body burden of lead refers to the total amount of lead in the blood, soft tissues, and bone (7).

Since lead is a cumulative poison, an assessment of BLB could provide essential information for determining whether an increase in lead compound utilization corresponds to a higher level of pollution in air, food, etc., and a subsequent increased accumulation of lead in human tissues (3).

Lead has an intracellular distribution within the soft tissues. The removal from intracellular compartments is slow and the amount of lead retained in soft tissues contributes around five percent to the total BLB. Lead retention in bone tissue makes a significant contribution to total BLB. Lead becomes firmly bound to the bone, and its removal is extremely slow. As lead continues to accumulate in the body, the skeleton eventually accounts for more than 95 percent of the BLB (3).

II. Regulation of Lead

Lead is regulated in the nonoccupational, environmental, and occupational arenas. More often than not, federal agencies are forced to confront environment and public health issues with limited information about the potential for a toxic substance to produce a harmful effect. However, the case of lead is far different from the usual situation where policy decisions are made in the face of limited scientific data. Some of the health consequences of exposure to lead have been known since ancient times. Today, the use of lead is ubiquitous in our environment, and lead is regulated in our workplaces, air, drinking water, waste, food, and paint (4,8).

Nonoccupational

Paint

Nonoccupational regulations involving lead are primarily focused on lead-based paint. These regulations began in 1971 when Richard Nixon signed the Lead-Based Paint Poisoning Prevention Act (LBPPPA) into law. This act prohibited the use of lead-based paint (1% lead by weight) in federally assisted housing and gave authority to what was then the United States Department of Health, Education, and Welfare (now the Department of Health and Human Services, DHHS) to make grants to states and local government for detecting and treating childhood lead poisoning. This act also authorized further grants for identifying and abating lead-based paint in public housing. Under LBPPPA, the Department of Housing and Urban Development (HUD) was given authority to develop methods of abatement for lead-based paint (9).

In 1972, HUD released regulations prohibiting the use of lead-based paint in HUD-associated housing. Amendments to LBPPPA occurred in 1973 which lowered lead content allowed in paint to 0.06% unless the Consumer Product Safety Commission (CPSC) determined that a higher amount was safe. The CPSC reported 0.5% lead by weight as a safe level. These amendments directed HUD to eliminate all lead paint in HUD-assisted housing constructed before 1950 to the extent practicable. HUD issued regulations implementing the requirements in 1976 (9).

In 1977, the CPSC declared dry paint films and similar coatings with lead content in excess of 0.06% lead by weight as "lead-based paint" and as hazardous materials. The CPSC banned the sale of these paints to consumers and banned their use where consumers may have

direct access to painted surfaces. CPSC also banned products that contained or were painted with lead-based paint (9). However, the CPSC made no mandate to address the leaded paint already in housing (10).

In the 1983 *Ashton vs. Pierce* case, public housing tenants alleged that HUD's regulations were deficient for failing to include intact lead-based paint as an immediate hazard. HUD was ordered to restructure its lead-based paint programs in this precedent-setting case. In 1987, Congress amended the LBPPPA and in 1988, the Stewart B. McKinney Homeless Assistance Amendments Act amended the LBPPPA again (7).

On April 1, 1990, HUD released interim guidelines for public housing authorities to follow in order to identify and abate lead-based paint in all public and Indian housing. These guidelines represented the most comprehensive information established on testing and abating lead-based paint until the 1995 HUD guidelines released under the authority of the Residential Lead-Based Paint Hazard Reduction Act of 1992, more commonly known as Title X, included in the Housing and Community Development Act of 1992 (7).

Title X provides for a comprehensive national approach to dealing with lead-based paint in the nation's housing stock. It changes the program philosophy from total abatement to a program of abatement and in-place management of priority hazards. It allows EPA and HUD to focus on hazardous conditions rather than the mere presence of lead-based paint (8).

Title X defines paint as lead-based if it has a dry film lead mass concentration equal to or greater than 0.5 percent lead by weight (5000 ppm) or a dry film area concentration greater than or equal to 1.0 mg/cm². Title X also defines lead-based paint as a toxic substance under TSCA. Since lead-based paint is a toxic substance, other housing regulations require federal housing

authorities to abate any and all lead-based paint in federally owned or subsidized dwellings where children live or could be expected to live (10).

Actual numerical criteria for classifying paint as lead-based vary from state to state, and even from one municipality to another within a state. However, the states and localities use the 0.5% and 1.0 mg/cm² to trigger the abatement of painted surfaces that are deteriorated or directly accessible to young children. Lead-based paint inspection and abatement activities must comply with the most stringent requirements if state and local regulations conflict with federal regulations. Current regulations do not mandate occupant protection when renovation or demolition is performed involving lead-containing paints with lead concentrations below the definition of lead-based paint (10).

A significant limitation in the definition of lead-based paint is that units of mass of lead per sample mass (percentage lead) do not correspond to units of mass of lead per unit area (mg/cm²). It is always important that all lead values be reported in the same units of measurement for a given test group. This will avoid the problem of conflicting outcomes (10).

The U.S. Occupational Safety and Health Administration's new standard for protecting construction workers from lead exposures are triggered by airborne lead levels, which in turn are based on health effects data. Worker protections under the OSHA standard are not triggered by a specific lead-in-paint concentration, since there is a lack of a reliable connection between lead-in-paint concentrations and airborne lead levels and "OSHA would have no idea what health effects might be triggered by such a surface concentration". OSHA requires that respiratory protection and airborne lead monitoring be conducted when workers disturb paint with any amount of lead

in it. Worker protections are then relaxed or tightened based on the outcome of the lead dust in air testing (10).

Title X mandated that EPA issue final regulations governing risk assessment, inspection, and abatement procedures, and the training program requirements for each discipline. The EPA will institute an approval process for training sponsors and delegate that authority to individual states upon an application form to the state. The EPA must institute and monitor laboratory certification and publish a list of approved labs annually (9).

Title X mandates sellers or lessors of target housing (housing built before 1978, the year the CPSC banned the residential use of lead-based paint (11)) to provide the buyer or lessee with information about hazards associated with lead-based paint. Numerous exposure studies are mandated by Title X including a study of occupational exposure, sources of lead exposure in children, identification of dangerous lead levels, and a study of the exposures received by renovators and remodelers (9).

Several Title X requirements have already been implemented. OSHA has promulgated the interim construction standards for lead, and a public education program has begun. The EPA established a toll-free telephone number for individuals concerned about lead, and a clearinghouse was set up to distribute information on lead (9).

Title X required that more than one dozen federal agencies-including HUD, EPA, OSHA, CDC, and NIOSH-must work together in the development of mandated regulations and guidelines. This requirement was intended to prevent the development of conflicting regulations among the agencies (9). The task force released its final report in the publication entitled "Putting the Pieces Together: Controlling Lead Hazards in the Nation's Housing" (11).

Title X of the Housing and Community Development Act of 1992 amended TSCA by adding Title IV which mandates that EPA promulgate a number of regulations. These are included in Table II.

TABLE II.

EPA regulations promulgated by EPA under the requirements of
TSCA Title IV amendments

1. TSCA section 402(a) Lead based Paint Activities Training and Certification Regulations requiring EPA to promulgate regulations ensuring that individuals engaged in lead based paint activities are trained, training programs are accredited, contractors are certified, and to set standards for performing abatement activities.
2. TSCA section 404(d) Model State Program requiring EPA to establish model state programs for compliance with training and accreditation regulations, including application process and compliance monitoring.
3. TSCA section 403 Identification of Dangerous Levels of Lead requiring EPA to promulgate regulations to identify lead based paint hazards in paint, dust, and soil.
4. Section 1018 Disclosure of Information Concerning Lead upon Transfer of Residential Property requiring EPA and HUD to jointly promulgate regulations mandating that purchasers/lessees receive EPA's lead pamphlet; sellers/lessors disclose all known lead hazards to purchasers/lessees; purchasers have a 10 day period for inspection for lead based paint hazards and sales contracts contain a lead warning statement.
5. TSCA section 406(b) Renovation Information Rule requiring EPA to promulgate a rule requiring renovators and remodelers to furnish customers with a copy of EPA's brochure prior to beginning work (8).

On July 14, 1994, EPA released a "Guidance on Residential Lead Based Paint, Lead Contaminated Dust, and Lead Contaminated Soil" to address these hazards under Section 403 of the TSCA. These recommendations were issued to serve as guidance until the promulgation of the section of the 403 rule (12).

Environmental

In recognition of lead poisoning as a significant public health problem, EPA began to develop a broad based strategy in 1991 for federal government wide involvement in dealing with lead exposures (8). However, lead has been regulated under the authority of the EPA for many years through various programs.

RCRA

In 1976, Congress enacted the Resource Conservation and Recovery Act (RCRA). RCRA was the outgrowth of the Solid Waste Act of 1965 and the Resource Recovery Act of 1970. RCRA was amended in 1984 by the Hazardous and Solid Waste Amendments (HSWA) (13,14). By RCRA, Congress attempted to provide "cradle to grave" management of hazardous waste by imposing regulatory requirements upon generators, transporters of hazardous waste, and owners and operators of treatment, storage, and disposal facilities (14).

