

Soluble Mesothelin-Related Peptides (MESOMARK[®])

FOR MONITORING PATIENTS DIAGNOSED WITH BIPHASIC OR EPITHELIOID MESOTHELIOMA

Test Highlights

- The MESOMARK[®] test measures the concentration of soluble mesothelin-related peptides (SMRP) that have been reported in the sera of patients with tumors of mesothelial origin. The test is FDA-approved as a Humanitarian Use Device for the monitoring of patients diagnosed with biphasic or epithelioid mesothelioma.

Clinical Background

- Malignant mesothelioma is a rare cancer of the serous lining of body cavities, including the chest (pleural mesothelioma), the abdominal cavity (peritoneal mesothelioma), and the heart (pericardial mesothelioma). Pleural mesothelioma is the most common and pericardial is the rarest form. Epidemiological studies suggest that this type of cancer develops in individuals who have had significant exposure to asbestos fibers. It is estimated that there are approximately 2,000–3,000 newly diagnosed cases annually in the United States. Malignant mesothelioma is an aggressive tumor with a poor survival time estimated at two to three months without treatment.

Clinical Utility

- Measurement of soluble mesothelin-related peptides (SMRP) may aid in the management of patients diagnosed with epithelioid or biphasic mesothelioma for monitoring disease progression and recurrence. For monitoring patients, an increase of 30 percent in SMRP concentration is considered significant.
- Concentrations of SMRP are higher in patients with mesothelioma compared to patients with pleural metastatic carcinomas (sensitivity 58 percent) or benign lesions associated with asbestos exposure (sensitivity 80 percent).¹
- At a cutoff concentration of 1.5 nM/L, SMRP had a sensitivity of 57 percent and a specificity of 95 percent in differentiating between patients with mesothelioma and asbestos-exposed controls.²

Limitations

- **Humanitarian Use Device. Authorized by federal law for use as an aid in the monitoring of patients diagnosed with biphasic or epithelioid mesothelioma. The effectiveness of this device for this use has not been demonstrated.**
- Caution should also be used when interpreting increased SMRP concentrations in patients with renal disease, hypertension and other forms of cancer, including ovarian and lung cancer.

Methodology

- MESOMARK (Fujirebio Diagnostics Inc., Malvern, PA) is a two-step enzyme-linked immunosorbent assay that quantifies SMRP in human serum. The assay employs two SMRP monoclonal antibodies, one used for capture and the other for detection. The antibody used for detection is labeled with HRP and, upon subsequent addition of a chromogenic substrate, produces a color change that is measured on a spectrophotometric microtiter plate reader.
- Clinical studies have demonstrated that 99 percent of healthy subjects had a MESOMARK value of less than 1.5 nmol/L.

Additional Ordering Notes

- Because MESOMARK is a test approved by the FDA as a Humanitarian Use Device, testing must be ordered using the following procedure(s):
 - The ordering physician must register with the Internal Review Board (IRB) for MESOMARK testing. Go to fdi.com/mesomark to obtain IRB certification online. The ordering physician may also wish to notify his or her local IRB, if required.
 - The test should be ordered using the ARUP test request form. The full name of the ordering physician must be included on the ARUP form to ensure timely testing of the sample.
 - ARUP does not accept samples directly from physician offices. ARUP only accepts samples from established clients. To send a sample to ARUP, contact your local hospital/reference laboratory to determine if they are an ARUP client and can send the sample. If they cannot send the sample to ARUP, contact ARUP Client Services at (800) 522-2787 to find an ARUP client in your area.
 - Forms and information about MESOMARK testing and IRB registration may be accessed at fdi.com/mesomark.

References

1. Scherpereel A, et al. Soluble mesothelin-related peptides in the diagnosis of malignant pleural mesothelioma. *J Respir Crit Care Med* 2006;173:1155–60.
2. Beyer HL, et al. MESOMARK: A potential test for malignant pleural mesothelioma. *Clin Chem* 2007;53:666–72.
3. Robinson BW, Lake RA. Advances in malignant mesothelioma. *N Engl J Med* 2005;353:1591–603.

Test Information

0081284 Soluble Mesothelin-Related Peptides (MESOMARK®)

For specific collection, transport, and testing information, refer to the ARUP Web site at www.aruplab.com.

For information on test selection, ordering, and interpretation, refer to ARUP Consult® at www.arupconsult.com.