

# Health Consultation

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Exposure Investigation Report

FORMER AMERICAN BERYLLIUM SITE  
TALLEVAST, MANATEE COUNTY, FLORIDA

EPA FACILITY ID: FLD004100731

MARCH 20, 2006

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

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HEALTH CONSULTATION

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Prepared by:

Division of Health Assessment and Consultation  
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Atlanta, Georgia

**Exposure Investigation Report**  
**Former American Beryllium Site**  
**Tallevast, Manatee County, Florida**  
**EPA Facility ID: FLD004100731**  
**March 16, 2006**



**Division of Health Assessment and Consultation**  
**Agency for Toxic Substances and Disease Registry**  
**U.S. Department of Health and Human Services**  
**Atlanta, Georgia**

## Executive Summary

This exposure investigation, conducted by the Agency for Toxic Substances and Disease Registry (ATSDR) with the help of the Florida Department of Health (DOH) and the Sarasota County Health Department (CHD), completes the retesting of participants with **abnormal, borderline, or uninterpretable** beryllium lymphocyte proliferation test (**BeLPT**) results obtained by the Manatee CHD and the Florida DOH's first exposure investigation.

The Manatee County Health Department (CHD) began testing residents of the Tallevast community of Manatee County, Florida for beryllium sensitization using the BeLPT in December 2004 and January 2005 as a response to concerns about possible exposure to beryllium dust from the Loral American Beryllium Company (ABC) plant which operated from 1961 to 1996. The Loral ABC plant manufactured ultra-precision machine parts using beryllium components for the aerospace industry and the ballistic missile program for the defense industry. A total of 237 participants were tested using the BeLPT, with 7 abnormal results (3 former workers, 3 household contacts, and 1 community resident), 4 borderline results (1 former worker, 1 household contact, and 2 community residents), and 2 uninterpretable results (2 community residents).

The Florida DOH became involved due to community concerns for testing and to extend testing to include both Manatee and non-Manatee County residents (including out-of-state participants). As part of a state cooperative agreement program between ATSDR and the state of Florida, an exposure investigation was conducted by the Florida DOH to augment the BeLPT testing already begun by the Manatee CHD. Clinics were held at the Sarasota CHD in March 2005 and a total of 107 participants were tested. Fifteen participants from outside the area also were tested after having their blood samples obtained at a private laboratory or physician's office, increasing the total number tested to 122. Two borderline results were obtained (1 former worker from out-of-state and 1 community resident) in this first exposure investigation.

ATSDR then conducted a second exposure investigation, reported in this document, in April 2005 at the Sarasota CHD to retest all participants with an abnormal, borderline, or uninterpretable BeLPT result. Retesting is both recommended and essential in confirming beryllium sensitization.<sup>1</sup> A total of 9 participants were retested (including 1 former worker from out-of-state). Arrangements were made for the other 6 participants with an abnormal, borderline, or uninterpretable result from Manatee CHD's testing program to be tested elsewhere (see background, page 5). Of these 9 participants, 2 former workers and 1 household contact were considered beryllium sensitized and were referred to a pulmonologist for further evaluation.

## Objectives and Rationale

The purpose of this exposure investigation is to identify and retest participants tested by the Manatee CHD and the Florida DOH who had an abnormal, borderline, or uninterpretable BeLPT result. These individuals may be sensitized to beryllium and may

need further evaluation for possible beryllium-related disease. A second BeLPT will assure sufficient information to make appropriate medical referral and consultation.

A summary of the BeLPT results from both the Manatee CHD as well as the Florida DOH is included in this report. There were a total of 359 participants, which included former Loral ABC workers, household contacts (individuals who lived with former workers), and community residents who live or previously lived in the Tallevast community of Manatee County, Florida. These individuals may be at risk of developing beryllium sensitivity or chronic beryllium disease as a result of being exposed to beryllium dust.

## **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 at a 5-acre facility at 1600 Tallevast Road in the Tallevast community of 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 albetmet (a 60% beryllium/ 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 55 gallon drums. At the time of a Florida Department of Environmental Protection (DEP) inspection in 1994, the filters had been accumulating for approximately 4 years and a method of disposal had not been determined.

Behind the main plant was a grinding area, a wire machining section, and an electronic discharge machining department. The lubricating oils used in this area were filtered and treated as hazardous waste after they were changed out. Sludges produced in this area were estimated to be 97% diatomaceous earth and 3% beryllium. The sludge was then sent to a recycler for beryllium reclamation.<sup>2</sup> Chemicals used and wastes generated at the facility included oils, petroleum-based fuels, solvents, acids, and metals. In 1996, Lockheed Martin Corporation purchased the Loral ABC plant and closed it later that year. Former workers did report beryllium dust inside the facility and on the uniforms they wore home. In addition, building exhaust ventilation fans may have released beryllium dust outside the plant.

Beryllium is a naturally occurring element. It is present in a variety of materials, such as rocks, coal, oil, soil, and volcanic dust. Two kinds of mineral rocks, bertrandite and beryl, are mined commercially for beryllium.<sup>3</sup> Beryllium is the fourth lightest element and is a useful material for highly technological applications, including nuclear weapons and reactors, aircraft and space vehicle structures, automobiles, etc. Found in more than 45 minerals, beryllium is present at low levels in soil and air in most urban centers.<sup>4</sup>

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. Numerous interviews with former workers and community members revealed that the former ABC plant was no exception. The Florida DEP documented numerous reports from former workers of dust throughout the plant, the lack of adequate vacuum collection systems, and inadequate facilities for workers to change clothes and clean up 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 become a health concern for the families of those workers, as well as community members who had frequent contact with these workers.