Congress defined a "hazardous waste" under subtitle C of RCRA but left it up to EPA to develop the regulatory framework that would identify those wastes. EPA prescribed a test procedure such that wastes are identified under one of several lists or by rendering characteristic responses when subjected to a test protocol. The four characteristics for hazardous waste identification are ignitability, corrosivity, reactivity, or toxicity as determined by the Toxicity Characteristics Leaching Procedure (TCLP) (14). Lead is regulated under RCRA as a characteristic waste under TCLP (8,14).

CERCLA

Since lead is included in RCRA, it goes without saying that regulations concerning lead are included in the Comprehensive Environmental Response, Compensation, and Liability Act of

1980 (CERCLA), commonly known as Superfund. CERCLA provides a system of identifying and cleaning up chemical and hazardous substances released into the air, water, groundwater, and on land. It defines "hazardous waste" by incorporating those substances listed in the Clean Air Act, RCRA, and TSCA. CERCLA established a trust fund to pay for cleaning up environmental contamination where no responsible party could be found. In 1986, CERCLA was reauthorized by congress to provide additional funding and include additional provisions (13).

SDWA

The Safe Drinking Water Act of 1974 (SDWA) was promulgated to provide protection to underground sources of drinking water. The act protects areas having an aquifer that is the sole source of water supply to that area from being contaminated, and it regulates underground injection to protect usable aquifers from contamination (14). The SDWA was amended in 1986 and included the banning of lead in public drinking water distribution systems and the limiting of the lead content of brass used for plumbing to 8% (5).

Drinking water standards have also been set by EPA at two levels. The primary standards define contaminant levels in drinking water as levels above which the water source requires treatment. These are maximum contaminant levels (MCL) and are enforceable by law. The second level of protection is based on the Maximum Contaminant Level Goals (MCLG) which are determined to be safe by toxicologic and biomedical considerations, independent of feasibility. MCL are set as close as possible to MCLG. EPA's goal (MCLG) for lead in drinking water is zero. The MCL for lead is 5 $\mu\text{g/l}$ (4).

CAA

The Clean Air Act (CAA) was originally passed in 1955 and addressed polluted air around industrial cities. It was amended in 1970 and 1977 to include National Ambient Air Quality Standards (NAAQS) that applied to some of the most common pollutants. Lead was included in that list. Amendments in 1990 increased the number of pollutants on the NAAQS list (5). Provisions in the CAA also ordered the reduction of almost all lead in gasoline during the 1970s and 1980s and completely prohibited the use of lead as a gasoline additive through the 1990 amendments. The NAAQS for lead in air the general public may breathe is $1.5 \mu\text{g}/\text{m}^3$ averaged over a calendar quarter (4).

FDA

The Food and Drug Administration (FDA) is responsible for regulating lead contamination in food. FDA's goal is less than $100 \mu\text{g}/\text{day}$ as the total lead intake by children one to five years of age (4). The quantity of lead in the United States diet has decreased markedly in recent years due to the restricted use of lead soldered side seam cans (5). Dietary intake of lead has been thought to decrease since the 1940s when estimates were 400 to $500 \mu\text{g}/\text{day}$ for U.S. populations to present levels of under $100 \mu\text{g}/\text{day}$ for adults (6). FDA estimated that about 20% of all dietary lead comes from canned food and that about two-thirds of that results from lead solder in cans. In 1979, over 90% of all food cans were lead soldered; in 1986, this figure was 20%, or less than 2 million cans. However, imported canned foods are not included in these figures and may still contain lead (4).

Occupational

OSHA

The Occupational Safety and Health Administration (OSHA) came into existence on April 28, 1971 when the Occupational Safety and Health Act of 1970 officially became effective. The Occupational Safety and Health Administration has the regulatory authority to protect workers from hazardous conditions they may experience in their workplace. The National Institute for Occupational Safety and Health (NIOSH) was established under the Occupational Safety and Health Act to undertake health studies of alleged hazardous conditions, and to develop criteria to support revisions of, or recommendations, to OSHA for new health standards (15).

To prevent the health hazards associated with lead exposure, OSHA developed an exposure standard for lead (29CFR1910.1025). This comprehensive standard specifies an 8-hour time weighted average permissible exposure limit (PEL) for lead ($50\mu\text{g}/\text{m}^3$) and an action level ($30\mu\text{g}/\text{m}^3$). OSHA mandates periodic determination of blood lead levels (PbB) for those exposed to air concentrations at or above the action level for more than 30 days per year. If the PbB level of a worker is determined to be greater than $40\mu\text{g}/100$ grams of whole blood, the worker must be notified and provided with a medical examination. If the PbB level of a worker is $60\mu\text{g}/100$ grams of whole blood, the employer is required to remove the employee from the exposure with maintenance of seniority and pay until PbB falls below $40\mu\text{g}/100$ grams of whole blood. It also established requirements for air testing, medical monitoring, respiratory protection, protective clothing, engineering controls, employee training, and hygiene facilities and practices (16).

The problem with the General Industry Lead Standard lies in the fact that not all occupational settings are covered by the regulation. Workers in construction, including lead abatement workers, are excluded from coverage. On June 3, 1993, OSHA's new interim standard for lead in the construction industry (29CFR1926.62) went into effect. It was mandated by Title X and it brings construction guidelines closer in line with OSHA's General Industry Standard (17).

III. Lead Testing Methods

Sampling

Air

The NIOSH Manual of Analytical Methods, fourth edition, lists two methods for lead analysis: Method 7105-Lead by Graphite Furnace Atomic Absorption Spectrophotometer and Method 7082-Lead by Flame Atomic Absorption Spectrophotometry. The air sampling requirements are the same for both methods. The methods suggest using a 0.8 μ m cellulose ester membrane filter, 37 mm, in a two piece cassette with a flow rate in the range of 1 to 4 liters per minute. The minimum volume is listed as 1 liter at 0.05 mg/m³ and the maximum volume is reported as 1500 liters. Two to ten field blanks should be sent to the analyzing laboratory per set of samples. The range for Method 7105 is 0.05 to 100 μ g per sample and the estimated LOD is 0.02 μ g per sample. The range for Method 7082 is 10 to 200 μ g per sample with an estimated LOD of 2.6 μ g per sample. These methods are for elemental lead and lead compounds except alkyl lead. These two methods can also be used for paint samples (18).

OSHA method ID-121, Method for the Analysis of Metal Particulate in Workplace Atmospheres by Atomic Spectrophotometry, recommends a mixed cellulose ester membrane

filter for collection of the lead sample in air. This method reports a theoretical detection limit of 0.01 $\mu\text{g/ml}$, an analytical detection limit of 0.05 $\mu\text{g/ml}$, and a sensitivity of 0.5 $\mu\text{g/ml}$ (19).

Soil

Standard protocols have not been established for measuring soil lead concentration. In the absence of standard testing protocols, a wide variety of testing protocols are in use. It should be recognized that soil lead concentrations vary both vertically and horizontally, and therefore at a given soil sampling location, highly divergent soil sampling results will be obtained based on the selection of sampling protocol (17).

Water

Water samples can be taken in accordance with standard EPA protocols or from methods reported in *Standard Methods for the Examination of Water and Wastewater*. This publication lists several methods for analyzing lead content in water and waste water. Method 3500-Pb is a dithizone colorimetric method. The dithizone method uses an acidified sample containing μg quantities of lead. The sample is mixed with ammoniacal citrate-cyanide reducing solution and extracted with dithizone in chloroform to form a cherry red lead dithizonate. The color of the solution is measured photometrically (20).

Methods 3113B Electrothermal Atomic Absorption Spectrometric Method, 3111B Atomic Absorption Spectrophotometer with direct Air-Acetylene Flame, 3130 Metals by Anodic Stripping Voltametry, and 3120B Metals by Plasma Emission Spectroscopy are also listed in this publication for the analysis of lead in water and wastewater (20).

Surface Dust

The complete field sampling and analytical method for collecting surface dust samples is contained in the HUD guidelines on lead based paint. The guidelines call for either composite or single-surface sampling. Composite sampling can reduce the total number of samples analyzed, but information on individual rooms is lost. Single-surface sampling gives room specific information, but additional samples are required (17).

When sampling for lead dust in housing, the guidelines recommend that dust samples be collected, at a minimum, from the entryway, the child's principal play area, two children's bedrooms, and the kitchen or bathroom. Within these rooms, dusts samples should be taken from the following locations: floors near friction or impact surfaces or deteriorated paint, window sills, window wells, and cabinets with deteriorated paint housing dishes, eating utensils, etc. (17).

Paint

A complete protocol for sampling both intact and defective paint can be found in the HUD guidelines on lead-based paint. In general, to collect a paint chip sample, all layers of the paint should be removed, but none of the substrate. This is usually simple for defective or deteriorating paint, but it is important to not sample only the peeling layers. A heat gun is recommended to soften layers that are still intact for easy removal. Intact paint in good condition should not be sampled if part of a risk assessment, since intact paint does not pose an immediate hazard (21). The NIOSH Manual of Analytical Methods specifies either a 0.1 g paint chip sample or a 2 cm² large paint chip sample piece for microwave digestion for lead in paint chips and other matrices (18).

Analytical Methods

Analytical methods can be broken down into three categories: analytical tests, survey tests, and screening tests.

Analytical Tests

For the purpose of this discussion, analytical test will be defined as those that have a very high level of element specificity, have results that are highly accurate and highly precise, have results generated using a documented process with standard operating procedures, and have a fully documented and executed procedure for instrument calibration (10). The most commonly found instruments used to conduct analytical testing for lead are listed in Table III.

TABLE III.

