

FINAL REPORT

Patient:
Sex:
DOB:
Client:
Provider:
Tumor Location:
Specimen ID:
Collected:

Received:
Reported:
Tumor Diameter:
Head or Neck Location:
Perineural Invasion:
Immunosuppressed:
Poor Differentiation:

The clinicopathologic information above, provided from the pathology report, test requisition form, and submitted clinical documentation, is not independently verified by Castle and is incorporated into the integrated 40-GEP result (i40-GEP). If any information is inaccurate or has changed since testing, contact Castle Biosciences at 866-788-9007. As with all tests, these results should be evaluated within the context of the patient's other risk factors and overall clinical scenario.

Class Result with Metastasis and Local Recurrence Risk

Class 2B

This signature is associated with the highest risk of metastasis and local recurrence within 3 years.

Metastasis-Free Survival **66.2%**

Local Recurrence-Free Survival **82.1%**

The Decision DX-SCC test is validated to predict a patient's individual risk of metastasis (regional or distant) and local recurrence. The test was validated in a multicenter study evaluating 572 patients diagnosed with localized cSCC, and had one or more high-risk factors, who underwent definitive surgery with reported negative margins (R0). Patients had a median follow-up time of 4.3 years. Those without a metastatic event had a minimum follow-up of 3 years.

Three-year metastasis-free survival (MFS) for the overall study population was 88.8%.
Three-year local recurrence-free survival (LRFS) for the overall study population was 90.7%.

Response to Adjuvant Radiation Therapy (ART)

High likelihood of benefit

The performance of the DecisionDx-SCC integrated test (i40-GEP) in predicting response to ART was validated in a multicenter study in patients diagnosed with localized cutaneous SCC eligible for ART by the presence of clinicopathologic risk factors.

In this study patients with Class 2B tumors showed a significant 50% reduction in metastatic risk when treated with ART, while Class 2A patients did not show reduction in metastatic risk. Class 1B patients are less likely to benefit due to lower metastatic incidence, while Class 1A patients are identified as likely safe to defer due to the lowest rate of metastasis.

About the Test

The DecisionDx-SCC test is a qRT-PCR assay of 6 control and 34 discriminant genes (40 in total) that uses an integrated algorithm founded on the neural network algorithm comprised of two gene expression signatures to assign disease risk. A nested algorithm, focusing on a subset of the 40 genes and integrating five clinicopathologic factors, was added to provide enhanced metastatic and local recurrence risk prediction with maintained ART benefit prediction. DecisionDx-SCC is indicated for patients with cutaneous squamous cell carcinoma (cSCC) and one or more high-risk factors (see Test Requisition Form). The test predicts individual metastatic risk, risk of local recurrence, and response to ART to help inform risk appropriate management.

The 34 discriminating genes are: ACSBG1, ALOX12, APOBEC3G, ATP6V0E2, BBC3, BHLHB9, CEP76, DUXAP9, GTPBP2, HDHC3, ID2, LCE2B, LIME1, LOC100287896, LOC101927502, MMP10, MRC1, MSANTD4, NFASC, NFIC, PDPN, PI3, PLS3, RCHY1, RNF135, RPP38, RUNX3, SLC1A3, SPP1, TAF6L, TFAP2B, ZNF48, ZNF496 and ZNF839. Six control genes consist of BAG6, FXR1, KMT2C, KMT2D, MDM2, MDM4. The 5 integrated clinicopathologic factors are: immunosuppression, tumor diameter, poor differentiation, perineural invasion, and head or neck location.

For additional information about the development, validation and clinical use of the DecisionDx-SCC test, including references, scan the QR code.



SAMPLE