

Health Consultation

Exposure Investigation Report

Beryllium Sensitivity Testing

FORMER AMERICAN BERYLLIUM SITE
TALLEVAST, MANATEE COUNTY, FLORIDA

EPA FACILITY ID: FLD004100731

DECEMBER 5, 2005

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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Prepared by:

Florida Department of Health
Bureau of Community Environmental Health
Under Cooperative Agreement with the
Agency for Toxic Substances and Disease Registry

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Foreword

This exposure investigation report summarizes beryllium sensitivity tests conducted between December 2004 and April 2005 by the Florida Department of Health in conjunction with Manatee and Sarasota County Health Departments. Participants included former American Beryllium workers, household members, and Tallevast community residents.

Evaluating exposure: Florida DOH scientists begin by reviewing available information about environmental conditions at the site. The first task is to find out how much contamination is present, where it is on the site, and how people might be exposed to it. Usually, Florida DOH does not collect its own environmental sampling data. We rely on information provided by the Florida Department of Environmental Protection (DEP), the U.S. Environmental Protection Agency (USEPA), and other government agencies, businesses, and the public.

Evaluating health effects: If evidence is found that people are being exposed—or could be exposed—to hazardous substances, Florida DOH scientists will take steps to determine whether that exposure could be harmful to human health. Their assessment focuses on public health; that is, the health impact on the community as a whole, and is based on existing scientific information.

Developing recommendations: In an evaluation report—such as this exposure investigation report—Florida DOH outlines its conclusions regarding any potential health threat posed by a site, and offers recommendations for reducing or eliminating human exposure to contaminants. The role of Florida DOH in dealing with hazardous waste sites is primarily advisory. For that reason the evaluation report will typically recommend actions to be taken by other agencies—including the EPA and Florida DEP. If, however, the health threat is immediate, Florida DOH will issue a public health advisory warning people of the danger and will work to resolve the problem.

Soliciting community input: The evaluation process is interactive. Florida DOH starts by soliciting and evaluating information from various government agencies, the organizations or individuals responsible for cleaning up the site, and from community members who live near the site. Any conclusions are shared with the organizations and individuals who provided information. Once an evaluation report has been prepared, Florida DOH seeks feedback from the public. *If you have questions or comments about this exposure investigation report, we encourage you to contact us. Please write to:*

Susan Skye
Health Assessment Team
Bureau of Community Environmental Health
Florida Department of Health
4052 Bald Cypress Way, Bin # A-08
Tallahassee, FL 32399-1712

Or call us at: (850) 245-4299, or toll-free during business hours: 1-877-798-2772

Executive Summary

This exposure investigation report summarizes blood collection procedures and beryllium sensitivity test results for 359 former American Beryllium workers, household members, and residents who live or previously lived in the nearby Tallevast community in Manatee County, Florida. These individuals may have become sensitized to beryllium by breathing beryllium dust from the former American Beryllium site.

Between 1961 and 1996, the former American Beryllium site created beryllium dust during manufacture of ultra-precision beryllium parts in Tallevast, Florida. Former workers, household members, and nearby residents were concerned they were exposed to the dust and may be at risk of developing chronic beryllium disease.

Between January 2004 and April 2005, the Florida Department of Health (DOH) in cooperation with the Manatee and Sarasota County Health Department (CHDs) collected blood samples from 359 former workers, household members, and residents. The National Jewish Medical Center laboratory tested these samples for beryllium sensitivity.

Of the 359 tests reviewed for this report, 348 (97%) were not beryllium sensitive; nine (2.5%) were abnormal, borderline, or uninterpretable for beryllium sensitivity; and two (0.5%) did not supply a sufficient volume of blood for analysis. The nine participants with abnormal, borderline, or uninterpretable beryllium sensitivity test results were retested. A comparison of the rates of beryllium sensitivity covered in this report to rates of beryllium sensitivity found in other beryllium test programs will be included in a separate ATSDR report summarizing retesting of nine individuals.

Objectives and Rationale

The objective of this health consultation is to summarize blood collection procedures and beryllium sensitivity test results for 359 former American Beryllium workers, household members, and Tallevast community residents who live or lived near the former American Beryllium facility. These individuals may have become sensitized to beryllium by breathing beryllium dust from the former American Beryllium facility. Beryllium sensitized individuals are at risk of developing chronic beryllium disease. A pulmonologist (lung doctor) should evaluate individuals who have become sensitized to beryllium. Only a specialist can diagnose chronic beryllium disease.

Test results covered in this report are applicable only to the persons tested and are not generalizable to other community members or to other sites. The U.S. Agency for Toxic Substances and Disease Registry (ATSDR), Manatee County, Manatee County Health Department, and Sarasota County Health Department provided financial or staff support for this testing.

Background

Between 1961 and 1996, the former American Beryllium site manufactured ultra-precision beryllium machine parts at a five-acre facility at 1600 Tallevast Road in the Tallevast community, Manatee County, Florida. The main plant consisted of numerous machining departments that included lathes, milling, jig boring, deburring, grinding, and electrical discharge machining. The machining of beryllium, aluminum, titanium, and alubemet (a 60% beryllium and 40 % aluminum blend) produced beryllium-containing dust (TetraTech 1994).

The former American Beryllium site collected wastewater in a holding pond on the southeast corner of the site (DEP 1994). In 1996, Lockheed-Martin purchased the former American Beryllium site and ceased operations. In 2000, Wiring Pro International (WPI) purchased the former American Beryllium facility from Lockheed-Martin. WPI manufactures light cable wire. Lockheed-Martin, however, retains responsibility for environmental contamination.

In June and December 2004, the Florida DOH and Manatee CHD attended public meetings in Tallevast to gather health concerns and answer health questions.

Site Description

The Tallevast community is in southern Manatee County midway between Sarasota and Bradenton (Figure 1). The neighborhood is a blend of single-family homes, and light commercial/industrial development. The Tallevast community surrounds the former American Beryllium site. Homes and Tallevast Road are north of the former facility. The former Spindrift fiberglass boat manufacturing facility is to the west. The Sarasota-Bradenton International Airport is to the southwest. The Tallevast Community Center, a golf course, and homes are to the south. More homes and undeveloped land are to the east (Figure 2).

Community Health Concerns

In summer and fall 2004, former American Beryllium workers and Tallevast community residents expressed concern they had breathed beryllium dust from the former American Beryllium site. They were concerned about developing chronic beryllium disease and requested beryllium sensitivity testing.

Methods

Exposure Investigation Design

ATSDR and the Florida DOH prepared a detailed beryllium sensitivity protocol including procedures, questionnaires, consent forms, quality assurance, and data analysis (Appendix A). In January 2005, ATSDR approved this plan and provided funding. Exceptions to this plan include:

1. ATSDR and Florida DOH agreed to postpone medical grand rounds by a beryllium disease expert pending a review of the beryllium sensitivity test results.

2. Result letters, fact sheets, and telephone/in-person conversations rather than a public meeting served to educate test participants.
3. Since only nine participants needed re-testing, the Manatee CHD and the Florida DOH mailed results and talked with participants on the phone rather than in person.

Target Population

The Manatee CHD required participants to meet one of the following criteria:

1. Current Manatee county residents who worked at the former American Beryllium site between January 1, 1961 and December 31, 1996.
2. Current Manatee county residents born prior to January 1, 1997 (12 years and older) who were household members of former workers between January 1, 1961 and December 31, 1996.
3. Current Manatee county residents who lived within 0.25 mile of the former American Beryllium site anytime between January 1, 1961 and December 31, 1996.

The Florida DOH and Sarasota CHD required participants to meet one of the following criteria:

1. Former American Beryllium workers between January 1, 1961 and December 31, 1996 currently living in any county.
2. Household members of former American Beryllium workers between January 1, 1961 and December 31, 1996 and born prior to January 1, 1997 (12 years and older) currently living in any county.
3. Residents who lived within 0.50 mile of the former American Beryllium site between January 1, 1961 and December 31, 1996 currently living in any county.

Biologic Sampling

Data Collection/Sampling Procedures

In fall 2004, the Florida DOH began investigating the possibility of testing for beryllium sensitivity using the beryllium lymphocyte proliferation test (BeLPT). Tallevast community leaders reported 25 residents and former workers had been tested and four were sensitive to beryllium. It was unclear if these four individuals received confirmatory testing. The Florida DOH and the Manatee CHD, spoke with pulmonologists (lung doctors) before requesting funding to make sure local physicians were available if needed after blood testing.

In December 2004, the Manatee CHD announced a county funded program to test former American Beryllium workers, household members, and nearby Tallevast residents for beryllium sensitivity. This program was limited to Manatee County residents. In December 2004 and January 2005, the Manatee CHD collected blood samples at the Mt. Tabor church and the CHD. They collected blood samples from 237 people. Of the 237, 163 were Tallevast residents (10 former workers, 37 household members, and 116 residents) and 74 were non-Tallevast residents (56 former workers and 18 household members). Thirteen participants were children between 10

and 17 years old. The National Jewish Medical Center tested the blood samples for beryllium sensitivity using the beryllium lymphocyte proliferation test (BeLPT).

In February 2005, the Florida DOH announced an ATSDR funded program to test more former workers, household members, and Tallevast residents. The Florida DOH requested this funding to include both Manatee and non-Manatee County residents for beryllium sensitivity testing. The Florida DOH made hundreds of phone calls soliciting participation including calls to individuals living in other towns and states. The Florida DOH recorded phone numbers, addresses, relationships to workers, and dates of work at the former American Beryllium facility. The Florida DOH called during business hours, evenings, and weekends. The Sarasota CHD assisted with scheduling appointments, phone calls and paperwork. They also assisted with coordinating blood testing with the nursing staff. Florida DOH issued a press release soliciting participation and mailed fact sheets to former workers, household members, and Tallevast residents (Appendix B through F). The Bradenton Herald and other newspapers publicized the testing.

In March 2005, the Florida DOH and Sarasota CHD collected blood samples from 107 individuals at their Sarasota clinic (17 former workers, 46 household members and 44 residents from Manatee, Sarasota, Pinellas, Hillsborough, Pasco, and Marion Counties). One individual was 14 years old; the others were 18 years or older. The Florida DOH helped coordinate the collection and answer questions. Each participant signed a consent form and filled out a questionnaire (Appendix G and H). The National Jewish Medical Center tested the blood samples for beryllium sensitivity (BeLPT).

Also in March 2005, the Sarasota CHD shipped blood collection kits (with instructions and lab forms) to 22 out-of-town/state individuals. The Florida DOH coordinated this out-of-town/state testing. Fifteen individuals (2 former workers, eight household members and five residents) sent a blood sample to the National Jewish Medical Center for beryllium sensitivity testing. One was 16 years old; the others were 18 years or older. Seven individuals who received a collection kit did not send a blood sample.

Florida DOH shared the same blood sample collection and shipment instructions with Manatee CHD nursing staff, Sarasota CHD nursing staff, and out-of-town/state participants. Florida DOH instructed them to collect a single 30-milliliter sample and ship overnight to the National Jewish Medical Center laboratory (Appendix I). The laboratory did not analyze blood samples received more than 24 hours after collection.

In late 2004 and early 2005, Florida DOH, Manatee CHD, and Sarasota CHD worked with two former American Beryllium workers to compile the names, phone numbers, jobs, and years of service of 543 former workers and household members. In February 2005, the US Department of Energy (DOE) announced a nation-wide program to test former workers in the beryllium industry for beryllium sensitivity. This included individuals who worked at the former American Beryllium site in 1967, 1968 and the 1980s. Later DOE expanded coverage to individuals who worked at the former American Beryllium site regardless of the date.

Laboratory Analytical Procedures

During the months of December through April 2005, National Jewish Medical and Research Center received the participants' blood overnight in green-top heparinized vacutainer tubes at room temperature and analyzed the blood for beryllium sensitivity using the beryllium lymphocyte proliferation test (BeLPT).