As a result of these concerns the Manatee CHD tested participants using the BeLPT who met at least one of the following criteria:

1. Current Manatee county residents who were former workers at the ABC plant during the period from January 1, 1961 to December 31, 1996.
2. Family members of former workers at the ABC plant (who are current Manatee county residents) born prior to January 1, 1997 who lived with a former ABC plant worker in the Tallevast community during the period from January 1, 1961 to December 31, 1996.
3. Members of the Tallevast community who physically resided in homes located within a 0.25 mile radius of the former ABC plant at anytime during the period from January 1, 1961 to December 31, 1996 and are current Manatee county residents.

Staff from the Manatee CHD held clinics on December 16, 2004, and on January 19 and 26, 2005 to collect single 30-mL blood samples for BeLPT testing from those participants who met their testing criteria. The samples were shipped to the National Jewish Medical and Research Center Laboratory in Denver, Colorado in accordance with their handling and shipping procedures. (See Appendix A of Exposure Investigation Protocol II)

The Manatee CHD took single blood samples from 237 participants. Participants were categorized as either Tallevast or non-Tallevast residents, former workers (FWs), household contacts of former workers (HCs), or residents in the community (Res). Thirteen children between the ages of 10 and 17 years were also tested.

Tallevast Residents

10 FWs  
37 HCs  
116 Res

Non-Tallevast Residents

56 FWs  
18 HC

The following BeLPT results from Manatee CHD were obtained:

	<u>Abnormal</u>	<u>Borderline</u>	<u>Un-interpretable</u>	<u>Normal</u>
Former Workers (FWs)	3	1		62
Household Contacts (HCs)	3	1		51
Community Residents (Res)	1	2	2	111
<b>Totals</b>	7	4	2	224

On the basis of these results, 13 participants were referred for retesting.

Six of these participants were handled by the Manatee CHD as follows:

- 2 of the abnormal FWs were referred for retesting through a program sponsored by the Department of Energy (D.O.E.). Their results are unknown at the time of this report.
- 2 of the abnormal HCs were retested using split sampling on January 19, 2005 by the Manatee CHD; these were again abnormal and referred to a pulmonologist for further evaluation.
- 1 of the borderline community residents was retested using split sampling on January 19, 2005 by the Manatee CHD and was found to be normal.
- 1 of the uninterpretable community residents was retested using split sampling on January 26, 2005 by the Manatee CHD and was found to be normal.

The remaining 7 participants from this group were referred to participate in the ATSDR exposure investigation reported in this document.

The Florida DOH, as part of a state cooperative agreement program between ATSDR and the state of Florida, then conducted an exposure investigation to augment BeLPT testing already completed by the Manatee CHD to further extend the scope of testing beyond Manatee County. Participants living in Manatee, Sarasota, Pinellas, Hillsborough, Pasco, and Marion counties were represented. A total of 4 clinics were held at the Sarasota CHD on March 7 and 8, 2005, and again on March 14 and 15, 2005. Participants were selected who met at least one of the following criteria:

1. Former workers of the ABC plant during the period from January 1, 1961 to December 31, 1996 who now reside either within or outside Manatee County, Florida.
2. Family members of former workers at the ABC plant who were born prior to January 1, 1997 and lived with a former worker during any period from January 1, 1961 to December 31, 1996 and who now reside either within or outside Manatee County, Florida.
3. Members of the Tallevast community who physically resided in homes located within a 0.50 mile radius of the former ABC plant during the period from January

1, 1961 to December 31, 1996 and are now either residents within or outside Manatee County, Florida.

The Florida DOH's exposure investigation utilized staff from the Sarasota CHD to collect single 30-mL blood samples for BeLPT testing from 107 participants who met their testing criteria. There was 1 child, age 14, included in this group. These samples were shipped to the National Jewish Medical and Research Center Laboratory in accordance with their handling and shipping procedures. (See Appendix A of Exposure Investigation Protocol II)

Twenty-two individuals living outside the area also received a blood sampling kit with supplies and instructions on the mailing of their samples. Fifteen participants, including a 16 year-old child, responded by having their blood drawn either at their physician's office or at a private laboratory. These samples were then shipped to the National Jewish Medical and Research Center Laboratory using the same handling and shipping procedures. All 15 participants mailed their original signed consent forms and questionnaires back to the Florida DOH.

The participants meeting the criteria for Florida DOH's BeLPT testing were as follows:

- 19 FWs
- 54 HCs
- 49 Res

The following BeLPT results from the Florida DOH were obtained:

	Abnormal	Borderline	Un-interpretable	Normal
Former Workers (FWs)		1		18
Household Contacts (HCs)				54
Community Residents (Res)		1	2*	46
<b>Totals</b>		2	2	118

Of the 107 participants attending the clinics held by the Florida DOH, only 1 BeLPT result from a community resident (Res) was borderline. This person was referred for retesting as part of ATSDR's exposure investigation.

Of the 15 out-of region participants, 1 BeLPT result from a former worker (FW) was borderline. A second blood sampling kit was mailed out to him and he was included in ATSDR's exposure investigation.

