Diagnostic Test for Melanocytic Lesions

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THE UNIVERSITY OF
SYDNEY

Diagnostic

> **TRL 3-4**
> **Pre-Clinical**

Problem
Melanoma diagnosis relies heavily on histopathological examination, which is subjective and can lead to over- or under-diagnosis. The current gold standard—histopathology—has limitations due to interobserver variability, leading to potential misdiagnosis. Accurate differentiation between melanoma and naevi is critical, as misclassification can result in unnecessary treatment or overlook early-stage melanoma. The increasing incidence of melanoma diagnoses without a corresponding rise in mortality suggests overdiagnosis, necessitating more objective and reliable diagnostic tools to complement traditional histopathology. Underdiagnosis of melanoma may lead to poor patient outcomes.

Solution
MIAdx is a molecular diagnostic assay that utilises DNA sequencing to effectively differentiate melanoma from benign naevi. It measures specific gene alterations and calculates a probability of melanoma with high specificity (over 95%), addressing the subjective limitations of histopathology. By cleverly combining the information encoded in genomic alterations, MIAdx provides an objective assessment, reducing the risk of over- and under-diagnosis and improving clinical decision-making for melanocytic lesions.

Intellectual Property Status
This technology is the subject of an Australian provisional patent application.

Potential Commercial Applications
MIAdx has applications in diagnostic laboratories, hospitals, and oncology centres.

It serves as an ancillary tool for pathologists, improving the accuracy of melanoma diagnoses.

The technology is particularly relevant for cases where histopathological assessment is challenging or equivocal.

It can be integrated into existing diagnostic workflows, offering a value-added service.

As a licensing opportunity, MIAdx appeals to diagnostic companies seeking to expand their oncology portfolio.

With its high specificity, MIAdx could become a standard adjunct in melanoma diagnostics, catering to a growing market driven by increased skin cancer screenings.

Inventors
The team includes world leading melanoma researchers and clinical key opinion leaders at USYD, the Melanoma Institute of Australia, and Royal Prince Alfred Hospital, Sydney Local Health District:

Prof Richard Scolyer AO, Prof Georgina Long AO, Dr Ismael Vergara Correa, Dr Andrew Colebatch, A/ Prof James Wilmott.

Image from Microsoft

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