Decision Dx MELANOMA

Informing clinical decision making for patients with invasive melanoma

CASTLE BIOSCIENCES

DecisionDx MELANOMA

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For Healthcare Professionals

For Patients

CastleTestInfo.com
MyMelanoma.com

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Test Overview

DecisionDx MELANOMA

DecisionDx®-Melanoma is a gene expression profile (GEP) test designed to predict individual risk of recurrence including likelihood of sentinel lymph node positivity in Stage I, II and III melanoma

PATIENT ELIGIBILITY

- ✓ Stage I-III cutaneous melanoma
- ✓ Newly diagnosed up to 3 years (or up to 5 years after diagnosis with clinical rationale)
- ✓ All histologic subtypes, including acral
- ✓ Availability of tissue from primary biopsy

NOT ELIGIBLE

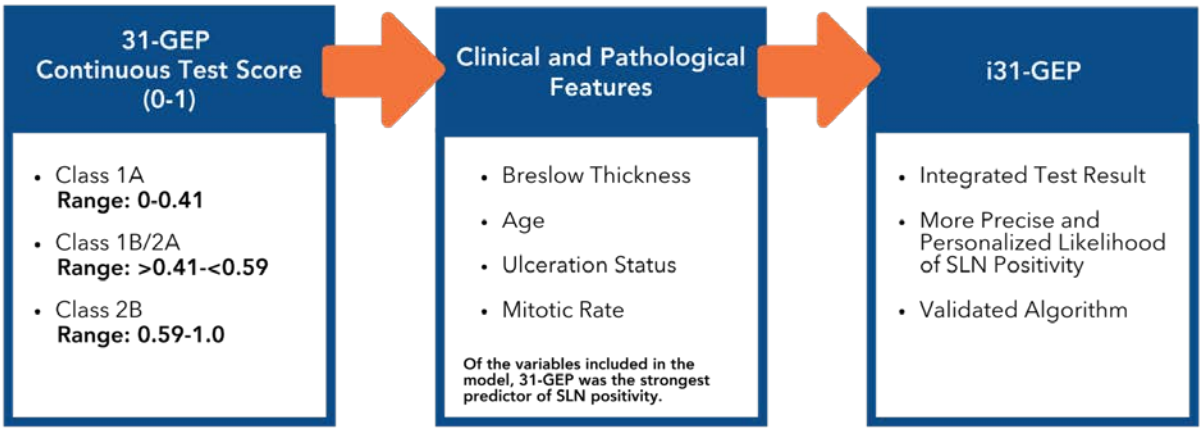
- Melanoma in situ (Stage 0)
- Patients with metastatic melanoma
- Mucosal melanoma
- Age < 18 years

RESULTS

Risk of Recurrence: The DecisionDx-Melanoma 31-gene expression profile (GEP) class designation significantly stratifies risk of recurrence or metastasis for patients with Stage I, II or III melanoma. Patients are classified as one of the following:

Class 1A:	Lowest risk of recurrence/metastasis within 5 years
Class 1B/2A:	Increased risk of recurrence/metastasis within 5 years
Class 2B:	Highest risk of recurrence/metastasis within 5 years

Likelihood of SLN Positivity: Using a validated algorithm, the patient's clinical and pathologic factors are incorporated with the patient's DecisionDx-Melanoma Continuous Test Score. This integrated test result (i31-GEP) provides a more precise and personalized SLN positivity risk prediction, identifying patients with a low risk of SLN positivity who could potentially forgo the procedure and those patients at high risk of SLN positivity who should consider and be offered a SLNB.



PROGNOSTIC GENES

The DecisionDx-Melanoma test includes 3 control genes and 28 prognostic genes important for tumor progression, including migration and metastasis, cellular differentiation, chemokine activity, immune response and angiogenesis.

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Contact us at:
866-788-9007
www.CastleTestInfo.com

Laboratory Address:
3737 N. 7th Street, Ste. 160
Phoenix, AZ 85014

DDXCM-009v1-032021

Test Overview

DecisionDx MELANOMA

HOW TO ORDER

The test ordering is easy, with minimal burden to you and your office staff. The following documents are needed for every order:

- **Requisition Form (completed and signed)**

  - Hard copy or utilize online portal

- **Letter of Medical Necessity (completed and signed)**
- **Pathology Report (primary biopsy specimen)**

  - Include excision report if available

- **Copy of Patient's Insurance Information**

Submit all documentation at Portal.CastleBiosciences.com or fax to 866-329-2224

All test orders are processed within 24 hours of receipt.

TURN AROUND TIME

On average, results are available within 5 days from the time a sample is received in the Castle Biosciences laboratory. Results will be sent via fax and available to view online through our secure physician portal. Delivery via US mail is available upon request.

TISSUE REQUIREMENTS

We can accept formalin-fixed, paraffin-embedded (FFPE) tissue in the form of block or slides.

If sending slides, we require: 1 H&E + 9 unstained slides (5-micron sections). 40% tumor content is required.

Performance characteristics of the signature have not been established for tissue other than FFPE primary cutaneous melanocytic lesions.

PATIENT ACCESS

Castle Biosciences works with all insurance providers, including Medicare, Medicaid, commercial insurers, and the VA, to secure payment coverage for the DecisionDx-Melanoma test. Castle will submit insurance claims and manage the insurance billing process on behalf of patients. The company also sponsors an industry-leading Patient Assistance Program with the belief that quality care should not depend on financial considerations.