\*A community resident had a blood sample drawn by his wife, a nurse, at their home on March 21, 2005; however, there was insufficient sample to run the test and due to a medical condition, he elected not to have the sample redrawn.

\*Another community resident had a BeLPT test drawn on March 14, 2005 at the Sarasota CHD, and an insufficient blood sample was obtained. His blood was again collected in

April; however, the split sample was not sent to Specialty Laboratories and the fraction sent to the National Jewish Medical and Research Center Laboratory was not obtained in the required 24-hour time period. No response was received to a message left on his answering machine or to a letter sent by staff of the Florida DOH.

### **Target Population**

ATSDR retested all 7 participants from Manatee CHD and 2 participants from the Florida DOH who had an abnormal, borderline, or uninterpretable result on their first BeLPT. A total of 9 participants were retested in this exposure investigation. Another participant was also tested for the first time and their BeLPT was sent to only one laboratory (Specialty Laboratories).

### **Demographics**

The Tallevast community is located between Sarasota and Bradenton in southern Manatee County, Florida. The neighborhood is a blend of single family homes, as well as light commercial and industrial development.

According to the Bureau of the Census, U.S. Department of Commerce 2000, about 200 people, comprising approximately 80 households, lived within a 0.50 mile radius of the former ABC plant. Approximately 80% of these were black and 13% white. Other racial/ethnic groups include American Indians (5%), and Hispanics (2%).

### **Methods**

Once the protocol and the attached consent form received proper approval from the Florida DOH and ATSDR, arrangements were made for participants with an abnormal, borderline, or uninterpretable BeLPT result to be retested.

The Sarasota CHD held 2 clinics on April 20 and April 21, 2005 to retest 8 participants. They provided the staff to handle consent forms, blood draw tubes and shipping materials needed for sending the blood samples to the National Jewish Medical and Research Center in Denver, Colorado and to Specialty Laboratories in Valencia, California, according to their instructions.

Split sampling was used in retesting of these individuals to better identify those who may be beryllium sensitized. This involved obtaining blood, splitting the sample into equal aliquots, and sending the samples to the 2 laboratories mentioned above.

A blood sampling kit was also sent by the Florida DOH to 1 out-of-state participant who had a borderline result on his first BeLPT. This kit included instructions on how to collect the sample as well as where the samples should be sent.

One participant, a community resident, had a single blood sample drawn for the first time and it was sent to Specialty Laboratories. This was the only BeLPT obtained on this individual.

Plans for blood collection and shipping procedures are described in Appendices A and B of the Exposure Investigation Protocol II for beryllium sensitivity blood testing.

After the results were obtained, a letter was sent to each participant explaining their results as well as a copy of their lab test. Staff at the Florida DOH attempted to call each participant to see if there were questions about the results or recommendations.

## **Biologic Sampling**

### **Data Collection/ Sampling Procedures**

A total of 60-mL of blood was obtained from each of the 8 participants at clinics held by the Florida DOH. The samples were split into two 30-mL aliquots, handled, and promptly shipped via overnight carrier according to the established protocols of the National Jewish Medical and Research Center in Denver, Colorado, and of Specialty Laboratories in Valencia, California.

One out-of-state participant was retested according to the same protocol utilizing the same laboratories.

A single 30-mL blood sample was collected from one participant that was sent to Specialty Laboratories in Valencia, California.

(See Appendices A and B for blood collection and shipping procedures of Exposure Investigation Protocol II)

Unfortunately, 5 of the samples obtained did not reach the National Jewish Medical and Research Center in the recommended time period and could not be used. This necessitated repeat sampling on 3 individuals that was completed at the Sarasota CHD on May 12, 2005. The results of the other 2 participants could be interpreted on the basis of 2 BeLPT results.

### **Laboratory Analytic Procedures**

The beryllium lymphocyte proliferation test (BeLPT) was developed to identify individuals who are sensitized to beryllium. In general terms, the BeLPT is performed by culturing T-lymphocytes from peripheral blood (used in this investigation) or broncho-alveolar (lung) fluid with and without beryllium salts. The proliferative response of lymphocytes stimulated by beryllium salts in the culture media is compared to that of unstimulated lymphocytes, based on their incorporation of tritiated thymidine (a radioactive nucleoside precursor) into the lymphocytes' DNA. The ratio of thymidine uptake by stimulated vs. unstimulated lymphocytes is called the **stimulation index (SI)**.

The BeLPT is currently the most widely accepted test for determining beryllium sensitivity. The false positive rate is 1%-2%; false negative rates can be as high as 25%-38%. Therefore, the strength of this test lies in serially screening at-risk populations.<sup>1</sup>

Because of these limitations, it is recommended that a person not be considered beryllium sensitized unless an initial abnormal BeLPT result is confirmed by one or more concurrent (where a split blood sample is sent to 2 separate labs) or subsequent abnormal BeLPT results (where the blood sample is sent to the same lab on separate dates).<sup>1</sup>

### **Data Analysis Procedures**

The National Jewish Medical and Research Center Laboratory in Denver, Colorado, is one of 4 labs in the U.S. that performs beryllium lymphocyte proliferation testing (BeLPT). They were selected because of their established competency in performing the test and have considerable experience in interpreting the test.

Specialty Laboratories in Valencia, California, was also selected based on recommendations made by colleagues at ATSDR who have worked with them on other projects.

