DermTech

PIGMENTED LESION ASSAY

AND NON-INVASIVE SKIN COLLECTION KIT TO IDENTIFY LESIONS AT HIGH-RISK FOR MELANOMA

IS IT MELANOMA?

DermTech's Pigmented Lesion Assay (PLA) provides physicians with a non-invasive option to identify clinically atypical pigmented lesions (or moles) at high risk for melanoma. 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.

OBJECTIVE VS. SUBJECTIVE

The diagnosis of early stage melanoma is inaccurate by visual assessment and histopathologic slide review. The false negative diagnosis for melanoma in-situ/Stage 1a melanoma was found to be 35% in a recent large scale study of pathologists in the US. By comparison, the PLA has a negative predictive value of 99% and significantly reduces the number needed to biopsy.*

WHEN SHOULD I TEST?

The PLA 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 risks to surgical biopsy including patients who are anti-coagulated, at risk for infection, and at risk for poor wound healing or elevated abnormal scarring
- Surgical biopsy refused or contraindicated

	CURRENT PATHWAY	PLA
Test Purpose	Rule-out melanoma	Rule-out melanoma
Type	Surgical biopsy/ histopathology	Noninvasive gene expression
Negative Predictive Value	83%	99%
Probability of Missed Melanoma	17%	1%
Number Biopsied to Identify One Melanoma	25	2.7

The above table compares the key performance metrics of the PLA versus the current pathway (visual assessment and surgical biopsy/histopathology) for managing pigmented lesions.

THE TEST

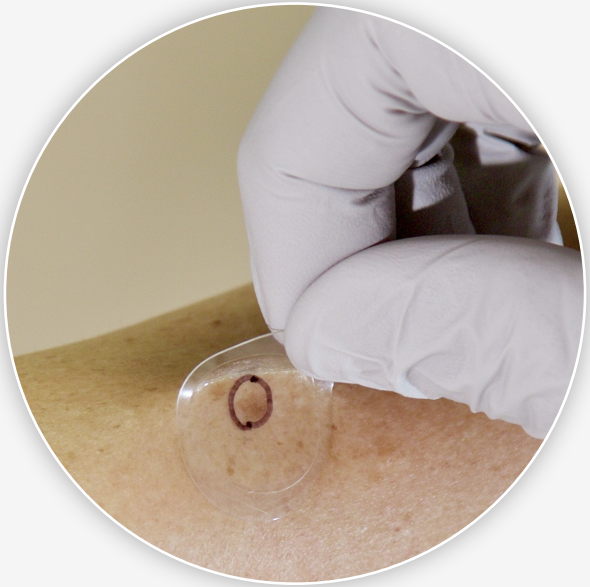
DermTech's PLA detects the expression of two specific genes, PRAME and LINC00518. These two genes belong to separate classes of molecules that are known to have roles in oncogenesis, and both are elevated in melanoma. Gene expression results are summarized in a molecular pathology report.

GENE EXPRESSION

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%. If the test is negative, the lesion has less than a 1% chance of being melanoma. PLA positive lesions are generally surgically biopsied to establish the diagnosis. PLA negative lesions are generally monitored. 2-gene (LINC and PRAME) positive samples have a 93% correlation to melanoma by histopathology. PRAME only positive samples have a 50% correlation to melanoma by histopathology. LINC only positive samples have a 7% correlation to melanoma by histopathology.



* Additional references available at www.dermtech.com.

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