



miRview™ meso

Differentiates mesothelioma from carcinomas in the lung and pleura



Product Description

miRview™ meso is a test designed to differentiate malignant pleural mesothelioma from peripheral adenocarcinomas of the lung or metastatic carcinomas involving the lung pleura. The test may be used to rule out mesothelioma in patients diagnosed with adenocarcinoma in the lung and pleura who have been exposed to mesothelioma-related substances, primarily asbestos particles and heavy metals. miRview™ meso leverages proprietary microRNA technology developed by Rosetta Genomics, and measures the expression level of three microRNA biomarkers: one mesothelioma marker and two carcinoma markers, to differentiate patients that have mesothelioma of the lung-pleura from patients that have non-mesothelioma tumors in the lung-pleura.

Clinical Importance

Malignant pleural mesothelioma is directly linked to exposure to asbestos particles, as well as to various heavy metals. Rescue workers, shipyard workers, and miners are at increased risk of developing mesothelioma.

Accurately diagnosing mesothelioma currently presents a challenge to physicians, with over 70% of primary lung cancer eventually involving the lung pleura, and several other cancers metastasizing to the lung. As mesothelioma patients require specific treatment regimens, accurately diagnosing mesothelioma is critical.

Currently, there is no single diagnostic test that is entirely conclusive for either malignant mesothelioma or metastatic tumor. For most antibodies commercially available, the diagnostic value of each of them and the value of their combinations in immuno histochemical panels is still under debate. In addition, pathological

diagnosis may suffer from significant inter-observer variability, and in the absence of specific and reliable markers, mesothelioma can be difficult to identify from other cancers.

Rosetta Genomics developed **miRview™ meso** to leverage the specificity of microRNA biomarkers for the differential diagnosis of mesothelioma.

Technical Information

- › The test result is a quantitative evaluation of the expression level of three microRNAs in the sample.
- › Sensitivity 100%, Specificity 94%, in identifying mesothelioma.
- › Specimen Requirements - Tumor % must be at least 30% (only if sending unstained slides).
- › Sample accepted:
 - Unstained Slides
 - Sections in Tubes
 - FFPE Blocks
- › Shipping and Handling - Ambient.
- › Turn Around Time - 10 business days.
- › Reference Range - miRview™ meso score is composed of two components, Score 1 and Score 2, that are used for sample classification:
 - When both test scores are greater than 0, the test result is interpreted as mesothelioma.
 - All other score combinations are interpreted as non-mesothelioma.

For more information please visit www.mirviewdx.com



miRview™ meso



Facilities Description

- Rosetta Genomics, Inc. laboratory is located in Philadelphia, PA
- › Licensed in Pennsylvania. Lab ID# 030877
 - › Rosetta Genomics, Inc. laboratory is CLIA certified. CLIA ID# 39D 1090331. miRview™ meso has been validated in accordance with the guidelines established by CLIA. Currently, Food and Drug Administration (FDA) approval is not required for miRview™ meso testing performed by Rosetta Genomics.

Literature References

About miRview™ meso

- › H. Benjamin, D. Lebanony, L. Cohen, Eran Elyakim, Nitzan Rosenfeld, Ayelet Chajut and Dalia Cohen. Differential diagnosis of mesothelioma using a microRNA assay. 2008 ASCO Proceedings - Abstract

About miRview™ technology

- › Eti Meirie, Danit Lebanony, Hila Benjamin, Yael Spector, Jingyao Zhong, Lahav Cohen, Shai Rosenwald, Marina Perlman, Zvi Bentwich, Mahesh Mansukhani, Ranit Aharonov, Iris Barshack & Dalia Cohen. MicroRNAs as powerful diagnostic tools for the differential diagnosis of lung tumors. Presented at the 2008 American Society of Clinical Oncology (ASCO) Annual Meeting.
- › Rosenfeld N, Aharonov R, Meiri E, et al: MicroRNAs accurately identify cancer tissue origin. Nat Biotechnol 26:462-9, 2008
- › Shai Rosenwald, Eti Meirie, Shlomit Gilad, Meital Ezagouri, Yael Spector, Alex Ben-Ari, Asaf Levy, Ranit Aharonov, Nitzan Rosenfeld & Iris Barshack. MicroRNA signature identifies tissue origin of primary and metastatic tumors. Presented at the 2008 American Society of Clinical Oncology (ASCO) Annual Meeting

About mesothelioma pathology and diagnosis

- › Suzuki, y. (2001). Pathology of human malignant mesothelioma preliminary analysis of 1,517 mesothelioma cases. Ind Health 39, 183-185
- › Klebe, S., Mahar, A, Henderson, D.W., and Roggli, VL. (2008). Malignant mesothelioma with heterologous elements: clinico-pathological correlation of 27 cases and literature review. Mod Pathol 21, 1084-1094

About pathologist interobserver variability

- › RW, Smith BJ, Platz CE, et al: Lung cancer histologic type in the surveillance, epidemiology, and end results registry versus independent review. J Natl Cancer Inst 96:1105-7,2004
- › Stang A, Pohlbeln H, Muller KM, et al: Diagnostic agreement in the histopathological evaluation of lung cancer tissue in a population-based case-control study. Lung Cancer 52:29-36, 2006

The performance characteristics of this test were determined by Rosetta Genomics in accordance with the requirements of CLIA (Clinical Laboratory Improvement Amendments of 1988). It has not been cleared or approved by the U.S. Food and Drug Administration. This test is intended to be used for clinical purposes and should not be considered to be for investigational or research use only. Decisions regarding care and treatment should be based on the independent medical judgment of the treating physician taking into consideration all available information concerning the patient's condition, including other tests.

For a sample miRview™ meso patient report, please visit <http://www.mirviewdx.com>

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