Data Analysis Procedures

The beryllium lymphocyte proliferation test (BeLPT) is performed by culturing T-lymphocytes from blood with and without beryllium salts. If these T-lymphocytes are sensitized to beryllium, they will begin to proliferate (as reflected by the incorporation of tritiated thymidine from the culture media). The ratio of the response of stimulated to that of unstimulated lymphocytes is called the stimulation index (*SI*). There are 6 values (or concentrations) possible for each test. An elevated *SI* as defined by the National Jewish Laboratory in 2 or more of the 6 values is indicative of beryllium sensitization (*BeS*). This is reported as an abnormal result. If 1 of the 6 values has an elevated *SI*, then this is reported to be a borderline result. If 0 of the 6 values have an elevated *SI*, then this is reported as a negative result. An uninterpretable result is also possible if the sample cannot be analyzed (e.g. a lack of adequate sample, an inability to culture T-lymphocytes, etc).

A person is not considered beryllium-sensitized unless an initial abnormal BeLPT is confirmed by one or more concurrent or subsequent BeLPTs. This can be achieved by initially splitting the first blood sample and sending it to two laboratories. For this exposure investigation, the blood samples were only analyzed by one laboratory. In a follow-up investigation done by ATSDR, all individuals with abnormal, borderline, and uninterpretable results from the first round of testing will be re-tested. This second blood sample will be split and a sample will be sent to both the National Jewish Laboratory and to Specialty Laboratories. A summary of the retesting results will be included in a separate ATSDR report.

Agency Roles

The Manatee CHD was responsible for coordinating testing of Manatee residents, former workers and household members. Their nursing staff collected the blood samples and sent samples to National Jewish Medical Research Center. The Manatee CHD scheduled appointments, made phone calls, answered questions, and hand-delivered results to participants.

With the assistance of the Sarasota CHD the Florida DOH coordinated *BeLPT* testing of Manatee and non-Manatee former workers, residents and household members. Coordination included phone calls, answering questions, mailouts, physician letters, evaluating data, a press release, contact with the media and notifying participants of their blood test results.

Results

Target Population Demographics

In 2000, about 200 people lived within 0.5-mile of the site. Approximately 82% were black and 13% percent were white. Other racial/ethnic groups include 5% American Indian, Hispanic, or Latino (Census 2000).

Biological Sampling Results

Of the 359 tests reviewed for this report, 348 (97%) were not beryllium sensitive. In March and April 2005, Florida DOH mailed a cover letter and results to individuals not sensitive to beryllium (Appendix J). Florida DOH also included a fact sheet advising former workers to "...repeat the blood test if they develop symptoms including prolonged cough, unexplained shortness of breath or wheezing. It is generally recommended that you have a *BeLPT* blood test every one to three years if you are currently exposed to beryllium, and every three to five years if you are no longer exposed to beryllium" (Appendix K).

Of the 359 tests covered in this report, nine (2.5%) were abnormal, borderline, or uninterpretable for beryllium sensitivity. Of those nine, three were abnormal (one former worker, one household member, and one resident), five were borderline (two former workers and three residents), and one was uninterpretable (resident) (Table 1). They all received a phone call and a letter explaining their results (Appendix L, M, N or O). If requested, the Florida DOH also mailed a letter with copies of the participants' results to their physicians (Appendix P).

Because a second test is required to confirm beryllium sensitivity, all nine individuals with abnormal, borderline, or uninterpretable results were retested. ATSDR will issue a report on the retest results. For those residents and household members of former workers who are confirmed beryllium sensitive, Florida DOH will refer them to a Sarasota pulmonary specialist familiar with beryllium sensitization and chronic beryllium disease. Florida DOH will refer former workers who are confirmed beryllium sensitive to US DOE for follow-up.

Two out of the 359 people tested (0.5%) did not supply a sufficient volume of blood for analysis. These two individuals declined retesting.

As of June 2005, the US Department of Energy collected blood samples from 141 former American Beryllium workers. 13 of the 141 (9%) were abnormal, borderline, or uninterpretable for beryllium sensitivity.

Discussion

Beryllium Toxicity

Beryllium is a metal that can enter someone's body if they breathe beryllium dust, eat beryllium-containing food, or drink contaminated water. When someone breathes air containing beryllium

dust, beryllium particles are deposited in the lungs. The beryllium they breathe dissolves in the lungs and only moves slowly into the bloodstream. Some of the beryllium deposited in the lungs can be moved to the mouth and then swallowed; the rest can remain in the lungs for a long time. The bloodstream carries a small amount of beryllium from the lungs, stomach, and intestines to the kidneys. If someone inhales beryllium, it may take months to years before the body rids itself of beryllium. This is because it takes a long time before all the beryllium in the lungs enters the bloodstream (ATSDR 2002).

While beryllium has been recognized as a toxic substance since the 1930s, workplace practices to reduce worker exposure did not become common until the late 1970s or early 1980s. Based on interviews with former workers and community members, the former American Beryllium site was no exception. The Florida DEP documented numerous reports from former American Beryllium workers of dust throughout the facility, the lack of vacuum collection systems, and inadequate facilities for workers to change clothes and cleanup at lunch and/or after work. Many workers from the Tallevast neighborhood held unskilled jobs at the facility and were unaware of the exposure risks. Those workers may have carried beryllium dust home on their clothes. Beryllium dust is a health concern for the families of those workers and other community members who had frequent contact with workers.

The Beryllium Lymphocyte Proliferation Test (BeLPT) was developed to identify individuals who are or were sensitized to beryllium. In general terms, the BeLPT is performed by culturing T-lymphocytes from peripheral blood or broncho-alveolar (lung) fluid with and without beryllium salts. The proliferative response of lymphocytes stimulated by beryllium is compared to that of unstimulated lymphocytes, based on their incorporation of tritiated thymidine (a radioactive DNA precursor). The ratio of the stimulated-to-unstimulated lymphocytes is called the stimulation index (*SI*). An elevated *SI* is indicative of beryllium sensitization (*BeS*).

Limitations

1. The BeLPT only indicates beryllium sensitivity, not chronic beryllium disease.
2. The BeLPT is just one part of the process of determining if someone may have chronic beryllium disease. A physician must order other medical tests to make this determination.
3. The Florida DOH, Manatee CHD and Sarasota CHD contacted and tested as many former workers, household members and residents using the staff and resources available.
4. Presently, nothing surpasses the BeLPT for identifying individuals who may have beryllium related disease. However, while there is a false positive rate of only 1 to 2%, there is a 25 to 38% false negative rate reported for this test. It is also recommended that a person not be considered beryllium sensitized unless an initial abnormal BeLPT result is confirmed by one or more concurrent (split blood sample sent to two laboratories) or subsequent BeLPTs (two abnormal results from same laboratories on separate dates)(Stange 2004).

Child Health Considerations

In communities faced with air, water, or food contamination, the many physical differences between children and adults demand special emphasis. Children could be at greater risk than are adults from certain kinds of exposure to hazardous substances. Children play outdoors and sometimes engage in hand-to-mouth behaviors that increase their exposure potential. Children are shorter than are adults; this means they breathe dust, soil, and vapors close to the ground. A child's lower body weight and higher intake rate results in a greater dose of hazardous substance per unit of body weight. If toxic exposure levels are high enough during critical growth stages, the developing body systems of children can sustain permanent damage. Finally, children are dependent on adults for access to housing, for access to medical care, and for risk identification. Thus adults need as much information as possible to make informed decisions regarding their children's health.

It is likely that the health effects seen in children exposed to beryllium dust will be similar to the effects seen in adults. Little information exists on children and beryllium exposure. One report exists of a child living near a beryllium factory having chronic beryllium disease. It is unknown whether children differ from adults in their sensitivity to beryllium (ATSDR 2002).

Test results for all 15 children (10-17 years old) covered in this report were not sensitive to beryllium.

Conclusions

348 (97%) of the 359 former American Beryllium workers, household members, and Tallevast residents covered in this report were not sensitive to beryllium.

Nine (2.5%) out of 359 people covered in this report were abnormal, borderline, or uninterpretable for beryllium sensitivity. Of those nine, three were abnormal for beryllium sensitivity (one former worker, one household member, and one resident), five were borderline (two former workers and three residents), and one was uninterpretable (resident).

Two (0.5%) out of the 359 people covered in this report did not supply a sufficient volume of blood for analysis.

The nine participants covered in this report with abnormal, borderline, or uninterpretable beryllium sensitivity test results were retested and results are included in a separate report. Final determinations of their beryllium sensitivity status will be discussed in this report.

Recommendations

Former workers that tested not sensitive to beryllium should be tested again every three to five years.

Former American Beryllium workers should direct inquires about beryllium sensitivity testing to US DOE contractor Donna Cragle (Oakridge Institute) at 1-866-219-3442.

Public Health Action Plan

Past Actions:

In August 2004, the Florida DOH coordinated indoor air testing in four buildings near the former American Beryllium site. In August 2005, ATSDR published an indoor air testing health consultation report.

In April 2005, Florida DOH mailed beryllium sensitivity test results, the former American Beryllium site information, beryllium toxicity information, and general program information to 38 Bradenton/Sarasota area physicians (Appendix P).

Planned Actions:

By the end of 2005, ATSDR plans to report on re-testing of nine participants covered in this report who originally tested abnormal, borderline, or uninterpretable for beryllium sensitivity. The Florida DOH will follow-up with those participants referred to pulmonologists.

The DOE stated they would test all former American Beryllium workers who worked at the facility from 1961 to 1996. Former workers should direct inquires about beryllium sensitivity testing to US DOE contractor Donna Cragle (Oakridge Institute) at 1-866-219-3442.

Authors, Technical Advisors

Authors, Technical Advisors

Susan Skye

Biological Scientist IV
Florida Department of Health
Bureau of Community Environmental Health

Florida DOH Designated Reviewer

Randy Merchant

Program Administrator
Florida Department of Health
Bureau of Community Environmental Health

ATSDR Technical Project Officer

Jennifer Freed

Technical Project Officer
Division of Health Assessment and Consultation
Superfund Program and Assessment Branch
Agency for Toxic Substances and Disease Registry

