



NEWS RELEASE

# New Publication Shows Strong Analytic Validity of Castle Biosciences' DecisionDx-Melanoma Test for Cutaneous Melanoma

4/10/2018

## PDF Version

Friendswood, Texas – April 10, 2018 – Castle Biosciences, Inc., a provider of molecular diagnostics to improve cancer treatment decisions, today announced the publication of a study confirming the robust, reproducible performance characteristics of the DecisionDx<sup>®</sup>-Melanoma test that utilizes tumor biology to predict individual risk of melanoma recurrence and sentinel lymph node positivity independent of traditional factors.

A substantial percentage of early-stage melanoma patients develop metastases, and thus patients with initial Stage I or II disease account for up to two-thirds of those who die from melanoma after diagnosis with localized or regional disease. Therefore, accurate methods for predicting metastatic risk are of paramount importance to implement risk-appropriate management plans that enable early identification of disease progression and timely intervention with current treatment options.

The manuscript titled, "Analytic validity of DecisionDx-Melanoma, a gene expression profile test for determining metastatic risk in melanoma patients," was published in the journal *Diagnostic Pathology*. The study evaluated performance metrics of the 31-gene expression profile (GEP) test and included 7,023 cutaneous melanoma tumor samples analyzed in Castle Biosciences' CLIA-certified, CAP-accredited laboratory. The study reports on concordance of test results from inter-assay, inter-instrument, and inter-operator validation as well as sample and reagent stability studies.

[Key Study Findings:](#)



- Reproducibility and reliability of the DecisionDx-Melanoma test performed on primary tumor formalin-fixed paraffin-embedded (FFPE) specimens met validation requirements for a clinical test.
- Inter-assay concordance was 99% ( $R^2 = 0.96$ ). Inter-instrument concordance was 95% ( $R^2 = 0.99$ ).
- Technical success was 98.2% on 7,023 clinical samples tested indicating consistent high performance using available tumor biopsy tissue and compares favorably to the performance of other genomic classifier tests performed on FFPE specimens. Technical success for the most recent 6-month period examined (January 1, 2016-June 30, 2016) remained high at 99%.
- Robust sample and reagent stability was observed.

“Molecular testing in cutaneous melanoma is performed to predict metastatic risk, so high technical success and reliability are critical,” said study co-author John F. Stone, Ph.D., Laboratory Director for Castle Biosciences. “Since its introduction in 2013, the DecisionDx-Melanoma test has been ordered for more than 23,500 U.S. patients to help guide patient management decisions. The consistent, robust performance of the GEP test, as evidenced by this analytical validation study, supports the continued use and adoption of the test in clinical practice.”

The publication is open access and may be found on the journal’s website:

<https://diagnosticpathology.biomedcentral.com/articles/10.1186/s13000-018-0690-3>

#### About DecisionDx-Melanoma

The DecisionDx-Melanoma test uses tumor biology to predict individual risk of melanoma recurrence and sentinel lymph node positivity independent of traditional factors. Using tissue from the primary melanoma, the test measures the expression of 31 genes. The test has been validated in three multi-center studies that have included 690 patients and have demonstrated consistent results. Performance has also been confirmed in four prospective studies including 702 patients. The consistent high performance and accuracy demonstrated in these studies, which combined have included over 1,300 patients, provides confidence in disease management plans that incorporate DecisionDx-Melanoma test results. Prediction of the likelihood of sentinel lymph node positivity has also been validated in two prospective multi-center studies which included over 1,400 patients. Clinical impact has been demonstrated in multi-center and single-center studies showing that test results impact clinical management decisions for one of every two patients tested. More information about the test and disease can be found at [www.SkinMelanoma.com](http://www.SkinMelanoma.com).

#### About Castle Biosciences

Castle Biosciences is a molecular diagnostics company dedicated to helping patients and their physicians make the best possible treatment and follow-up care decisions based on the individual molecular signature of their tumor. The Company currently offers tests for patients with cutaneous melanoma (DecisionDx<sup>®</sup>-Melanoma; [www.SkinMelanoma.com](http://www.SkinMelanoma.com)) and uveal melanoma (DecisionDx<sup>®</sup>-UM and DecisionDx<sup>®</sup>-

PRAME; [www.MyUvealMelanoma.com](http://www.MyUvealMelanoma.com)), with development programs in other underserved cancers. Castle Biosciences is based in Friendswood, TX (Houston), and has laboratory operations in Phoenix, AZ. More information can be found at [www.CastleBiosciences.com](http://www.CastleBiosciences.com).

DecisionDx-Melanoma, DecisionDx-UM and DecisionDx-PRAME are the trademarks of Castle Biosciences, Inc. Any other trademarks are the property of their respective owners.

## Contact

Derek Maetzold, President and CEO

866-788-9007

[IR@castlebiosciences.com](mailto:IR@castlebiosciences.com)

**PDF Version**