You can get more information about insurance coverage, claims processing, and financial assistance by calling 866-788-9007 and selecting option #3.

All of our testing is conducted in Castle Biosciences' CAP-accredited, CLIA-certified laboratory in Phoenix, AZ.

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Expert Panel: Clinical Workflow for DecisionDx®-Melanoma

DecisionDx MELANOMA

CLINICAL SUMMARY

A Dermatologist's Guide to Implementation of Gene Expression Profiling in the Management of Melanoma

Shawn G. Kwatra, MD; Howard Hines, MD; Yevgeniy R. Semenov, MD; Shannon C. Trotter, DO; Elizabeth Holland, RN, BSN; and Sancy Leachman, MD, PhD

OBJECTIVE

To provide clarification of use options and a rational clinical workflow to guide appropriate application of the 31-GEP test in everyday practice

DESIGN

Expert panel of five leading dermatologists with experience using the 31-GEP convened virtually in May 2020 and reviewed the following:

- ✓ Validation and clinical impact data supporting the use of sentinel lymph node biopsy
- ✓ Existing primary and meta-analyses for 31-GEP testing in melanoma risk assessment
- ✓ AJCC, NCCN, and Melanoma Prevention Working Group (MPWG) data and guidelines for GEP in melanoma risk assessment
- ✓ Experiences, rationales, and scenarios in which 31-GEP testing may be helpful for risk assessment

CONCLUSION

- The 31-GEP test is useful and actionable for patient care when applied in accordance with current NCCN guidelines
- The 31-GEP test can inform multidisciplinary conference discussion and can assist with determining the intensity of imaging, surveillance, and follow-up care
- Patient-specific features of the disease and individual circumstances should be considered in the decision to use 31-GEP testing
- It is important to incorporate a shared decision-making model implemented by the multidisciplinary team and the patient that is tailored to individual needs and preferences

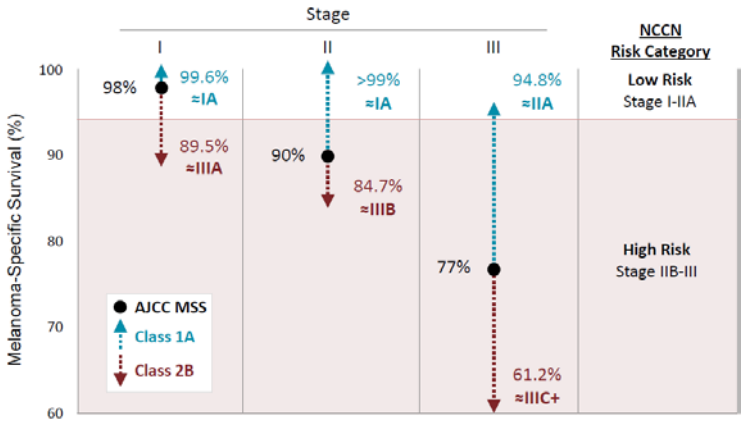

Figure 1. Data from cohort study (N=690) demonstrated that the 31-GEP test further informs risk analysis obtained by the American Joint Committee on Cancer (AJCC) staging protocol in patients with melanoma

METRICS	GEP % (95% CI)	SLNB % (95% CI)	GEP & SNLB % (95% CI)
RFS	**n=1,479**	**n=867**	**n=867**
Sensitivity	76 (71-80)	57 (51-63)	88 (84-92)
Specificity	76 (73-78)	74 (70-77)	52 (48-56)
DMFS	**n=1,223**	**n=867**	**n=867**
Sensitivity	76 (70-82)	61 (55-68)	90 (85-94)
Specificity	69 (66-72)	72 (68-75)	48 (44-52)

Table 1. Independent and combined accuracy metrics of GEP and SLNB in patients with GEP results and SLNB status

CI: Confidence interval; DMFS: distant metastasis-free survival; GEP: gene expression profile; RFS: recurrence-free survival; SLNB: sentinel lymph node biopsy

Adapted from Greenhaw et al. *J Am Acad Dermatol* 2020;83:745-53

BOTTOM LINE

The 31-GEP is supported by a robust and consistent body of evidence demonstrating clinical value in conjunction with SLNB for the prognosis of patients with melanoma. The panel recommends a clinical workflow that integrates 31-GEP testing under the umbrella of current national guidelines.

