A NOVEL MOLECULAR VIEW

clinical view

Non-invasive melanoma associated gene expression

microscopic view

DermTech
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, gaze 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 minimal patient discomfort while maximizing the collection of stratum conumtissue 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.

**Molecular Pathology Report**

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

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**LINC00518: DETECTED**

**PRAME: DETECTED**

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

**GEA EXPRESSION POSITIVE**

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

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**References:**


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**Assay Completion and Results**

**Patient Name:** Philip

**Date Collected:** 11/01/2023

**DOB:** 12/12/2005

**Sex:** F

**Patient History:**

Chief complaint: Pigmented skin lesions.

**Family History:**

Father: History of melanoma.

**Allergies:**

Pen: Allergic to latex.

**Lesions:**

Type: Pigmented skin lesions.

Size: 1 cm x 1 cm

Location: Right arm

**Diagnosis:**

Malignant melanoma.

**Assay Conducted:**

Plaque melanoma-identifying RNA signature.

**Result:**

Positive

**Conclusion:**

The patient is positive for melanoma. The lesion should be treated as malignant and referred to a dermatologist for further care.

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**Laboratory Information:**

DermTech, Inc.

1100 McFerrin, Suite 600

San Antonio, TX 78210

1-866-450-4223

www.dermtech.com

06A2073519

**FDA 510(k) Clearance:**

Premarket approval of this test was granted under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing.

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**Diagnostic Performance:**

The PLA was developed and its performance characteristics determined by DermTech. It has not been cleared or approved by the US Food and Drug Administration (FDA) and does not require the user to go through premarket 510(k) review. This test is not labeled for diagnostic use. DermTech, Inc. is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing.

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**Turnaround Time:**

5-10 business days from receipt of sample.