



miRview™ mets: Solving the Mystery of Cancer of Unknown Primary (CUP)

Identifying the primary origin of a metastasis



Product Description

miRview™ mets identifies the tissue-of-origin of a metastatic tumor. The test identifies 25 different tumor types, including, but not limited to, tumors with the following tissue origins: colon, liver, brain, breast, kidney, lung, ovary, pancreas, prostate and testis. The test leverages proprietary microRNA technology developed by Rosetta Genomics, and measures the expression level of 48 microRNA biomarkers. The test uses a proprietary classifier to assign a primary site to the cancer sample based on the microRNA expression in the tumor.

Clinical Importance

In the U.S., hundreds of thousands of patients are diagnosed each year with a cancer that has already metastasized without identifying its primary site. Oncologists and pathologists are often faced with a diagnostic dilemma when trying to identify the primary origin of a patient's metastasis. As metastases need to be treated according to their primary origin, accurate identification of the primary origin of the metastases can be critical for determining appropriate treatment. Current diagnostic methods include a wide range of costly, time consuming, and at times inefficient tests including physical examination of the patient, histopathology analysis of the biopsy, and imaging methods such as chest X-ray, CT and PET scans.

Unfortunately, for approximately 70,000 patients each year in the US alone, the primary origin of the metastases is never identified, and the patient's cancer is labeled "Cancer of Unknown Primary" (CUP). Rosetta Genomics has developed miRview™ mets to apply the benefits of microRNA biomarkers for the identification of tumor origin.

Technical Information

- › The test includes a quantitative evaluation of the expression level of 48 microRNA biomarkers.
- › The test uses a combination of a decision-tree and a K-nearest neighbor classifier.
- › In the majority of cases the test reports a single answer with 90% sensitivity and 99% specificity.
- › 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.

For more information please visit www.mirviewdx.com

Facility 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# 39D1090331. All laboratory tests have been validated in accordance with applicable requirements. Currently, Food and Drug Administration (FDA) approval is not required for miRview™ mets testing performed by Rosetta Genomics.



miRview™ mets: Solving the Mystery of Cancer of Unknown Primary (CUP)

miRview™ | mets
Take a closer look

Literature References

About miRview™ mets

- 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 Cancer of Unknown Primary

- Blaszyk, H., Hartmann, A & Bjornsson, J. (2003). Cancer of unknown primary: clinicopathologic correlations. *APMINS*, 111,1089-94
- Hainsworth, J.D. & Greco, F.A (1993). Treatment of patients with cancer of an unknown primary site. *N Engl J Med*, 329, 257 -63
- Pimiento, J.M., Teso, D., Malkan, A, Dudrick, S.J. & Palesty, JA (2007) Cancer of unknown primary origin: a decade of experience in a community-based hospital. *Am J Surg*, 194,833-7; discussion 837 -8
- Shaw, P.H., Adams, R., Jordan, C. & Crosby, T.D. (2007). A clinical review of the investigation and management of carcinoma of unknown primary in a single cancer network. *Clin Oncol (R Coil Radiol)*, 19,87-95
- Varadhachary, G.R., Abbruzzese, J.L. & Lenzi, R. (2004). Diagnostic strategies for unknown primary cancer. *Cancer*, 100, 1776-85

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™ mets patient report, please visit <http://www.mirviewdx.com>

3711 Market Street, Suite 740, Philadelphia, PA 19104, T: 1.888.522.7971
www.mirviewdx.com

Cat # 0802