MelaPro Dx

New River Labs
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CONFIDENTIAL

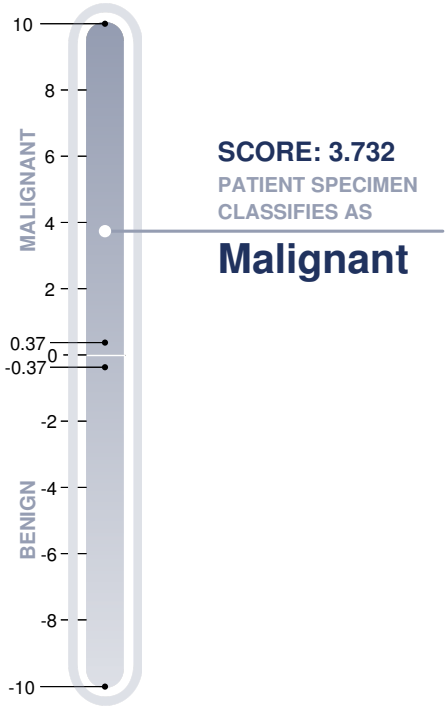
MelaPro Dx Test Result

M01-1800004

Ordering Information

PATIENT	Name: **Sample Patient** Address: 123 West Street Austin, TX 78701 Gender: **M** Age: **63** DOB: **01/01/1955** Accession #: **M01-1800004**
ORDERED BY	**Jane Doe** **ABC Pathology** ABC street Springfield, GA 83921 jdoe@abcpathology.com (512) 555-1111
SPECIMEN	Specimen Type: **FFPE Tissue Sections** Physician Diagnosis: **D0372 Melanoma in situ of left lower limb, including hip** Collection Date: **12/06/2018** Received Date: **12/07/2018** Report Date: **12/14/2018**

Result



SCORE: 3.732

PATIENT SPECIMEN CLASSIFIES AS

Malignant

Result Interpretation

Histology guided mass spectrometry profiling is performed on the patient specimen. The molecular profile of the patient specimen is assigned a score based on a validated algorithm. The assigned score classifies a patient specimen as likely benign, indeterminant, or malignant.

- **Benign:** Score ranging from -10.000 to -0.371
- **Indeterminant:** Score ranging from -0.370 to +0.370
- **Malignant:** Score ranging from +0.371 to +10.000

Intended Use

MelaPro Dx is a clinically validated test for the in vitro analysis of cutaneous melanocytic lesions. The test utilizes histology guided mass spectrometry profiling to differentiate between malignant melanomas and benign nevi in formalin fixed paraffin embedded (FFPE) tissues. The test result is intended to provide additional scientific data to aid the ordering physician in the diagnostic process. This data is not intended to be used as diagnostic information without the review of the ordering physician. The ordering physician should consider this result, along with all other histopathological data, clinical examinations, and other relevant findings, to make an overall diagnosis.

MelaPro Dx is validated for seven (7) melanoma subtypes (acral lentiginous, desmoplastic, lentigo maligna, nevoid, nodular, Spitzoid, and superficial spreading), three (3) benign nevus subtypes (acral, conventional, and Spitz), and metastatic melanoma. MelaPro Dx has not been validated for non-cutaneous neoplasms, non-melanocytic neoplasms, re-excision specimens, specimens directly exposed to radiation therapy, or specimens from patients currently, or recently, receiving chemotherapy. Therefore, these specimens are not suitable for testing and will be rejected. Refer to the MelaPro Dx Technical Specifications at www.newriverlabs.com for more information.

Authorized Signature

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