Results of the BeLPT are reported as abnormal, borderline, uninterpretable, or normal.

The BeLPT is performed on peripheral blood mononuclear cells (T-lymphocytes) and are then cultured *in vitro* in the presence and absence of beryllium salts (such as beryllium sulfate, or BeSO<sub>4</sub>). Generally 3 concentrations of beryllium sulfate are used (10<sup>-4</sup>, 10<sup>-5</sup>, and 10<sup>-6</sup> molar concentrations of BeSO<sub>4</sub>). Tritiated thymidine is added for the last 24 hours of incubation. Cell proliferation is then measured (in counts/minute) as a result of incorporation of tritiated thymidine in dividing cells. The beryllium-specific cellular immune response is then quantified and reported as a **stimulation index (SI)**, which is the ratio of the counts/minutes of radioactivity in the cells stimulated by BeSO<sub>4</sub> divided by the counts/minute for that person's cells that were not stimulated by beryllium. An SI of approximately 2 or 3 is considered positive, depending on the laboratory used. With 6 possible test results using 3 concentrations of BeSO<sub>4</sub> measured on days 5 and 7, an abnormal result is defined by having 2 or more elevated SI values, a borderline result is defined as having 1 elevated SI value, and a normal result is defined by having no elevated SI values. An uninterpretable result is also possible if the sample cannot be analyzed (e.g., due to a lack of adequate sample, an inability to culture the T-lymphocytes, etc.).<sup>4</sup>

Interpretation of the results obtained was based on an occupational paradigm developed by ATSDR staff. According to this paradigm, a participant would be considered beryllium sensitized if any 2 of the 3 BeLPT results are abnormal or borderline. (See Appendix C of Exposure Investigation Protocol II)<sup>5</sup>

## Agency Roles

ATSDR prepared the protocol and contracted with the National Jewish Medical and Research Center and Specialty Laboratories for BeLPT testing.

The Florida DOH assisted with the development of the protocol, coordinated the collection of the blood samples, and helped in the evaluation of the data.

The Sarasota CHD furnished the space and the staff to draw the blood samples and the mailing of the samples to the appropriate labs.

## Results

### Biological Sampling Results

The following results for repeat BeLPT testing done by ATSDR were obtained:

	<b>Previous Test National Jewish Lab Manatee CHD</b>	<b>Repeat Test Specialty Lab</b>	<i>Repeat Test National Jewish Lab</i>
1. Former Worker	Borderline	Abnormal	Stability exc.
2. Household Contact	Abnormal	Borderline	Stability exc.
3. Former Worker	Abnormal	Normal	Stability exc./Normal
4. Resident	Uninterpretable	Normal	Stability exc./Normal
5. Resident	Borderline	Normal	Normal
6. Resident	Borderline	Normal	Normal
7. Resident	Abnormal	Normal	Normal
	<b>Florida DOH</b>		
8. Resident	Borderline	Normal	Stability exc./Normal
9. Former Worker	Borderline	Abnormal	Abnormal

Stability exceeded (exc.) in the table above means that 5 of the blood samples did not arrive to the National Jewish laboratory within a 24-hour time period and were unable to be tested. This necessitated a repeat blood sample for 3 of the participants (Stability exc./Normal).

Because a person can be considered beryllium sensitized if an initial abnormal BeLPT result is confirmed by one or more concurrent or subsequent abnormal or borderline BeLPT results, the former worker and household contact from the table above (**1.** and **2.**) were not retested, but were considered beryllium sensitized on the basis of 2 test results.<sup>1</sup> The former worker (**9.**) was also considered beryllium sensitized on the basis of 3 test results. They were referred to a pulmonologist for further medical evaluation.

Three participants, a former worker (3.) and 2 community residents (4. and 8.) were contacted and asked to return on May 12, 2005 to the Sarasota CHD. A single blood sample (30-mL) was drawn and sent again to the National Jewish Laboratory. Those BeLPT results on those participants returned normal.

Three participants (5., 6., and 7.) were considered normal on the basis of 3 test results.

A BeLPT test done at the Sarasota CHD on April 21, 2005 on a community resident not included in the table above was sent only to Specialty Labs and was normal. This was the first and only test done on this individual.

## Discussion

Beryllium disease was first reported in the 1930s in workers exposed to beryllium-containing phosphorus in the fluorescent lamp industry.<sup>6</sup> Industry standards and environmental controls for beryllium were established in the 1950s. While the numbers of workers with potential beryllium exposure in the United States is not known, some estimates suggest that as many as 800,000 individuals have been exposed to beryllium.<sup>4</sup>

Exposure to beryllium that causes disease generally occurs by breathing beryllium dust, as a result of processing beryllium metal, alloys, oxides, and ceramics by industry.<sup>7</sup> Therefore, certain beryllium industrial processes and job tasks, such as machinists or grinders in the ceramics or nuclear weapons manufacture, increase the risk of developing an immune response and disease.<sup>4</sup>

Beryllium exposure can result in a condition known as **beryllium sensitivity (BeS)**, or **chronic beryllium disease (CBD)**, also referred to as **berylliosis**.

