PIGMENTED LESION ASSAY TEST REPORT

1.866.450.4223 | 1.858.450.4222 | www.dermtech.com
11099 N. Torrey Pines Rd., Suite 100 | La Jolla, CA 92037

PATIENT INFORMATION

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

Specimen source: Skin sample collected with DermTech's non-invasive Adhesive Skin Biopsy Kit.

GENE EXPRESSION RESULTS

GENE EXPRESSION

***LINC00518*: NOT DETECTED**

***PRAME*: NOT DETECTED**

Clinical variables and patient history should be considered in the decision to surgically biopsy.

Macrodissection Report:

DermTech

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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).

Expression of *LINC00518* and/or *PRAME* is found more frequently in lesions with a histopathologic diagnosis of melanoma. If one or both target genes are detected, we also provide an algorithmic lesion score based on 4 additional genes (PLA Score, Range 0-100) that may allow characterization of the lesion subtype (melanoma, melanoma in situ, atypical nevus, conventional nevus or other non-melanoma skin lesions).

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 non-vellus 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 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.

REFERENCE MATERIAL AND ASSAY PERFORMANCE

Expression of *LINC00518* and/or *PRAME* genes has been studied in a validation set of 319 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 0.48 mm. About 75% of nevi were atypical nevi. In this study, ninety-two percent (92%) of melanomas demonstrated detectable levels of *LINC00518* and/or *PRAME* expression versus only 36% of non-melanoma samples, giving a sensitivity of 92% and a specificity of 64%. **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).**

The PLA Score has been evaluated in post hoc analyses of samples from the validation study. The median PLA Score is higher in cutaneous melanomas that express *LINC00518* and/or *PRAME* versus non-melanoma lesions that express *LINC00518* and/or *PRAME* as shown in the PLA Score table on the previous page. The specificity can increase to 77% when the detection of *LINC00518* and/or *PRAME* is used in combination with a PLA Score threshold of 8. Appropriate surgical biopsy and clinical follow up should be considered based on the *LINC00518* and/or *PRAME* expression and the PLA Score.

References: 1. Ferris et al., Utility and decision impact of a non-invasive molecular assay for cutaneous melanoma. Manuscript submitted. 2. Gerami et al. Development and validation of a non-invasive 2-gene molecular assay for cutaneous melanoma. Manuscript submitted. 3. Gerami et al., Development of a novel noninvasive adhesive patch test for the evaluation of pigmented lesions of the skin. J Am Acad Derm 71:237-344, 2014. 4. Wachsman et al., Noninvasive genomic detection of melanoma. Br J Dermatol 164(4):797-806, 2011.