Instruments Used to Conduct Analytical Testing for Lead

1.	Atomic absorption (AA) and graphite furnace atomic absorption (GFAA) spectrometer. These are the most commonly used instrument types. A flame (AA) or a furnace (GFAA) may be used as the excitation source.
2.	Inductively coupled plasma spectrometer (ICP). ICP is faster than the AA or GFAA. It can either measure emitted light in the atomic emission spectroscopy version (ICP-AES), or it can separate and quantify individual atomic isotopes in the mass spectrometer version (ICP-MS).
3.	X-ray fluorescence analyzer (XRF). XRF is available as a laboratory instrument, but in less common use. It irradiates samples with gamma radiation and then detects and measures the emitted x-rays.
4.	Ultraviolet/visible spectrometer. This is not very common today. It measures the light absorbed by lead solutions at a specific frequency/wavelength (spectroscopic analysis). Compounds that form colored solutions in the presence of lead may also be used and the light absorbed is then measured at a specific frequency/wavelength as before (colorimetric analysis).
5.	Voltametric cell. Anodic stripping voltametry (ASV) is in common use for blood analysis. It deposits metals in blood onto an electrode and then selectively and quantitatively strips off the lead (10).

The data generated from analytical tests are usually the most expensive. However, they are considered the “gold standard” if conducted in a qualified third-party laboratory and are admissible as evidence in a court of law (10).

Survey Tests

Survey testing for lead is conducted in the field and yields a numerical result. Various measurement techniques can be used to conduct survey testing. ASV and colorimetric instruments are available for use as survey instruments, but their use in the field is rare. The most common lead survey testing instrument is the field-portable XRF (10).

The XRF uses a gamma emitter to ionize lead atoms in a paint sample. The ionized lead atoms then return to a normal state and emit x-rays in proportion to the amount of lead present. The XRF determines the amount of lead present by detecting and quantifying the emitted x-rays. The lead concentration is reported in milligrams of lead per square centimeter of surface (mg/cm^2). The data generated from the XRF is used to determine where analytical testing is needed, or where the lead content is such that no further testing is required. There are several different kinds of XRF instruments, and the LODs and maximum quantifiable amounts of lead vary among them. For instance, one analyzer will indicate a maximum of $10 \text{ mg}/\text{cm}^2$ while another instrument has the ability to quantify up to $100 \text{ mg}/\text{cm}^2$. What matters most when surveying a site for the presence of lead-based paint is that the amount of lead in the paint is significantly greater than the regulatory limit of $1.0 \text{ mg}/\text{cm}^2$ for federally funded public housing (10).

Screening Tests

Screening tests are very sensitive to the presence of lead and respond to a yes/no question about lead content. They are highly precise around a transition or endpoint. However, they allow for verification of only one side of the yes/no response (10).

Screening test results can be evaluated in a two by two statistical table. A result in which the screening test detects lead (by color change) at the percent lead by weight detection limit would be represented by a positive result. If the screening test fails to detect the presence of lead (by no color change) at the percent lead by weight detection limit, the result would be indicated as a negative result.

Two kinds of errors can occur when evaluating the screening tests, false negatives and false positives. A false negative result occurs when the test kit fails to detect the presence of lead in paint at or above the percent lead by weight detection limit, but in fact, the paint is shown by laboratory analysis to contain lead equal to or greater than the detection limit. Similarly, a false positive result occurs when the test kit detects lead equal to or greater than the lead by weight detection limit, but laboratory analysis shows that the paint does not contain lead equal to or greater than the detection limit (22).

Two aspects of the objective evaluation of screening tests are important: 1) accuracy and 2) precision or variability. Two indices evaluate the accuracy of a test. These are sensitivity and specificity. These indices can be determined by administering the screening tests on one group of paint samples considered to be lead-based paint samples (by the 0.5% lead by weight federal threshold) and to another group of samples considered not to be lead-based paint and then comparing the results. The sensitivity is defined as the ability of a test to give a positive result

when the sample tested is truly a lead-based paint. Specificity is the ability of the test to give a negative result when the sample tested is not a lead-based paint (23).

Table IV shows the two by two table and the relationships between false negative, false positive, sensitivity, and specificity.

TABLE IV.

Two by Two Table Showing False Negative, False Positive,
Sensitivity, and Specificity

Test or Examination	Lead Present (Pb-based paint)	No lead present (at detection limit)
Positive Result	A (true positive)	B (beta error, β) (false positive)
Negative Result	C (alpha error, α) (false negative)	D (true negative)
Totals	A + C	B + D

Sensitivity (in percent) = $A/(A+C) \times 100$

Specificity (in percent) = $D/(B+D) \times 100$ (27)

Variability of the screening test evaluation exists in interpretation. This can be Interindividual, representing inconsistency of interpretation among different readers of the screening test results, or Intraindividual, reflecting the failure of a reader to be consistent with herself in independent interpretations of the same set of results (23).

Almost all screening tests for lead are colorimetric tests. They most commonly use sulfide or rhodizonate to screen for the presence of lead (10). Screening tests detect the presence of lead in paint by a chemical reaction that occurs when chemicals in the kit are exposed to lead. This reaction causes a color change to occur if lead is present in the paint (22). The chemistry of

the colorimetric tests can be adjusted to answer if lead is above the regulatory concentration. These tests are very sensitive to the presence of lead and are rapid in comparison to the other methods available, but do not quantify the amount of lead present. Proprietary tests are also on the market for use as colorimetric screening tests (10).

Chemical colorimetric tests can be destructive or indestructive depending on the specific test and manufacture. Some tests involve cutting the tested surfaces with a utility knife and applying the chemical to exposed underlying layer of paint. Other tests require removing a portion of the paint and performing the test away from the painted surface. Still others test only the intact surface of the paint (10).

Interferences can occur with the colorimetric tests and need to be considered. For example, sodium sulfide will give positives when used on painted steel surfaces (iron sulfide is black). The color change may also be difficult to detect if the paint surface is red or black, depending on the colorimetric test used. However, the screening colorimetric tests are the least expensive tests to conduct (10).

The limits of detection for screening test kits vary with individual kits and manufacturers. These limits are based on the ability of the kits to detect lead in paint down to a specified percent lead by weight. For example, several of the kits were reported to detect lead in paint down to 0.5% lead by weight 100 percent of the time (25).

Rhodizonate

The warning color for the rhodizonate kits is pink (26). Rhodizonate and lead result in a pink/red precipitate of lead rhodizonate (10). The color change that occurs is easy to see unless the paint itself is red or pink (26). Rhodizonate has been recommended by manufacturers to

replace sodium sulfide kits which may give false positives for other types of metals as well as some latex paints (27).

Sodium Sulfide

Sodium Sulfide kits indicate lead in paint yielding a gray to black color. Sulfide and lead result in a black precipitate of lead sulfide. It may be hard to see a positive reaction from sodium sulfide on dark paint (26). Sodium sulfide kits may give false positives for other types of metals as well as some latex paints. The safety of the sodium sulfide kits for use by the general public has been questioned due to the fact that the sodium sulfide substance is very toxic. If the substance is not handled carefully and disposed of properly, it can give off a sulfide gas that is flammable (27).

Sayre and Wilson reported the use of sodium sulfide for testing lead in 1970. Their report explained the method of testing for lead in paint through the precipitation of lead as an insoluble black sulfide through the lead and sodium sulfide reaction. The report also stated that black sulfides could be formed by iron, nickel, mercury, molybdenum, and copper. The quantities of these metals in paints were thought to be low enough not to cause interference. However, it was suggested that testing of paint-covered metal surfaces that may contain iron or copper must be done with care to avoid precipitation of these two metals (28).

Proprietary

Proprietary chemistry is utilized in some screening tests. Although the exact chemistry is not known, the reaction can be inferred from the color of the change that takes place.

Previous Evaluations

EPA

In May 1995, the EPA released its report entitled "A Field Test of Lead- Based Paint Testing Technologies". The study described in the report was funded by the EPA and HUD. The study was managed by the EPA and was conducted collaboratively by two organizations under contract to the EPA, Midwest Research Institute and QuanTech (22).

The impetus for this study came from the passage of Title X of the Residential Lead Based Paint Hazard Reduction Act of 1992. This Act mandated that the federal government establish guidelines for lead-based paint hazard evaluation and reduction. This study was designed to respond to that mandate and focused on two field testing technologies: field portable XRF instruments and chemical screening test kits. Six XRF instruments and six chemical test kits were evaluated. A pilot study was conducted during March and April 1993 in Louisville, Kentucky, and the full study was conducted from July through October 1993 in Denver, Colorado and Philadelphia, Pennsylvania. Paint from a total of 1290 locations in 22 housing units was tested. The tested locations represent a variety of paint types, substrate, architectural designs, and lead levels in paint. The study tested units from both multifamily housing units, where units tend to be quite similar to each other, and from single-family homes (22).

The overall study goal was to collect information about field measurement methodologies sufficient to allow EPA and HUD to establish guidance and protocols for lead hazard identification and evaluation. Consistency, real world comparability, and quality control were concerns of the field testing portion of the study. To ensure consistency, testing was standardized as much as possible. A template was designed for test locations throughout the

study housing units, and the different measurement techniques were systematically assigned to consistent test locations within the template (22).

