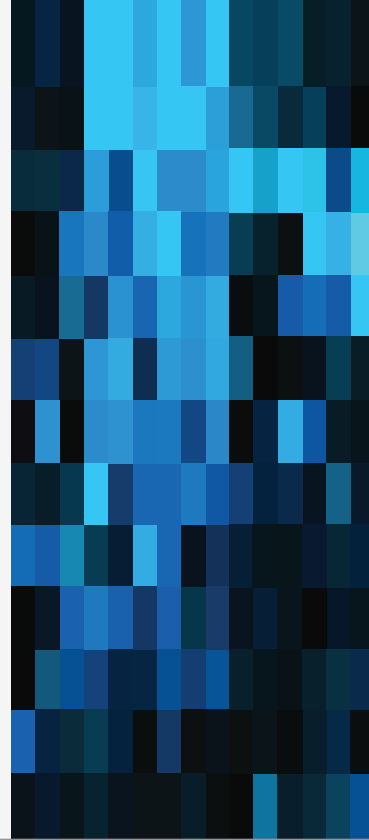clinical view

A NOVEL
MOLECULAR VIEW

Non-invasive melanoma associated
gene expression from DermTech

microscopic view

Test Criteria:

The PLA is intended for use on pigmented skin lesions, which are suspicious of melanoma, including those that meet one or more ABCDE criteria. The test has not been validated on samples from mucosal surfaces, the palms of the hands, the soles of the feet, sites that have previously been biopsied, or bleeding or ulcerated lesions. As with all test, results should be interpreted by the physician in conjunction with clinical findings and patient risk assessment.

Patents Received:
No. 6,720,145 - "Method of detection of biological factors in epidermis"
No. 6,949,338 - "Methods and kits for obtaining and analyzing skin samples for the detection of nucleic acids"
No. 7,183, 057 - "Tape stripping methods for analysis of skin disease and pathological skin state"
No. 7,297,480 - "Method for detection of melanoma"

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 (Clinical Laboratory Improvement Amendments) licensed laboratory located at the company's La Jolla, 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. For additional information visit: dermtech.com

DermTech

EXPAND YOUR CLINICAL AND MICROSCOPIC ASSESSMENTS WITH NON-INVASIVELY OBTAINED GENE EXPRESSION INFORMATION.

The PLA provides physicians with non-invasively obtained gene expression information for clinically atypical skin lesions. The PLA test begins with a non-invasive biopsy using the provided adhesive skin biopsy collection kit. Each kit contains all of the necessary component to complete the non-invasive skin biopsy including the adhesive patches, instructions for use, alcohol prep pad, gauze pad, a pen for outlining the lesion, and a pre-paid self addressed FedEx shipping pack.

The unique properties of the adhesive patches allow for the collection of skin samples with minimum patient discomfort while maximizing the collection of stratum cornuem tissue for our PLA. Once specimens are received in the DermTech Laboratory, RNA is isolated from the epidermal material on the patches , and the expression levels of 2 genes are measured. The PLA's melanoma-identifying RNA signature is similar in adhesive patch samples and metastatic melanoma tissue.

Gene Expression

The PLA detects the presence or absence of expression for two specific genes, PRAME and LINC00518. These two genes belong to separate classes of molecules that are known to have roles in oncogenesis, and both are elevated in melanoma. This profile was developed by screening the entire genome for differential gene expression between melanoma and non-melanoma pigmented skin lesions.

GENE EXPRESSION POSITIVE

LINC00518: DETECTED
PRAME: DETECTED

Molecular Pathology Report

The PLA molecular pathology report provides a positive or negative gene expression result.

The negative predictive value of a test indicates how often a negative result is truly negative. The PLA has a NPV of 99%.

PLA Pigmented Lesion Assay
MOLECULAR PATHOLOGY TEST REPORT
1.866.450.4223 | 1.858.450.4222 | dermtech.com
11099 N. Torrey Pines Rd., Suite 100 | La Jolla, CA 92037

PATIENT INFORMATION

Patient Name:		Sample ID:	
MRN#:		Body Site:	
DOB:		Date Collected:	
Age:		Date Received:	
Sex:		Date Reported:	
Referring Physician:		Fax Number:	
Address:		City/State/Zip:	

TEST RESULTS

GENE EXPRESSION STATUS: **POSITIVE**	*LINC00518*:	**DETECTED**
RISK STATUS: **HIGH (RED)**	*PRAME*:	**DETECTED**

Expression of LINC00518 and/or PRAME is found in lesions with a histopathologic diagnosis of melanoma. If one or both of the genes are detected, the test is positive.

Macro-dissection Report/Comments:

Risk Status Interpretation:

🟢 **LOW (GREEN):** Melanoma associated gene expression negative. Consider surveillance per standard of care.

🟠 **MODERATE (ORANGE):** Positive for a single gene (LINC only or PRAME only). Recommend biopsy and histopathologic assessment. The proportion of pigmented lesions that are histopathologically diagnosed as melanoma is lower (12%) in single gene positive samples (LINC only or PRAME only) than in double gene positive samples.

🔴 **HIGH (RED):** Positive for both LINC and PRAME genes. Recommend biopsy and histopathologic assessment The proportion of pigmented lesions that are histopathologically diagnosed as melanoma is higher (92%) in two gene positive samples (both LINC positive and PRAME positive) than in single gene positive samples.

Laboratory Director: Joseph Voland, MD. FCAP
CLIA # 05D2073519   CAP # 9043605   L01008-08   Page # 1 of 2