

INFORMATION ON BERYLLIUM TESTING NATIONAL SUPPLEMENTAL SCREENING PROGRAM (NSSP)

What is the purpose of the beryllium testing in the NSSP?

The main purpose of this beryllium testing is to determine for former workers whether or not they may have become sensitized to beryllium and are at an elevated risk for chronic beryllium disease (CBD).

What is the Beryllium Lymphocyte Proliferation Test (Be-LPT)?

In the Be-LPT, disease-fighting blood cells that are normally found in the body, called lymphocytes, are examined in the laboratory and separated from other blood cells. Beryllium and other test agents are then added to small groups of these lymphocytes. If these lymphocytes react to the beryllium in a specific way, the test results are "abnormal." If they do not react to beryllium, the test is "normal."

Experts believe that the Be-LPT shows abnormal results in individuals who have become "sensitized" or "allergic" to beryllium. It is unclear what this sensitization means. Studies have shown it to be an early sign of CBD in many individuals. In others, sensitization might simply mean that the person was exposed to beryllium and that his or her body has reacted. It might mean that an individual is more likely than others to get CBD. You are being offered the Be-LPT because doctors believe it is useful in detecting cases of CBD early or cases that might otherwise be missed or diagnosed as another type of lung problem. Once CBD is identified, doctors can determine the treatment that is needed to minimize the lung damage that CBD causes.

As in any other medical test, the Be-LPT sometimes fails or provides unclear results. The laboratory calls these results "uninterpretable." Even when the test appears successful, it may appear abnormal when a person is not sensitized or allergic to beryllium. This is called a "false abnormal" result. It is also possible that the test will show "normal" results when a person is actually "sensitized" to beryllium. This is a "false normal" result. If you have an "uninterpretable" or borderline abnormal blood Be-LPT result, you may be asked to provide another blood sample so the test can be repeated. A repeat test may be offered to confirm an abnormal test result. If you have two "abnormal" tests in a row, you may want to consider further medical tests to confirm or rule out CBD. **Remember that you may refuse further tests at this point or at any point during your medical evaluations.**

If your Be-LPT is "abnormal," future testing may be covered by the Department of Labor Energy Employees Occupational Illness Compensation Program Act of 2000 (DOL EEOICPA), and ORAU staff will make sure you have the information you need to apply for these benefits.

Do I have to have the Be-LPT done?

No. Your participation is strictly voluntary. You may refuse any of the tests offered to you, including the Be-LPT. If you change your mind, you are free to participate further in the program at any time. Talking with your family, your doctor, or other people you trust may help you decide. Health professionals in the clinic that provide the tests can also help answer any questions that you might have.

What will happen if I decide to have the Be-LPT blood test?

A small amount of your blood (about 2-4 Tablespoons) will be drawn from a vein in your arm and sent to one or two laboratories. There is little physical risk in drawing blood. Slight pain and bruising may occur in a few individuals. Rarely, a needle puncture may become infected. A chest x-ray may also be offered when you have the Be-LPT, if you are experiencing any symptoms that may be related to CBD.

When will I receive the results of my Be-LPT blood test?

It could take 5 to 6 weeks for you to receive a letter informing you of your test results. The test itself usually takes 8 days to perform. The testing laboratory reports results to the ORAU physician who will notify you.

If my Be-LPT results show that I am not sensitized to beryllium, is my beryllium testing finished?

This is a good question. A small percentage of workers who have normal test results will be found to have abnormal results on their second or third test. In some cases a worker who is no longer working with beryllium and no longer actively exposed to beryllium may develop the sensitization many years later. If you have had a normal test and develop concerns about having CBD symptoms or a respiratory condition that your physician cannot diagnose, we will offer you retesting if funding is still available.

Could an abnormal Be-LPT affect my work with beryllium in the future?

If you are found to have a consistently abnormal Be-LPT or if you have CBD, it is advisable to stay away from environments where beryllium may be present. IF YOU RETURN TO WORK AT A DOE SITE, a federal regulation requires that the results of beryllium sensitization and disease testing be transferred to your regular site medical file. This may directly affect your right to work with beryllium at a DOE site. Also, the chance of loss of confidentiality of this information may be higher once the test results are transferred to your medical file.

What will happen to the records of the medical examination results?

Your test results will be treated as confidential medical records (to be maintained for 75 years after your last examination) and used or disclosed only as provided by the Privacy Act of 1974, the Americans with Disabilities Act (ADA), or as required by a court order or under other law. The results of tests and examinations may be published in reports or presented at meetings, but will not identify any individuals. The results of your Be-LPT and other screening tests will be made available to you and, upon your request, to your personal physician.

