Comprehensive Diagnostic Offering

Highly accurate and objective gene expression profile tests for melanocytic lesions of uncertain malignant potential



Quantifies expression of 23 genes from primary melanocytic lesion biopsy using RT-PCR

Includes 2 variants of PRAME

Designed to classify lesions objectively and accurately as benign, intermediate or malignant

DecisionDx DiffDx·Melanoma

Quantifies expression of 35 genes from primary melanocytic lesion biopsy using RT-PCR

Applies a validated neural network algorithm

Designed to classify lesions objectively and accurately as benign, intermediate or malignant

Intended Use for GEP Testing

Gene expression profile testing aids in characterizing these lesions as suggestive of benign or malignant and can aid with better management decisions. It should be interpreted in the context of other clinical, laboratory and histopathologic information.

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Cases that are appropriate for testing

- Broad differential diagnosis
- ✓ "Borderline" or "Equivocal" or "Challenging" or "uncertain" cases
- Uncertain malignant potential (eg: MELTUMP)
- Histologically equivocal lesions
- Ancillary testing inconclusive or discordant*
- Benign nevi or melanocytic neoplasm of uncertain potential with re-excision recommendation that suggests diagnostic uncertainty
- Moderately or severely dysplastic nevi with recommendation to re-excise that suggests diagnostic uncertainty
- Cases within 6 months of the original biopsy date

Cases not included above may also be appropriate for testing.**

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Leveraging the Strengths of both myPath Melanoma and DiffDx-Melanoma

myPath Melanoma

- Over 35,000 lesions tested in the clinical setting
- Validated in over 1,300 melanocytic neoplasms
- Reported sensitivity of 94% and specificity of 96% when compared to clinical outcomes
- Can be used with pediatric patients
- Measured an 80% reduction in excisions with benign test results

DiffDx-Melanoma

- Provides increased clarity in cases when the myPath Melanoma result is intermediate*
- Developed using neural networks an artificial intelligence approach to machine learning for model development
- Validated on a wide variety of subtypes
- Low rate of intermediate cases

Inform the Entire Patient Management Plan

For patients diagnosed with invasive melanoma, Castle Biosciences' DecisionDx[®]-Melanoma prognostic testing informs clinical and management decisions (studied in 5,700+ patients; 30 peer-reviewed publications)

- Intensity of follow-up, surveillance imaging, and referrals
- Predicts likelihood of SLNB positivity and outcomes

*DiffDx-Melanoma will only be performed on myPath intermediate cases of patients 18 years or older



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