nevome™ (PLA)

WHAT IS NEVOME?

At DermTech, we believe in cutting the uncertainty, not the patient.

Nevome is the first test to identify high-risk pigmented lesions by analyzing known genomic risk factors for melanoma. This revolutionary new test uses tissue samples collected non-invasively and includes both RNA gene expression and DNA mutation analysis to provide a more complete picture of lesions at high risk for melanoma. The RNA gene expression detects two genes, LINC and PRAME, that are over-expressed in melanoma. If either gene is detected, the test is positive.

WHEN SHOULD I TEST?

Nevome is intended for use on pigmented skin lesions, which are clinically suspicious for melanoma. These lesions may meet one or more ABCDE criteria. Nevome uses include:

- Lesions being followed for change.
- Lesions in cosmetically sensitive areas.
- Lesions on patients with potential contra-indications to surgical biopsy including patients that are anti-coagulated, those at risk for infection, and those at risk for poor wound healing or elevated abnormal scarring.

NON-INVASIVE SOLUTION

DermTech provides physicians with a non-invasive option for the biopsy of clinically atypical pigmented lesions (or moles) using an adhesive patch rather than a scalpel. DermTech provides highly accurate, objective information to the physician to improve patient care and comfort through advanced molecular pathology gene expression.

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FOR MORE INFORMATION ABOUT NEVOME

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DNA MUTATION ANALYSIS

Nevome analyzes mutations of the BRAF, NRAS and TERT genes, which are found in primary and metastatic melanoma.

These genes are associated with lesions that have the potential to metastasize. Double mutations in these genes are associated with borderline lesions, melanoma in-situ lesions and invasive melanoma lesions. Nevome includes these mutations to identify high risk lesions.

RNA GENE EXPRESSION

When LINC or PRAME is detected, the test is positive for melanoma associated gene expression. Nevome has a sensitivity of 91%, a specificity of 69% and an NPV of 99%.

Cut the uncertainty, not the patient.

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"
Patent Pending No. 62562250. 2017. "Non-invasive skin-based detection methods"

* The test has not been validated for samples collected from mucosal surfaces, the palms of hands, the soles of feet, sites that have been previously biopsied, areas where non-vellus hair cannot be sufficiently trimmed (e.g. scalp), bleeding or ulcerated lesions, pediatric patients, and patients with a Fitzpatrick skin type IV or higher. As with all tests, results should be interpreted by the physician in conjunction with clinical findings and patient risk assessment. The test is not intended for screening or for use on non-pigmented lesions, nor should it be used to confirm a clinical diagnosis of melanoma.

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