Conclusions: RM has the potential to become an excellent cytodiagnostic tool that can both accurately and objectively discriminate cancer from normal cells.

2003 BRAF Mutation Testing of Pigmented Melanomas using the Idylla Platform

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Background: *BRAF* mutations are present in ~50% of all melanomas and targeted therapy has been associated with improvement in overall and progression-free survival. Timely assessment of mutation status is important for clinical decision making. Melanomas with high melanin content can be problematic for molecular assays due to inhibition of PCR. We evaluated *BRAF* mutation testing using the Idylla platform from Biocartis. This platform has recently been introduced into the United States, and offers cartridge-based testing for concurrent BRAF V600E/E2/D and V600K/R/M mutation detection with minimal hands-on time and low sample input requirement.

Design: Twenty-three FFPE melanoma samples from our medical center with known *BRAF* mutation results from reference lab testing were retrospectively identified. Cases included cytology cell blocks (8), small biopsies (4), and excisional biopsies/resection specimens (10). During pathologist review of H&E stained slides, pigment scores were rendered as 0 (no pigment, n=5), 1 (moderate pigment, n=10), or 2 (abundant pigment, n=7). This sample cohort included 14 *BRAF*mutation positive and 7 mutation negative samples. Testing on the Idylla platform was compared to reference lab testing for sensitivity and specificity. Reproducibility, limit of detection, and melanin interference were also evaluated.

Results: Sensitivity and specificity of *BRAF* mutation detection were 100% as compared to reference lab testing in 21 samples. Abundant melanin did not inhibit the assay, as demonstrated by samples with a pigment score of 2 successfully resulted. Tissue input requirement was low, with a single 5 ?m section tested for small biopsies and resections. Cell block material with as few as ~400 tumor cells in the background of red blood cells was successful in detecting BRAF V600E. Two samples in this cohort contained insufficient DNA for testing, including one cell block and one needle core biopsy. Results were reproducible, and as little as 1% mutant allele of V600E and V600K was detected using Horizon Discovery control material. The assay required only 10-15 minutes of total hands-on time and the instrument time was ~90 minutes, including extraction.

Conclusions: *BRAF* mutation assay on the Idylla platform provides robust testing for melanomas with high melanin content, including limited cytology cell block material. Total assay time of <2 hours facilitates prompt results to guide patient care decisions.

2004 Muse (Microscopy with UV Surface Excitation), A Slide-Free Technique to Evaluate Surgical Pathology Specimens

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Background: MUSE is a novel ex-vivo microscopy technique that employs ultraviolet light- excitation of common fluorescent tissue dyes within about 10 microns of the surface of fresh or fixed specimens. The method requires about 2 minutes of sample preparation and generates full-color, high-resolution images at 200 msec per 1mm^2; these can be color-converted to resemble H&E. The MUSE procedure does not harm the tissue for future use in the traditional H&E preparation or molecular testing. The aim of this study was to evaluate MUSE on a wide range of surgical pathology cases.

Design: 20 samples of different surgical pathology cases (kidney, thyroid, intestine, breast, prostate, lung, liver and skin) evaluated by six board-certified pathologists and three pathology residents after brief training. For each case, “Diagnostic Score” (% of correct answers) and “Comparison Scores” (0: Not useful/ 1: useful but not diagnostic / 2: diagnostic but weaker than H&E / 3: Equal to H&E / 4: Stronger than H&E) were determined by comparing the MUSE images with the corresponding conventional FFPE-H&E images generated by whole-slide scanning.

Results: Results indicate that MUSE is a promising modality for histopathology, generating an average diagnostic score of 80% and a comparison score of 2.4.