Beryllium sensitivity refers to an asymptomatic condition whereby a person becomes sensitized (or allergic) to beryllium. This hypersensitivity to beryllium has been estimated to range from 1% to 2%, but may be as high as 16% in exposed workers (depending on their job task).<sup>8</sup>

Chronic beryllium disease refers to a chronic inflammatory lung disease which causes an interstitial pneumonitis with infiltration of lymphocytes, histiocytes, and plasma cells.<sup>9</sup> It is similar in its disease presentation to sarcoidosis and generally worsens if not treated and has a mortality rate ranging from 5% to 38%. CBD usually progresses very slowly over a number of years following exposure. On average, about 6 to 10 years is required to develop disease; however, there have been reports from as early as 4 months to greater than 30 years. Symptoms of CBD generally include fatigue, non-productive cough, chest pain, and a gradually progressive shortness of breath. Anorexia, weight loss, fevers, night sweats, and arthralgias are also commonly reported.<sup>4</sup>

Beryllium sensitivity and chronic beryllium disease are typically considered to be associated with occupational exposure. However, sensitization has occurred in security guards, secretaries, and other custodial staff working at beryllium facilities where the air

concentrations of beryllium are below that of current workplace exposure limits.<sup>10</sup> CBD has been reported in a family member who was exposed to beryllium dust from a worker's clothing.<sup>11</sup>

The beryllium lymphocyte proliferation test (BeLPT) was developed as an in vitro immunologic test to help identify individuals who may be either sensitized to beryllium or at risk for the development of CBD. The test can be performed from a peripheral blood sample (most common) or from broncho-alveolar (lung) fluid. Presently, nothing surpasses the BeLPT in the screening and surveillance of beryllium related health effects.<sup>12</sup>

### **Limitations**

While the BeLPT false positive rate is only 1% to 2%, there is a fairly high false negative rate ranging from about 25% to 38%. Therefore it is recommended that a person not be considered beryllium sensitized unless an initial abnormal BeLPT result is confirmed by one or more concurrent (a split blood sample sent to 2 labs) or subsequent abnormal BeLPT results (a blood sample sent to the same lab on separate dates).<sup>1</sup>

The BeLPT is only useful in identifying beryllium sensitivity. A person who is considered sensitized needs a referral to a pulmonologist for further medical evaluation to determine if they have CBD.

Because of the specialized nature of the BeLPT, there are only 4 laboratories in the U.S. that are capable of performing the test.

### **Child Health Considerations**

At this time, little information exists concerning children and beryllium related disease. It is likely that the health effects seen in children exposed to beryllium dust will be similar to that of adults. It is also unknown as to whether children differ from adults in their sensitivity to beryllium.<sup>3</sup>

The BeLPT was performed on a total of 15 children, ages 10 to 17, and all were normal.

### **Conclusions**

Of the 359 participants tested, ATSDR's exposure investigation revealed 2 former workers and 1 household contact who were considered to be beryllium sensitized. Manatee CHD also reported 2 household contacts, both retested on January 19, 2005, who were also considered beryllium sensitized. These participants were referred to a local pulmonologist for further medical evaluation for possible chronic beryllium disease. Overall, 1.4% (5 /359) of the participants in this investigation was considered beryllium sensitized. Considering former workers only, the rate of sensitization was 2.35% (2 /85), and for household contacts it was 2.75 % (3 /109). No community residents (0 /165) in

this exposure investigation were found to be beryllium sensitized. The low percentage of positive test results may be due partly to the fact that the Loral ABC plant was primarily a grinding and machining facility and did not have stack emissions.<sup>13</sup> It appears that exposed workers of high grade beryllium, such as machinists and grinders, as well as their family members may be at significant risk of beryllium sensitivity/disease from a lack of adequate workplace hygiene controls.<sup>8</sup> The rate of sensitization without disease in a few published studies has ranged from 1% to 2%.<sup>4</sup> These sensitized individuals should remain under close medical supervision and followed closely for signs of clinical progression.<sup>4</sup>

## **Recommendations**

Former ABC workers who have not been tested should direct their inquiries to the U.S. Department of Energy (D.O.E.) contractor Donna Cragle of the Oakridge Institute at 1-866-219-3442. As of February 2005 the D.O.E. began a nationwide program to test former workers in the beryllium industry for beryllium sensitivity. This includes all former ABC workers regardless of their work dates.

While there is no consensus on how often serial BeLPT testing should be offered to former workers with normal initial results, one study did suggest approximate 3-year intervals to a group of current and former employees who were no longer occupationally exposed.<sup>1</sup> Serial testing allows for the identification of those individuals who may have normal-to-abnormal BeLPT conversions or an initial false negative BeLPT result. Therefore some degree of continued surveillance should be offered to this group.

The 2 former workers and 1 household contact in ATSDR's exposure investigation considered beryllium sensitized were referred to a pulmonologist for further evaluation.

Two participants, a former worker and a community resident, tested abnormal on their first BeLPT result but subsequently tested normal on follow-up testing. It was recommended that they should be retested again next year in that they may be considered to be at a slightly higher risk of becoming beryllium sensitized in the future.

The remaining 4 participants in this investigation, all community residents, were considered to be non-beryllium sensitized and therefore do not presently need medical follow-up unless symptoms appear.

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**Exposure Investigation Protocol II**  
**Beryllium Sensitivity Blood Testing**  
**Tallevast Community**  
**Manatee County, Florida**  
**EPA Facility ID: FLD004100731**  
**March 16, 2006**

## 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 of 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 4 years and a method of disposal had not been determined.

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).<sup>1</sup> 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.