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Figures and Tables

Figure 1: Site Location Map

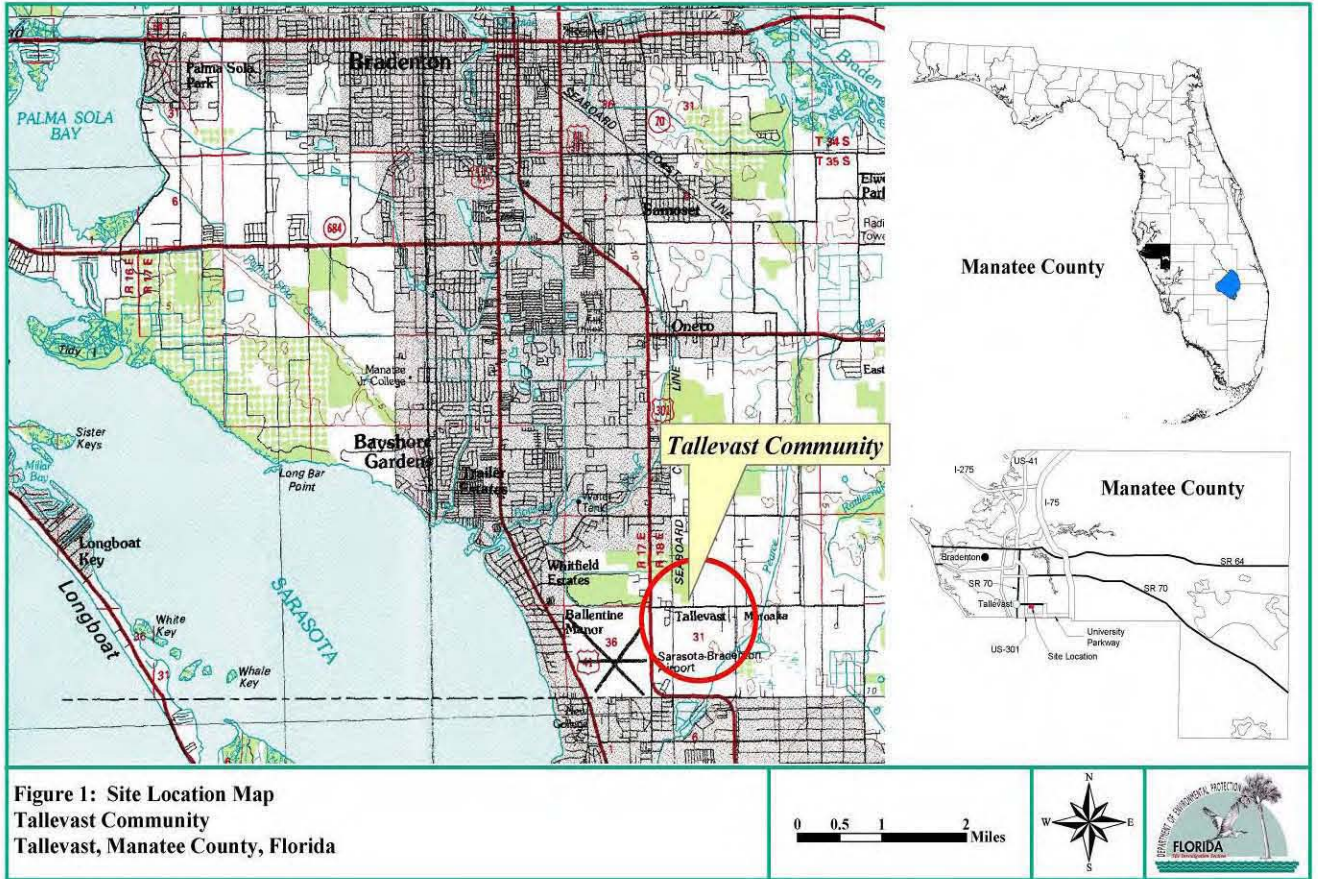


Figure 2: Street Map of the Tallevast Area Surrounding the former American Beryllium Site
Figure 2 — Tallevast Community Site Map



Table 1. Abnormal, Borderline, and Uninterpretable Beryllium Sensitivity Test Results

Participant	Beryllium Sensitivity Test Result	Where Blood Drawn
resident	borderline (1/27/05)	Manatee CHD
former worker	borderline (1/20/05)	Manatee CHD
resident	abnormal (1/27/05)	Manatee CHD
resident	uninterpretable (1/27/05)	Manatee CHD
resident	borderline (1/27/05)	Manatee CHD
former worker	borderline (3/17/05)	Out of State
former worker	abnormal (1/27/05)	Manatee CHD
household member	abnormal (1/27/05)	Manatee CHD
resident	borderline (3/8/05)	Sarasota CHD
resident	insufficient blood volume	Sarasota CHD
resident	insufficient blood volume	Private Clinic

APPENDIX A – Blood Testing Protocol – February 2005

Exposure Investigation Protocol Beryllium Sensitivity Blood Testing Tallevast Community Manatee County, Florida Cost Recovery no. A950

Background

Between 1961 and 1996, the Loral American Beryllium Company (ABC) manufactured ultra-precision machine parts for the aerospace industry and the ballistic missile program of the defense industry in the Tallevast community, Manatee County, Florida. This facility specialized in the production of close tolerance beryllium components. In 1996, the main plant consisted of numerous machining departments that included lathes, milling, jig boring, deburring, grinding and electrical discharge machining. The machining of beryllium, aluminum, titanium, and a 60% beryllium and 40% aluminum alloy took place in the main plant. The dust and cuttings from beryllium machining were recovered for reclamation through a central dust collecting system using vacuum lines. Beryllium dust traveled to a bag-house where the dust was filtered out, recovered, and accumulated for recycling. Workers used hand vacuums to collect beryllium dust around the machinery. The dust collected onto a paper filter and was discarded into a 55 gallon drum. At the time of a Florida Department of Environmental Protection (DEP) inspection in 1994, the filters had been accumulating for approximately four years and a method of disposal was not determined for the filters.

Behind the main plant, the facility also had a grinding area, wire machining section and electronic discharge machining department. The lubricating oils used in this area were filtered and treated as D001 hazardous waste after they were changed out. Sludges produced in this area were assumed to be 97% diatomaceous earth and 3% beryllium. The sludge was sent to a recycler for beryllium reclamation (DEP 1994). Chemicals used and wastes generated at the facility included oils, petroleum-based fuels, solvents, acids, and metals. In 1996, Lockheed Martin Corporation purchased the American Beryllium Company and closed it later that year. Former workers reported beryllium dust inside the facility and on the uniforms they wore home. In addition, building ventilation fans may have spread beryllium dust to nearby homes.

While beryllium has been recognized as a toxic substance since the 1930s, workplace practices to reduce worker exposure did not become common until the late 1970s or early 1980s. Based upon many interviews with former workers and community members, the former ABC plant was no exception. The Florida DEP has documented numerous reports from former workers of dust throughout the plant, the lack of vacuum collection systems, and inadequate facilities for workers to change clothes and cleanup at lunch and/or after work. Many workers from the Tallevast neighborhood surrounding the former ABC plant held unskilled jobs at the plant and were simply unaware of the exposure risks. The potential for beryllium dust to have traveled home with many of these workers is potentially significant and has now become a health concern for the families of those workers as well as community members who had frequent contact with the workers.

In this investigation, the Florida Department of Health (DOH) and the Sarasota Department of Health (DOH) will test former workers of the Loral ABC, their family members, and residents who lived within .50 miles of the facility. Blood samples will be collected from the participants and tested for sensitization to beryllium. This investigation is being conducted in response to a request from the Florida DOH. This investigation is being conducted as a public health service to former workers and residents who are at potential health risk because of possible past exposures to beryllium. The results of this test are applicable only to the persons tested, and are not generalizable to other community members or to other sites.

Beryllium Sensitization and Chronic Beryllium Disease

Exposure to beryllium can potentially result in a condition known as *beryllium sensitivity (BeS)* or in *chronic beryllium disease (CBD)*, which is sometimes referred to as *berylliosis*.

Beryllium sensitivity (BeS) refers to an asymptomatic condition whereby a person becomes sensitized (or allergic) to beryllium. This group of people includes those who have been exposed to beryllium through work (occupational exposure), family members of beryllium workers who may be exposed to beryllium dust via contact with their clothing, or possibly through environmental exposure (such as living within close proximity to a beryllium plant).

Chronic beryllium disease (CBD), or *berylliosis*, refers to a chronic inflammatory lung disease which is caused by exposure to beryllium. *CBD* usually progresses very slowly over a number of years; however, there have been cases where the disease may progress quickly. The latency period between exposure and detectable disease averages 10 to 15 years, with a range of several months to 30 years.

It should be noted that the majority of people who are exposed to beryllium do not develop sensitivity or disease. The rate of sensitization (without disease) has been estimated based on a small number of published studies to range from 1 to 3%. *CBD*

occurs in about 2 to 6% of the exposed population. What is not known at this time is how often sensitization progresses to disease.

The *Beryllium Lymphocyte Proliferation Test (BeLPT)* is a test that was developed to identify individuals who are or were sensitized to beryllium. In general terms, the *BeLPT* is performed by culturing T-lymphocytes from peripheral blood or broncho-alveolar (lung) fluid with and without beryllium salts. The proliferative response of lymphocytes stimulated by beryllium is compared to that of unstimulated lymphocytes, based on their incorporation of tritiated thymidine (a radioactive DNA precursor). The ratio of the stimulated-to-unstimulated lymphocytes is called the **stimulation index (SI)**. An elevated **SI** is indicative of beryllium sensitization (*BeS*).

Presently, nothing surpasses the *BeLPT* for identifying individuals who may have beryllium related disease. However, while there is a false positive rate of only 1 to 2%, there is a 25 to 38% false negative rate reported for this test. It is also recommended that a person not be considered beryllium sensitized unless an initial abnormal *BeLPT* result is confirmed by one or more concurrent (split blood sample sent to 2 labs) or subsequent *BeLPTs* (2 abnormal results from same lab on separate dates).²

Objectives and Rationale

The Manatee County Health Department (CHD) has already begun testing former workers of the ABC plant, their family members as well as community residents who live in Manatee county with \$60,000 of county appropriated funds. A single blood sample (the *BeLPT*) was collected from each participant and sent to the National Jewish Immunology Laboratory in Denver, Colorado, for *BeLPT* testing. To date, the Manatee CHD have tested 94 people with 43 being former workers. They plan to test up to 250 people who meet their criteria for testing. As of January 6, the Manatee CHD test results indicate two people with abnormal results, one borderline result and one uninterpretable result.

There have also been reports that 25 people have had *BeLPT* testing done on their own with 4 being abnormal. According to a former union worker, the people who tested abnormal after having blood testing through their personal physicians used several labs including National Jewish, Cleveland Clinic, and the University of Pennsylvania. A few used other unknown labs.

As part of a state cooperative agreement program between the Agency for Toxic Substances and Disease Registry (ATSDR) and the state of Florida, an exposure investigation will be conducted by the Florida Department of Health (DOH) which will augment the *BeLPT* testing already begun by the Manatee CHD. This will involve blood sampling to test for possible beryllium sensitivity (*BeLPT*) for up to 200 participants, in addition to the 250 participants Manatee county is planning to test.

Because a second abnormal BeLPT is required to confirm beryllium sensitivity, ATSDR (in conjunction with the Florida DOH) will propose a second exposure investigation to retest all participants of this first investigation who had either an **abnormal** result, a **borderline** result, or an **uninterpretable** result. Blood samples will be collected and split and sent to 2 labs (the National Jewish Immunology Laboratory and Specialty Labs). This will enable ATSDR along with the Florida DOH and the Manatee CHD to more accurately confirm beryllium sensitivity.

Target Population

The Manatee CHD is currently offering free voluntary blood tests for beryllium exposure (*BeLPT*). They are offering a 1 time blood sampling for up to 250 participants who meet the following criteria:

1. Current Manatee county residents who are former workers at the ABC plant during the period of January 1, 1961 to December 31, 1996.
2. Family members of former workers at the ABC plant (who are current Manatee county residents) who were born prior to January 1, 1997 and lived with former workers in the Tallevast, Florida community during the period of January 1, 1961 to December 31, 1996.
3. Members of the Tallevast, Florida community who physically resided in homes located within a .25 mile radius of the former ABC plant located at 1600 Tallevast Road, Tallevast, Florida at anytime during the period of January 1, 1961 to December 31, 1996 and are current Manatee county residents.

The Manatee CHD has already tested 94 participants meeting these criteria. 43 participants were former workers, the other 51 were a combination of family members and community residents. There have been no children tested. All blood samples have been sent to the National Jewish Hospital's Immunology Laboratory in Denver, Colorado. The results of the *BeLPT* on the 94 participants are as follows:

- 3 abnormal results
 - 1 former worker, who tested negative 2 years ago (lab unknown) who is now abnormal. He will be referred for retesting to the Department of Labor, Savannah River Resource, 1708 Bunting Drive, N. Augusta, S.C. 29841.
 - 2 household contacts, both tested abnormal, of a former worker testing negative. They will be retested using county funds.
- 1 borderline result
 - A community resident, a female, living within a .25 mile radius of the former ABC plant who will be retested using county funds.
- 1 uninterpretable result
 - A community resident, a female, living within a .25 mile radius of the former ABC plant who will also be retested with county funds.

- 89 negative results
Dr. Branic, the Medical Director of the Manatee CHD, reports that the county has already committed to having these 5 participants retested using split sampling, with half of the blood sample sent to the National Jewish Laboratory and half sent to Specialty Labs. Another 148 participants on January 26, 2005 will have the *BeLPT* done and sent to the National Jewish Laboratory for first time testing.

The Florida DOH proposes to perform the *BeLPT* test on up to 200 participants who meet the following criteria:

4. Former workers of the ABC plant during the period of January 1, 1961 to December 31, 1996 who now reside either inside or outside of Manatee County.
5. Family members of former workers at the ABC plant who were born prior to January 1, 1997 and lived with former workers in the Tallevast, Florida community during the period of January 1, 1961 to December 31, 1996 who now reside either inside or outside of Manatee County. This can include children 12 years and older.
6. Members of the Tallevast, Florida community who physically resided in homes located within a .50 mile radius of the facility at anytime during the period of January 1, 1961 to December 31, 1996 and are now either residents inside or outside of Manatee County.

