introducing a novel molecular view

Non-invasive melanoma associated gene expression from DermTech
The Test

The Pigmented Lesion Assay (PLA) provides physicians with non-invasively obtained gene expression information for clinically atypical pigmented skin lesions. The PLA test begins with the non-invasive specimen collection using the provided adhesive skin biopsy collection kit. A single kit contains all of the necessary components to complete the non-invasive biopsy collection including the adhesive patches, instructions for use, a marking pen for lesion outlining, and a pre-addressed/pre-paid FedEx shipping pack. DermTech provides these kits to physicians using the Pigmented Lesion Assay.

The unique properties of the adhesive patches allow for the collection of skin samples with minimal patient discomfort while maximizing the collection of tissue for our Pigmented Lesion Assay.

Once specimens are received in the DermTech laboratory, RNA is isolated from the epidermal material on the patches, and the expression levels of 6 genes are measured. In our studies, the PLA’s melanoma-identifying RNA signature is similar in adhesive-patch samples and metastatic melanoma tissue.

Gene Expression

The PLA MAGE (Melanoma Associated Gene Expression) detects the presence or absence of expression for two specific genes PRAME and LINC00518 and is used as the primary profile assessment. 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.

The PLA Score

A gene expression profile derived from the levels of PRAME, LINC00518, CMIP, ACTB, B2M, and PPIA, associated with melanoma, is reported as a PLA Score from 0-100. This profile was developed by screening the entire genome for differential gene expression between melanoma and non-melanoma pigmented skin lesions.

The PLA reflects the underlying tumor biology. In a study that compared PLA Scores from adhesive-patch sampled melanomas and biopsied metastatic tumor tissues, our data showed no statistical differences between adhesive-patch sampled melanomas and biopsied melanoma metastases.

The PLA is not a prognostic test based on static genomic DNA; instead it gives an objective evaluation of a pigmented lesion’s behavior at the time of the patient visit. The specimen’s PLA score captures the current state of the specimen’s dynamic melanoma-associated gene expression profile. The PLA Molecular Pathology Report allows physicians to rapidly assess this number by comparing it to the melanomas used in the PLA validation studies.

The table to the right shows the number of cases and median PLA scores for the histopathological subtypes seen in DermTech’s validation studies. Higher PLA scores are seen in melanomas (both in situ and invasive), while lower PLA scores are seen in atypical nevi, and still lower scores are seen in conventional nevi and other non-melanoma lesions.

When PLA Scores of less than 8 are applied post-hoc to PLA MAGE-positive specimens, specificity can increase from 64% to 77%.
Test Criteria:

The test is intended for use on pigmented skin lesions, which are suspicious of melanoma, including those that meet one or more ABCDE criteria, and for which the clinician would like additional information prior to surgical removal.

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. Non-melanoma skin cancers may have a low PLA score. Low scoring lesions should be followed clinically. 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.

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: www.dermtech.com