

# Non-Invasive Lesion-Specific Classification Of Nevus And Melanoma Using A MicroRNA Signature.

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## TECHNOLOGY DESCRIPTION

This invention describes a method using novel microRNA (miRNA) biomarkers, a novel analytical approach, and a novel machine learning based classifier to determine whether a melanocytic lesion on a patient's skin is a benign nevus or a melanoma. Sample collection can be performed either before biopsy (by collecting cells with adhesive tape) or after biopsy (by fixing the skin sample and microdissection for melanoma cells). In both cases, RNA is then isolated from the sample and a RT-qPCR assay is used to measure the expression levels of a suite of novel miRNA biomarkers, followed by processing using a trained classifier to generate a risk assessment. This process has been validated in a pilot study, and it is currently being tested in a large patient cohort. Unlike previous melanoma diagnosis approaches, this method uses a previously unreported set of miRNAs whose signatures are robust and have high classification potential for distinguishing between nevi and melanoma, rather than between only primary and metastatic melanoma. Furthermore, collection of cells using adhesive tape is lesion-specific and non-invasive, allowing the test to be used successively on the same lesion or patient, and the miRNA from the sample are much more stable than mRNA collected in the same way. Finally, risk level analysis is performed by a newly developed machine learning classifier.

## VALUE PROPOSITION

- ▶ This objective diagnostic method represents an improvement over the current standard of care, visual inspection, which is often subjective and error-prone; this allows for early detection of melanoma while it is still curable, thereby reducing the number of patients with advanced stage melanoma
- ▶ Can be used with multiple sample collection methods including biopsy and adhesive tape
- ▶ Adhesive tape sample collection, in particular, is simple and non-invasive and can be developed as part of a user-friendly melanoma identification kit for both clinicians and consumers
- ▶ miRNA is robust and stable, unlike mRNA, which is easily degraded
- ▶ The novel miRNA suite can differentiate between nevi and melanoma (not just primary vs. metastatic melanoma), and with further refinement can potentially be used to stage melanomas without biopsy

## RELATED MATERIALS

### CONTACT

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### OTHER INFORMATION

#### KEYWORDS

diagnostic, melanoma, miRNA, nevi, cancer, biomarker, classifier

#### CATEGORIZED AS

- ▶ **Medical**
  - ▶ Diagnostics
  - ▶ Disease: Cancer
  - ▶ Disease: Dermatology

#### RELATED CASES

2018-072-0

▶ Torres, R., Lang, U. E., Hejna, M., Shelton, S. J., Joseph, N. M., Shain, A. H., Yeh, I., Wei, M. L., Oldham, M. C., Bastian, B. C., & Judson-Torres, R. L. (2020). MicroRNA Ratios Distinguish Melanomas from Nevi. *The Journal of Investigative Dermatology*,

▶ PCT/US2019/023834

## PATENT STATUS

Patent Pending

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