

# DecisionDx®-Melanoma Can Identify Melanoma Patients with Low Risk of Sentinel Lymph Node Positivity Who May Safely Forego Biopsy Surgery, New Independent Study Affirms

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Using the DecisionDx-Melanoma test to guide sentinel lymph node biopsy (SLNB) surgery decisions could have significantly reduced the number of unnecessary SLNBs by 33% for patients with T1-T2 melanoma tumors

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- Castle Biosciences, Inc. (Nasdaq: CSTL), a company improving health through innovative tests that guide patient care, today announced the publication of a new study further demonstrating that DecisionDx-Melanoma can precisely predict sentinel lymph node (SLN) positivity risk to help guide risk-aligned SLNB decisions, potentially reducing the number of unnecessary procedures and increasing the SLNB positivity yield if the procedure is performed. The paper, published in the World Journal of Surgical Oncology and titled "Integrating the melanoma 31-gene expression profile test with clinical and pathologic features can provide personalized precision estimates for sentinel lymph node positivity: an independent performance cohort," is available [here](#).

"While SLNB is a common procedure used to determine possible tumor metastasis, our current criteria for biopsy may be overestimating a person's risk of having a positive node, meaning we are probably performing more surgeries than necessary," said lead author Joseph Bennett, M.D., MBA, surgical oncologist and system chief of surgery at LifeBridge Health in Baltimore, Maryland. "By using the DecisionDx-Melanoma test to accurately stratify patient risk and help guide these important decisions and discussions with patients, we can avoid doing SLNB procedures in low-risk patients without missing melanoma metastases."

“Our DecisionDx-Melanoma test has significant clinical utility in helping to rule-out and rule-in SLNB procedures, as this study showed,” added Derek Maetzold, president and chief executive officer of Castle Biosciences. “And as demonstrated by data we shared earlier this year from our ongoing prospective, multicenter DECIDE study, patients with low-risk DecisionDx-Melanoma results whose providers use the test to help guide decisions to avoid SLNB surgery still experience good outcomes.” <sup>1</sup>

The DecisionDx-Melanoma test integrates a patient’s tumor biology with their personal clinicopathologic factors to help answer the likelihood of SLN positivity and risk of recurrence in patients with melanoma. Current National Comprehensive Cancer Network (NCCN) guidelines suggest foregoing SLNB when the likelihood of finding a positive SLN is less than 5%, to consider SLNB when between 5-10% and to offer the surgery when the likelihood is above 10%. This study evaluated the performance of DecisionDx-Melanoma in predicting the risk of SLN positivity in 156 melanoma patients with known SLN outcomes at the ChristianaCare Helen F. Graham Cancer Center & Research Institute.

In the study, none of the patients (0/30) considered low-risk by the DecisionDx-Melanoma test (less than 5% predicted risk of SLN positivity) had a positive SLN, compared to a 31.9% SLN positivity rate (30/94,  $p < 0.001$ ) in patients predicted to have greater than 10% risk by the test. Of the 91 patients in the study who had American Joint Committee on Cancer eighth edition (AJCC8) T1-T2 tumors, the DecisionDx-Melanoma test identified 30 of them as low-risk, demonstrating a significant potential SLNB reduction rate of 33% in this patient population (30/91,  $p < 0.001$ ). Further, DecisionDx-Melanoma accurately downstaged or upstaged patients to a more definitive status to either forego or offer the SLNB procedure.

The results of this study demonstrate that DecisionDx-Melanoma can allow for more precise and personalized management of melanoma patients, improving patient selection for the SLNB surgical procedure and reducing unnecessary procedures and their associated healthcare costs. Moreover, the data provide evidence that DecisionDx-Melanoma can identify patients with a low risk of SLN positivity who may safely forego SLNB, as well as those with a higher risk who may want to consider the surgery.

## About DecisionDx®-Melanoma

DecisionDx-Melanoma is a gene expression profile risk stratification test. It is designed to inform two clinical questions in the management of cutaneous melanoma: a patient’s individual risk of sentinel lymph node positivity and a patient’s personal risk of melanoma recurrence and/or metastasis. By integrating tumor biology with clinical and pathologic factors using a validated proprietary algorithm, DecisionDx-Melanoma is designed to provide a comprehensive and clinically actionable result to guide risk-aligned patient care. DecisionDx-Melanoma has been shown to be associated with improved patient survival and has been studied in more than 10,000 patient samples. DecisionDx-Melanoma’s clinical value is supported by more than 50 peer-reviewed and published studies, providing

confidence in disease management plans that incorporate the test's results. Through June 30, 2024, DecisionDx-Melanoma has been ordered more than 173,000 times for patients diagnosed with cutaneous melanoma. Learn more at [www.CastleBiosciences.com](http://www.CastleBiosciences.com).

## About Castle Biosciences

Castle Biosciences (Nasdaq: CSTL) is a leading diagnostics company improving health through innovative tests that guide patient care. The Company aims to transform disease management by keeping people first: patients, clinicians, employees and investors.

Castle's current portfolio consists of tests for skin cancers, Barrett's esophagus, mental health conditions and uveal melanoma. Additionally, the Company has active research and development programs for tests in other diseases with high clinical need, including its test in development to help guide systemic therapy selection for patients with moderate-to-severe atopic dermatitis, psoriasis and related conditions. To learn more, please visit [www.CastleBiosciences.com](http://www.CastleBiosciences.com) and connect with us on [LinkedIn](#), [Facebook](#), [X](#) and [Instagram](#).

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## Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning: the continued ability of the DecisionDx-Melanoma test to precisely predict SLN positivity risk, guide risk-aligned SLNB decisions and allow certain patients to safely forego SLNB. The words "can," "may" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation: subsequent study or trial results and findings may contradict earlier study or trial results and findings or may not support the results shown in this study, including with respect to the discussion of DecisionDx-Melanoma in this press release; actual application of our tests may not provide the aforementioned benefits to patients; and the risks set forth under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, and in our

other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, except as may be required by law.

1. Society of Surgical Oncology SSO 2024 Annual Meeting. Ann Surg Oncol 31 (Suppl 1), 1–294 (2024).

**<https://doi.org/10.1245/s10434-024-15179-y> : view presentation here**

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