# PIGMENTED LESION ASSAY
# MOLECULAR PATHOLOGY TEST REPORT

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## PATIENT INFORMATION

| | | | |
|---|---|---|---|
| Patient Name:: | | Sample ID: | |
| DOB: | | Date Collected: | |
| Age: | | Date Received: | |
| Sex: | | Date Reported:: | |
| Referring Physician:: | | Fax Number:: | |
| Address:: | | City/State/Zip:: | |

## GENE EXPRESSION RESULTS

**GENE EXPRESSION**

**POSITIVE**

***LINC00518*: DETECTED**

***PRAME*: DETECTED**

**Expression of *LINC00518* and/or *PRAME* is found in lesions with a histopathologic diagnosis of melanoma. If one or both of the genes are detected, the test is positive.**

**Macrodissection Report/Comments:**

## ASSAY DESCRIPTION AND INTENDED USE

**The DermTech Pigmented Lesion Assay (PLA) is intended for use under the direction of a physician to provide information on gene expression associated with melanoma.** The assay provides information on whether gene expression is detected for *LINC00518* (Long Intergenic Non-protein Coding RNA518), a member of a newly described class of regulatory RNA molecules, and/or *PRAME* (PReferentially expressed Antigen in MElanoma). The test is intended for use on pigmented skin lesions suspicious of melanoma, including those that meet one or more ABCDE criteria, and for which a clinician would like additional information prior to surgical biopsy. It is not intended for screening or for use on non-pigmented lesions, nor should it be used to confirm a clinical diagnosis of melanoma. The test has been validated in samples collected using the Adhesive Skin Biopsy Kit, distributed by DermTech, and used according to the Instructions for Use (IFU). Lesions should be at least 5 mm in diameter and not larger than 16 mm. Lesions are macrodissected to ensure that tissue from the pigmented lesion and not the surrounding skin will be used for analysis. 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 hair cannot be sufficiently trimmed (e.g. scalp), bleeding or ulcerated lesions, pediatric patients, and patients with Fitzpatrick skin type IV or higher. Non-melanoma skin cancers may be negative based on *LINC00518* and/or *PRAME* gene expression. As with all tests, results should be interpreted by the physician in conjunction with clinical findings and patient risk assessment.

## REFERENCE MATERIAL AND ASSAY PERFORMANCE

Expression of *LINC00518* and/or *PRAME* genes has been studied in a validation set of 398 samples. Of the studied melanomas, about a third were read histopathologically as melanoma *in situ* or lentigo maligna and the median thickness of invasive melanomas was 0.45 mm. About 75% of nevi were atypical nevi. In this study, n*inety-one percent (91%) of melanomas demonstrated detectable levels of LINC00518 and/or PRAME expression versus only 32% of non-melanoma samples, giving a sensitivity of 91% and a specificity of 69%.* **At a calculated 7% melanoma prevalence, the negative predictive value is greater than 99% (a patient with a negative test has a less than 1% chance of having melanoma).** *References: see www.dermtech.com*

This test was developed and its performance characteristics determined by DermTech. It has not been cleared or approved by the US Food and Drug Administration; FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing.