

# CRT Licensing Opportunity



## MCM Proteins - Screening Markers for Anal Cancer

- Markers for early detection of anal cancer using anal swabs
- Rising incidence of anal squamous cell carcinoma
- Validated screening marker for the early detection of cancer
- Granted US, EP and JP patent on the target antigen

DIAGNOSTICS | Validation

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### Introduction

MCM or minichromosome maintenance family proteins are essential for the initiation of DNA replication. They are present throughout the cell cycle but are down-regulated following cell cycle exit and differentiation. Research in the laboratories of Professor Ron Laskey and Dr Nick Coleman (The Hutchison/MRC Research Centre, Cambridge) has demonstrated that antibodies against MCMs enable ready identification of malignant and pre-malignant cells. This has prompted a clinical application in cancer screening approaches that rely on the detection of malignant or pre-malignant cells exfoliated from surface epithelia. A study has recently been undertaken in Dr Coleman's laboratory to investigate the applicability of MCMs in improving the detection of anal neoplasia. Neoplasia in the anal canal has many analogous features to that of the cervix, where MCMs have already proved successful as screening markers.

### Background

Anal squamous cell carcinoma (SCC) and squamous intraepithelial lesions (SILs) are of increasing incidence and clinical importance. SIL is a pre-malignant condition that can progress to invasive SCC through different grades of severity of disease called low grade SIL (warts and AIN1) and high grade SIL (AIN1/2). Since current approaches to screening for SIL are ineffective and because the market is large, particularly in the USA, an effective anal cancer screening biomarker that could identify low and high grade SIL disease would produce large potential future benefits, both financial and clinical.

### Study Data

235 cytology samples (high/low grade SIL disease) were obtained via blindly inserted anal swabs. MCM status was determined by immunohistochemistry. Sensitivity values of 84% were observed in specimens from patients with AIN 2/3. Higher sensitivities can likely be attained by adoption of a more targeted anal sampling methodology.

### Commercial Opportunity

Diagnostic products based on antibodies targeting MCM proteins are being developed with commercial partners for cervical (late stage) and bladder cancer. CRT are looking for a partner to develop MCM-based diagnostic tests for anal cancer. Granted patents (US, EP and JP) relating to the target antigen and MCM specific antibodies are available. Data is available under CDA.

### References

- Gonzalez, *et al.*, Nat. Rev. Can. 2005 5: 135-141  
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