As a result of this concern, the Manatee County Health Department (CHD) tested 250 participants for beryllium sensitization using the **Beryllium Lymphocyte Proliferation Test (BeLPT)**. The 250 participants were all Manatee County residents who were either former workers of the Loral ABC plant, family members of former workers, or residents who lived within 0.25 miles of the facility. The testing, which involved blood samples

sent to the National Jewish Medical and Research Center in Denver, Colorado, was conducted in December 2004 and January 2005 with county appropriated funds.

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 was conducted to augment the BeLPT testing already begun by the Manatee CHD and to extend the population being tested. It involved blood sampling to test for possible beryllium sensitization (BeLPT) on an additional 200 participants living either inside or outside of Manatee County, Florida. These participants included some former workers of the Loral ABC plant not covered by the D.O.E., family members of former workers of the Loral ABC plant, or residents who lived within 0.50 miles of the facility. This exposure investigation was completed in March 2005. Blood samples were sent to the National Jewish Medical and Research Center in Denver, Colorado.

This protocol describes a follow-up exposure investigation to retest all participants of Manatee CHD as well as those tested by the Florida Department of Health (DOH) whose BeLPT results were either **abnormal**, **borderline**, or **uninterpretable** (see **Data Analysis Procedures** section for definitions). The retesting of these participants is recommended and essential in confirming beryllium sensitization.

### **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 bronco-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 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 (where a split blood sample is sent to 2 labs) or subsequent BeLPTs ( where 2 abnormal results are obtained from the same lab on separate dates).<sup>2</sup>

### **Objectives and Rationale**

The two previously described beryllium testing programs (Manatee CHD and the Florida DOH Exposure Investigation) performed a single BeLPT on each participant. Of the 250 participants screened by the Manatee CHD for beryllium sensitization, the number of participants testing **abnormal, borderline, or uninterpretable** were as follows:

- 7 participants **abnormal**
- 3 participants **borderline**
- 1 participant **uninterpretable**

A second testing program was carried out as an exposure investigation by the Florida DOH as part of their Cooperative Agreement with ATSDR. The Florida DOH along with the Sarasota CHD conducted four screening clinics during the week of March 7 and March 14, 2005. Blood samples were obtained on up to 200 participants who met the testing criteria set forth in the first exposure investigation protocol. These samples were sent to the National Jewish Medical and Research Center in Denver, Colorado to test for possible beryllium sensitization using the BeLPT. These results for this first exposure investigation are not yet available.

This Exposure Investigation will retest all participants of both of these investigations who had an **abnormal, a borderline, or an uninterpretable** result. Blood samples will be collected and split, then sent to 2 labs (the National Jewish Medical and Research Center and Specialty Laboratories). This repeat testing is recommended in order to better confirm beryllium sensitization.

## **Target Population**

ATSDR, with the assistance of the Florida DOH, will offer repeat BeLPT sampling of all participants of Manatee CHD as well as Florida DOH's first exposure investigation who had either an **abnormal, borderline, or uninterpretable** result.

## **Agency Roles**

ATSDR will prepare a protocol and will contract with the National Jewish Medical and Research Center and Specialty Laboratories for BeLPT testing.

The Florida DOH will coordinate the collection of specimens. Education for the community will continue to be provided by the state as well. Medical Grand Rounds by a noted expert in the field of beryllium disease is also being planned. The Sarasota County Health Department (CHD) will also aid the Florida DOH with this second exposure investigation.

## **Methods**

Once the protocol and the attached informed consent form have received proper agency approval by both the Florida DOH and ATSDR, arrangements will be made for participants to be retested.

Within 2 weeks prior to BeLPT retesting, the Florida DOH and the Sarasota CHD will have consent forms, blood-draw tubes, and shipping materials ready for sending blood samples to the National Jewish Medical and Research Center in Denver, Colorado and to Specialty Laboratories in Valencia, California.

## **Data Collection/Sampling Procedures**

Blood (60-mL) will be collected, split evenly into 2 portions (30-mL each), handled, and promptly shipped by overnight carrier, according to established protocols at the National Jewish Medical and Research Center and Specialty Laboratories, by the Florida DOH and the Sarasota CHD. Both of these laboratories serve as reference labs for the BeLPT, and have been selected to test the samples in this exposure investigation. National Jewish was used in the first exposure investigation as well. Plans for blood collection and shipping procedures are described in **Appendices A and B**.

## **Data Analysis Procedures**

The National Jewish Medical and Research Center in Denver, Colorado, is one of 4 labs in the U.S. that performs beryllium lymphocyte proliferation testing (BeLPT). It was selected because they have established their competency in performing the test and have considerable experience interpreting the test. Specialty Laboratories is also one of 4 labs in the U.S. to do the BeLPT. They were recommended by colleagues at ATSDR who have worked with them on other projects.

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 each lab 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 none 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 the 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. In this exposure investigation, all participants with **abnormal, borderline, or uninterpretable** results from the first round of testing will be retested. This second blood sample will be split and sent to both the National Jewish Laboratory and to Specialty Laboratories. Interpretation of these results will be based on an occupational paradigm (see **Appendix C**). Results from both rounds of testing of each participant will be reviewed to determine beryllium sensitization. After review of all three sampling results (first round testing and second round testing) from each participant, they will be considered sensitized, not sensitized, or questionably sensitized. Referral to a Pulmonary Specialist (MD) will be recommended on all participants who are sensitized or questionably sensitized.