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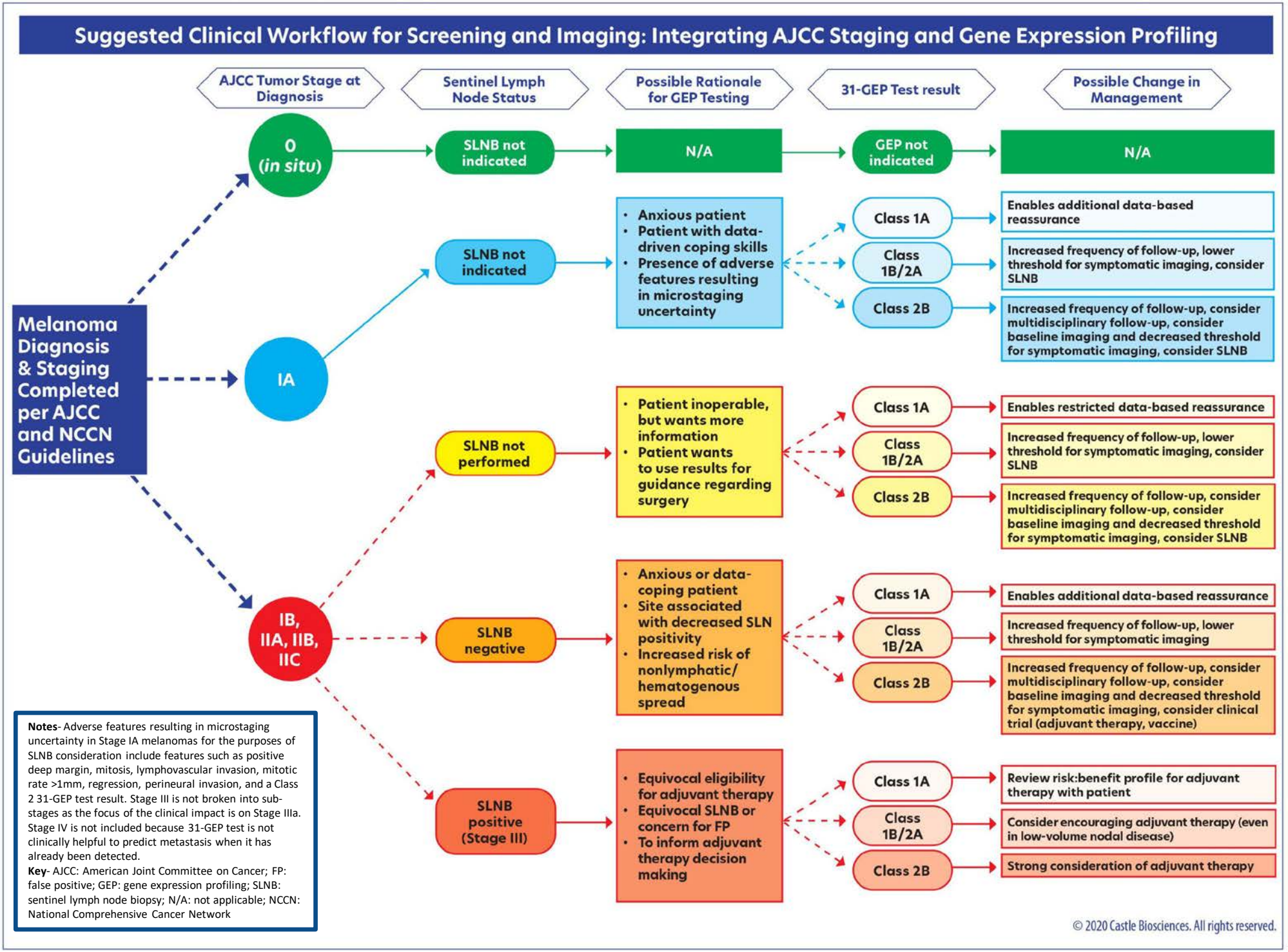

Figure 2. A proposed clinical algorithm for implementing 31-GEP testing in different clinical situations within current AJCC staging and integrating it into the NCCN guidelines for cutaneous melanoma

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Phoenix, AZ 85014
Customer Service: 866-788-9007

Fax completed form to: 866-329-2224
Alternate fax: 602-266-9597

DecisionDx-MELANOMA
DecisionDx-CMSeq

Requisition Form

I. Ordering Entity Information

Name of Ordering Physician, PA, NP*

Specialty NPI

Address*

City / State / Zip*

( ) ( )
Telephone* Fax*

Institution / Practice Name*

II. Patient Information

Last Name* First Name* MI

DOB* Gender SSN / MR#

Address*

City / State / Zip*

( )
Telephone*

Email

III. Billing Information

Submitting Diagnosis ICD-10 Code*

Method of Payment:
☐ Private Insurance ☐ Patient Self-Pay
☐ Medicare ***Section V required*** ☐ Medicaid
☐ Client Bill *(contracted entities only)*

Primary Insurance Co. Name Policy#

( )
Insurance Co. Phone#

Secondary Insurance? ☐ Yes ☐ No
(If yes, attach copy of front/back of secondary insurance card)

IV. Test Menu (REQUIRED)

Primary Test: ☐ DecisionDx-Melanoma Gene Expression Profile

Additional Testing: (check box, if desired) ☐ DecisionDx-CM***Seq*** Sequencing Test *(BRAF, NRAS, KIT)*

V. Medicare Only *Required for patients with traditional Medicare as primary insurance*

At time of tissue collection, was this patient: ☐ Non-hospital ☐ Hospital Outpatient ☐ Hospital Inpatient If hospital inpatient, date of discharge: _____

If specimen is stored for more than 30 days from the date of collection, please provide the date specimen is pulled from archive: _____

VI. Clinical Information *REQUIRED FOR ALL PATIENTS

Has the patient had a sentinel lymph node biopsy for *this* melanoma? ☐ No ☐ Yes; please provide surgical pathology report if available

If yes, what was the result? ☐ Node(s) Negative ☐ Node(s) Positive

VII. Required Signature

X
SIGNATURE OF TREATING CLINICIAN*

Printed Name

Date

This signature confirms this test to be medically necessary for this patient. This clinician provides consultation and/or treatment for melanoma and will use the results in the management of the patient.

