



NEWS RELEASE

New Publication Confirms Analytic Validity of Castle Biosciences' DecisionDx-UM Test for Uveal Melanoma in its Clinical Laboratory

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Friendswood, TX – August 10, 2017 – 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®-UM test, the standard of care prognostic tool for patients with uveal melanoma (UM), an aggressive form of eye cancer.

The paper titled, "Gene Expression Profiling in Uveal Melanoma: Technical Reliability and Correlation of Molecular Class with Pathologic Characteristics," was published online this week in the journal *Diagnostic Pathology*. The study evaluated performance metrics of the 15-gene expression profile (GEP) test in Castle's CLIA-certified laboratory setting, including concordance of test results from samples subjected to repeat testing, description of technical success, and correlation of results with pathologic variables. These metrics are especially important factors in validating the accuracy of UM molecular tests since most UM patients receive eye-sparing radiotherapy, thus limiting the amount of available tissue.

Key Study Findings

- Reproducibility and reliability of the DecisionDx-UM test were demonstrated through 100% concordance of molecular classifications and high correlation of algorithmic associated scores (i.e., discriminant scores) on samples subjected to inter-assay, intra-assay, and inter-site testing. Inter-operator/instrument testing was found to be 96% concordant for Class 1 versus Class 2 results.

- Technical success was 96.3% on 5516 clinical samples tested since 2010, consistent with the findings first reported at the time of the test's original development.
- Of DecisionDx-UM clinical reports issued since 2010, 43.4% were Class 1A, 22.4% were Class 1B, and 34.2% were Class 2, proportions similar to those in the prospective, multicenter Cooperative Ocular Oncology Group (COOG) study¹ that reported initial clinical validity for the test.

"Molecular testing in uveal melanoma is performed on limited and precious samples, so high technical success and reliability are critical," said Federico Monzon, M.D., Chief Medical Officer of Castle Biosciences and study author. "The DecisionDx-UM test is currently used in approximately 80% of UM patients in the U.S. as part of their diagnostic workup. The consistent robust performance of the GEP test, as evidenced by this study, supports the continued use and adoption of the assay in clinical practice to better inform patient management decisions."

The publication is open access and may be found at: <http://rdcu.be/uLs4>

DecisionDx-UM is the only prognostic test for uveal melanoma that has been clinically validated for accuracy in multiple prospective and retrospective multicenter and single-center studies.¹⁻⁶ According to a 446-patient study conducted by the Collaborative Ocular Oncology Group, the DecisionDx-UM test is clinically and statistically superior to all other prognostic factors in predicting metastatic risk, including clinical and pathologic factors, as well as chromosome 3 testing.¹ These results are comparable to previous and subsequent single-center and multicenter prospective and retrospective studies.²⁻⁶ Two published clinical utility studies have shown clinically significant impact on patient management.^{7,8}

About DecisionDx-UM

The DecisionDx-UM test measures the gene expression profile (GEP), or molecular signature, of an individual's tumor and identifies with high accuracy the likelihood of metastasis. The DecisionDx-UM test is standard of care in the management of uveal melanoma in the majority of ocular oncology practices (more than 130 specialists ordered the test in 2016). Since 2009, the American Joint Committee on Cancer (AJCC; v7 and v8) has included gene expression profiling for identification of Class 1 and 2 as a prognostic factor recommended for clinical care. The AJCC is the only national organization that reviews uveal melanoma and the DecisionDx-UM test is the only clinically available GEP test for use in the U.S. The test has been validated in multiple prospective and retrospective studies. It is estimated that nearly 8 in 10 diagnosed patients in the U.S. receive DecisionDx-UM as part of their diagnostic workup. More information about the test and disease can be found at www.MyUvealMelanoma.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®-Melanoma;

www.SkinMelanoma.com) and uveal melanoma (DecisionDx®-UM and DecisionDx®-PRAME; **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**.

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

1. Onken MD, Worley LA, Char DH, et al. Collaborative Ocular Oncology Group report number 1: Prospective validation of a multi-gene prognostic assay in uveal melanoma. *Ophthalmology* 2012;119:1596-603.
2. Onken MD, Worley LA, Tuscan MD, et al. An accurate, clinically feasible multi-gene expression assay for predicting metastasis in uveal melanoma. *J Mol Diagn* 2010;12:461-7.
3. Chappell MC, Char DH, Cole TB, et al. Uveal melanoma: Molecular pattern, clinical features, and radiation response. *Am J Ophthalmol* 2012;154:227-32.e2.
4. Correa ZM & Augsburger JJ. Sufficiency of FNAB aspirates of posterior uveal melanoma for cytologic versus GEP classification in 159 patients, and relative prognostic significance of these classifications. *Graefes Arch Clin Exp Ophthalmol* 2014;252:131-5.
5. Demirci H, Ozkurt ZG, Slimani N, et al. Gene expression profiling test of uveal melanoma: prognostic validation. In American Society of Ophthalmic Plastic & Reconstructive Surgery Fall Scientific Symposium. 2015: Las Vegas, NV.
6. Correa ZM & Augsburger JJ. Independent prognostic significance of gene expression profile class and largest basal diameter of posterior uveal melanomas. *Am J Ophthalmol* 2016;162:20-7e1.
7. Aaberg TM, Cook RW, Oelschlager KM, et al. Current clinical practice: differential management of uveal melanoma in the era of molecular tumor analyses. *Clin Ophthalmol* 2014;8:2449-60.
8. Plasseraud KM, Cook RW, Tsai T, et al. Clinical performance and management outcomes with the DecisionDx-UM gene expression profile test in a prospective multicenter study. *J Oncology* 2016; doi:10.1155/2016/53257622016.

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