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Validation and Utility of a Non-Invasive 2-Gene Molecular Assay for Cutaneous Melanoma

Laura K. Ferris, MD, PhD^a, Burkhard Jansen, MD^b, Jonathan Ho, MD^a, Klaus J. Busam, MD^c, Kenneth Goss, MD^d, Doyle D. Hansen, MD^e, John P. Alsobrook II, PhD^b, Zuxu Yao, PhD^b, and Pedram Gerami, MD^f

Background: To minimize the number of melanomas missed, clinicians generally biopsy 10 or more benign nevi for each melanoma. This low specificity results in many unnecessary procedures for patients.

Approach: We have previously reported on a pigmented lesion assay (PLA) concept where samples are obtained non-invasively via adhesive patch sampling. We here evaluated the performance of a novel and optimized gene signature using two genes, *LINC* and *PRAME*, to distinguish benign nevi from melanoma in prospectively collected samples (n=319). In addition, using a web based multi-reader multi-case study, 45 dermatologists each evaluated 60 representative clinical and dermatoscopic images of clinically atypical pigmented lesions from the validation study, first without and then with PLA data.

Results: The PLA is a sensitive and specific method for detection of cutaneous melanoma (AUC 0.91, NPV>99%, sensitivity 92%, specificity 64%). Dermatologists who incorporated the PLA into their biopsy decision improved their relative biopsy specificity by 77.3 % (p<0.001), and improved biopsy sensitivity from 95.0% to 98.6% (p=0.01), compared to their decision without the PLA.

Innovation and Relevance: The PLA is a non-invasive tool that enables dermatologists to significantly improve biopsy specificity, thus removing fewer benign nevi, while maintaining or improving sensitivity.

Presenting Author:

Laura Ferris, MD, PhD

Department of Dermatology, University of Pittsburgh

3601 Fifth Avenue, Fifth Floor, Pittsburgh, PA 15238

Phone: 412-647-2013

Email: ferrislk@upmc.edu

^aDepartment of Dermatology, University of Pittsburgh, Pittsburgh, PA

^bDermTech Inc, La Jolla, CA

^cMemorial Sloan Kettering Cancer Center, New York, NY

^dSkin Surgery Medical Group, San Diego, CA

^eEast County Dermatology Medical Group, El Cajon, CA

^fDepartment of Dermatology, Northwestern University, Chicago, IL

About DermTech:

DermTech is a molecular diagnostics company focused on developing non-invasive gene expression tests to aid the clinical diagnosis of skin cancer and other skin conditions. DermTech operates a CLIA laboratory located at the company's LaJolla, CA headquarters. DermTech's technology allows the analysis of skin samples biopsied non-invasively using an adhesive patch rather than a scalpel. DermTech provides highly accurate, objective information to the physicians to improve patient care through advanced molecular pathology gene expression information.



DermTech.com • 1.866.450.4223
11099 N. Torrey Pines Rd., Suite 100 • La Jolla, CA 92037