



miRview™ squamous: Knowing the difference

Differentiating squamous from non-squamous non-small cell lung cancer



Product Description

miRview™ squamous classifies non-small cell lung carcinoma tumors into two histological groups: cancers of squamous histology, and non-squamous cancers. The test leverages proprietary microRNA technology developed and validated by Rosetta Genomics, and measures the expression level of a squamous microRNA biomarker to differentiate patients that have squamous cell carcinoma of the lung from patients that have non-squamous non-small cell lung cancer.

Clinical Importance

When administered targeted therapy, whether currently available or under development, patients with squamous cell carcinoma of the lung have demonstrated varying response patterns ranging from a high incidence of severe or fatal hemoptysis (internal bleeding in the lungs) to overall poor response to treatment. Current methods for differentiating squamous from non-squamous non-small cell lung cancer are not standardized, are difficult to reproduce, and have low accuracy. Studies that reviewed the accuracy and reproducibility of histopathological classification of lung cancer found that 30%-40% of samples were misclassified.

Technical Information

- › The test score is a quantitative evaluation of the expression level in the sample of a microRNA gene strongly expressed in squamous tissues and tumors.
- › Sensitivity - 97%; Specificity - 91% in identifying squamous cell lung cancer.

- › In blinded tests of lab-to-lab concordance, two labs reached the same classification in > 95% of classified samples.
- › 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™ squamous score is used for tumor classification:
 - A score below 2.5 is interpreted as evidence of squamous differentiation.
 - A score above 2.5 is interpreted as evidence of non-squamous differentiation.

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™ squamous testing performed by Rosetta Genomics.



miRview™ squamous: Knowing the difference



Literature References

About miRview™ squamous

- › Justin A. Bishop, Hila Benjamin, Hila Cholakh, Ayelet Chajut, Douglas P. Clark, and William H. Westra. Accurate Classification of Non-Small Cell Lung Carcinoma Using a Novel MicroRNA-Based Approach. *Clinical Cancer Research*, Volume 16, number 2, pp 610 -619. January 2010
- › Danit Lebanony, Hila Benjamin, Shlomit Gilad, Meital Ezagouri, Avital Dov, Karin Ashkenazi, Nir Gefen, Shai Izraeli, Gideon Rechavi, Harvey Pass, Daisuke Nonaka, Junjie Li, Yael Spector, Nitzan Rosenfeld, Ayelet Chajut, Dalia Cohen, Ranit Aharonov, and Mahesh Mansukhani. 2009 Diagnostic Assay Based on hsa-miR-205 Expression Distinguishes Squamous From Nonsquamous Non-Small-Cell Lung Carcinoma *Journal of Clinical Oncology*, Volume 27, Number 12, pp 2030 - 2036.
- › 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.
- › Shai Rosenwald, Junjie Li, Danit Lebanony, Jingyao Zhong, Hila Benjamin, Yael Spector, Meital Ezagouri, Eran Elyakim, Ranit Aharonov, Mahesh Mansukhani, Dalia Cohen, Shlomit Gilad. MicroRNA as a Diagnostic Tool for Non Small Cell Lung Cancer. Presented at the 2008 American Association for Cancer Research (AACR) Annual Meeting.

About Targeted Therapy Side Effects

- › Johnson DH, Fehrenbacher L, Novotny WF, et al: Randomized phase II trial comparing bevacizumab plus carboplatin and paclitaxel with carboplatin and paclitaxel alone in previously untreated locally advanced or metastatic non-small-cell lung cancer. *J Clin Oncol* 22:2184-91, 2004

- › Martin H. Cohen, Joe Gootenberg, Patricia Keegan and Richard Pazdur: FDA Drug Approval Summary: Bevacizumab (Avastin®) Plus Carboplatin and Paclitaxel as First-Line Treatment of Advanced/Metastatic Recurrent Nonsquamous Non-Small Cell Lung Cancer. *Oncologist* 2007;12 ;713-718 (DOI: 10.1634/theoncologist.12-6713)
- › Besse B, Ropert S, Soria JC: Targeted therapies in lung cancer. *Ann Oncol* 18 Suppl 9:ix135-42, 2007
- › Herbst RS, Johnson DH, Mininberg E et al. Phase 1/11 Trial Evaluating the Anti-Vascular Endothelial Growth Factor Monoclonal Antibody Bevacizumab in Combination With the HER-1/Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Erlotinib for Patients With Recurrent Non-Small-Cell Lung Cancer. *J Clin Oncol* 2005; 23: 2544-2555.

About Pathologist Interobserver Variability (In Identifying Subtypes of Lung Cancer)

- › Field 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™ squamous patient report, please visit <http://www.mirviewdx.com>