

A Rapid PCR Test for Early Cancer Diagnosis

quantitative Malignancy Index Diagnostic System v2 (qMIDS^{v2})

A novel qPCR-based diagnostic test for detecting oral cancer risk and predicting patient prognosis. qMIDS^{v2} is a low cost, rapid, minimally invasive requiring only 1mm³ of biopsy material and is applicable to multiple cancer types.

Background

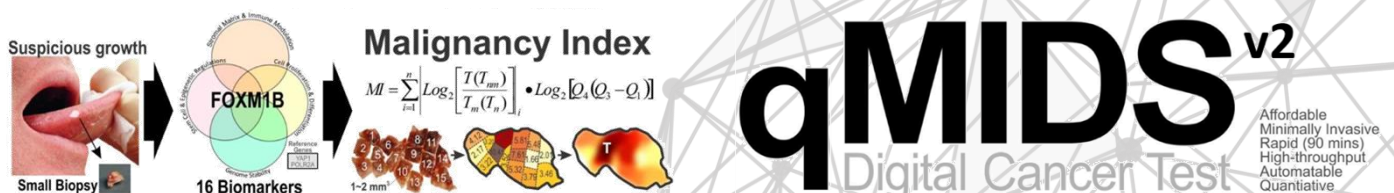
Head and neck squamous cell carcinoma (HNSCC) is the sixth most common malignancy worldwide, with more than 90% of cancers of the head and neck initiating from the squamous cells. Approximately 70% of oral cancers including HNSCC, arise from non-healing mouth ulcers or suspicious growths known as oral premalignant disorders (OPMDs). The majority of OPMDs are benign, however a small percentage (10 to 12%) become malignant. Current diagnosis involves scalpel surgery to obtain a large 5-20mm biopsy, which is analysed by an oral pathologist for cellular abnormalities - a subjective process that is unable to differentiate between low and high risk OPMDs. If not diagnosed early, the five-year survival rate for HNSCC drops from nearly 90% down to 50%. As such, identifying high-risk OPMDs before they progress to malignancy would encourage earlier treatment interventions, significantly improving survival rates and preventing unnecessary overtreatment.

The Problem

- >10 million global OPMD cases/year creating a significant healthcare burden.
- Current diagnosis requires a large biopsy, taken during a highly invasive surgical procedure.
- Diagnosis is subjective and dependent on the experience of the pathologist.
- Pathology cannot differentiate between low and high-risk OPMDs.
- There are currently no biomarkers for the diagnosis of high-risk OPMDs.

Invention: Benefits & Application

A novel, affordable, high-throughput, qPCR-based diagnostic test called quantitative Malignancy Index Diagnostic System v2 (qMIDS^{v2}). qMIDS^{v2} can accurately differentiate between low and high-risk OPMDs using a panel of 16 biomarker genes: 14 disease-associated genes (including *FOXM1*, a key gene in 39 different cancer types) and 2 reference genes. qMIDS^{v2} has an algorithm that produces a numerical digital malignancy index ranging from 0 (no disease) to 20 (high risk). The first iteration of the test (qMIDS^{v1}) has been tested on head and neck cancers, vulva and skin cancers with promising results.



Patent

A patent claiming the use of qMIDS^{v2} for cancer diagnosis has been filed. Queen Mary Innovation are now seeking partners who would be interested in licensing this technology for commercial development.

Patent Application Number: WO 2021/013891

Project Development

The qMIDS^{v1} diagnostic test was first validated using UK and Norwegian tissue samples, and subsequently validated in China using ethnic Han Chinese specimens. The validation process led to the collection of over 24,000 data points, which allowed further refinement of the biomarker panel. Development of a second iteration of the test called qMIDS^{v2} followed.

An international multi-cohort study validating the qMIDS^{v2} technology in 535 patients from UK, China and India was recently published. qMIDS^{v2} demonstrated highly comparable results amongst the three ethnically and geographically diverse cohorts. Test performance results are tabulated below:

OVERALL TEST:		UK	China	India
Sensitivity:	TP/(TP+FN)	88%	88%	97%
Specificity:	TN/(TN+FP)	96%	91%	86%
Accuracy:	(TP+TN)/Total	92%	89%	93%
Sample Size:	(n)	282	35	95

Inventor

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qMIDS^{v2} Website: <https://sites.google.com/view/qmids/home>

Publication

Teh, M.T., et al., Molecular Signatures of Tumour and Its Microenvironment for Precise Quantitative Diagnosis of Oral Squamous Cell Carcinoma: An International Multi-Cohort Diagnostic Validation Study. *Cancers (Basel)* **2022**, 14, DOI: 10.3390/cancers14061389.