Agency Roles

In addition to conducting the *BeLPT* on 250 residents in county and retesting the 5 participants with **abnormal**, **borderline**, or **uninterpretable** results, the Manatee CHD will also compile a list of pulmonary specialists in Bradenton and Sarasota, Florida who are familiar with current treatment protocols for beryllium sensitization and chronic beryllium disease and are willing to accept new patients. This will ensure appropriate follow-up for those participants with abnormal results.

The Florida DOH will prepare a protocol and will conduct this exposure investigation which will provide a first round of *BeLPT* testing of 200 more participants living inside and outside of Manatee County. Education for the community will be provided by the state as well. The possibility of a Medical Grand Rounds by a noted expert in the field of beryllium disease is also being discussed. The Sarasota County Health Department (CHD) will also aid the Florida DOH with the exposure investigation.

ATSDR will review the Florida DOH protocol and propose amendments as necessary. ATSDR will also propose a follow-up exposure investigation to confirm those participants who are beryllium sensitized. This follow-up EI will involve the retesting of all participants (of the original 450) who either test **abnormal**, **borderline**, or **uninterpretable** on the first *BeLPT*.

Methods

Once the protocol, the attached informed consent form, and the questionnaire (which determines eligibility to participate) has received proper agency approval by both the Florida DOH and ATSDR, the Florida DOH and the Sarasota CHD will hold a public meeting to discuss the protocol and to distribute the questionnaire. Within 2 weeks of ATSDR's approval, the Sarasota CHD and the Florida DOH will mail a fact sheet to inform former workers, their family members, and nearby residents about the *BeLPT*. Within 2 weeks following the mailing of the fact sheet, the Florida DOH and the Sarasota CHD will hold another public meeting to answer questions and solicit consent forms (which must be signed by each participant prior to blood drawing) for the *BeLPT*. Two weeks prior to *BeLPT* testing, the Florida DOH and the Sarasota CHD will have consent forms, blood-draw tubes, and shipping materials ready for sending samples to the National Jewish Immunology Laboratory.

Data Collection/ Sampling Procedures

Blood (30 ml) will be collected, handled, and promptly shipped by overnight carrier, according to established protocols at the National Jewish Hospital Immunology Laboratory in Denver, Colorado, by the Florida DOH and the Sarasota DOH. This laboratory serves as the reference lab for the *BeLPT*, and has been selected to test the samples in this exposure investigation. Plans for blood collection and shipping procedures are described in **Appendix A**.

Data Analysis Procedures

The National Jewish Hospital Immunology Laboratory in Denver, Colorado, is one of four labs in the U.S. to do the beryllium lymphocyte proliferation test (*BeLPT*). It was selected because they were the first to develop the test, have established their competency in performing the test and have considerable experience interpreting the test.

The *BeLPT* is performed by culturing T-lymphocytes from blood with and without beryllium salts. If these T-lymphocytes are sensitized to beryllium, they will begin to proliferate (as reflected by the incorporation of tritiated thymidine from the culture media). The ratio of the response of stimulated to that of unstimulated lymphocytes is called the **stimulation index (SI)**. There are 6 values (or readings) possible for each test. An elevated **SI** as defined by the National Jewish Laboratory in 2 or more of the 6 values is indicative of beryllium sensitization (*BeS*). This is reported as an **abnormal** result. If 1 of the 6 values has an elevated **SI**, then this is reported to be a **borderline** result. If 0 of the 6 values have an elevated **SI**, then this is reported as a **negative** result. An **uninterpretable** result is also possible if the sample cannot be analyzed (e.g. a lack of adequate sample, an inability to culture T-lymphocytes, etc).

A person is not considered beryllium sensitized unless an initial **abnormal *BeLPT*** is confirmed by 1 or more concurrent or subsequent *BeLPTs*. This can be achieved by initially splitting the first blood sample and sending it to 2 labs. However, for this exposure investigation, the first round of blood samples will be sent to the National Jewish Laboratory. In a follow-up investigation, all those individuals with **abnormal**,

borderline, and **uninterpretable** results from the first round of testing will then be re-sampled; this second blood sample will be split and a sample will be sent to both the National Jewish Laboratory and to Specialty Labs. This is the rationale for the second exposure investigation proposed by ATSDR.

Questionnaire

A beryllium sensitivity screening questionnaire has been developed by the Sarasota CHD. It has been reviewed by the Florida DOH and ATSDR. Its purpose is to select individuals who meet the criteria set forth by this exposure investigation to participate and to identify any confounding factors which may interfere with the test (see **Appendix B**).

Quality Assurance

The Florida DOH will use chain-of-custody forms to document sample collection, storage, shipment and the description of the requested analysis. The original forms will be sent along with the blood samples to the National Jewish Immunology Laboratory in Denver, Colorado, with a copy being maintained by the Florida DOH.

Risk/Benefit Information

Donating a blood sample poses no risks other than the possibility of minor pain during venipuncture and possible bruising. The potential benefits are that these participants will learn if they may be sensitized to beryllium. There is still the possibility that even if a participant tests negative on the *BeLPT*, they could still be sensitized or become sensitized to beryllium in the future, even without further exposure. It is important to inform all participants that if their test result is negative they should consider being retested at some future date if they believe that they are at a high risk for developing beryllium disease.

Informed Consent Procedures

Potential participants will be informed of the purpose of this exposure investigation and any benefits or risks should they choose to participate. It will be stressed that participation is strictly voluntary, and they may withdraw from the investigation at any time without penalty (see **Appendix C**).

Procedures for Notifying Participants of Individual Results

Individual test results and an explanation of their significance will be provided in writing to each participant upon completion of the exposure investigation by the Florida DOH.

There will be face-to-face communication between a representative of the Florida DOH, the Sarasota CHD, or the Manatee CHD for all participants who test **abnormal**,

borderline, or uninterpretable to help them understand the need for retesting in order to confirm beryllium sensitization.

Assurance of Confidentiality

Individual results will not be made available to the public and confidentiality will be protected to the fullest extent possible by law. Individual test results may be released only to other federal, state, and local public health and environmental agencies. These agencies must also protect this confidential information. All records and computer files related to this exposure investigation will be locked and password protected, respectively.

Estimated Budget

Program publicity	
Printing color fact sheets (500 @ \$1: in kind contribution by DOH)	\$0
Postage for fact sheets (500 @ \$0.40= \$200: in kind contribution by DOH)	\$0
Sample collection by Sarasota CHD (210 @ \$30)	\$6300
Sample kits for blood draw (tubes, container, etc) (215@\$5)	\$1075
Sample shipment by Sarasota CHD (210 @ \$4)	\$840
Beryllium lymphocyte proliferation test (<i>BeLPT</i>) 210 @ \$198	\$41,580
Program administration: includes staff time for tracking, follow-up, results delivery, patient education and data management	
(SCHD In kind contribution)	\$5000
 Total estimated program cost: -----	
\$49,795	

APPENDIX B – Press Release February 2005

For Immediate Release

Hodges
February 25, 2005

Contact: Lindsay

850-245-4111

FREE TESTING FOR HOUSEHOLD MEMBERS OF FORMER AMERICAN BERYLLIUM WORKERS AND NEARBY RESIDENTS ANNOUNCED

Tallahassee - Today, the Sarasota County Health Department (CHD) and Florida Department of Health (DOH) announced a sign up for free blood beryllium sensitivity testing for up to 200 household members of former workers and for residents living within ½ mile of the former American Beryllium facility. In March, the Sarasota CHD will collect blood samples for household members and nearby residents at one of its clinics. The Department of Energy (DOE) will be testing former workers who were employed at the American Beryllium facility when the plant did business with DOE. DOE will be contacting former workers in the next few weeks.

This testing is in addition to recent beryllium sensitivity testing by the Manatee County Health Department. If you are a household member who lived with a former American Beryllium (Tallevast) worker anytime from 1961 to 1996 or lived within a half a mile near the former American Beryllium facility in Tallevast anytime from 1961 to 1996 and would like to participate, **you must call Mary Ellen Thornton at the Sarasota CHD (941) 861-6092.** All participants must be at least 12 years old.

Former workers were most likely exposed to beryllium dust. Household members of former workers are next most likely exposed to beryllium dust from former worker's clothes. To date, 91 household members of former workers and residents have requested testing. To date 109 slots are still available.

The federal Agency for Toxic Substances and Disease Registry (ATSDR) in Atlanta will pay for testing of up to 200 household members of former workers and nearby residents. There is no cost to participants. If individual tests need repeating, re-testing will also be free of charge. Re-testing will be done in April.

The beryllium sensitivity blood test may tell if an individual was exposed to beryllium and developed sensitivity. For individuals who have developed beryllium sensitivity, Florida DOH will refer them to a local pulmonologist (lung doctor) for follow-up. Follow-up testing or medical treatment will be the responsibility of the individual. Some beryllium-sensitive individuals may eventually develop chronic beryllium disease.

To participate in this beryllium sensitivity testing, eligible participants must call Mary Ellen Thornton at the Sarasota CHD (941) 861-6092 (8:00 a.m - 5:00 p.m.)

APPENDIX C - Letter to Bradenton Area Participants

March 8, 2005

Dear *****:

The federal Agency for Toxic Substances and Disease Registry (ATSDR) is paying for blood sensitivity testing 200 household members of former workers of American Beryllium, residents and some former workers. Participants must have worked at the former American Beryllium facility from 1961-1996, lived with a former worker or lived within a ½ mile of the facility during this timeframe.

Please call Mary Ellen Thornton at the Sarasota County Health Department (CHD) at (941) 861-6092 (8:00 a.m.-5:00 p.m.) for an appointment. She is scheduling appointments the first two weeks of March.

If you have any questions, please call me toll free at 1-877-798-2772 or 850-245-4444 ext. 2310.

Sincerely,

Susan Ann Bland
Biological Scientist
Division of Environmental Health

SAB
Enclosures

APPENDIX D – Letter to Out of Town/Out of Bradenton Area Participants

March 8, 2005

Dear *****:

The federal Agency for Toxic Substances and Disease Registry (ATSDR) is paying for blood sensitivity testing 200 household members of former workers of American Beryllium, residents and some former workers. Participants must have worked at the former American Beryllium facility from 1961-1996, lived with a former worker or lived within a ½ mile of the facility during this timeframe. Most of these people live in Florida and will be tested at the Sarasota County Health Department (CHD) in March.

Because you live further away, I spoke with you and said I would ship you a blood sampling kit to take to your local physician or laboratory. Once you read this letter, please fill in the enclosed questionnaire and consent form and sign. Please fax this paperwork to me ASAP at (850) 487-0864. I will call you to tell you I received this information.

Next, please call your doctor and ask where you should have your blood tested locally. You may have to pay for a physician visit to have their phlebotomist draw your blood or they may send you to a nearby laboratory. Please make an appointment ASAP to have your blood tested by March 25th. Please bring the enclosed Blood Collection Procedure for Beryllium Lymphocyte Proliferation Test (BeLPT) instructions, the blood sampling kit and the Tallevast Community Update fact sheets with you to your appointment.

The person doing your beryllium sensitivity blood test must follow the enclosed instructions exactly. If they have any questions, please ask them to call me at 850-245-4444 ext. 2310.

After your blood is shipped to National Jewish Medical and Research Center in Denver, Colorado, it will take three weeks for your results. I will call you with your results and also mail you a letter with a copy of your results.

If you have any questions, please call me toll free at 1-877-798-2772 or 850-245-4444 ext. 2310.

Sincerely,

Susan Ann Bland
Biological Scientist
Division of Environmental Health

SAB
Enclosures (blood testing kit w/ paperwork)

Tallevast Community Update

February 2005

Tallevast, Manatee County, Florida

Beryllium Sensitivity Testing by Florida DOH and Sarasota County Health Department

Note: If you have received this fact sheet, we received your name and address and your verbal request to participate in beryllium sensitivity blood testing.