At each test location, chemical test kits were used first. The individuals who did the field testing were selected to represent typical homeowners who might purchase test kits for their personal use. They had no specific scientific background or prior training. The test kits were rotated among the testers during the study. After each tester completed a test location, the used area of the template was covered to prevent subsequent testers from observing the results obtained by other testers. One of the test kits was an exception to this. The Massachusetts state-approved kit was only used by state-certified inspectors. For this kit, a state-certified inspector was brought in and the kit was not included in the kit rotation.

It was expected that the results of the pilot study would be similar for kits based on similar chemistry, that is, rhodizonate or sodium sulfide, so that fewer kits would need to be included in the full study. However, the test results were not similar for kits utilizing similar chemistry, so the same six kits were included in the full study (22).

After test kits were tested, paint samples were taken. Paint was removed from specified locations on the template and sent to a laboratory for spectroscopic analysis by a modified NIOSH method 7082. The results of the screening tests were compared to these lead concentrations (22).

The laboratory analysis provided two key results. First, laboratory analysis results exhibited a wide range of lead levels. Second, lead levels appeared to vary significantly across the same painted surface (22).

Approximately 20% of the samples analyzed in this study were equal to or greater than the federal threshold of 1.0 mg/cm², while 29% were equal to or greater than the federal threshold of 0.5% lead. A rough numerical equivalence between results reported as mass of lead per unit area (mg/cm²) and as percent lead by weight (%) was found in the study data. A regression plot of results expressed in percent lead by weight versus mass of lead per unit area using a logarithmic scale showed good agreement between the two types of measurement units ($R^2 = 0.91$), with the following relationship:

PERCENT LEAD = 0.91 X (AREA LEAD)^{0.85}, where PERCENT LEAD = percent lead by weight (%) and AREA LEAD = mass of lead per unit area (mg/cm²).

This relationship suggests that 0.5% lead is roughly equivalent to 0.5 mg/cm² lead, while 1.0 mg/cm² lead is roughly equivalent to 1.0% lead. This demonstrates that the threshold of 1.0 mg/cm² lead is typically less stringent than 0.5% lead (22).

The kits used in the study were from five different manufacturers: three rhodizonate based kits, two sodium sulfide based kits, and one proprietary kit. The rhodizonate kits included were LeadCheck™ and the sanding and coring versions of Lead Alert™. The sodium sulfide kits were Lead Detective™ and a Massachusetts state-approved kit. The Lead Zone™ kit was the proprietary kit (22).

Table V presents the overall false positive and false negative rates for test kits compared to laboratory analytical results using the 1.0 mg/cm² threshold and the 0.5% threshold (22).

TABLE V.

Overall False Positive and False Negative Rates for Test Kits
Compared to Laboratory Analytical Results Using the
1.0 mg/cm² and 0.5% Threshold

Test Kit	False Positive Percentage (1.0 mg/cm ²)	False Positive Percentage (0.5%)	False Negative Percentage (1.0 mg/cm ²)	False Negative Percentage (0.5%)
Lead Check™	46%	42%	6%	11%
Lead Alert™: Coring	15%	11%	24%	36%
Lead Alert™: Sanding	9%	10%	53%	67%
Lead Detective™	36%	32%	23%	27%
Lead Zone™	28%	25%	14%	25%
State Sodium Sulfide	65%	62%	1%	6%

(22).

None of the test kits used in this study demonstrated low rates of both false positive and false negative results when compared to laboratory analytical results using the federal thresholds, 1.0 mg/cm² and 0.5%. The false positive and false negative rates presented in Table V exclude results of tests on painted plaster substrates for the Lead Alert™ kit since the manufacturer does not recommend use of these kits on plaster. It was noted that these classification results apply strictly to the set of samples and kits in this study, and classification results for a different set of samples or kits could be different (22).

The substrate underlying the paint was shown to affect false positive and false negative rates for test kits. For the LeadCheck™ kit, the false positive rate on drywall was considerably lower than on the other five substrates (brick, concrete, metal, plaster, and wood) for both federal thresholds. False negative rates in mg/cm² on concrete and plaster were higher than on the other substrates. For percent by weight, false negative rates were higher on concrete, drywall, metal, and plaster than on brick and wood. Some of these differences in false negative rates may be caused by sulfates found in plaster dust, gypsum, and stucco. The LeadCheck™ kit includes a confirmation procedure to guard against false negative results caused by sulfates (22).

The Lead Alert™: Coring and Sanding had very similar patterns of response. The manufacturer states that this kit is prone to negative interferences from gypsum and plaster dust. High false negative rates were observed on plaster and drywall for percent lead by weight measurements and on plaster for mg/cm² measurements. However, the sample size for drywall was very small. False negative rates on brick were much lower than on the other substrates for both types of measurements. For mg/cm² measurements, false positive rates were lowest on plaster and drywall substrates, and highest on brick. For percent lead by weight measurements, false positive rates were lowest on drywall, plaster, and wood substrates, and highest on brick (22).

The manufacturer of The Lead Detective™ does not recommend use on metal, but does recommend application on wood, drywall, and plaster. False positive rates were consistent for both types of measurements on all substrates except brick, which had a higher false positive rate. False negative rates were lowest on wood and highest on brick and concrete substrates. Thus, this kit did not perform much better on wood, plaster, and drywall than on metal so that the

manufacturer's recommendations were not shown to be of concern in this study (22).

The instructions in the Lead Zone™ kit only mention testing on wood and metal. False positive rates were the same on all substrates for both types of measurements. False negative rates were lower on brick, wood, and concrete, and higher on the other substrates. The false negative rate on metal was the highest of all substrates using percent lead by weight measurements. The manufacturer's instructions do not include mention of using this kit on substrates where it performed similarly to its performance on wood, but do mention its use on metal, where its false negative rate was substantially larger than its false negative rate on wood (22).

The State Sodium Sulfide kit contained instructions with a caution not to test directly on metal. For metal substrates, a paint chip can be removed and tested separate from the substrate. This kit had very high false positive rates for both types of measurements on all substrates except drywall. False negative rates were low on all substrates for mg/cm² measurements. For percent lead by weight measurements, this kit had higher false negative rates on metal, plaster, and drywall than on the other substrates (22).

In addition to the descriptive statistics on false positive and false negative rates, estimates of operating characteristic (OC) curves of the test kits were provided. The OC curves show the probability that the test kit gives a positive reading on paint having true lead concentration at some fixed level. It is a function of the true lead concentration:

$$OC(t) = \text{Prob}(\text{test kit positive} \mid \text{true Pb} = t)$$

Test kit performance was evaluated relative to a standard of 1.0 mg/cm² lead on the painted surface (22).

Mathematical representation of an OC curve takes the form of a statistical model. Two aspects of an OC curve are of particular interest, the 50% point of the OC curve (the lead level at which a 50% chance of a positive result is obtained), and the probability of observing a positive result at a true lead level of 1.0 mg/cm².

An enhanced logistic model was used to define the OC curve. The model has four parameters, denoted a, b, c, and d, which together describe the model completely. The model was fit to the data by substituting estimated values for these parameters, using the method of nonlinear least squares (NLS) (22).

The enhanced logistic model was described as a function of the natural logarithm of the ICP measurement, rather than the ICP measurement itself. Referring to the logarithm was preferred, because the ICP levels obtained in the study were highly concentrated at lower values. Attributes of the OC curve were more readily apparent when graphed against the logarithm (22).

In its fullest mathematical generality an OC curve can be any function of the logarithm of lead concentration with values between 0 and 1. The class was restricted further to functions that were nondecreasing because higher lead levels should not indicate smaller probabilities of observing a positive test kit result. The nonparametric technique known as monotone regression was used to derive an estimate of the OC curve, subject to the constraint that it be nondecreasing in a way that does not restrict it to a specified functional form. The estimate was plotted with the OC curve derived from the enhanced logistic model to give a graphical assessment of how well the model fit the data. Quantities such as probabilities and 50% points could be estimated from the enhanced logistic model to assess model fit. Because the monotone regression is a step function, these estimates may not be uniquely defined, in which case the middle of the range of

possible candidates was reported (22).

Another simple graphical assessment of the model-estimated OC curve was done by plotting the running mean against the log (ICP) measurements. The running mean was obtained at a point $\log(\text{ICP}) = t$ by averaging zeros (for negatives) and ones (for positives) for a small subset of the data having log (ICP) close to t . Unlike monotone regression, the running mean is not designed to be a nondecreasing function of the lead level. Its virtue resides in its ability to graphically demonstrate where this assumption may be violated (22).

OC curves were constructed for each of the test kits by substrate. From these OC curves, the 50% point of the OC curve and the estimated probability of observing a positive result at a true lead level of 1.0 mg/cm^2 were determined. The last quantity is also referred to as the threshold probability (22).

Figure 1. illustrates the performance of an “ideal” test kit. The following feature highlight this as an ideal case:

- The model, monotone regression, and running mean are in close agreement.
- The probability of a positive result approaches zero as the lead level diminishes, and approaches one as the lead level increases.
- The transition from low to high probabilities is sharp, as indicated by the steepness of the plotted curves.
- The transition from low to high probabilities occurs near a lead level of 1.0 mg/cm^2 .

The fact that the three curves are in close agreement indicates that the model was an appropriate choice for describing test kit performance. None of the test kits evaluated in the study were able to emulate the performance of the ideal case in all respects.

Figure 2. illustrates characteristics of nonoptimal test kit performance observed with the Lead Check™ kit on wood substrate.

