DermTech
P: 858.450.4222 | F: 858.264.2188 | dermtech.com
12340 El Camino Real | San Diego, CA 92130

Pigmented Lesion Assay
MOLECULAR PATHOLOGY REPORT

PATIENT AND SPECIMEN INFORMATION

Patient Name		Body Site	
DOB		Date Collected	
Sex		Date Reported	
MRN #		Kit ID/Accn ID	
Ordering Provider		Reference #	

TEST RESULT

Pigmented Lesion Assay (RNA Gene Expression): NEGATIVE

LINC00518: NOT DETECTED	**PRAME:** NOT DETECTED

Comments: The specimen is comprised of skin cells collected using four adhesive patches from a single pigmented lesion. Except as noted below there is no visible blood, exudate, hair, or other contaminant. The lesion border is demarcated on each sticker, and each macro-dissected specimen contains the demarcated area (images on file). The specimen is submitted for qPCR analysis.

[ADD MACRO CONTENT OR FREE TEXT IF NEEDED].

RESULT INTERPRETATION

NEGATIVE

No biomarkers detected. The tested lesion is unlikely to be melanoma (negative predictive value 99%).[1,2] Consider clinical surveillance for changes in appearance.

Negative predictive value (NPV) indicates the probability the lesion is not a melanoma.

See page 2 for more information.

DermTech
P: 858.450.4222 | F: 858.264.2188 | dermtech.com
12340 El Camino Real | San Diego, CA 92130

TEST DESCRIPTION, INTENDED USE, AND PERFORMANCE

The Pigmented Lesion Assay is a laboratory-developed test that detects genomic biomarkers associated with melanoma in pigmented skin lesions ('moles').[1] The test is intended to rule out melanoma and guide biopsy decisions for pigmented skin lesions that a qualified healthcare provider has assessed as having a low-to-moderate probability of being melanoma[1,2,4-6] using established clinical parameters such as the ABCDE criteria.[7,8] The test is not intended for lesions considered probable or definite melanomas, non-melanocytic lesions, or lesions that have previously been biopsied, excised, or otherwise treated.

This test is not designed to and does not diagnose melanoma. As with other molecular tests, false positive and false negative results and discordance with histopathology may occur. Appropriate management, including the decision to biopsy as well as duration or frequency of follow-up examination, is ultimately determined by a healthcare provider based on assessment of all relevant clinical and laboratory data.

This test detects expression of LINC00518 (long intergenic non-protein coding RNA 00518) and PRAME (preferentially expressed antigen in melanoma) using reverse transcription quantitative polymerase chain reaction RT-qPCR.[9] In a clinical validation study of 398 samples, 91% of melanomas demonstrated detectable levels of LINC00518 and/or PRAME gene expression versus 31% of non-melanoma samples, resulting in a sensitivity of 91% and specificity of 69%.[1]

When applied to lesions assessed as having a low-to-moderate probability of being melanoma (melanoma prevalence of approximately 4-7%), this test's negative predictive value (NPV) is approximately 99%[1,2,6,10-12] The positive predictive value (PPV) ranges from approximately 15% to 67%, depending on the biomarkers detected.[1,3] Among lesions that tested positive and underwent biopsy for histopathologic interpretation (melanoma or non-melanoma) by three experienced dermatopathologists, the following PPVs were observed:

Biomarker(s)	Approximate PPV
LINC00518 Only[3]	15%
PRAME Only[3]	19%
LINC00518 & PRAME[1]	67%

REFERENCES

[1]Gerami P, et al. *J Am Acad Dermatol.* 2017;76(1):114-120 e112. [2]Skelsey M, et al. *SKIN The Journal of Cutaneous Medicine.* 2021;5(5):512-523. [3]Data on file. DermTech, Inc. [4]National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Melanoma: Cutaneous. Version 2.2023. Accessed September 21, 2023. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf [5]Skudalski L, et al. *J Am Acad Dermatol.* 2022;86(3):503-512. [6]Ferris LK, et al. *JAMA Dermatol.* 2017;153(7):675-680. [7]Abbasi NR, et al. *JAMA.* Dec 8 2004;292(22):2771-2776. [8]Abbasi NR, et al. *Arch Dermatol.* Apr 2008;144(4):469-474. [9]Yao Z, et al. *Assay Drug Dev Technol.* 2016;14(6):355-363. [10]Ferris LK, et al. *Melanoma Res.* 2018;28(5):478-482. [11]Ferris LK, et al. *Dermatol Online J.* 2019;25(5). [12]Ferris LK, et al. *J Invest Dermatol.* 2019;139(5):1127-1134.

Laboratory Director: Bashar Dabbas, MD, FCAP
CLIA # 05D2073519