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 mutation risk factors for melanoma. This revolutionary new test uses tissue samples collected non-invasively with an adhesive patch. When combined with the Pigmented Lesion Assay (PLA) gene expression analysis, the additional DNA mutation analysis can provide a more complete picture of lesions or moles at high risk for melanoma. Nevome analyzes mutations in BRAF, NRAS and TERT promoter genes, while the PLA analyzes the gene expression of LINC and PRAME.

WHEN SHOULD I TEST?
Nevome can currently be ordered if the PLA test is positive. Nevome and the PLA are intended for use on pigmented skin lesions, clinically suspicious for melanoma. These lesions may meet one or more ABCDE criteria. Nevome uses include:
• Lesions positive for LINC or PRAME.
• Lesions being followed for change.
• Lesions in cosmetically sensitive areas.
• Lesions on patients with potential contraindications 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 and mutation testing.
DNA MUTATION ANALYSIS

Nevome identifies hotspot driver mutations in BRAF, NRAS and TERT genes found in melanoma. Mutations of these genes are found in early stage (MIS / Stage 1) primary cutaneous and metastatic melanoma. Nevome includes these mutations to identify high risk lesions. The combined RNA/DNA test has a sensitivity of 97% and a negative predictive value of >99%.

RESEARCH PUBLICATIONS

- “Validation of Non-invasive Gene Expression(PLA) Against High Risk Driver Mutations (BRAF, NRAS, and TERT) in Cutaneous Melanoma” was first shared as a late-breaking presentation at AAD 2018. The research validated the high performance of the PLA against key driver mutations in melanoma. These mutations (included in the Nevome test) are found to correlate with histopathologic criteria and on prognosis. 97% of the histopathologically confirmed melanoma samples were either PLA positive or Nevome mutation positive.

- “Real-world experience and clinical utility of a non-invasive gene expression test for primary cutaneous melanoma and validation against high risk driver mutations in BRAF, NRAS, and the TERT promoter,” was presented at IID 2018. Hotspot driver mutation analysis additionally validated the gene expression results and combining gene expression and mutation analyses was shown to further improve the test performance.

* 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 or non-melanoma skin cancer, nor should it be used to confirm a clinical diagnosis of melanoma.