### **Questionnaire**

A beryllium sensitivity screening questionnaire has been developed by the Sarasota CHD. It has been reviewed by the Florida DOH and ATSDR. It is being used again because some of the participants of Manatee CHD's screening program used a different questionnaire when they were sampled the first time. The purpose of the questionnaire is to identify any confounding factors which may interfere with the test (see **Appendix D**).

### **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 both the National Jewish Medical and Research Center in Denver, Colorado, and to Specialty Laboratories in Valencia, California, 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 are sensitized to beryllium. This will assure appropriate referral to a

Pulmonary Specialist for CBD medical evaluation. Early diagnosis and treatment may favorably alter the course of the disease. There is still the possibility that even if participants test **normal** 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 **normal** they should consider being retested at some future date if they believe that they are at high risk for developing beryllium disease. They should discuss this with their private physician.

**Informed Consent Procedures**

Potential participants will be informed of the purpose of this 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 E**).

**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 this 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 have been retested to explain their results and the need for possible referral.

**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, 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**

This budget will be based on the assumption that approximately 5% of all participants who were tested in the first round (the first exposure investigation) will have a result that will need retesting. The number of participants will be estimated to be 22 (5% of 450 totals).

Beryllium lymphocyte proliferation test ( <i>BeLPT</i> ) 22@ \$400	\$8,800.00
Sample collection by Sarasota CHD 22@ \$30	\$660.00
Sample tubes and draw supplies 44@ \$1	\$44.00
Sample shipment by Sarasota CHD 44@ \$4	\$176.00
Program administration: patient education and data management, tracking, follow-up and results delivery, possible grand rounds,etc	\$5000.00
<b>Total estimated program cost:</b>	<b>\$14,680.00</b>

## References

1. Florida Department of Environmental Protection. Hazardous waste inspection report for Loral American Beryllium. Tallahassee; 1994.
2. Stange AW, Furman FJ, Hilmas DE. The beryllium lymphocyte proliferation test: relevant issues in beryllium health surveillance. *Am Industr Med* 2004; 46: 453-462.

## Appendix A.

### Blood Collection and Shipping for the BeLPT

#### National Jewish Clinical Reference Laboratories

**Website:** [http://www.njc.org/lab/beryllium\\_blood.html](http://www.njc.org/lab/beryllium_blood.html)

*Below are collection and shipping instructions for the BeLPT. We offer discounts based on volume; please contact the Beryllium Program at (303) 398-1722 for information on setting up an account, testing in quantity, other beryllium-related services, or with comments, questions or concerns.*

*All specimens sent to the laboratory should conform to all Federal and IATA shipping regulations.*

#### **Sample:**

- 1. Call the Clinical Immunology Lab at (303) 398-1184 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- there are no limits on the number of samples you may collect and ship each day.*
- 2. Draw 30 ml of blood into sterile, green-top heparinized vacutainers. Blood collection kits (3 10-ml green-top vacutainers and one safety mailer) are available from National Jewish for an additional \$5 per test.*
- 3. Label tubes with patient`s name, date of blood draw and “LPT-Beryllium”.*
- 4. For each sample sent, please enclose a requisition with the name of the patient.*
- 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. FedEx, UPS, Airborne Express) to reach National Jewish the morning after it is drawn. National Jewish does not pay for overnight shipping charges.*

## Appendix B. Specialty Laboratories

### #1470: Beryllium-Induced Lymphocyte Proliferation

[Print View](#)

#### Components

NAME	METHOD	REFERENCE RANGE	UNITS
PHA SI Day 3	<a href="#">ITL</a>	> 50	SI
Be Sulfate SI (1uM) Day 5	<a href="#">ITL</a>	< 3.0	SI
Be Sulfate SI (10uM) Day 5	<a href="#">ITL</a>	< 3.0	SI
Be Sulfate SI (100uM) Day 5	<a href="#">ITL</a>	< 3.0	SI
Be Sulfate SI (1uM) Day 7	<a href="#">ITL</a>	< 3.0	SI
Be Sulfate SI (10uM) Day 7	<a href="#">ITL</a>	< 3.0	SI
Be Sulfate SI (100uM) Day 7	<a href="#">ITL</a>	< 3.0	SI
TTX SI Day 7	<a href="#">ITL</a>	> 3.0	SI
Interpretation		Normal	

Turn-Around Time
8-11 days

Setup Schedule
Tue-Sat@10:00

#### Specimen Requirements

	TYPE	VOLUME	TEMPERATURE	INSTRUCTIONS
<b>PRIMARY</b>				
1	Whole Blood Heparin	30 (20) mL	Ambient - 48 Hour(s)	See COLLECTION INSTRUCTIONS.
<b>ALTERNATE</b>				
	Whole Blood ACD	30 (20) mL	Ambient - 48 Hour(s)	

CPT Code
86353x8

**NOTE:**  
Diagnostic code required for third party reimbursement. An individual is considered positive if two of the six determinations on day 5 and day 7 are positive