VIII. Additional Order Information

Name of Treating Clinician *(if different than section I)*

( ) ( )
Phone # Fax#

Mailing Address (☐ same as requestor)

City / State / Zip

Institution/Practice Name

Email address for report notification

Additional Clinician *(optional)*

( ) ( )
Phone # Fax#

Mailing Address (☐ same as requestor)

City / State / Zip

Institution/Practice Name

Email address for report notification

IX. Laboratory Information

Please fax this requisition along with a copy of the pathology report from the *primary* biopsy and excision *(if available)*

Facility where tissue is maintained: _____ Date of Collection: _____

Phone: _____ Fax: _____

FOR INTERNAL USE ONLY

Received: _____ Processed by: _____ Materials received: _____

PR/Initials: _____ DTL: _____ Note: _____

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Phoenix, AZ 85014
Customer Service: 866-788-9007

DecisionDx-MELANOMA
DecisionDx-CMSeq

Requisition Form Completion Instructions

1. **Section I**: Complete with information of the ordering Entity.

2. **Section II**: Complete with patient information.

3. **Section III**: Provide the ICD-10 code and patient's diagnosis. Select Method of Payment. Please complete with billing information including a copy of the front and back of the insurance card (if applicable). If the person completing this requisition is not in possession of the information necessary for completion of the billing information section, please provide the name/department and contact information of the appropriate party from whom this information can be obtained:

   Name: _____ Department: _____
   Phone: _____Fax: _____

   *If a copy of the front and back of the insurance card is provided, no further information is needed in this section of the requisition. A billing face sheet is also sufficient, in lieu of copy of card.

4. **Section IV**: Select the desired test by checking the appropriate box. One can order Gene Expression profile alone, DecisonDx CMSeq NGS panel alone, or both tests concurrently.

5. **Section V**: Applicable only for patients with Traditional Medicare as their primary insurance.

6. **Section VI**: Check the appropriate box regarding the patient's current sentinel lymph node biopsy status for this melanoma. If the patient has had a SLNB performed, please provide a copy of the surgical path report along with the completed requisition.

7. **Section VII:** The ordering clinician must sign this section. **For purposes of ordering this test, the "ordering clinician" section can be signed only by a physician, advanced practice registered nurse (APRN) or representative Physician Assistant (PA)**

8. **Section VIII:** Complete with information for the treating clinician and/or additional clinicians. If the mailing address is the same as for the ordering clinician, check the box "same as requestor". Be sure to select the preferred method by which results should be communicated and provide an email address if you wish to receive electronic notification that the report is available.

9. **Section IX:** Complete this section with the name of the facility where the tissue from which slides for testing will be requested. Provide the name and phone # of an individual to whom a tissue request should be made.

FAX THE FOLLOWING DOCUMENTS TOLL FREE AT 1-866-329-2224
(Alternate fax: 602-222-5200)
*Order confirmation will be sent to the ordering clinician via fax within 24 hours of receipt

- ☐ Completed requisition
- ☐ Pathology report(s)
- ☐ Signed letter of medical necessity

NEW i31-GEP INTEGRATED TEST RESULT FOR LIKELIHOOD OF SLN POSITIVITY WITH EXPANDED DATA COHORT

DecisionDx-MELANOMA HCP Guide to the Patient Report

Personalized Risk Prediction Beyond Clinicopathologic Factors

DecisionDx-Melanoma Class Result

Class 1A	**Lowest risk** of recurrence and/or metastasis within 5 years
Class 1B/2A	**Increased risk** of recurrence and/or metastasis within 5 years
Class 2B	**Highest risk** of recurrence and/or metastasis within 5 years

SLNB positivity information now on page 2

5-Year Outcomes

NEW Expanded validation cohort (total n=1,477) for 5-year outcomes from published meta-analysis (Greenhaw et al. *JAAD* 2020).

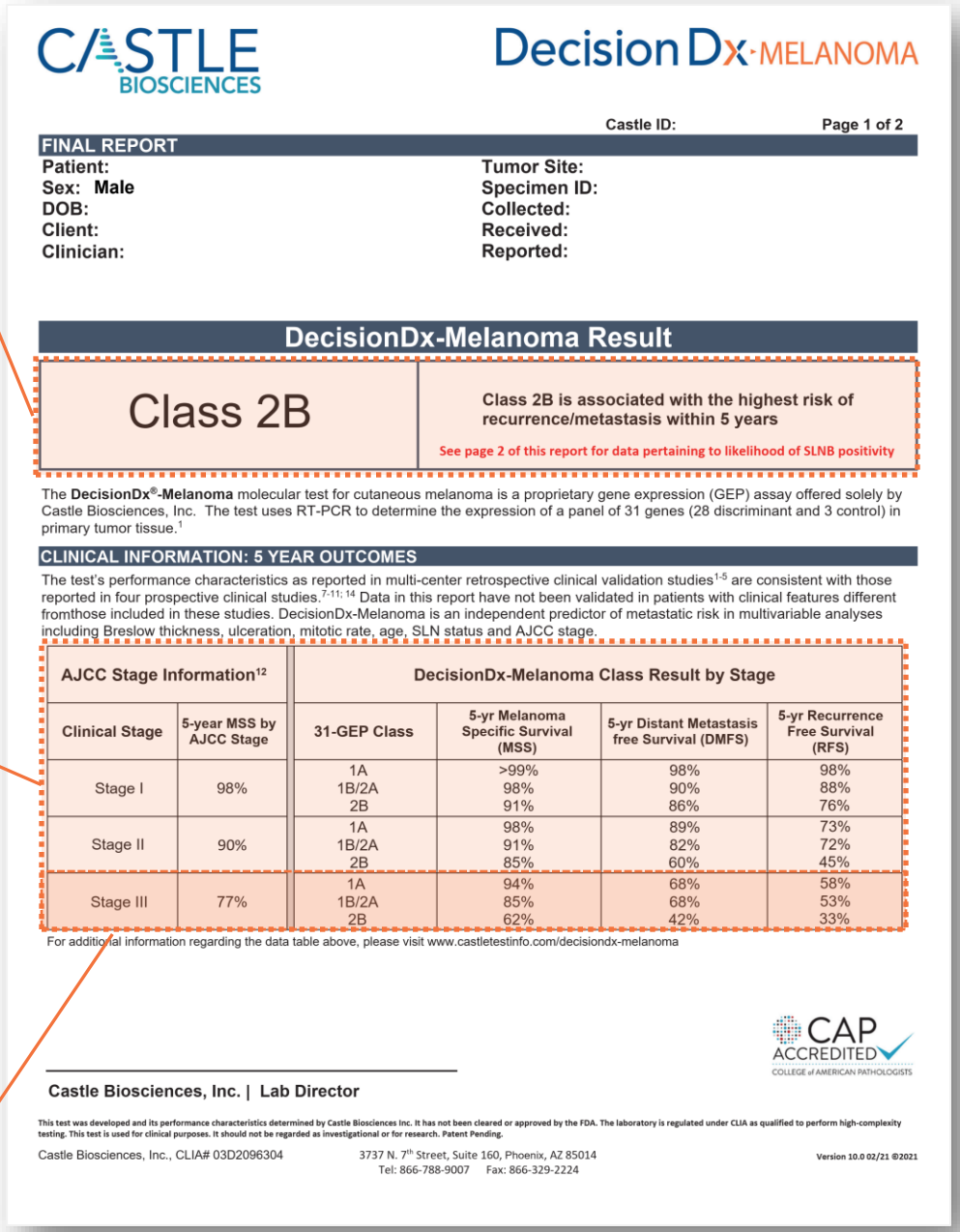
- Includes 4 independent patient cohorts
- DecisionDx-Melanoma is an **independent predictor of metastatic risk** in multivariate analyses including Breslow thickness, ulceration, mitotic rate, age, SLN status and AJCC stage.

