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 21/4856; H04N 21/485; H04N 21/6547
 See application file for complete search history.

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Dermatech



PLA Pigmented Lesion Assay
MOLECULAR PATHOLOGY REPORT

P: 888.420.4222 | F: 888.284.2788 | Dermatech.com
11000 N. Torrey Pines Road, Suite 100 | La Jolla, CA 92037

PATIENT INFORMATION	
Patient Name:	KIT ID / ACOG ID:
Reference #:	Body Site:
MFIM #:	Date Collected:
DOB (Age):	Date Received:
Sex:	Date Reported:
Referring Physician:	Fax Number:
Address:	City/State/Zip:

TEST RESULTS

Gene Expression Status: Positive

Risk Status: Moderate (Orange)

LINC00518: 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.

Macro-dissection Report/Comments: The pre-specimen consists of adhesive patches containing four tissue samples. Except as noted, each patch contained tissue material which was free of obvious contamination with blood, exudate, hair or other contaminants. Each patch had a central circle delineating the margin around the tissue material. Examination of each of the macrodissected specimen revealed that the lesional tissue material was excised at the margin. Each sample was identified for qPCR analysis. Images of all 4 of the macrodissections are kept on file and are available for review.

Interpretation:

- LOW (GREEN):** Melanoma associated gene expression negative. Consider surveillance per standard of care.
- MODERATE (ORANGE):** Positive for a single gene (LINC only or PRAME only). Recommend biopsy and histopathologic assessment. The proportion of pigmented lesions that are histopathologically diagnosed as melanoma is lower in single gene positive samples (50% for PRAME only positives and 7% for LINC only positives) than in double gene positive samples.
- HIGH (RED):** Positive for both LINC and PRAME genes. Recommend biopsy and histopathologic assessment. The proportion of pigmented lesions that are histopathologically diagnosed as melanoma is higher in two gene positive samples (92% for both LINC and PRAME positives) than in single gene positive samples.

FIG. 1



PLA Pigmented Lesion Assay
MOLECULAR PATHOLOGY REPORT

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11000 N. Torrey Pines Road, Suite 100 | La Jolla, CA 92037

PATIENT INFORMATION			
Patient Name:		Kit ID / Accn ID:	
Reference #:		Body Site:	
MRN #:		Date Collected:	
DOB (Age):		Date Received:	
Sex:		Date Reported:	
Referring Physician:		Fax Number:	
Address:		City/State/Zip:	

TEST RESULTS

Gene Expression Status: Positive

Risk Status: Moderate (Orange)

LINC00518: 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.

Macro-dissection Report/Comments: The pre-specimen consists of adhesive patches containing four tissue samples. Except as noted, each patch contained tissue material which was free of obvious contamination with blood, exudate, hair or other contaminants. Each patch had a central circle delineating the margin around the tissue material. Examination of each of the macrodissected specimen revealed that the lesional tissue material was excised at the margin. Each sample was orientated for qPCR analysis. Images of all 4 of the macrodissections are kept on file and are available for review.

Interpretation:

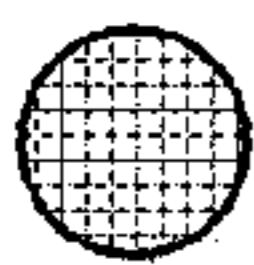
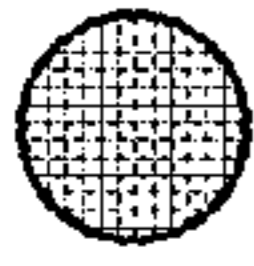
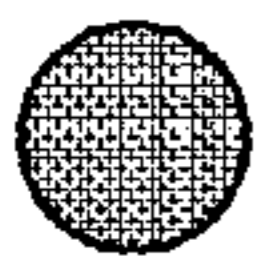
-  **LOW (GREEN):** Melanoma associated gene expression negative. Consider surveillance per standard of care.
-  **MODERATE (ORANGE):** Positive for a single gene (LINC only or PRAME only). Recommend biopsy and histopathologic assessment. The proportion of pigmented lesions that are histopathologically diagnosed as melanoma is lower in single gene positive samples (50% for PRAME only positives and 7% for LINC only positives) than in double gene positive samples.
-  **HIGH (RED):** Positive for both LINC and PRAME genes. Recommend biopsy and histopathologic assessment. The proportion of pigmented lesions that are histopathologically diagnosed as melanoma is higher in two gene positive samples (93% for both LINC and PRAME positives) than in single gene positive samples.

FIG. 2