Between 1961 and 1996, the Loral American Beryllium Company (ABC) manufactured ultra-precision machine parts in Tallevast, Manatee County. These parts were made for the space industry and defense missiles. ABC specialized in the production of beryllium components. The work made beryllium dust. In 1996, Lockheed Martin Corporation purchased ABC, closing it later that year. Former workers reported beryllium dust inside ABC and on the clothes they wore home. Household members of former workers may have been exposed to beryllium dust. In addition, fans in the building may have spread the dust to nearby homes.

The Florida DOH and the Sarasota County Health Department (CHD) plan to test household members of former workers of American Beryllium and residents who lived within a half mile of the facility between 1961 and 1996. Another federal agency will be testing all the former workers. In March, the Sarasota CHD will collect blood samples from up to 200 people. National Jewish Medical and Research Center will analyze the samples for a reaction, or sensitivity, to beryllium. Florida DOH and the Sarasota CHD are conducting this testing as a public health service to household members of former American Beryllium workers and nearby residents. The results of this test are specific for the individuals tested and may not apply to other individuals.

Please see attached page for answers to frequently asked questions about blood testing at the Sarasota CHD.

Why the Florida Department of Health (DOH) Gets Involved

One of the roles of the Florida Department of Health (DOH) is to coordinate biological sampling, in this case, blood. These samples are analyzed at a certified lab. The Sarasota CHD will collect the blood samples. This blood test may tell you if you are sensitive to beryllium.

When will the Sarasota CHD conduct blood testing?

The Sarasota CHD will conduct blood testing during the weeks of March 7 and March 14, 2005. Please call Mary Ellen Thornton at (941) 861-6092 for an appointment. These dates are only for those participants who have not been tested at the Manatee CHD. All participants who need re-testing will be scheduled in April.

What will DOH do with the Test Results?

Within three weeks of the test, Florida DOH will provide individual test results and an explanation of their significance to the people tested.

Florida DOH or Sarasota CHD staff will call all participants who test **abnormal**, **borderline**, or **uninterpretable** (see attached sheet for definitions of these terms). We will help these participants understand the need for retesting in order to confirm beryllium sensitization.

DOH and the CHD will maintain confidential records throughout this process. No personal medical information will be given to anyone else without that person's approval.

For more information: Call DOH toll-free during regular business hours at (877) 798-2772.

Ask to speak to Susan Bland.

The U.S. Agency for Toxic Substances and Disease Registry (ATSDR) funds 100% of Florida DOH activities at hazardous waste sites, including the cost of this document, approximately 9 cents per copy.

**Florida Department of Health, Bureau of Community Environmental
Health**

**4052 Bald Cypress Way, Bin #A-08
Tallahassee, Florida 32399-1712**

*For more information on DOH
activities at hazardous waste sites in
Florida, go to:*

<http://www.myfloridaeh.com/hsee/SUPERFUND/>

*For more information about the
former American Beryllium site, go
to:*

[http://www.doh.state.fl.us/environment
/community/SUPERFUND/hazwastew
ork/](http://www.doh.state.fl.us/environment/community/SUPERFUND/hazwastework/)

APPENDIX F - Beryllium Sensitivity Fact Sheet (Attachment to March 8 letters)

1. What is a BeLPT test?

The beryllium lymphocyte proliferation test (BeLPT) is a simple blood test.

2. Can you test my urine? Or my hair?

Research has shown that urine tests and tests on hair are not able to determine beryllium sensitivity.

3. Do I need to fast prior to my blood test?

No, your test results are not affected by food or drink.

4. How does prednisone (steroids) affect my results?

If you are on steroids, please do not discontinue your medication without consulting your personal physician. It is advisable that you be off steroids for 3 months prior to the BeLPT.

5. Who should have a Beryllium Lymphocyte Proliferation Test (BeLPT)?

- Current and retired workers exposed to beryllium, beryllium alloys and beryllium dust and/or fumes
- People who work in buildings where beryllium is machined, even if you do not personally handle the beryllium should also consider being tested (this is known as bystander exposure and usually includes janitorial and administrative staff)
- Family members of workers who are exposed or have had known exposure to contaminated clothing or other materials should consider testing
- Others who have known exposure to beryllium dust or fumes

6. Will the BeLPT tell me whether or not I have Chronic Beryllium Disease?

No, the BeLPT may only tell you if you have beryllium sensitivity.

7. If my BeLPT comes back NORMAL, what should I do?

If you are a former worker, repeat BeLPT testing is advised every three to five years, or sooner if you develop symptoms including prolonged coughing, unexplained shortness of breath and wheezing.

8. If my BeLPT comes back ABNORMAL, what should I do?

A second confirming blood test is recommended before seeing a pulmonologist for further evaluation. Former workers who are eligible for Department of Labor benefits need only one abnormal BeLPT to file a claim. Please call the Department of Labor at 1-877-336-4272 for more information.

9. If my BeLPT comes back BORDERLINE, what should I do?

Repeat it. If the repeat test comes back normal, you may consider being retested every one to two years or sooner if symptoms develop. If your repeat test comes back abnormal or borderline, an evaluation with a pulmonologist is recommended to rule out Chronic Beryllium Disease.

10. If my BeLPT comes back UN-INTERPRETABLE, what should I do?

Repeat the test.

11. Where will the test be performed?

The Sarasota County Health Department will collect the blood samples. The BeLPT will be performed at the National Jewish Medical and Research Center in Denver, Colorado.

12. Who will pay for my test?

The federal Agency for Toxic Substances and Disease Registry (ATSDR) will fund initial testing and re-testing for those who test abnormal, indeterminate or borderline.

13. How long will it take to receive my test results?

It usually takes about two to three weeks to receive the test results.

14. Who will notify me of my test results?

If your test result is abnormal, borderline or indeterminate, the DOH will call you and let you know your results and schedule you for a re-testing date. They will also send you a letter with your results. If your results are normal, the DOH or the Sarasota County Health Department will send you a letter with a copy of your results.

Appendix G - Adult Consent/Adolescent Assent Form - Former American Beryllium Company

This form tells you about a study to find out if some people are sensitive to beryllium as a result of being exposed to beryllium dust from the former Loral American Beryllium Company. The Florida Department of Health (DOH) and the Sarasota County Health Department (CHD) together with the Agency for Toxic Substances and Disease Registry (ATSDR) are offering free voluntary blood tests for beryllium sensitivity for up to 200 former workers, family members of former workers, and residents who used to live or now live near the former facility in the Tallevast community of Manatee County, Florida.

The reason for this blood test is to see if you are sensitive to beryllium. Some people who are exposed to beryllium dust may develop chronic beryllium disease, which affects your lungs.

We are asking you to be in our study because you have either worked at the American Beryllium Company in the past, you are a family member of a former worker at the facility, or you live close to the facility.

What will we do?

If you choose to be in this study here is what we will do:

- ask about your health, job, and habits
- get 30 milliliters (about 6 teaspoons) of blood from your arm with a needle

We think this will take about 30 minutes to answer the questions and about 10 minutes to collect the blood.

We will send your blood sample to the National Jewish Clinical Laboratory in Denver, Colorado and they will test it to see if you may be sensitive to beryllium.

Could I be hurt?

Giving blood may hurt a little. You may have a bruise afterwards. Some people faint when they give blood. If your test result comes back okay, there is still a chance you may be sensitive to beryllium, even if you are no longer in contact with it. You can talk to your doctor to see if more testing is needed.

Will I get anything from this study?

By having your blood tested, you will learn whether you may be sensitive to beryllium. It is important that you understand that your test result may come back as **abnormal** (which means you may be sensitive to beryllium), **borderline** (which means you may or may not be sensitive to beryllium), **uninterpretable** (which means that the test could not be done), or **negative** (which means you are probably not sensitive to beryllium). If your test result comes back either **abnormal**, **borderline**, or **uninterpretable**, you will need

to be tested again to be sure that you are sensitive to beryllium or not. ATSDR will arrange for re-testing.

You will be provided a copy of your blood test results within 1 month unless something unusual happens.

The Florida DOH will prepare a report called a health consultation within 3 months after all test results have come back. The report will explain the testing results including conclusions and recommendations.

What about my privacy?

We will protect your privacy as much as the law allows. We will give you an investigation ID number. This number, not your name, will go on your blood sample and the questionnaire. We will not use your name in any reports we write about this study. We will keep a record of your name, address, and ID number so that we can send you the results of the test we do on your blood. The papers with your name on them will be kept in a locked file cabinet away from where we keep the filled out questionnaire and the blood samples.

Are there any costs?

You do not have to pay to be a part of this study. You will not be paid for being in this study. If you discuss your test results with your own doctor and he or she decides to do more testing on you, you or your insurer will have to pay for the costs of those tests.

What if I do not want to do this?

You can choose to be in this study or not. If you decide not to be in this study nothing will happen to you. If you join the study, you do not have to answer any questions you don't want to. You can stop being a part of the study at any time.

How can I find out more?

You may have questions about this study. If so, you can ask anyone here right now. If you have questions later or think you have been harmed by this study, you can call Susan Bland, Biological Scientist with the Florida DOH toll free at 1-877-798-2772, or Homer Rice, Environmental Health Director with the Sarasota CHD at (941) 861-6134.

Consent Statement

I have read this consent form or it has been read to me. I have had a chance to ask questions about this study and my questions have been answered. I agree to be a part of this study. I understand that my blood sample is only for one test. If my test comes back abnormal, borderline or indeterminate, ATSDR will arrange for re-testing. This retesting

is necessary to find out if I am sensitive to beryllium or not. Any follow-up treatment is my responsibility. I have marked below the parts I will do.

Yes **No** Fill out a questionnaire

Yes **No** Let some of my blood be taken for testing

Please Check One Box

I give consent for my blood test results to be given to the Florida DOH, ATSDR, the Sarasota CHD, the Florida Department of Environmental Protection (DEP) and the Environmental Protection Agency (EPA).

I DO NOT give consent for my blood test results to be given to the Florida DEP and the EPA.

Please Check One Box

I give consent for my blood test results to be given to my own doctor (please write doctor's name and address below).

Doctor's _____ Name

_____ First Last

_____ Address

_____ City State Zip code

I DO NOT give consent for my blood test results to be given to my own doctor.

Participant's Signature

Date

I have read the consent form to the person named above. He/she has asked questions about the study and had his/her questions answered.

Signature of person giving oral consent

Appendix H – Manatee and Sarasota County Health Department Beryllium Sensitivity Screening Questionnaire

Date: _____

Name: _____ DOB: _____

(Last) (First) (Middle Initial) (Maiden Name)

Address: _____

City State Zip
Code

Male Female Race: _____ Hispanic Non-Hispanic

Former worker:

Household member: Relationship to worker: _____

Tallevast Community member:

When was your first definite exposure to Beryllium? Date _____ Do not know _____

When was your last exposure? Date _____ Do not know _____

During the time of your Beryllium exposure what were your job titles? _____
N/A _____

How many hours per week were spent actively working with Beryllium? _____
N/A _____

Work History

During what years were you employed at the former American Beryllium Plant? N/A

1960 61 62 63 64 65 66 67 68 69 **1970** 71 72 73 74 75 76 77 78 79 N/A

1980 81 82 83 84 85 86 87 88 89 **1990** 91 92 93 94 95 96 N/A

Adding all intervals, how many years total have you worked at the former American Beryllium

Plant? _____ N/A _____

Do you think you might have been over-exposed to Beryllium dust or fumes in accident or unusual incident? Yes No If yes, please describe

Has a doctor ever told you that you have pulmonary tuberculosis? Yes
No

Has a doctor ever told you that you have sarcoidosis? Yes
No

Have you ever had a skin rash? Yes No

If yes, was the rash biopsied? Yes No

If yes, was the rash related to beryllium? Yes No Unknown

Has a health care provider ever told you that you have an abnormal chest x-ray or any lung or respiratory disease? Yes No

Have you ever been treated with steroids? Yes No

If yes, have you ever been treated with Prednisone? Yes No

Have you been treated with Prednisone in the last three months? Yes No

Have you ever smoked cigarettes? ("No" means less than 20 packs of cigarettes or 12 ounces of tobacco in a life-time or less than one cigarette a day for one year) Yes
No

Do you now smoke cigarettes or have you smoked cigarettes within the past month?