NEW MSS, DMFS and RFS risk prediction provided by AJCC clinical stage for each DecisionDx-Melanoma class result.

- DecisionDx-Melanoma class **refines risk estimates** for survival when compared to AJCC v8.
- **Significant difference** between lowest risk (Class 1A) and highest risk (Class 2B) for all stages and all outcomes.
- For reference, the table now includes 5-year MSS by AJCC stage.

Stage III Clinical Experience (n=312)

Now includes Class Result sub-classification (A/B)



CASTLE BIOSCIENCES — DecisionDx-MELANOMA

Castle ID: Page 1 of 2

FINAL REPORT

Patient:
Sex: Male
DOB:
Client:
Clinician:

Tumor Site:
Specimen ID:
Collected:
Received:
Reported:

DecisionDx-Melanoma Result

Class 2B

Class 2B is associated with the highest risk of recurrence/metastasis within 5 years

See page 2 of this report for data pertaining to likelihood of SLNB positivity

The **DecisionDx®-Melanoma** molecular test for cutaneous melanoma is a proprietary gene expression (GEP) assay offered solely by Castle Biosciences, Inc. The test uses RT-PCR to determine the expression of a panel of 31 genes (28 discriminant and 3 control) in primary tumor tissue.[1]

CLINICAL INFORMATION: 5 YEAR OUTCOMES

The test's performance characteristics as reported in multi-center retrospective clinical validation studies[1-5] are consistent with those reported in four prospective clinical studies.[7-11; 14] Data in this report have not been validated in patients with clinical features different fromthose included in these studies. DecisionDx-Melanoma is an independent predictor of metastatic risk in multivariable analyses including Breslow thickness, ulceration, mitotic rate, age, SLN status and AJCC stage.

AJCC Stage Information[12]		DecisionDx-Melanoma Class Result by Stage			
Clinical Stage	5-year MSS by AJCC Stage	31-GEP Class	5-yr Melanoma Specific Survival (MSS)	5-yr Distant Metastasis free Survival (DMFS)	5-yr Recurrence Free Survival (RFS)
Stage I	98%	1A	>99%	98%	98%
		1B/2A	98%	90%	88%
		2B	91%	86%	76%
Stage II	90%	1A	98%	89%	73%
		1B/2A	91%	82%	72%
		2B	85%	60%	45%
Stage III	77%	1A	94%	68%	58%
		1B/2A	85%	68%	53%
		2B	62%	42%	33%

For additional information regarding the data table above, please visit www.castletestinfo.com/decisiondx-melanoma

CAP ACCREDITED — COLLEGE of AMERICAN PATHOLOGISTS

Castle Biosciences, Inc. | Lab Director

This test was developed and its performance characteristics determined by Castle Biosciences Inc. It has not been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. Patent Pending.

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NEW i31-GEP INTEGRATED TEST RESULT FOR LIKELIHOOD OF SLN POSITIVITY WITH EXPANDED DATA COHORT

DecisionDx-MELANOMA HCP Guide to the Patient Report

Personalized Risk Prediction Beyond Clinicopathologic Factors

NEW Integrated Test Result incorporating clinicopathologic factors with the 31-GEP continuous score to provide **precise, personalized likelihood of positive SLNB**.

- Artificial intelligence-based neural network algorithm (i31-GEP)
- Independently validated in patients with T1-T4 cutaneous melanoma.
- Algorithm was developed in 1,398 patients and validated in 1,674 consecutively tested patients.

