



You are receiving this information because you have been diagnosed with malignant mesothelioma, a rare form of cancer, associated with exposure to asbestos. In this disease, cancer (malignant) cells are found in:

- the sac lining the chest (the pleura),
- the lining of the abdominal cavity (the peritoneum), or
- the lining around the heart (the pericardium).

Certain proteins, called biomarkers, may be released into the blood by these cancer cells. One or more samples of your blood can be tested for a specific biomarker called Soluble Mesothelin-Related Peptide or SMRP. Measuring the amount of SMRP in your blood, along with all other available clinical information, may aid in the monitoring of patients diagnosed with epithelioid or biphasic mesothelioma. You must voluntarily decide whether or not you want to have this blood test.



Patient Information

The information in this brochure may contain unfamiliar words or phrases. Please ask the doctor or a member of their staff to explain any words or phrases that you do not clearly understand.



The MESOMARK assay is a “humanitarian use” device test developed by Fujirebio Diagnostics, Inc. This test device is approved by the U.S. Food and Drug Administration (FDA) as a "humanitarian use" device, which means the effectiveness of this device for this test has not been demonstrated.

What is involved in the testing?

If you choose to take part in this testing, you will be asked to provide one or more samples of blood (approximately 2 teaspoons each time). No additional visits to your physician are required. The blood will be obtained from a vein using a needle. Your blood sample will be sent to a laboratory for testing. The blood test results will be used along with all other available clinical and laboratory data to make decisions about your care.

Risks of testing

False Negative Test Result. Because the SMRP protein is not produced by every mesothelioma tumor, a false negative test result is possible. A false negative test means that a test which should have given a positive result gives a negative one in error. The risk of a false negative MESOMARK test is minimized since your doctor will NOT be using the MESOMARK result alone, but in addition to all your other clinical and laboratory information.

Benefits of testing

The effectiveness of this device has not been demonstrated, however, the measurement of SMRP may allow your doctor to have additional information on your treatment response.

What are the costs?

The cost of the blood test may not be reimbursable by your health insurance; therefore, you may be required to pay part or all of the costs associated with this testing. You may want to check with your insurance company to see if this test is covered.

Your alternatives

You may choose not to have this testing and may withdraw from participating in this testing at any time. Your decision to have or withdraw from this testing will not influence the availability of future medical care and will involve no penalty or loss of benefits to which you are otherwise entitled.

Who to call with questions

If you have any questions or problems during this testing, or if you think that you may have experienced an injury related to this testing, you should contact the doctor who ordered this blood test for you.

If you have any questions as a Humanitarian Use Device participant, please contact Kim Lerner, Chairman of the Investigational Review Board (IRB) toll free (877) 888-IIRB (4472) during regular business hours (Eastern Standard Time). The IRB is a group of people who provide oversight review of this type of medical testing as required by Federal regulations.