Yes No

How many cigarettes do you smoke per day now? Cigarettes per day _____ NA

How old were you when you first started smoking? Age in years _____ NA

How old were you when you stopped smoking? Age in years _____ Still smoking

Any other comments:

APPENDIX I – National Jewish Medical and Research Center Lab Form and Instructions

NATIONAL JEWISH
 Medical and Research Center
 1400 Jackson Street
 Denver, Colorado 80206

303-398-1974 303-270-2175 Fax
 800-550-6227 800-652-9556 Fax ClinRefLabs@njmc.org

BERYLLIUM LYMPHOCYTE PROLIFERATION TEST (BeLPT)

Patient Last, First Name, M.I. (Required)		Date of Birth	<input type="checkbox"/> Male <input type="checkbox"/> Female	Mail results to: (Required)
Collection Date:	Collection Time:	Patient ID:	Diagnosis (ICD-9) Code:	Electronic delivery to Heather Davis for result letter/patient notification
Referring Physician: Self pay (American Beryllium Corp)		Physician UPIN #	Physician Phone #	Referring physician name: American Beryllium Corp
Fax: <input type="checkbox"/> Fax Results		Facility Phone #		Folder name on Biosweb: American Beryllium Corp
COMPLETE SECTION BELOW ONLY IF YOU DO NOT WANT YOUR ACCOUNT BILLED				
Please Bill: <input type="checkbox"/> Medicare <input type="checkbox"/> Colo. Medicaid <input type="checkbox"/> Patient (Pre-Pay) <input type="checkbox"/> Check <input type="checkbox"/> Credit Card <input type="checkbox"/> Visa <input type="checkbox"/> Mastercard <input type="checkbox"/> Other		Name of Responsible Party (Last, First, M.I.):		Medicare (HIC) #
Credit Card# _____ Exp. Date _____		Street Address:		Medicaid ID #
		City	State	Zip
		Telephone #		Patient Bills must be prepaid or accompany specimen

BERYLLIUM LYMPHOCYTE PROLIFERATION:

(Must be scheduled in advance: 303-398-1906)

- BER1 Beryllium lymphocyte proliferation - Blood
 BER1 Beryllium lymphocyte proliferation - Bronchoalveolar Lavage

RESULT DELIVERY BY:

- Electronic Delivery
 Fax results (Hard copy to follow)

RELEASE OF INFORMATION AUTHORIZATION

I, _____, hereby authorize National Jewish Medical and Research Center to release medical information concerning Beryllium Lymphocyte Proliferation Testing to the above named individual.

For De-identified specimens only:

- I hereby certify that *Authorization for Release of Medical Information* on this patient is on file at this location.

 Signature

 Date

COMMENTS

(If billing address is different from the "Send Results to:" address please indicate here.)

Form A 023

#1 respiratory hospital in the U.S.
US News & World Report

Blood Collection Procedure For Beryllium Lymphocyte Proliferation Test (BeLPT)

Below are collection and shipping instructions for the BeLPT. Please contact Heather Davis, Beryllium Program Coordinator, at (303) 398-1906, or davish@njc.org, with any beryllium-related questions, comments or concerns. **Thank you for choosing National Jewish!**

1. Call (303) 398-1906 to schedule the test, preferably 24 hours in advance. Alternatively, you may send a fax to (303) 270-2175. Please include the number of specimens you anticipate sending. We accept samples Monday through Saturday.
2. Draw 30 ml of blood into sterile, green-top heparinized vacutainers.
3. **Label tubes with patient's name, date of blood draw and "LPT-Beryllium".**
4. For each sample sent, please enclose a requisition with highlighted fields completed. Payment, either by check or credit card, or Medicare information, if applicable, must accompany the specimen. The cost per test is **\$259.00**.
5. **Pack the vacutainers in a Styrofoam container. Do not refrigerate. Keep at room temperature. Do not pack on ice. Avoid temperature extremes.**
6. **Label package "Human Blood - Deliver Immediately. Do Not Freeze. Perishable."**
7. The blood must be shipped via priority overnight courier (i.e. Fed-Ex, UPS, Airborne Express) to reach National Jewish the morning after it is drawn. A pre-paid airbill has been provided for your convenience.
8. **Deliver to:** National Jewish Medical and Research Center
Beryllium Lab, Room M017
1400 Jackson St.
Denver, CO 80206
Phone: (303) 398-1288
9. Results are available in 7 to 10 days and will be mailed to the patient and any other individuals she/he designates on the requisition.

APPENDIX J – Letter to Participants Informing of Normal Blood Test Results March 2005

March 2005

CONFIDENTIAL

Name
Address

Dear *****:

Your blood beryllium sensitivity tests analyzed in March 2005 by National Jewish Medical and Research Center were normal. A copy of your blood test results are enclosed. The third line under “interpretation” of your results tells you your actual result. Also, please read the enclosed fact sheet from National Jewish Research Center explaining your test results in detail.

Even though your test results were normal, if you are a former worker, you should repeat this test if you develop symptoms including prolonged coughing, unexplained shortness of breath or wheezing. It is generally recommended that you have a BeLPT every one to three years if you are currently exposed to beryllium, and every 3 to 5 years if you are no longer exposed to beryllium. Some people who have had a normal test in the past will develop an abnormal test later.

Per your request, I sent a copy of your blood test results to Dr. *****. If you have any questions about your blood test results, please call me toll free at 1-877-798-2772 or at 850-245-4444 ext. 2310.

Sincerely,

Susan Ann Bland
Biological Scientist
Bureau of Community Environmental

Health
SAB
Enclosures

APPENDIX K - Fact Sheet to Participants with Normal Test Results

Understanding Your Normal BeLPT Result

What is a normal test result?

Each blood test is made up of six individual measurements of the blood's reaction to beryllium. The six measurements represent different amounts of beryllium and different lengths of time to test for stimulation by beryllium. A normal test result is one in which all 6 stimulation indices (SIs) are below the cut-off value of 2.5. Simply put, this means that your cells did not proliferate, or grow, when mixed with beryllium in the laboratory. Different laboratories use different cut-off values, based on tests that they have done on normal people who have never been exposed to beryllium.

What does a normal test result mean?

A normal test result means that you are not sensitized to beryllium at this time. Sometimes people with normal tests will still have beryllium sensitization or may have chronic beryllium disease. One normal test gives approximately 80% certainty that the test is truly normal.

Should I be retested? If so, when?

Because CBD or beryllium sensitization can develop years after you are exposed to beryllium, you should have a BeLPT regularly. It is generally recommended that you have a BeLPT every one to three years if you are currently exposed to beryllium, and every 3 to 5 years if you are no longer exposed beryllium. Some people who have had a normal test in the past will develop an abnormal test later.

I have a 2.5 on my result. Is this "almost abnormal"?

All beryllium stimulation values (SI) that are 2.5 or lower are considered normal. The BeLPT can determine only if a person's cells have a normal or abnormal response to beryllium. A person with higher SI values within the normal range does not have a greater chance of having sensitization or CBD than a person with lower SI values.

I have symptoms of CBD. Is it possible that my test result is a "false negative"?

Approximately 20% of patients with CBD can have normal ("negative") blood BeLPT results. If you have symptoms or other medical tests results that suggest possible CBD, it is advisable to have your doctor still consider CBD as a possibility. In such situations, either a repeat blood BeLPT or possibly a bronchoalveolar lavage (lung washing) BeLPT will be abnormal.

What is a "mitogen" and what do the results mean?

A mitogen is a substance that causes everyone's cells to multiply in number (proliferate). By contrast, beryllium causes cells to proliferate only in individuals with beryllium sensitization or CBD. National Jewish uses the mitogen "phytohemagglutinin" (PHA) as part of the BeLPT. By testing cells with a mitogen, we can make sure the cells are alive and can respond appropriately. In the National Jewish Beryllium Laboratory, mitogen SI values of 3.0 or higher indicate that the cells were alive and healthy at the time of the test. We call this mitogen a "positive control."

I did not have a mitogen response. What does this mean?

There are a number of technical reasons why your blood may not have shown a mitogen response. Your test results are still valid if the cells respond to "antigen" (Candida protein), even if the mitogen response is missing or low. If the cells do not respond to either mitogen or to antigen, your test is uninterpretable, as we cannot determine if your cells were still alive at the time that we performed the test.

What is an antigen and what do the results mean?

An antigen is a substance that most people have been exposed to, and that causes normal cells to multiply (proliferate). By contrast, beryllium causes cells to proliferate only in individuals with beryllium sensitization or CBD. National Jewish uses the antigen *Candida albicans* (common yeast protein) as part of the BeLPT. Testing cells with an antigen helps ensure the cells are generally capable of multiplying when stimulated. In the National Jewish Beryllium Laboratory, antigen SI values of 3.0 or higher indicate the cells are alive and normal at the time of the test.

I did not have an antigen response. What does this mean?

There are a number of technical reasons why your blood may not have shown an antigen response. Your test results are still valid if the cells respond to mitogen even if the Candida antigen response is missing or low. If the cells do not respond to either mitogen or to antigen, your test is uninterpretable, as we cannot determine if your cells were still alive at the time that we performed the test.

I do not have six beryllium SIs on my test result; one or more are missing. What does this mean?

The BeLPT is six beryllium tests in one. The cells are divided into six groups: three different concentrations of beryllium measured at two different points in time. If there is a technical problem with the cells in one of the groups, the SI for that group will not be reported. At least 3 SIs from the beryllium-stimulated groups must be found to be of sufficient quality to be interpreted by one of our expert beryllium physicians. Up to three of the six beryllium "tests" must be of good reliability to be interpreted. If there are fewer than 3 beryllium SIs reported, the test was not considered to be reliable and is reported as "uninterpretable." This does not mean that there is anything wrong with your blood. Your test usually just needs to be repeated.

For more information on interpreting your test results, please contact the Beryllium Program at 800-423-8891 x1722, or beryllium@njc.org.

**APPENDIX L – Letter to Participants -
Borderline/Uninterpretable/Abnormal Blood Test Results March 30,
2005**

Name
Address

Dear _____:

Your blood beryllium sensitivity test analyzed by National Jewish Medical Research Center on _____ was (borderline/uninterpretable/abnormal). Therefore, you will need to have a repeat test done at the Sarasota County Health Department. Please call Mary Ellen Thornton at (941) 861-6092 and set up an appointment for April 20 or 21. Please drink at least eight glasses of water the day of your test and for two days before.

A copy of your blood test results is enclosed. The third line under “interpretation” of your results tells you your actual result. Also, please read the enclosed fact sheet from National Jewish Medical and Research Center explaining your test results in detail.

I will call you after I receive your repeat test results and explain your results to you. I will also send you another letter and enclose your repeat test results. The Federal Agency for Toxic Substances and Disease Registry (ATSDR) is paying for the re-testing. There will be no charge to you for blood test.

If you are a former worker, you should repeat the blood beryllium sensitivity test in three to five years or sooner if you develop symptoms including prolonged coughing, unexplained shortness of breath or wheezing.

Per your request, I sent a copy of your blood test results to Dr. _____.
If you have any questions about your blood test results, call me toll free at 1-877-798-2772 or at 850-245-4444 ext. 2310.

Sincerely,

Susan Ann Bland
Biological Scientist
Bureau of Community Environmental

Health
SAB
Enclosures

APPENDIX M- Fact Sheet to Participants with Abnormal Test Results

Understanding Your Abnormal BeLPT Result

What is an abnormal test result?

An abnormal test result is one in which any two or more stimulation indices (SIs) are above the cut-off value of 2.5. Each BeLPT is made up of six beryllium tests in one. Simply put, if two or more of these six beryllium stimulations are elevated, this means your cells proliferated, or grew, when mixed with beryllium.

What does an abnormal test result mean?