DecisionDx-Melanoma Class Result

31-GEP Score (range 0-1)

Class 1A: Lowest risk 0-0.41
Class 1B/2A: Increased risk >0.41 to <0.59
Class 2B: Highest risk 0.59-1.0

Patient-Specific Clinicopathologic Factors

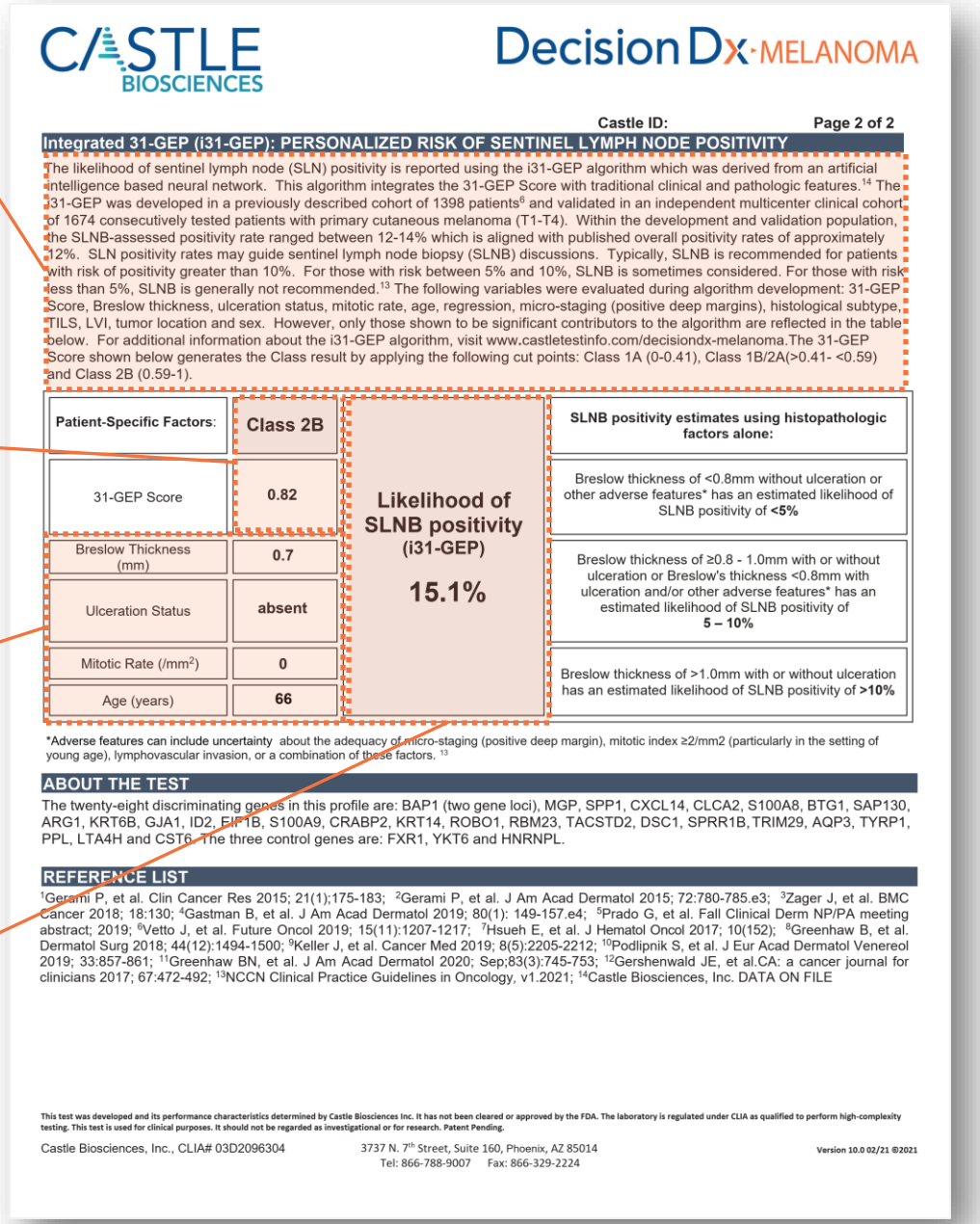
Castle populates algorithm using information from the pathology report(s) submitted with the tissue to be tested.

Likelihood of SLNB positivity (%)

- The newly validated algorithm (i31-GEP) integrates the DecisionDx-Melanoma 31-GEP score (range 0-1) with clinicopathologic factors to provide a more precise and personalized SLN positivity risk prediction.

- Guidelines suggest:
  - <5% likelihood: avoid SLNB
  - 5-10% likelihood: discuss and consider SLNB
  - >10% likelihood: recommend SLNB

More information about the Integrated Test Result (i31-GEP)
www.CastleTestInfo.com/DecisionDx-Melanoma



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Integrated 31-GEP (i31-GEP): PERSONALIZED RISK OF SENTINEL LYMPH NODE POSITIVITY

The likelihood of sentinel lymph node (SLN) positivity is reported using the i31-GEP algorithm which was derived from an artificial intelligence based neural network. This algorithm integrates the 31-GEP Score with traditional clinical and pathologic features.[14] The 31-GEP was developed in a previously described cohort of 1398 patients[6] and validated in an independent multicenter clinical cohort of 1674 consecutively tested patients with primary cutaneous melanoma (T1-T4). Within the development and validation population, the SLNB-assessed positivity rate ranged between 12-14% which is aligned with published overall positivity rates of approximately 12%. SLN positivity rates may guide sentinel lymph node biopsy (SLNB) discussions. Typically, SLNB is recommended for patients with risk of positivity greater than 10%. For those with risk between 5% and 10%, SLNB is sometimes considered. For those with risk less than 5%, SLNB is generally not recommended.[13] The following variables were evaluated during algorithm development: 31-GEP Score, Breslow thickness, ulceration status, mitotic rate, age, regression, micro-staging (positive deep margins), histological subtype, TILS, LVI, tumor location and sex. However, only those shown to be significant contributors to the algorithm are reflected in the table below. For additional information about the i31-GEP algorithm, visit www.castletestinfo.com/decisiondx-melanoma.The 31-GEP Score shown below generates the Class result by applying the following cut points: Class 1A (0-0.41), Class 1B/2A(>0.41- <0.59) and Class 2B (0.59-1).