Figure 1. Ideal OC curve

Figure 2. Actual OC curve for Lead Check™ on Wood substrate

High levels of lead were not always detected with complete certainty using test kits. The statistical model estimated the limiting probability of a positive test kit result at high levels of lead using the laboratory ICP spectroscopic results reported in mg/cm² units. In number of cases, the limiting probability was much lower than the desired value of 100%. This occurred for four of the six kits: Lead Alert™: Coring on metal; Lead Alert™: Sanding on concrete, metal, and wood; Lead Detective™ on concrete, metal, and plaster; and Lead Zone™ on plaster (22).

Estimates of the limiting probability of a positive result as the lead level in the paint sample approached zero using the laboratory ICP spectroscopic results were provided and reported in mg/cm² units. It would be desirable for the limiting probability to be zero; otherwise, the kit would produce some positive results even for paint samples with very low lead levels. However, every kit exhibited a non-zero limiting probability of a positive result on at least one substrate. This occurred on metal substrates for all six kits. With the sodium sulfide kits, Lead Detective™ and State Sodium Sulfide, most substrates had a non-zero limiting probability of a positive result. For the other four test kits, limiting probabilities of a positive result equaled or exceeded 20% for LeadCheck™ on metal and plaster, Lead Alert™: Coring on brick, and Lead Zone™ on concrete. For LeadCheck™, Lead Detective™ and State Sodium Sulfide, limiting probabilities for the wood substrate were positive (22).

The probability of a positive test kit result at 1.0 mg/cm² and 0.5% for the site kits are shown in Table VI. Considerable variation among results for each kit and each substrate is seen the table.

TABLE VI.

Probability of a Positive Test Kit Result at 1.0 mg/cm² Lead and 0.5% Lead

	Brick		Concrete		Drywall		Metal		Plaster		Wood	
Test Kit	1.0	0.5%	1.0	0.5%	1.0	0.5%	1.0	0.5%	1.0	0.5%	1.0	0.5%
LeadCheck™	0.95	0.95	0.69	0.68	0.49	0.48	0.93	0.62	0.69	0.68	0.91	0.83
Lead Alert™:Coring	0.93	0.73	0.27	0.23	N/A	N/A	0.66	0.26	N/A	N/A	0.57	0.28
Lead Alert™:Sanding	N/A	N/A	0.5	0.13	N/A	N/A	0.39	0.05	N/A	N/A	0.02	0.03
Lead Detective™	0.81	0.80	0.58	0.55	0.34	0.31	0.74	0.43	0.51	0.46	0.78	0.58
Lead Zone™	0.82	0.81	0.27	0.51	0.64	0.55	0.59	0.19	0.55	0.53	0.8	0.62
State Sodium Sulfide	0.99	0.998	0.95	0.93	0.68	0.59	0.94	0.83	0.95	0.91	0.95	0.87

(22).

As noted earlier, the 0.5% lead level is a more stringent Federal threshold than 1.0 mg/cm² given that 0.5% lead is roughly equivalent to 0.5 mg/cm² lead. Therefore, the probability of a positive test kit result would be expected to be larger at the 1.0 mg/cm² level than at the 0.5 % level since higher lead levels should not indicate smaller probabilities of observing a positive test kit result. However, the probabilities for the two thresholds are very close in most cases. The OC curves for the test kits demonstrate this by the steepness of the plotted curves between 0.5 and 1 mg/cm².

The lead levels in mg/cm² and percent lead by weight at which there was a 50% chance of the occurrence of a positive test kit result are shown in Table VII. There was significant variation in 50% probability levels for both different kits used on the same substrate and the same kit used on different substrates. The only exception was the state sodium sulfide kit which

reached a 50 % probability of a positive result at low lead levels on all substrates for both types of measurements (22).

TABLE VII.

Lead Level in mg/cm² and % Lead by Weight at which there is a 50% Probability
of a Positive Test Kit Result

	Brick		Concrete		Drywall		Metal		Plaster		Wood	
Test Kit	mg/cm ²	%	mg/cm ²	%	mg/cm ²	%	mg/cm ²	%	mg/cm ²	%	mg/cm ²	%
LeadCheck™	0.02	0.02	0.19	0.16	1.14	0.56	0.34	0.32	0.13	0.14	0.03	0.07
Lead Alert™:Coring	0.33	0.13	1.84	1.14	N/A	N/A	0.65	1.09	N/A	N/A	0.77	0.97
Lead Alert™:Sanding	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1.24	1.68
Lead Detective™	0.05	0.01	0.60	0.33	N/A	N/A	0.55	0.63	0.98	0.58	0.20	1.36
Lead Zone™	0.08	0.07	1.38	0.49	0.31	0.35	0.82	1.03	0.71	0.44	0.15	0.26
State Sodium Sulfide	0.01	0.01	0.01	0.01	0.08	0.13	0.08	0.08	0.02	0.02	0.04	0.09

(22).

The lead levels at which there is a 50% probability of a positive test kit result should be essentially the same in mg/cm² and % lead by weight since % lead by weight is roughly equivalent to mg/cm² lead. Table VII. shows that there is some discrepancy between the results. These differences are related to the difficulty of removing a paint-chip sample from the substrate, and the corresponding potential for including pieces of the substrate in the sample. Unless the substrate in the sample contains as much or more lead as the paint itself (an unlikely occurrence), the percent by weight values reported by the laboratory will be lower than if no substrate is

included in the sample. Substrate inclusion will generally have a much smaller effect on the reported mg/cm² values. Brick and concrete were especially prone to substrate inclusion. Substrate inclusion was fairly common with soft plaster samples, particularly when dealing with plaster in poor condition. Substrate was sometimes included with wood and drywall samples, but this was less important since wood and drywall paper are much lighter than the other substrates. Clean samples were generally the rule with metal. These effects are shown in Table VII for the various substrates (22).

The primary result of the test kit evaluation was that they varied widely in their performance in classifying paint against either the 1.0 mg/cm² or 0.5% Federal threshold. The results of the study showed that the probability of a positive classification when the sample's lead level was equal to the Federal thresholds varied depending on the kit and equal to the Federal thresholds varied depending on the kit and substrate and that high levels of lead would not always be detected by some test kits. Furthermore, there were numerous cases of positive test results at lead levels well below the Federal thresholds. No single kit achieved a low rate of both false positive and false negative results. Two out of the six kits tested were prone to false negative results. The other four kits had a tendency to produce false positive results, even at levels well below Federal thresholds. The overall conclusion concerning the use of the chemical test kits was that the test kits should not be used for lead paint testing (22).

Further, the performance of the test kits varied with different types of substrates. Most kits usually produced a positive result on a least one substrate, even for very low lead levels. This suggests positive interferences with the chemicals in the kits. On the other hand, some test kits demonstrated negative interferences on some substrates, as indicated by not always giving a

positive result for high levels of lead (22).

Consumer Reports

The July 1995 issue of *Consumer Reports* contained an evaluation of lead test kits in the article "Lead in Paint: Test Kits". *Consumer Reports* purchased eight lead paint testing kits that are typically designed for consumer use on the open market without revealing who purchased the kits or that they were to be used in a battery of testing studies. Paint was premixed with varying, and known, amounts of lead present which was then applied to wooden surfaces before the lead paint test kits were used. Results of the screening tests were compared to the known lead concentration (27). The results of the *Consumer Reports* evaluation are shown in Figure 3.

Within type, listed in order of increasing price

Product	Cost	Tests per kit	Sensitive down to ¹	Convenience	Comments
TEST-AT-HOME-KITS					
Lead Zone	\$5	6	5.0 percent	Very easy to use. Results in 5 minutes or less. Can run check test.	Other uses: dishes, ceramics, crystal, soil, sand.
Acc-U-Test	7	Many ²	0.05	Very easy to use. Results in 5 minutes or less.	Dark paint can mask results. Alternate method for dark paint takes 24 hours. Other uses: pottery, household dust.
Know Lead	15	4	0.5	Very easy to use. Results in 5 minutes or less. Can run check test.	Other uses: dinnerware, ceramics, glassware, toys, soldered cans, plumbing.
LeadCheck Swabs	18	8	0.5	Very easy to use. Results in 5 minutes or less. Can run check test.	Red paint can mask results. Not for gypsum (sheetrock), stucco, plaster dust. Other uses: household dust, soil, solder, crystal, ceramics.
The Lead Detective	30	Many ²	0.05	Very easy to use. Results in 5 minutes or less. Can run check test.	Dark paint can mask results. Not for iron and copper, painted metal. Other use: pottery.
Lead Solutions	30	5	5.0	More steps and longer wait than with others.	Use solution within 48-72 hours. Other uses: soil, household dust, plumbing.
Merck EM Quant Pb++ 10077	73	100	5.0	Very easy to use. Results in 5 minutes or less.	Other uses: water, vehicle exhaust (to detect presence of leaded gas).
MAIL-ORDER LAB-TEST KITS					
Clean Water	20 ³	1	0.05	Turnaround time about 10 days	—
Home Diagnostics #402	20 ³	1	4	Unacceptably long turnaround time	—

¹ Reflects maximum sensitivity when applied to hardboard panels coated with multiple layers of leaded and unleaded paint.

² The solution comes in a bottle with dropper. Number of uses varies.

³ Not including postage.

⁴ Complete results had not reached us five weeks after samples were sent.

One to avoid One test-at-home kit we tested, the Sensidyne Lead Alert Professional All-in-One (\$62), is not rated and cannot be recommended. Several samples failed to detect lead levels as high as 5 percent.

