

NON-INVASIVE ADHESIVE SKIN BIOPSY KIT



IS IT MELANOMA?

DermTech's Pigmented Lesion Assay (PLA) 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.

WHEN SHOULD I TEST?

The PLA test is intended for use on pigmented skin lesions, which are clinically suspicious for **melanoma**. These lesions may meet one or more ABCDE criteria.

PLA uses include:

- 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

To learn more about DermTech's PLA assay and obtain Adhesive Skin Biopsy Collection Kits, please visit our website www.dermtech.com



ADHESIVE SKIN BIOPSY COLLECTION KIT:

The unique properties of the adhesive patches allows for the collection of skin samples with **minimal patient discomfort and recovery time**, while maximizing the collection of tissue for our PLA. A single kit contains all of the necessary components to complete the non-invasive biopsy:

- Adhesive patches
- Instructions for use
- Marking pen for outlining the lesion
- Pre-paid FedEx shipping pack

THE TEST

DermTech's PLA MAGE (Melanoma Associated Gene Expression) detects the 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. These gene expression results are summarized in a molecular pathology report.

GENE EXPRESSION

LINC00578: DETECTED

PRAME: DETECTED



Concordance Diagnosis (398 cases)	LINC and/or PRAME	
	Detected	Not Detected
Melanoma	91%	9%
Non-melanoma	31%	69%

Sensitivity: 91% Specificity: 69%

When one or more of the genes is detected, the gene expression is positive. The PLA has a sensitivity of 91%, and a NPV of 99%.

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.

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"

* 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-velus 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.



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