Patient-Specific Factors:	Class 2B
31-GEP Score	0.82
Breslow Thickness (mm)	0.7
Ulceration Status	absent
Mitotic Rate (/mm²)	0
Age (years)	66

Likelihood of SLNB positivity (i31-GEP)
15.1%

SLNB positivity estimates using histopathologic factors alone:

- Breslow thickness of <0.8mm without ulceration or other adverse features* has an estimated likelihood of SLNB positivity of **<5%**
- Breslow thickness of ≥0.8 - 1.0mm with or without ulceration or Breslow's thickness <0.8mm with ulceration and/or other adverse features* has an estimated likelihood of SLNB positivity of **5 – 10%**
- Breslow thickness of >1.0mm with or without ulceration has an estimated likelihood of SLNB positivity of **>10%**

*Adverse features can include uncertainty about the adequacy of micro-staging (positive deep margin), mitotic index ≥2/mm2 (particularly in the setting of young age), lymphovascular invasion, or a combination of these factors. [13]

ABOUT THE TEST

The twenty-eight discriminating genes in this profile are: BAP1 (two gene loci), MGP, SPP1, CXCL14, CLCA2, S100A8, BTG1, SAP130, ARG1, KRT6B, GJA1, ID2, EIF1B, S100A9, CRABP2, KRT14, ROBO1, RBM23, TACSTD2, DSC1, SPRR1B, TRIM29, AQP3, TYRP1, PPL, LTA4H and CST6. The three control genes are: FXR1, YKT6 and HNRNPL.

REFERENCE LIST

[1]Gerami P, et al. Clin Cancer Res 2015; 21(1);175-183; [2]Gerami P, et al. J Am Acad Dermatol 2015; 72:780-785.e3; [3]Zager J, et al. BMC Cancer 2018; 18:130; [4]Gastman B, et al. J Am Acad Dermatol 2019; 80(1): 149-157.e4; [5]Prado G, et al. Fall Clinical Derm NP/PA meeting abstract; 2019; [6]Vetto J, et al. Future Oncol 2019; 15(11):1207-1217; [7]Hsueh E, et al. J Hematol Oncol 2017; 10(152); [8]Greenhaw B, et al. Dermatol Surg 2018; 44(12):1494-1500; [9]Keller J, et al. Cancer Med 2019; 8(5):2205-2212; [10]Podlipnik S, et al. J Eur Acad Dermatol Venereol 2019; 33:857-861; [11]Greenhaw BN, et al. J Am Acad Dermatol 2020; Sep;83(3):745-753; [12]Gershenwald JE, et al.CA: a cancer journal for clinicians 2017; 67:472-492; [13]NCCN Clinical Practice Guidelines in Oncology, v1.2021; [14]Castle Biosciences, Inc. DATA ON FILE

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Your Patients Have Access to an Industry-Leading Financial Assistance Program

Healthcare Provider Signs Letter of Medical Necessity (LOMN)

- A signed LOMN will be needed and can be submitted with the test requisition form
- For your convenience, a LOMN template is available upon request

Castle Biosciences Submits Claim to Patient's Insurance Company

- After a patient report is issued, Castle Biosciences bills all third party insurance including Medicare/Medicaid and VA
- Castle Biosciences will send a letter to the patient notifying them of our claim submission

Patient Receives Explanation of Benefits (EOB)

- Patients will receive an EOB from their insurance plan
- This is not a bill, but the EOB may show an "Amount Due From Patient" or state "Patient Responsibility"

Patient Asked to Sign Appeal Consent Form

- Depending on the patient's insurance plan requirements, Castle Biosciences may require assistance during the reimbursement process to file claims and appeals on the patient's behalf

At Castle Biosciences, our goal is to ensure all patients have access to our tests. We believe the availability of testing should not be limited by a patient's ability to pay.

Reimbursement Information or Questions:
866-788-9007, option 3
Reimbursement@CastleBiosciences.com

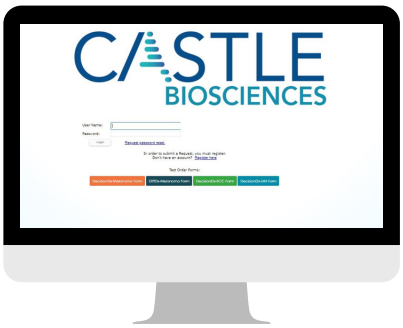
DecisionDx MELANOMA DecisionDx-SCC

Ordering a DecisionDx test for your patient is a simple process.