Figure 3. *Consumer Reports* Rating Chart (29)

The rating chart reports “maximum sensitivities (of the test kits)” in the “sensitive down to” column. It is unclear how *Consumer Reports* defines “maximum sensitivity”. It is assumed that “maximum sensitivity” is defined as being equal to a 100% probability of a positive response. For example, the Lead Zone kit would have a 100% probability of a positive response at the 5.0% lead by weight level.

The report stated the following information about some of the test kits: “Two kits did detect lead at low levels, Acc-U-Test™ and the Lead Detective™. They are good on light paint. For darker paint, Know Lead™ or Lead Check™ could be used. The Sensidyne Lead Alert Professional All-In-One™ kit could not be recommended due to the fact that it would not give accurate results even when the instructions were followed precisely” (29).

Pace Environ’s Lead Alert Professional All-In-One™ kit singled out in *Consumers Reports* is distributed by Sensidyne™. It was singled out as unreliable because it failed to detect lead present in paint at levels as high as five percent. L. Graham Best, Jr., executive vice president of Pace Environs, Inc. released a statement to *Lead Detection and Abatement Contractor* that Pace Environs was “very surprised that analysts could not get accurate results even when instructions were followed closely”. Best said that *Consumer Reports* has recommended the same Lead Alert™ product by the Frandon™ brand name as an acceptable product in previous articles. Best added that the Sensidyne™ product was identical to the Frandon™ product with the exception of the instruction circular and graphics (27).

Consumer Reports was also questioned about recommending the use of sodium sulfide kits. Several lead test kit manufacturers do not recommend sodium sulfides because it can give false positives for other types of metals as well as some latex paints. Other concerns surrounding

the recommendations of sodium sulfides include the fact that they are very toxic and can give off a flammable sulfide gas if not handled and disposed of properly (27).

Eight chemical test kits were examined and it was found that "most 'test-at-home kits' clearly indicated paint with high lead levels if instructions were closely followed and every layer of paint was exposed".

Lead Check

The distributor of the Lead Check™ test kit, Hybrivet Systems, Inc. conducted a field study to determine the effectiveness of field tests for the detection of lead in paint. Ninety-six sites were used to evaluate the performance of three field lead testing methods, Lead Check™ Swabs, XRF, and sodium sulfide (Lead Check™ I). Ten test sites were selected from each of ten houses in the Boston area. The sites were selected to include a variety of substrates, varied paint condition and histories, and varied test situations (30).

A Massachusetts Licensed Inspector analyzed all surfaces by each method in triplicate in the field. A paint chip was taken and submitted for AAS at a licensed and certified analytical laboratory at each site. The AAS value was taken as the standard, reference value for each site. The other results were then compared to this standard (30).

The results of the study were analyzed by the author using the McNemar's test for significance of changes. The null hypothesis was rejected and the alternate hypothesis was accepted concluding that the test kit results were not equal to the AAS results (31). Even though the data was rejected by the McNemar test, it is important to point out that the Lead Check™ Swabs indicated a lead hazard in 100% of the samples for AAS results indicating the presence of lead at 0.5% (the lead abatement level). The Lead Check™ Swabs gave no false negative results

for AAS results indicating levels of lead between 0.1 and 0.5% where lead was present but below the abatement level. For the AAS results indicating less than 0.1% lead, the Lead Check™ Swabs indicated the presence of lead in three sites. These sites had been previously abated. Pink color developed clearly on the substrate and not on the paint (30).

Hybrivet Systems, Inc. came to the conclusion that the Lead Check™ Swabs perform effectively as a field test to screen for hazardous levels of lead. In this study, Lead Check™ Swabs correctly identified the presence of lead above the 0.5% abatement guideline in 100% of the sites and gave no false negative results (30).

Comparison of Results

Consumer Reports was contacted to request a complete description of the study methodology, the sample size used, and a printout of test results that would allow calculation of sensitivity, specificity, false positives, and false negatives. *Consumer Reports* responded that they could not assist with this request. Due to the lack of information provided by the *Consumer Reports* article, it was difficult to compare this report and the EPA report directly.

There were some major differences in the way that the two studies were performed. The *Consumer Reports* study used paint with known amounts of lead premixed in it, and the analyzers knew what the results should have indicated. It also seemed that the analyzers had a scientific background, which could have influenced their observations (27). The EPA study used actual lead paint present in housing, and the analyzers did not know what results to expect. The analyzers in the EPA study had no scientific background (22). *Consumer Reports* only tested the test kits on wood substrate. The EPA study tested the kits on six different substrates: brick, concrete, drywall, metal, plaster, and wood (22). *Consumer Reports* concluded that, with the

exception of one brand, the test kits worked "pretty much as expected" (27). The EPA report concluded that "test kits should not be used for lead paint testing" (22).

Consumer Reports reached different conclusions than the EPA concerning the use of chemical lead test kits. *Consumer Reports* recommendation of the kits was based on their measurement of "maximum sensitivity". If "maximum sensitivity" is defined as being equal to a 100% probability of a positive response, there is a discrepancy between *Consumer Reports* results and those reported in the EPA study. For the Lead Zone™ kit, *Consumer Reports* reports a "maximum sensitivity" of 5.0%. From the OC curve reported in the EPA study for the Lead Zone™ kit on wood substrate, the probability of a positive response is approximately 90% at 5.0% lead by weight. This is the closest agreement for a kit between the two studies. For the Lead Detective™, *Consumer Reports* reports a "maximum sensitivity" of 0.05%. From the OC curve reported in the EPA study for the Lead Detective™ kit on wood substrate, the probability of a positive response is approximately 30% at 0.05% lead by weight. For Lead Check™, *Consumer Reports* reports a "maximum sensitivity" of 0.5%. From the OC curve reported in the EPA study for the Lead Check™ kit on wood substrate, the probability of a positive response is approximately 85% at 0.5% lead by weight. The EPA OC curves rarely indicated a 100% probability of a positive response for any of the test kits (22, 27).

III. Purpose

The purpose of this study follows:

To repeat the *Consumer Reports* analysis of commercially available chemical test kits on wood boards painted with paint containing lead in varying percent lead by weight concentrations

within the range identified in the EPA study, and subjecting these results to the descriptive analysis performed in the EPA study.

Statement of Hypothesis

The null hypotheses follow:

Ho: The results of the presence of lead as determined by the screening test kits will be positive if the actual lead content present in the paint applied to the wood boards is equal to or greater than the manufacturer stated detection limit of the screening test or the Federal threshold of 0.5% lead by weight, or the results of the presence of lead as determined by the screening test kits will be negative if the actual lead content present in the paint applied to the wood boards is less than the manufacturer stated detection limit of the screening test or the Federal threshold of 0.5% lead by weight; the specificity and sensitivity of the screening tests will be equal to one.

The alternative hypotheses follow:

Ha: The results of the presence of lead as determined by the screening test kits will be negative if the actual lead content present in the paint applied to the wood boards is equal to or greater than the manufacturer stated detection limit of the screening test or the Federal threshold of 0.5% lead by weight, or the results of the presence of lead as determined by the screening test kits will be positive if the actual lead content present in the paint applied to the wood boards is less than the manufacturer stated detection limit of the screening test or the Federal threshold of 0.5% lead by weight; the specificity and sensitivity of the screening tests will not equal one.

IV. Materials and Methods

Test Kits

Three chemical screening test kits were analyzed. All three of the kits were analyzed in both the *Consumer Reports* and EPA studies. These kits were the LeadCheck™ swabs rhodizonate kit, The Lead Detective™ sodium sulfide kit, and the Lead Zone™ proprietary kit.

The kits are sensitive down to varying percentages of lead by weight. LeadCheck™ swabs are reported by the manufacturer as accurate 100% of the time down to 0.5% lead by weight, but the swabs will detect as low as 0.2% lead by weight (25,30). The EPA study reported the lead level at which a 50% chance of a positive result is obtained for the LeadCheck™ swabs on wood substrate as 0.113%. This EPA value is much lower than the manufacturer detection limit, and would suggest a large number of false positives (22). The Lead Detective™ manufacturer reported accurate determination 100% of the time at 1.0% lead by weight, but mentioned that one could extrapolate from 1.0% down to 0.5% lead by weight based on a gray scale included with the package. The Lead Detective™ manufacturer also stated that this kit is not for homeowners; users of this kit should be state-certified in lead testing (32). The lead level at which a 50% chance of a positive result is obtained for the Lead Detective™ was reported in the EPA study as 0.54% (22). The information provided with the Lead Zone™ kit stated a limit of detection at 5 ppm or 0.0005% lead by weight (33). The EPA study gave a lead level at which a 50% chance of a positive result is obtained of 0.42% for the Lead Zone™ kit. This EPA level is much greater than the manufacturer detection limit (22).

The operating characteristic curves for the three kits on wood substrate as reported in the EPA study are shown in Figures 4, 5, and 6. These curves show the 50% point in mg/cm², but

for the purpose of comparison, these values were converted above to % lead by weight using the conversion formula for wood substrate reported in the EPA study. This conversion formula is given by: $\log(\%Pb) = 0.86 \log(\text{mg/cm}^2) + 0.34$. Ideally, the 50% point would occur at a value just a little less than the critical value (22).