The voluntary surveillance program will provide free testing for beryllium sensitization. Identifiable information about you and your test results will be placed in a database that will be used by the surveillance team to notify you of results, keep track of where you are in the surveillance process, and to contact you about future testing. Some of these people may require access to records that identify you by name:

1. The ORAU NSSP staff who will review your results and maintain permanent files for your records
2. NSSP physicians from ORAU and National Jewish Medical and Research Center (NJMRC) or the University of Colorado Health Sciences Center (UCHSC) in Denver, Colorado, who will review your results and explain whether further testing is necessary for you
3. Data specialists from Occupational Health Link (OHL) in Boulder, Colorado, who will maintain the computer records and web site for the NSSP
4. Medical support staff at Comprehensive Health Services (CHS) in Cape Canaveral, Florida, who will make your appointment for your examination and send you information before your appointment
5. Others as required by the Americans with Disabilities Act, the Privacy Act of 1974, or as required by court order or under another law

The identifiers will be removed from your test results and the de-identified data will be stored in a database called the Comprehensive Epidemiologic Data Resource (CEDR). This database is maintained by DOE.

If you have additional questions about your participation in this program, you may call Dr. Donna Cragle, ORAU, at (865) 576-2866; Dr. Bill Stange, ORAU, at (303) 423-9585; or the Chair of the Oak Ridge Site-wide Institutional Review Board and the Chair of the Oak Ridge Site-wide Institutional Review Board at (865) 576-1725.

What laws protect my privacy if I consent to participate in the blood Be-LPT testing program?

State medical and nursing licensing boards enforce codes of ethics that require doctors and nurses to keep medical information confidential. The Privacy Act prevents unauthorized access to your records without your permission. The information in your records must be handled in accordance with the Americans with Disabilities Act and the Privacy Act of 1974. The consent form you sign also provides additional protection.

Can privacy and confidentiality of my medical records be guaranteed?

No. Access to or release of records could be required under court order, but it is unlikely. They would also be available as the Freedom of Information Act or Privacy Act provide, such as a showing of compelling circumstances affecting the health and safety of an individual, etc. If you apply for another job or for insurance, you may be requested to release the records to a future employer or an insurance company. **Personal identifiers will not be published in any reports.**

**NATIONAL SUPPLEMENTAL SCREENING PROGRAM
BERYLLIUM TESTING PROGRAM
INFORMED CONSENT STATEMENT**

Program Manager: Donna L. Cragle, Ph.D.
Center for Epidemiologic Research
Oak Ridge Associated Universities
P.O. Box 117, Oak Ridge, TN 37831-0117
Telephone (865) 576-2866

Sponsor: Department of Energy/Office of Health Services

PARTICIPANT'S AUTHORIZATION

I have read: (Initial items to indicate you have read them.)

- the attached information about the Be-LPT . I have had the opportunity to discuss any questions that I may have. I have read that the test results are confidential, but not anonymous, which means that my name will remain on my test results, but that testing staff will only discuss these results with me or people approved by me. I have been told that I am free to withdraw without penalty or loss of benefits at any time from all or any part of the program for which I am volunteering, including any part or all of the questionnaire, the blood test, or other medical tests. I have read that if the results of any test suggest a health problem, whether related to chronic beryllium disease or not, this will be discussed with me by the ORAU physician.
- that if I apply for another job or for insurance, I may be requested to release my medical records to a future employer or an insurance company.
- that the results of any tests, examinations, or analysis of this surveillance program may be published or presented at meetings, but that I will not be identified.
- that the records of my participation in this program and the results of any tests or examinations that I consent to are confidential medical records that may be used or disclosed only as provided by the Americans with Disabilities Act, the Privacy Act of 1974, or as required by a court order or under other law.
- that if I have additional questions about this program or my participation in it, I can contact Dr. Donna Cragle, ORAU, at (865) 576-2866; Dr. Bill Stange, ORAU, at (303) 423-9585; the Chair of the Central Beryllium Institutional Review Board or the Chair of the Oak Ridge Site-wide Institutional Review Board at (865) 576-1725.
- that I will be given a copy of this Consent Form and Fact Sheet after I have signed them.
- that only the Department of Labor can determine my eligibility for compensation benefits.

Please do not complete this section until you arrive at the clinic.

CONSENT STATEMENTS

I consent to having the blood test called the beryllium lymphocyte proliferation test or Be-LPT.

Participant (Please Print)

SSN

Participant Signature

Date

I have discussed any questions that the above program participant expressed concerning the Be-LPT.

Person Obtaining Consent (Please Print)

Date

Person Obtaining Consent (Signature)

Date

Consent Form approved by the Oak Ridge Site-wide Institutional Review Board and the Central Beryllium Institutional Review Board (FWA 00005031) for a period of up to 12 months effective June 10, 2007 and ending June 9, 2008. The signed letter of approval is on file at the ORAU NSSP office.