#### Clinical Utilities

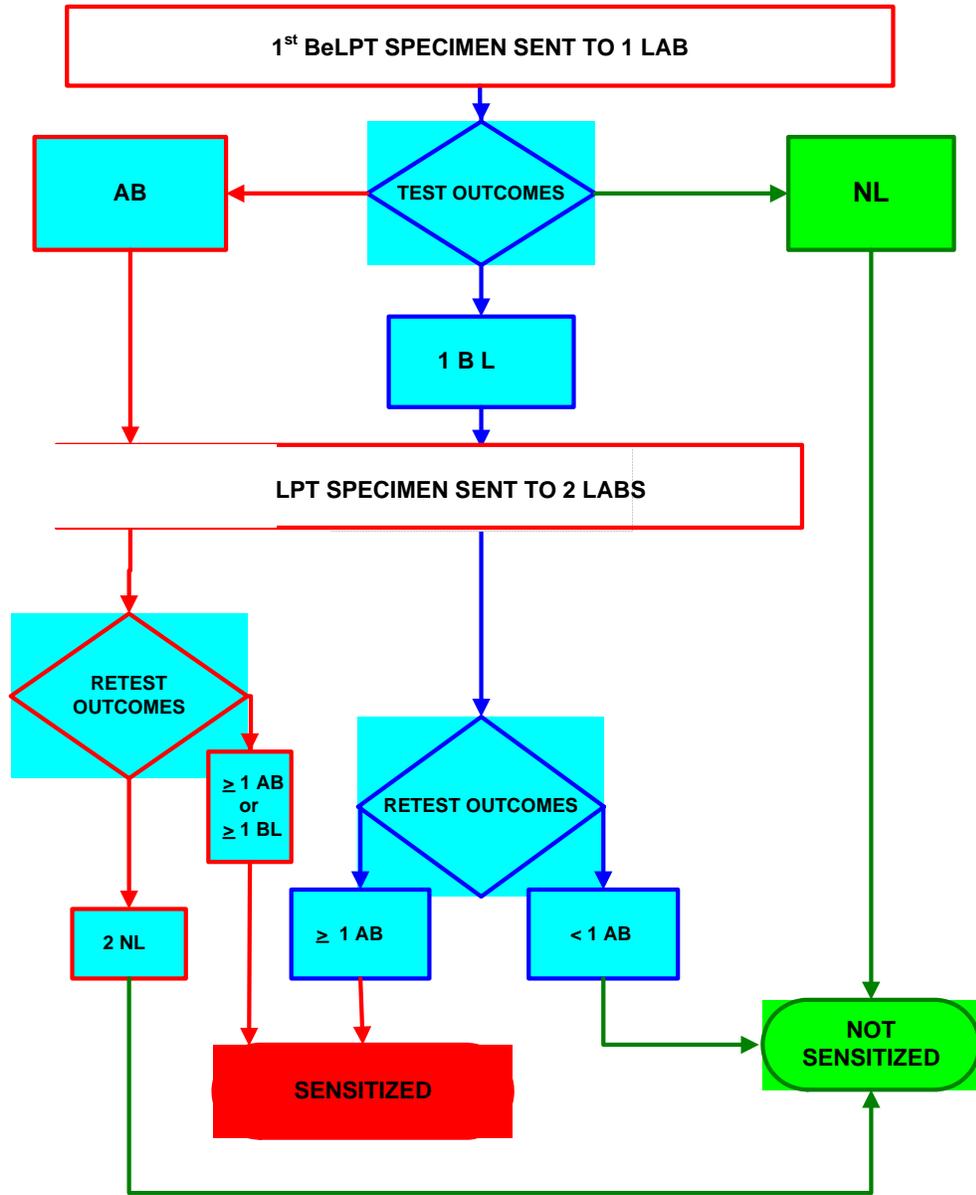
Assay is utilized as a preliminary diagnostic tool to assess the potential for development of chronic beryllium disease. A repeatedly positive patient is considered sensitized to beryllium oxide. Negative patients must be monitored periodically to rule out future sensitization. A positive or borderline result must be repeated to confirm true biological sensitization.

#### Collection Instructions

Draw specimen in late afternoon for pick-up and delivery by overnight courier to arrive at Specialty within 24 hours of phlebotomy. Do not refrigerate or freeze.  
To avoid specimen rejection due to limited specimen stability for Beryllium testing, collect sample in the afternoon Monday-Thursday and ship by overnight courier. Specialty only accepts these specimens Tuesday-Friday within 24 hours of draw as they deteriorate rapidly thereafter.

## Appendix C.

### SINGLE LAB FOLLOWED BY TWO LAB CONFIRMATION



**LEGEND**

NL = NORMAL  
 AB = ABNORMAL  
 BL = BORDERLINE

SENSITIZED = EVIDENCE OF BeS or CBD  
 NOT SENSITIZED = WITHOUT EVIDENCE OF BeS OR CBD

**Appendix D**

**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 E**

## **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 repeat voluntary blood tests for beryllium sensitivity on all people who had **abnormal, borderline, or uninterpretable** results on their first blood test.

The reason for this repeat blood test is to see if you are sensitive to beryllium. We need at least two **abnormal** results to be sure you are sensitive and to refer you to a lung doctor. 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 of your test results on the first round of testing for beryllium sensitivity.

### **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 60 milliliters (about 12 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 split your blood sample into two tubes and send to the National Jewish Clinical Laboratory in Denver, Colorado, and to Specialty Laboratories in Valencia, California, 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 retested, 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 all of your test results come back either **abnormal** or **borderline**, we will recommend that you see a lung doctor. If your test comes back **uninterpretable**, we will recommend retesting again. You will be responsible for the cost of this test.

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 for two tests. 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