Figure 4. Lead Check™ OC Curve for Wood Substrate

Figure 5. Lead Detective™ OC curve for Wood Substrate

Figure 6. Lead Zone™ OC curve for Wood Substrate

Test Samples

Sample Size

The sample size estimates were calculated using Schlesselman's method for matched proportions (34). The false positive and false negative percentages reported in the EPA study for the three test kits of interest on wood substrate were used. The alpha value was set at 0.05 and the power at 0.9. The largest sample size calculated was 41. A sample size of 40 was used to test the three test kits.

Painted Boards

Paint containing varying amounts of lead was applied to ten inch long wood boards. A concentration range of 0.01 to 2 mg/cm² was determined based on the operating characteristic curves for the three test kits on wood substrate reported in the EPA study. The concentration range still bracketed the threshold probability. The EPA formula to convert lead weight per cm² to percent lead by weight in paint for wood substrate was used to determine the range in percent

lead by weight (22). The converted range was 0.04% to 3.97% lead by weight. This concentration range was divided into ten equal parts yielding the following concentrations: 0.04%, 0.48%, 0.91%, 1.35%, 1.79%, 2.22%, 2.66%, 3.10%, 3.53%, and 3.97%. Four wood boards were painted with paint containing lead at each of these ten concentrations for a total of 40 sample boards. Lead carbonate was added to white oil-based paint to achieve each of the percentages of lead by weight. An additional four wood boards were painted with lead-free paint and used as blanks. Lead carbonate was chosen to simulate actual lead-based paint that would be present in homes. Since the percent lead by weight concentrations refer to percent lead by weight in dry paint, the concentration of lead carbonate was adjusted to account for the volatiles in the paint. Five coats of this paint was applied to the wood boards and allowed to dry. The painted boards were then tested with each of the three test kits.

Test Methodologies

Test Kits

The screening test kits were tested in the laboratory on the painted boards. The boards were marked off into three sections and labeled from 1 to 44. The kits were used in accordance with the package directions by an untrained individual. The amount of lead present in the samples was not known to the individual performing the testing. The Lead Zone™ test kit was tested first on each of the 44 boards, and the results were recorded as positive or negative. The section was then covered and labeled so that the result would not affect subsequent test result determinations. Each Lead Zone™ test kit included a testing wipe that had to be saturated with water and then held onto the testing surface for two minutes. It was recommended that the surface be cut at an angle to expose all layers of paint. A pink color formed if lead was present.

In the event that no color formed, a confirmation test was included to insure that the wipe was working properly. The wipes were easy to use, and the color change was easy to interpret on the white paint.

The results from the Lead Detective™ kit were determined and recorded next, and the area was covered and labeled. The Lead Detective™ kit included one bottle of a measured amount of water and a bottle containing sodium sulfide crystals. The water was added to the sodium sulfide to dissolve the crystals. A dropper was placed on the mixture bottle in order to apply drops of the solution to the painted boards. Each board was cut with a V-shaped notch to expose all layers of the paint. Several drops of the solution were then applied to this area to achieve a color change. After two minutes, the color change varied from a light gray to a dark gray for a positive response and a pale yellow for a negative response. Lead containing paint chip samples were included with the kit so that the tester could observe the color change expected with a positive test. This kit was easy to use, but produced an off-white/tan color that was hard to discern as positive or negative.

The Lead Check™ swabs were used last and the 44 results were recorded as positive or negative. The swabs had to be activated by breaking two internal ampules. The surface was cut to expose all layers of paint. After activation, the swabs were rubbed onto the cut surface for approximately two minutes. The swabs contained an orange solution that was distinctive from the positive response observed by a pink color. A negative response had no color change, but the solution gave the boards an orange tint. These swabs were the easiest of the kits to use.

The results obtained from the testing procedures were compared to the actual lead content in the paint applied to the boards.

Data Analysis

Statistical methods for evaluation of screening tests

Statistical analysis was done on the results of the screening tests as compared to the true percent lead by weight concentration applied to the painted boards. The results were presented in two by two tables, comparing the false negative rate, false positive rate, sensitivity, and specificity. The manufacturer stated detection limits and the Federal threshold of 0.5% were used as critical values.

A result in which the screening test detected lead (by color change) was represented by a positive result. If the screening test failed to detect the presence of lead (by no color change), the result was indicated as a negative result. The results are presented in the format of Figure 7.

	True Lead Content		
Test Result	>Critical Value	<Critical Value	
Positive	A	B	A+B
Negative	C	D	C+D
	A+C	B+D	Σ
<p>Sensitivity $[A/(A+C)]$: Given that the true lead concentration is >critical value, the probability that the test result will be positive.</p> <p>Specificity $[D/(B+D)]$: Given that the true lead concentration is <critical value, the probability that the test result will be negative.</p> <p>False Positive $[B/(A+B)]$: Given that the true lead concentration is <critical value, the probability that the test result will be positive.</p> <p>False Negative $[C/(C+D)]$: Given that the true lead concentration is >critical value, the probability that the test result will be negative.</p>			

Figure 7. 2 x 2 Table

V. Results and Discussion

Table VIII gives the test kit results for each test kit on each board. The Lead Detective™ kit results are presented under two columns, Lead Detective™ 1 and Lead Detective™ 2. This is due to the fact that six of the results for the Lead Detective™ kit were questionable in regard to their positive or negative status. A color change occurred, but the tester was unable to discern if the color change was a positive or negative response. For the results labeled as Lead Detective™ 1, the six questionable results were recorded as positives. For the results labeled as Lead Detective™ 2, the questionable results were recorded as negatives. The Lead Detective™ kit manufacturer recommended training for the tester using the kit. Training could have prevented the discrepancy over the six questionable results, and provided clearer results for the study (32). After completing the testing, the tester concluded that the questionable results should have most likely been recorded as negatives. This conclusion was made on the basis of the color of the change that took place. The color developed into an off-white/tan hue instead of a gray hue (which was defined as a positive result). However, at the time of testing, the tester was not certain of these observations.

Table VIII.
Summary of Test Kit Results

Board #	Pb Conc.	Test Kit Results (0=negative, 1=positive)			
		Pb Zone	Pb Det. 1	Pb Det. 2	Pb Check
23	0	0	0	0	0
22	0	0	0	0	0
36	0	0	0	0	0
41	0	0	0	0	0
19	0.04	0	0	0	0
14	0.04	0	0	0	0
15	0.04	0	0	0	0
28	0.04	0	0	0	0
6	0.48	0	1	0	0
10	0.48	0	1	0	0
4	0.48	1	1	0	0
37	0.48	0	1	0	1
24	0.91	1	1	1	1
40	0.91	1	1	1	1
21	0.91	1	1	0	1
20	0.91	1	1	0	1
16	1.35	0	1	1	1
18	1.35	1	1	1	1
5	1.35	1	1	1	1
3	1.35	1	1	1	0
43	1.79	1	1	1	1
2	1.79	1	1	1	1
29	1.79	1	1	1	1
34	1.79	1	1	1	1
39	2.22	1	1	1	1
13	2.22	1	1	1	1
27	2.22	1	1	1	1
9	2.22	1	1	1	1
44	2.66	1	1	1	1
30	2.66	1	1	1	1
42	2.66	1	1	1	1
32	2.66	1	1	1	1
33	3.1	1	1	1	1
26	3.1	1	1	1	1
35	3.1	1	1	1	1
8	3.1	1	1	1	1
25	3.53	1	1	1	1
38	3.53	1	1	1	1
12	3.53	1	1	1	1
31	3.53	1	1	1	1
11	3.97	1	1	1	1
17	3.97	1	1	1	1
7	3.97	1	1	1	1
1	3.97	1	1	1	1

The results of classification in the two by two tables for each of the test kits are presented in Table IX.

Table IX.

2 x 2 Classification

Number Classified in 2 x 2 Table Cell									
Kit	A	B	C	D	Sens.	Spec.	FalsePos(%)	FalseNeg(%)	CriticalVal.
Manufacturers' Detection Limit:									
LeadZone ¹	32	0	8	4	0.8	1.0	0	66.7	.0005%
LeadDet.1 ²	28	8	0	4	1.0	0.33	22.2	0	1.0%
LeadDet.2 ²	28	2	0	10	1.0	0.83	6.67	0	1.0%
LeadCheck	31	1	1	7	0.97	0.88	3.13	12.5	0.5%
Federal Threshold:									
LeadZone	31	1	1	7	0.97	0.88	3.13	12.5	0.5%
LeadDet.1 ²	32	4	0	4	1.0	0.5	11.1	0	0.5%
LeadDet.2 ²	30	0	2	8	0.94	1.0	0	20	0.5%
LeadCheck	31	1	1	7	0.97	0.88	3.13	12.5	0.5%

¹the blanks were included for a sample size of 44 for LeadZone at this critical value due to the fact that the blanks were the only measures below the critical value.

²for the results labeled as LeadDet.1, the six questionable results were recorded as positives; for the results labeled as LeadDet.2, the questionable results were recorded as negatives.

For the Lead Zone™ kit, the manufacturer stated detection limit was 0.0005%. This required that the blanks be included in the two by two table due to the fact that zero was the only concentration tested that was below 0.0005%. This manufacturer stated detection limit was probably not reasonable since the kit is primarily used to determine if the lead concentration is above or below the Federal threshold of 0.5%.

Two tables were constructed for the Lead Detective™ kit at the manufacturer stated detection limit of 1.0% lead by weight. This was due to the fact that six of the results were questionable in regard to their positive or negative status as discussed earlier.

The manufacturer stated detection limit was equal to the Federal threshold for the Lead Check™ kit. Therefore, the results were the same at each of these critical values.