An abnormal ("positive") result indicates that your blood contains immune system cells (lymphocytes) that recognize beryllium as a foreign "antigen." People who have an abnormal blood response fall into two categories: 1) they may already have CBD or 2) they have the blood sensitization to beryllium but do not yet have CBD. National Jewish recommends a second test if this is your first abnormal result. If this is your second abnormal test result, we recommend you make an appointment with a doctor who is familiar with beryllium disease. Additional testing is necessary to determine if you have CBD. For more information on doctors at National Jewish who specialize in beryllium, or for help locating a physician in your area, please contact the Beryllium Program at 1-800-423-8891, x1722.

I have an abnormal BeLPT. Should I have blood drawn for another BeLPT? If so, when?

If this is your first abnormal test result, we recommend a second test as soon as possible to confirm that you are beryllium sensitized. It is highly likely that the second test will also be abnormal, although occasionally the second test will be normal. In that situation, we recommend waiting 3 to 6 months and then repeating the test again.

If this is your second abnormal test result, we recommend an appointment with a doctor knowledgeable about beryllium to determine whether you have beryllium sensitization or CBD.

I have a high stimulation index (SI) value on my test result. Does this mean I have CBD?

Not necessarily. The BeLPT can determine only if a person's cells have a normal or abnormal response to beryllium. We do not rely on the size of the SI: the test gives a "yes" or "no" answer. If your test is abnormal, the SI number is not important. If your test is repeated, it is likely that the SI number will vary, although it is likely to still be above the cut-off.

What is a "false positive" result?

A "false positive" test means that the blood test was "abnormal" when it should have been "normal." This happens less than 10% of the time with the blood BeLPT. If an abnormal test repeats as abnormal, the chances that this is a "false positive" result is less than 1%.

What is a mitogen and what do the results mean?

A mitogen is a substance that causes everyone's cells to multiply in number (proliferate). By contrast, beryllium causes cells to proliferate only in individuals with beryllium sensitization or CBD. National Jewish uses the mitogen "phytohemagglutinin" (PHA) as part of the BeLPT. By testing cells with a mitogen, we can make sure the cells are alive and can respond appropriately. In the National Jewish Beryllium Laboratory, mitogen SI values of 3.0 or higher indicate that the cells were alive and healthy at the time of the test. We call this mitogen a "positive control."

I did not have a mitogen response. What does this mean?

There are a number of technical reasons why your blood may not have shown a mitogen response. Your test results are still valid if the cells respond to "antigen" (Candida protein), even if the mitogen response is "missing" or "low." If the cells do not respond to either mitogen or to antigen, your test is uninterpretable, as we cannot determine if your cells were still alive at the time that we performed the test.

What is an antigen and what do the results mean?

An antigen is a substance that most of us have been exposed to and that causes normal cells to multiply (proliferate). By contrast, beryllium causes cells to proliferate only in individuals with beryllium sensitization or CBD. National Jewish uses the antigen *Candida albicans* (common yeast protein) as part of the BeLPT. Testing cells with an antigen helps ensure the cells are generally capable of multiplying when stimulated. In the National Jewish Beryllium Laboratory, antigen SI values of 3.0 or higher indicate the cells are alive and healthy at the time of the test.

I did not have an antigen response. What does this mean?

There are a number of technical reasons why your blood may not have shown an antigen response. Your test results are still valid if the cells respond to mitogen even if the Candida antigen response is "missing" or "low." If the cells do not respond to either mitogen or to antigen, your test is uninterpretable, as we cannot determine if your cells were still alive at the time that we performed the test.

I do not have 6 SIs on my test result; one or more are missing. What does this mean?

The BeLPT is six beryllium tests in one. The cells are divided into six groups: three different concentrations of beryllium measured at two different points in time. If there is a technical problem with the cells in one of the groups, the SI for that group will not be reported. At least 3 SIs from the beryllium-stimulated groups must be found to be of sufficient quality to be interpreted by one of our expert beryllium physicians. Up to three of the six beryllium "tests" must be of good reliability to be interpreted. If there are fewer than 3 beryllium SIs reported, the test was not considered to be reliable and is reported as "uninterpretable." This does not mean that there is anything wrong with your blood. The test usually just needs to be repeated.

For more information on interpreting your test results, please contact the Beryllium Program at 1-800-423-8891 x1722, or beryllium@njc.org.

APPENDIX N – Fact Sheet to Participants with Borderline Test Results

Understanding Your Borderline BeLPT Result

What is a borderline test result?

A borderline test result is one in which any one stimulation index (SIs) is above the cut-off value of 2.5. Each BeLPT is made up of six beryllium tests in one. Simply put, if one or more of these six beryllium stimulations are elevated, this means your cells proliferated, or grew, when mixed with beryllium. It is uncommon for only one of the six tests to be elevated; in fact, an abnormal test requires two or more of the six test results to be elevated. A borderline test must be repeated.

What does a borderline test result mean?

A borderline result indicates that your blood may contain immune system cells (lymphocytes) that recognize beryllium as a foreign “antigen.” **People who have a borderline blood are not beryllium sensitized.** Further testing needs to be done. National Jewish recommends a second test if this is your first borderline result. If this is your second borderline test result, we recommend you contact National Jewish to discuss your results with a health care provider who is familiar with the health effects of beryllium exposure. You may then need to make an appointment with a doctor who is familiar with beryllium disease. Additional testing is necessary to determine if you have CBD. For more information on doctors at National Jewish who specialize in beryllium, or for help locating a physician in your area, please contact the Beryllium Program at 1-800-423-8891, x1722.

I have a borderline BeLPT. Should I have blood drawn for another BeLPT? If so, when?

If this is your first borderline test result, we recommend a second test as soon as possible. Your second test may be normal, abnormal or borderline.

I have a high stimulation index (SI) value on my test result. Does this mean I have CBD?

Not necessarily. The BeLPT can determine only if a person’s cells have a normal or abnormal response to beryllium. We do not rely on the size of the SI: the test gives a “yes” or “no” answer. If your test is abnormal, the SI number is not important. If your test is repeated, it is likely that the SI number will vary, although it is likely to still be above the cut-off.

What is a “false positive” result?

A “false positive” test means that the blood test was “abnormal” when it should have been “normal.” This happens less than 10% of the time with the blood BeLPT. If an abnormal test repeats as abnormal, the chances that this is a “false positive” result is less than 1%.

What is a mitogen and what do the results mean?

A mitogen is a substance that causes everyone's cells to multiply in number (proliferate). By contrast, beryllium causes cells to proliferate only in individuals with beryllium sensitization or CBD. National Jewish uses the mitogen "phytohemagglutinin" (PHA) as part of the BeLPT. By testing cells with a mitogen, we can make sure the cells are alive and can respond appropriately. In the National Jewish Beryllium Laboratory, mitogen SI values of 3.0 or higher indicate that the cells were alive and healthy at the time of the test. We call this mitogen a "positive control."

I did not have a mitogen response. What does this mean?

There are a number of technical reasons why your blood may not have shown a mitogen response. Your test results are still valid if the cells respond to "antigen" (Candida protein), even if the mitogen response is "missing" or "low." If the cells do not respond to either mitogen or to antigen, your test is uninterpretable, as we cannot determine if your cells were still alive at the time that we performed the test.

What is an antigen and what do the results mean?

An antigen is a substance that most of us have been exposed to and that causes normal cells to multiply (proliferate). By contrast, beryllium causes cells to proliferate only in individuals with beryllium sensitization or CBD. National Jewish uses the antigen *Candida albicans* (common yeast protein) as part of the BeLPT. Testing cells with an antigen helps ensure the cells are generally capable of multiplying when stimulated. In the National Jewish Beryllium Laboratory, antigen SI values of 3.0 or higher indicate the cells are alive and healthy at the time of the test.

I did not have an antigen response. What does this mean?

There are a number of technical reasons why your blood may not have shown an antigen response. Your test results are still valid if the cells respond to mitogen even if the Candida antigen response is "missing" or "low." If the cells do not respond to either mitogen or to antigen, your test is uninterpretable, as we cannot determine if your cells were still alive at the time that we performed the test.

I do not have 6 SIs on my test result; one or more are missing. What does this mean?

The BeLPT is six beryllium tests in one. The cells are divided into six groups: three different concentrations of beryllium measured at two different points in time. If there is a technical problem with the cells in one of the groups, the SI for that group will not be reported. At least 3 SIs from the beryllium-stimulated groups must be found to be of sufficient quality to be interpreted by one of our expert beryllium physicians. Up to three of the six beryllium "tests" must be of good reliability to be interpreted. If there are fewer than 3 beryllium SIs reported, the test was not considered to be reliable and is reported as "uninterpretable." This does not mean that there is anything wrong with your blood. The test usually just needs to be repeated. **For more information on interpreting your test results, please contact the Beryllium Program at 1-800-423-8891 x1722, or beryllium@njc.org.**

APPENDIX O- Fact Sheet to Participants with Uninterpretable Test Results

Understanding Your Uninterpretable BeLPT Result

What is an uninterpretable test result?

An uninterpretable test result is one in which none of the beryllium values for the test can be reported.

What does an uninterpretable test result mean?

Each blood test is made up of six individual measurements of the blood's reaction to beryllium. The six measurements represent different amounts of beryllium and different lengths of time to test for stimulation by beryllium. If there is a technical problem with the cells in one of the groups, the result for that group will not be reported. At least 3 results from the beryllium-stimulated groups must be found to be of sufficient quality to be interpreted by one of our expert beryllium physicians. If there are fewer than 3 beryllium results reported, the test was not considered to be reliable and is reported as "uninterpretable." Another reason for an uninterpretable test result is if the cells do not respond to either mitogen or to antigen (positive controls). Sometimes blood cells are fragile and die in the shipping of the blood or the processing steps. If your cells do not multiply when exposed to the positive control substances (PHA, Candida), we cannot determine if your cells were still alive at the time that we performed the test.

An uninterpretable test result does not mean that there is anything wrong with your blood. The test usually just needs to be repeated.

I have an uninterpretable BeLPT. Should I have blood drawn for another BeLPT? If so, when?

Because an uninterpretable test does not provide any information about beryllium sensitization, it is advisable that you have an uninterpretable test repeated within three months.

What is a mitogen and what do the results mean?

A mitogen is a substance that causes everyone's cells to multiply in number (proliferate). By contrast, beryllium causes cells to proliferate only in individuals with beryllium sensitization or CBD. National Jewish uses the mitogen "phytohemagglutinin" (PHA) as part of the BeLPT. By testing cells with a mitogen, we can make sure the cells are alive and can respond appropriately. We call this mitogen a "positive control."

I did not have a mitogen response. What does this mean?

There are a number of technical reasons why your blood may not have shown a mitogen response. Your test results are still valid if the cells respond to "antigen" (Candida protein), even if the mitogen response is "missing" or "low."

What is an antigen and what do the results mean?

An antigen is a substance that most of us have been exposed to and that causes normal cells to multiply (proliferate). By contrast, beryllium causes cells to proliferate only in individuals with beryllium sensitization or CBD. National Jewish uses the antigen *Candida albicans* (common yeast protein) as part of the BeLPT. Testing cells with an antigen helps ensure the cells are able to multiply when stimulated.

I did not have an antigen response. What does this mean?

There are a number of technical reasons why your blood may not have shown an antigen response. Your test results are still valid if the cells respond to mitogen even if the *Candida* antigen response is “missing” or “low

For more information on interpreting your test results, please contact the Beryllium Program at 1-800-423-8891 x1722, or beryllium@njc.org.

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APPENDIX P – April 2005 Florida DOH Letter to Participants’ Physicians

Dear Physician:

The Florida Department of Health (DOH), Bureau of Community Environmental Health, recently coordinated beryllium sensitivity blood testing for former workers, household members of former workers and residents living near a hazardous waste site in your area. The site’s name is the former American Beryllium site and it is at 1600 Tallevast Road, Bradenton. The facility formerly housed a machine parts manufacturing plant where metals, including beryllium, were milled, lathed, and drilled into various components.