Figure 1 - 2004

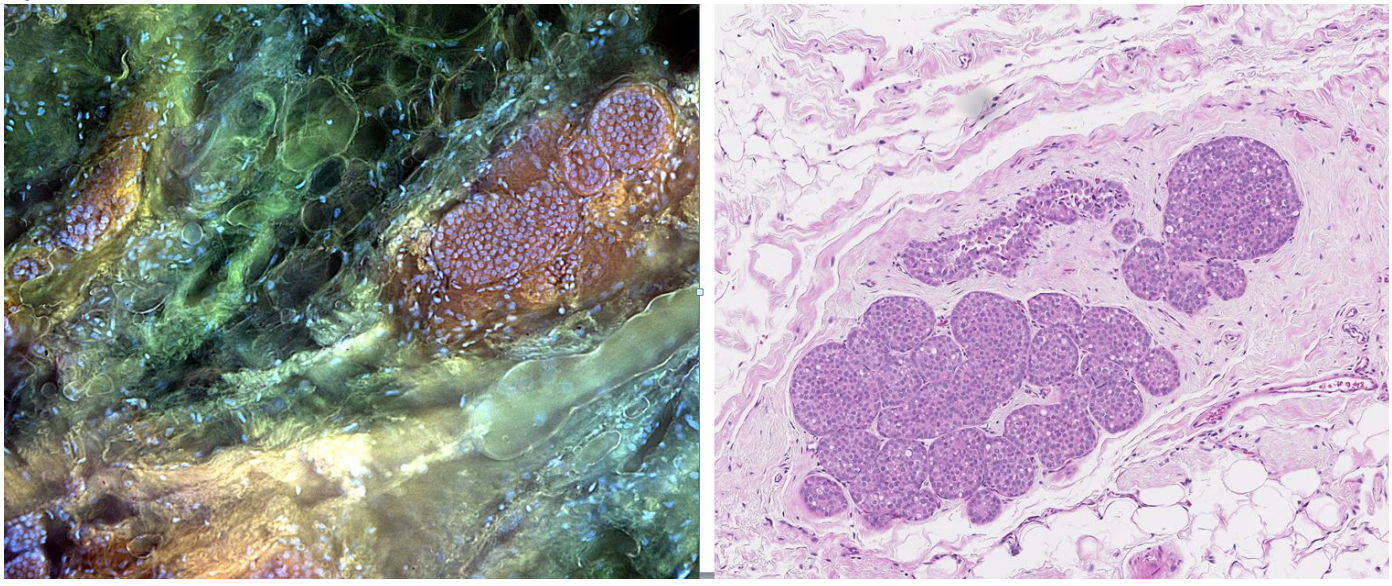
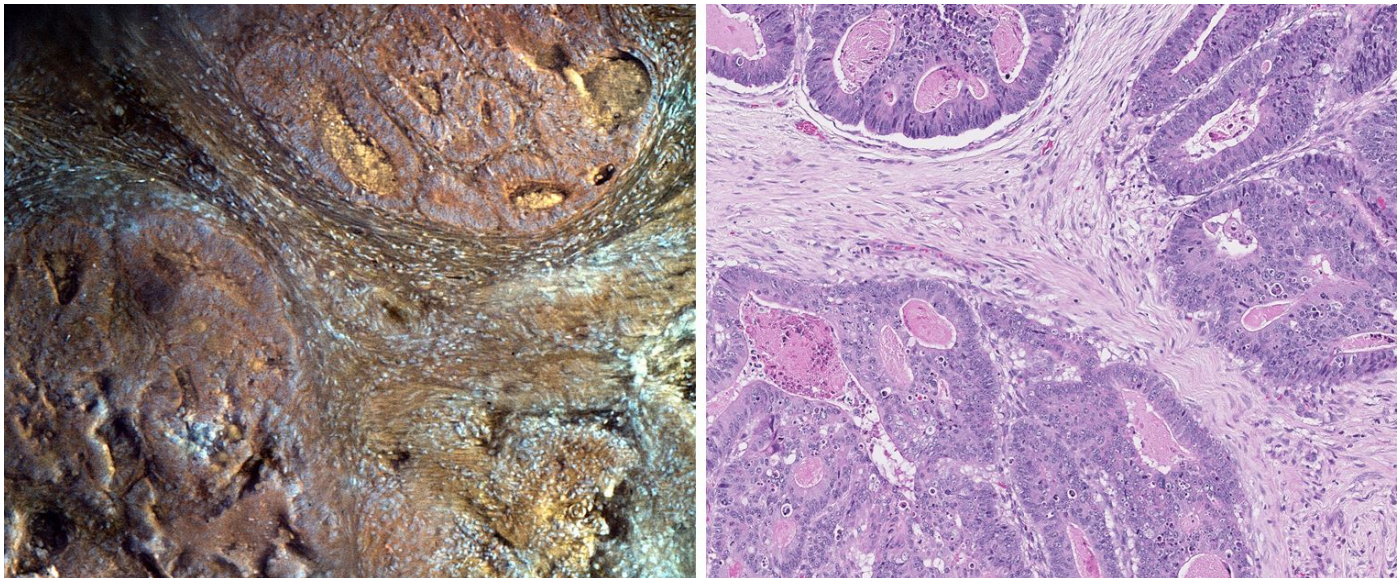


Figure 2 - 2004



Conclusions: MUSE represents a fast, reliable and inexpensive approach for evaluating surgical specimens. It could be a useful diagnostic tool, but in the implementation used here appears to be slightly weaker than H&E on providing all necessary histologic details. Going forward we continue to evaluate the application of MUSE in different clinical settings particularly in intraoperative consultations.