There was greater variation in the results at the manufacturers' stated detection limit than at the Federal threshold. The ranges for the sensitivity and specificity at the manufacturers' detection limits were 1.0 to 0.8 and 1.0 to 0.33, respectively. At the Federal Threshold, the sensitivity range was from 1.0 to 0.94, and the specificity range was from 1.0 to 0.5.

The confidence intervals were computed for the sensitivities and specificities at each of the critical values (35). These results are presented in Table X.

Table X.

Confidence Intervals for Sensitivity and Specificity

	Confidence Intervals			
Test Kit	Sensitivity		Specificity	
	Manufac. Det. Limit	Federal Threshold	Manufac. Det. Limit	Federal Threshold
Lead Zone™	0.8 (0.68, 0.92)	0.97 (0.92, 1.02)	1.0 (1.0)	0.88 (0.78, 0.98)
Lead Det.™1	1.0 (1.0)	1.0 (1.0)	0.33 (0.18, 0.48)	0.5 (0.34, 0.66)
Lead Det.™ 2	1.0 (1.0)	0.94 (0.86, 1.02)	0.83 (0.71, 0.95)	1.0 (1.0)
Lead Check™	0.97 (0.92, 1.02)	0.97 (0.92, 1.02)	0.88 (0.78, 0.98)	0.88 (0.78, 0.98)

At the manufacturers' detection limits, all of the sensitivity confidence intervals include 1.0 except the Lead Zone™ interval. The only specificity confidence interval that includes 1.0 is the Lead Zone™ confidence interval. At the Federal threshold, all of the confidence intervals for sensitivity include 1.0. The only specificity confidence interval at the Federal threshold that includes 1.0 is the Lead Detective™ 2 confidence interval. With the sensitivity confidence interval including 1.0, the probability that the test result will be positive given that the true lead concentration is greater than the critical value is 1.0 or 100%. It is of greater concern in this study that the sensitivity result be equal to 1.0 than the specificity be equal to 1.0. This is due to the fact that one would want a 100% probability of the test giving a positive result given that the true lead concentration is greater than the critical value. If the probability that the test result is negative given that the true lead concentration is less than the critical value is not equal to 1.0, the concern is much less since a positive result at a lead level less than the critical value would only require further testing by other methods, yielding a more accurate result. If the sensitivity probability was low, one could expect negative results at lead levels greater than the critical value which could lead to serious health consequences due to dangerous levels of lead being ignored.

Fisher's Exact Test was used to test for concordance of screening test results to actual lead concentration. This test was used because the predictive values in the cells of the observed tables were less than 5; this is a requirement of chi-square testing. Fisher's Exact Test was performed on the results from the kits at the two critical values with an alpha value set at 0.05. The null hypothesis for the exact test was that the test kit results were not related to the true lead concentration values. A p-value was calculated for the observed results. Given that the outcome

of the screening test was not related to the true lead concentration, the p-value was the probability of observing the distribution in the 2 X 2 tables by chance alone. All of the calculated p-values were below the 0.05 significance level; therefore, the null was rejected and the relationships between the test kit results and the true lead concentrations were not due to chance. Rejection of the null may have been, in part, due to small sample size (36.).

The false positive and false negative rates varied more using the manufacturers' stated detection limits as the critical values. At these critical values, the false positive range was from 0 to 22.2%, while the false negative range was from 0 to 66.7%. At the Federal threshold, the range of false positives was 0 to 11.1%, and the range of false negatives was 0 to 20%.

The false positive and false negative rates at the Federal threshold were compared with the rates published in the EPA study at the Federal threshold. These results are presented in Table XI.

Table XI.
False Positive and False Negative Rates for Test Kits at the 0.5% Federal Threshold

Test Kit	False Positive Rate (EPA)	False Positive Rate (computed)	False Negative Rate (EPA)	False Negative Rate (computed)
Lead Check™	42%	3.13%	11%	12.5%
Lead Detective™ 1	32%	11.1%	27%	0%
Lead Detective™ 2	32%	0%	27%	20%
Lead Zone™	25%	3.13%	25%	12.5%

In every case but the false negative rate for Lead Check™, the false positive and false

negative rates computed in this study were significantly lower than the rates reported in the EPA study. The computed false positive rates did not exceed 11.1%, and the false negative rates did not exceed 20%.

The false negative rates should hold more weight in deciding the ability of these test kits to detect the presence of lead in this study. This is due to the fact that there would be more concern if the kits failed to give a positive result, given that the actual lead content was greater than the critical value. If this occurred, the health consequences could be serious, and dangerous levels of lead would be ignored. However, if a false positive result occurred, further testing would be done by other methods, and the level of lead present would be determined to be acceptable.

It is also important to note that false positive and false negative rates are a function of the number of boards with lead present above or below the critical value. Given the same sensitivity and specificity, the false positive and false negative rates can change depending on the number of boards in the sample with lead concentration greater than the threshold (36).

The results at the Federal threshold of 0.5% provided better sensitivity, specificity, false positive rate, and false negative rate measures than the results at the manufacturer's stated detection limit for all kits. Since the major use of the kits would be to determine if the lead content in paint was above the Federal threshold of 0.5% lead by weight, the conclusions will be based on these results.

VI. Conclusions

The observed false positive and false negative rates for all three kits at the Federal threshold were found to be significantly lower than those reported in the EPA study (22). These

results suggest that the kits performed well at the Federal threshold. The Lead Check™ and Lead Zone™ kits had false negative rates of 12.5% and false positive rates of 3.13%. The false negative rate should hold more weight in deciding the ability of these kits to detect the presence of lead; however, the false negative rate would decrease if more boards with lead present below the 0.5% Federal threshold had been tested and included in this study. For example, if the blanks were included in the 2 x 2 table for Lead Zone™ at the Federal threshold (for a total sample size of 44), the false negative rate would decrease to 9%. The confidence intervals around the sensitivities for both kits included 1.0 or a 100% probability that the test kit result would be positive given that the true lead concentration is greater than 0.5% lead by weight. The specificity confidence intervals for the two kits were (0.78, 0.98) with a calculated value of 0.88. These values and intervals of specificity are very close to 1.0 or a 100% probability that the test result will be negative given that the true lead concentration is less than the Federal threshold. The null hypothesis of the Fisher's Exact Test was also rejected for these two kits at the Federal threshold signifying that the test kit results were related to the true lead concentration values, and the relationship was not simply due to chance (36). Based on these statistical tests, these two kits would be acceptable screening tests for lead in paint at the Federal threshold of 0.5% lead by weight.

The Lead Detective™ kit may be an acceptable screening test for lead in paint at the Federal threshold of 0.5% lead by weight if the tester was subjected to some training to recognize the positive versus negative color change. The data was analyzed using positive results for Lead Detective™ 1 and negative results for Lead Detective™ 2 for the six results in question. Regardless, neither set of results (Lead Detective™ 1 or 2) provided convincing results for all of

the statistical tests. Without the training, the Lead Detective™ 1 kit gave a false negative rate of 0% and a false positive rate of 11.1%. The confidence intervals for sensitivity and specificity at the Federal threshold for Lead Detective™ 1 were 1.0(1.0) and 0.5(0.34,0.66), respectively.

These results show an acceptable false negative rate and sensitivity and a tolerable false positive rate, but the specificity is greatly compensated. Fisher's Exact Test for Lead Detective™ 1 rejected the null hypothesis at the Federal threshold indicating that the test kit results were related to the true lead concentration values, and the relationship was not simply due to chance (36). On the basis of the false negative and positive rates, Fisher's Exact Test, and sensitivity the Lead Detective™ kit could be recommended as an acceptable screening test for lead in paint. However, the tester concluded after the testing that the questionable results for the Lead Detective™ kit should have been recorded as negatives. Therefore, the Lead Detective™ 2 analysis should determine the acceptability of the Lead Detective™ as a screening test for lead in paint.

The Lead Detective™ 2 analysis provided a false negative rate of 20% and a false positive rate of 0%. The confidence intervals for sensitivity and specificity were 0.94(0.86, 1.02) and 1.0(1.0), respectively at the Federal threshold. These rates of false positives, sensitivity, and specificity are allowable, and Fisher's Exact Test for Lead Detective™ 2 rejected the null hypothesis at the Federal threshold indicating that the test kit results were related to the true lead concentration values, and the relationship was not simply due to chance (36).. Regardless, the rate of false negatives was too high to recommend the Lead Detective™ kit for use as a screening test kit for lead in paint for homeowners. With the suggested training the kit may be an

appropriate screening test kit, but it should not be recommended for use by the average homeowner.

The results from this study are more in accordance with the *Consumer Reports* study than the EPA report on lead screening test kits. The “maximum sensitivities” for the three kits reported in the *Consumer Reports* article were 5.0% for the Lead Zone™ kit, 0.05% for the Lead Detective™ kit, and 0.5% for the Lead Check™ kit. Although these results are difficult to interpret, the *Consumer Reports* article suggested the use of the test kits for screening purposes. The differences in the results for this study from the EPA report results are clearly shown in the comparison of the computed rates of false positives and false negatives for this study to the EPA reported false positives and false negatives. The EPA report came to the conclusion that the test kits should not be used as screening tools for lead in paint. This analysis concludes that Lead Zone™ and Lead Check™ be recommended for use as screening tests for lead in paint, and the Lead Detective™ kit only be used by trained individuals for screening of lead paint.

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