In March 2005, your patient had beryllium sensitivity blood testing done at the Sarasota County Health Department (CHD). Your patient requested we send you a copy of their blood test results. Your patient’s blood test was normal. Even though their test was normal, we recommended further instructions to your patient. If they are a former worker, they should repeat this test if they develop symptoms including prolonged coughing, unexplained shortness of breath or wheezing. It is generally recommended that they have a BeLPT blood test every one to three years if they are currently exposed to beryllium, and every 3 to 5 years if they are no longer exposed to beryllium. Some people who have had a normal test in the past will develop an abnormal test later.

Please see the enclosed letter with results and fact sheet sent to your patient in April. Two other fact sheets dated February 2005 are also enclosed and were given to your patient prior to testing.

I am including the *Toxic Substances Health Effects Resource Directory* to provide you with additional information about environmental contaminants and potential health effects. I am also enclosing a fact sheet called “*Working for You at Hazardous Waste Sites.*” The fact sheet contains details about our program and the work we do.

In addition, I am enclosing information on taking an environmental exposure history to assist you in taking an environmental inventory of chemicals a patient may have been exposed to in their work, hobbies, or neighborhood.

The last fact sheet is information on beryllium developed by the Agency for Toxic Substances and Disease Registry (ATSDR) who funds our program.

I hope these materials will assist you in your practice. If you have any questions or need any additional materials, you may reach me toll-free at 877-798-2772, or at 850-245-4444 (x 2332), or via e-mail Lu_Grimm@doh.state.fl.us. If you have any questions specifically about the blood testing that your patient participated in, please call Susan Bland at the same phone numbers or via e-mail Susan_Bland@doh.state.fl.us.

Sincerely,

Lu Grimm, MA
Community Involvement/Health Education
Florida Department of Health
Bureau of Environmental Epidemiology
Superfund Health Assessment & Education Section

APPENDIX Q – Glossary of Environmental Health Terms

Absorption: How a chemical enters a person's blood after the chemical has been swallowed, has come into contact with the skin, or has been breathed in.

Acute Exposure: Contact with a chemical that happens once or only for a limited period of time. ATSDR defines acute exposures as those that might last up to 14 days.

Adverse Health Effect: A change in body function or the structures of cells that can lead to disease or health problems.

ATSDR: The Agency for Toxic Substances and Disease Registry. ATSDR is a federal health agency in Atlanta, Georgia, that deals with hazardous substance and waste site issues. ATSDR gives people information about harmful chemicals in their environment and tells people how to protect themselves from coming into contact with chemicals.

Background Level: An average or expected amount of a chemical in a specific environment. Or, amounts of chemicals that occur naturally in a specific environment.

Biota: Used in public health, things that humans would eat including animals, fish and plants.

Cancer: A group of diseases that occur when cells in the body become abnormal and grow, or multiply, out of control.

Carcinogen: Any substance shown to cause tumors or cancer in experimental studies.

CERCLA: See Comprehensive Environmental Response, Compensation, and Liability Act.

Chronic Exposure: A contact with a substance or chemical that happens over a long period of time. ATSDR considers exposures of more than one year to be *chronic*.

Completed Exposure Pathway: See **Exposure Pathway**.

Comparison Value: (CVs) Concentrations or the amount of substances in air, water, food, and soil that are unlikely, upon exposure, to cause adverse health effects. Comparison values are used by health assessors to select which substances and environmental media (air, water, food and soil) need additional evaluation while health concerns or effects are investigated.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA): CERCLA was put into place in 1980. It is also known as **Superfund**. This act concerns releases of hazardous substances into the

environment, and the cleanup of these substances and hazardous waste sites. ATSDR was created by this act and is responsible for looking into the health issues related to hazardous waste sites.

Concern: A belief or worry that chemicals in the environment might cause harm to people.

Concentration: How much or the amount of a substance present in a certain amount of soil, water, air, or food.

Contaminant: See **Environmental Contaminant**.

Dermal Contact: A chemical getting onto your skin. (see **Route of Exposure**).

Dose: The amount of a substance to which a person may be exposed, usually on a daily basis. Dose is often explained as “amount of substance(s) per body weight per day”.

Dose / Response: The relationship between the amount of exposure (dose) and the change in body function or health that result.

Duration: The amount of time (days, months, years) that a person is exposed to a chemical.

Environmental Contaminant: A substance (chemical) that gets into a system (person, animal, or the environment) in amounts higher than that found in **Background Level**, or what would be expected.

Environmental Media: Usually refers to the air, water, and soil in which chemicals of interest are found. Sometimes refers to the plants and animals that are eaten by humans. **Environmental Media** is the second part of an **Exposure Pathway**.

U.S. Environmental Protection Agency (EPA): The federal agency that develops and enforces environmental laws to protect the environment and the public’s health.

Epidemiology: The study of the different factors that determine how often, in how many people, and in which people will disease occur.

Exposure: Coming into contact with a chemical substance.(For the three ways people can come in contact with substances, see **Route of Exposure**.)

Exposure Assessment: The process of finding the ways people come in contact with chemicals, how often and how long they come in contact with chemicals, and the amounts of chemicals with which they come in contact.

Exposure Pathway: A description of the way that a chemical moves from its source (where it began) to where and how people can come into contact with (or get exposed to) the chemical.

ATSDR defines an exposure pathway as having 5 parts:

- Source of Contamination,
- Environmental Media and Transport Mechanism,
- Point of Exposure,
- Route of Exposure, and
- Receptor Population.

When all 5 parts of an exposure pathway are present, it is called a **Completed Exposure Pathway**. Each of these 5 terms is defined in this Glossary.

Frequency: How often a person is exposed to a chemical over time; for example, every day, once a week, twice a month.

Hazardous Waste: Substances that have been released or thrown away into the environment and, under certain conditions, could be harmful to people who come into contact with them.

Health Effect: ATSDR deals only with **Adverse Health Effects** (see definition in this Glossary).

Indeterminate Public Health Hazard: The category is used in Public Health Assessment documents for sites where important information is lacking (missing or has not yet been gathered) about site-related chemical exposures.

Ingestion: Swallowing something, as in eating or drinking. It is a way a chemical can enter your body (See **Route of Exposure**).

Inhalation: Breathing. It is a way a chemical can enter your body (See **Route of Exposure**).

LOAEL: Lowest **O**bserved **A**dverse **E**ffect **L**evel. The lowest dose of a chemical in a study, or group of studies, that has caused harmful health effects in people or animals.

MRL: Minimal **R**isk **L**evel. An estimate of daily human exposure by a specified route and length of time -- to a dose of chemical that is likely to be without a measurable risk of adverse, noncancerous effects. An MRL should not be used as a predictor of adverse health effects.

NPL: The National **P**riorities **L**ist. (Which is part of **Superfund**.) A list kept by the U.S. Environmental Protection Agency (EPA) of the most serious, uncontrolled or

abandoned hazardous waste sites in the country. An NPL site needs to be cleaned up or is being looked at to see if people can be exposed to chemicals from the site.

NOAEL: No Observed Adverse Effect Level. The highest dose of a chemical in a study, or group of studies, that did not cause harmful health effects in people or animals.

No Apparent Public Health Hazard: The category is used in ATSDR's Public Health Assessment documents for sites where exposure to site-related chemicals may have occurred in the past or is still occurring but the exposures are not at levels expected to cause adverse health effects.

No Public Health Hazard: The category is used in ATSDR's Public Health Assessment documents for sites where there is evidence of an absence of exposure to site-related chemicals.

PHA: Public Health Assessment. A report or document that looks at chemicals at a hazardous waste site and tells if people could be harmed from coming into contact with those chemicals. The PHA also tells if possible further public health actions are needed.

Plume: A line or column of air or water containing chemicals moving from the source to areas further away. A plume can be a column or clouds of smoke from a chimney or contaminated underground water sources or contaminated surface water (such as lakes, ponds and streams).

Point of Exposure: The place where someone can come into contact with a contaminated environmental medium (air, water, food or soil). For examples: the area of a playground that has contaminated dirt, a contaminated spring used for drinking water, the location where fruits or vegetables are grown in contaminated soil, or the backyard area where someone might breathe contaminated air.

Population: A group of people living in a certain area; or the number of people in a certain area.

PRP: Potentially Responsible Party. A company, government or person that is responsible for causing the pollution at a hazardous waste site. PRP's are expected to help pay for the clean up of a site.

Public Health Assessment(s): See PHA.

Public Health Hazard: The category is used in PHAs for sites that have certain physical features or evidence of chronic, site-related chemical exposure that could result in adverse health effects.

Public Health Hazard Criteria: PHA categories given to a site which tell whether people could be harmed by conditions present at the site. Each are defined in the Glossary. The categories are:

- Urgent Public Health Hazard
- Public Health Hazard
- Indeterminate Public Health Hazard
- No Apparent Public Health Hazard
- No Public Health Hazard

Receptor Population: People who live or work in the path of one or more chemicals, and who could come into contact with them (See **Exposure Pathway**).

Reference Dose (RfD): An estimate, with safety factors (see **safety factor**) built in, of the daily, lifetime exposure of human populations to a possible hazard that is not likely to cause harm to the person.

Route of Exposure: The way a chemical can get into a person's body. There are three exposure routes:

- breathing (also called inhalation),
- eating or drinking (also called ingestion), and
- or getting something on the skin (also called dermal contact).

Safety Factor: Also called **Uncertainty Factor**. When scientists don't have enough information to decide if an exposure will cause harm to people, they use "safety factors" and formulas in place of the information that is not known. These factors and formulas can help determine the amount of a chemical that is not likely to cause harm to people.

SARA: The Superfund Amendments and Reauthorization Act in 1986 amended CERCLA and expanded the health-related responsibilities of ATSDR. CERCLA and SARA direct ATSDR to look into the health effects from chemical exposures at hazardous waste sites.

Sample Size: The number of people that are needed for a health study.

Sample: A small number of people chosen from a larger population (See **Population**).

Source (of Contamination): The place where a chemical comes from, such as a landfill, pond, creek, incinerator, tank, or drum. Contaminant source is the first part of an **Exposure Pathway**.

Special Populations: People who may be more sensitive to chemical exposures because of certain factors such as age, a disease they already have, occupation, sex, or certain behaviors (like cigarette smoking). Children, pregnant women, and older people are often considered special populations.

Superfund Site: See NPL.

Survey: A way to collect information or data from a group of people (**population**). Surveys can be done by phone, mail, or in person. ATSDR cannot do surveys of more than nine people without approval from the U.S. Department of Health and Human Services.

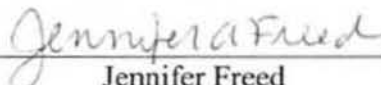
Toxic: Harmful. Any substance or chemical can be toxic at a certain dose (amount). The dose is what determines the potential harm of a chemical and whether it would cause someone to get sick.

Toxicology: The study of the harmful effects of chemicals on humans or animals.

Urgent Public Health Hazard: This category is used in ATSDR's Public Health Assessment documents for sites that have certain physical features or evidence of short-term (less than 1 year), site-related chemical exposure that could result in adverse health effects and require quick intervention to stop people from being exposed.

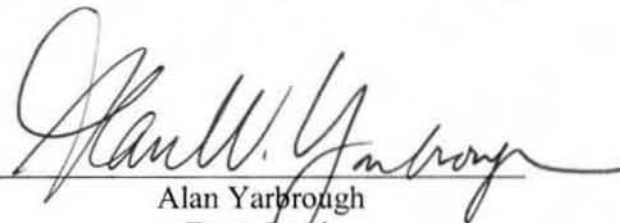
Certification

The Florida Department of Health, Bureau of Community Environmental Health prepared this beryllium sensitivity testing health consultation report for the former Loral American Beryllium site under a cooperative agreement with the Agency for Toxic Substances and Disease Registry. It is in accordance with the approved methods and procedures existing at the time the health consultation was begun. Editorial review was completed by the Cooperative Agreement partner.



Jennifer Freed
Technical Project Officer,
CAT, SPAB, DHAC

The Division of Health Assessment and Consultation, ATSDR, has reviewed this health consultation, and concurs with its findings.



Alan Yarbrough
Team Lead,
CAT, SPAB, DHAC, ATSDR