MOLECULAR PATHOLOGY TEST REPORT

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PATIENT INFORMATION

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

GENE EXPRESSSION RESULTS

GENE EXPRESSION

NEGATIVE

***LINC00518*: NOT DETECTED**

***PRAME*: NOT 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 is intended for use under the direction of a physician to provide information on gene expression associated with melanoma. The assay detects gene expression for LINC00518 (Long Intergenic Non-protein Coding RNA518), a member of the 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. If the pigmented lesion assay is positive, a histologic assessment should follow. Most physicians choose to perform a shave or punch biopsy.. The assay is not intended for use on non-pigmented lesions. The test has been validated in samples collected using the Adhesive Skin Biopsy Kit, and used according to the Instructions For Use (IFU). Lesions should be at least 5mm in diameter. For lesions larger than 16mm, multiple kits should be used. Lesions are macro-dissected 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 sufficiently be 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, ninety-one percent (91%) of melanomas demonstrated detectable levels of LINC00518 and/or PRAME expression versus only 31% 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 being positive for melanoma. (Gerami et al., *JAAD,* 2016) The utility study demonstrates that even pigmented lesion experts biopsy half as often and miss fewer melanomas when adding the pigmented lesion assay to their decision process. (Ferris et al., *Jama Dermatology*, 2017)

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.