1. **Requisition Form (Completed & Signed)**
   - Hard Copy or Utilize Online Portal
2. **Letter of Medical Necessity (Completed & Signed)**
3. **Pathology Report(Primary Biopsy Specimen)**
   - Include Excision Report if Available
4. **Copy of Patient's Insurance Information**

Submit all documentation at Portal.CastleBiosciences.com or fax to 866-329-2224

Convenient Physician Portal



- HIPAA compliant and secure
- Order online or download pdf order forms
- Easily access patient test information 24/7
- Upload all supporting documents including LOMN, pathology reports and patient insurance information
- Receive email notifications when a report is available to view

Results are typically available within 5 days from sample receipt.

For further information, please contact your Area Manager or call the Customer Service Team at 866-788-9007, option 1.

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Insurance and Financial Information

- Your healthcare professional has ordered a DecisionDx test from Castle Biosciences to learn more about the biology of your tumor.
- The test result will help your healthcare professional decide how to best manage your care.

For questions about insurance coverage, claims processing and financial assistance call 866-788-9007, option 3 or email: Reimbursement@CastleBiosciences.com

What you can expect:

1. Castle Biosciences will submit a claim to your insurance company for the test. You will receive a letter from Castle Biosciences notifying you that your claim was submitted.
2. Your insurance company will send you an "Explanation of Benefits" (EOB). **This is not a bill.**
3. Castle Biosciences may need your consent to submit appeals on your behalf. **Please sign and return the consent form if you receive one.**

DecisionDx-Melanoma
DiffDx-Melanoma DecisionDx-SCC

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Decision Dx MELANOMA

Patient Resource Guide

For more information visit:
MyMelanoma.com
866-788-9007
option #1

Understanding your options after cutaneous melanoma diagnosis

What is cutaneous melanoma?

Cutaneous melanoma is a form of skin cancer that develops when the skin cells that give skin its color (melanocytes) are damaged and begin to grow out of control. Damage to these skin cells is usually triggered by overexposure to ultraviolet (UV) radiation either from the sun or tanning beds. Though it is not the most common type of skin cancer, it is one of the most aggressive because of its ability to spread to other parts of the body.

If you or someone you love has been diagnosed with Stage I, II, or III melanoma, your healthcare professional may consider genomic testing to determine the risk of the cancer coming back (recurring) or spreading (metastasizing). This guide will help you understand important information about the DecisionDx-Melanoma genomic test, including the benefits of knowing your results.

What is your risk?

Traditional factors that indicate your tumor might be at higher risk of recurring include:

- How far the melanoma has invaded the skin (Breslow thickness)
- Whether the tumor is ulcerated
- How quickly the melanoma cells are multiplying (mitotic rate)
- Age

Today, due to advances in science, the DecisionDx-Melanoma test can provide additional, personalized information about your melanoma that traditional staging factors alone may miss.

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RISK IDENTIFIED

SkinMelanoma.com

What is the DecisionDx-Melanoma genomic test?

DecisionDx-Melanoma is a genomic test that uses a small sample of your melanoma tissue to measure the activity of 31 specific genes that can tell us how likely it is for the cancer to come back or spread within the next 5 years, and your likelihood of sentinel lymph node positivity.

What do the results mean?

The DecisionDx-Melanoma test result provides a genomic-based determination of your tumor's likelihood to metastasize (spread) within the next 5 years. These results should be interpreted along with your other risk factors and overall health.

The results will provide your individual risk class as one of the following:

CLASS 1A
Lowest risk of recurrence and/or metastasis

CLASS 1B/2A
Increased risk of recurrence and/or metastasis

CLASS 2B
Highest risk of recurrence and/or metastasis

Integrated Test Result:
Once your DecisionDx-Melanoma Class result is determined, it will be incorporated with your clinical and pathological risk factors (Breslow thickness, ulceration, mitotic rate, and age) to provide a precise, personalized likelihood of sentinel lymph node positivity. This individualized integrated test result can help you and your healthcare professional make decisions about the SLNB surgical procedure. Typically SLNB should be discussed and considered when a patient's risk of positivity is greater than 10%. For those with risk between 5% and 10%, SLNB is sometimes considered. For those with risk less than 5%, SLNB is generally not recommended.

What are the benefits of using the test?

Your healthcare professional can use your test results, in combination with other tests and procedures, to plan your treatment and ongoing management.

How do I request the DecisionDx-Melanoma test?

If you wish to have the DecisionDx-Melanoma test performed, please discuss it with your healthcare professional. Only a healthcare professional can order this test.

How is the test paid for?

Castle Biosciences works with all insurance providers, including Medicare, Medicaid, commercial insurers, and the VA, to secure payment for the DecisionDx-Melanoma test. Castle will submit insurance claims on your behalf and provide you with an update on your claim processing status. The company also offers a Patient Assistance Program with the belief that quality care should not depend on financial considerations. You can get more information about insurance coverage, claims processing and financial assistance by calling 866-788-9007 and selecting option #3.

DecisionDx-Melanoma testing process is easy:

Step 1

Your healthcare professional orders the DecisionDx-Melanoma test

Step 2

Castle Biosciences works with your healthcare professional's pathology laboratory to obtain a tissue sample from your original biopsy

Step 3

Castle Biosciences analyzes your tissue sample with the DecisionDx-Melanoma genomic test

Step 4

Castle Biosciences sends your test results to your healthcare professional, so that they can discuss your individual results with you and determine next steps

Additional Testing Available from Castle Biosciences

DecisionDx-CM*Seq*

DecisionDx-CM*Seq* gene sequencing test is a separate test that can determine whether there are alterations in three important genes in your melanoma tumor, BRAF, NRAS and KIT. In certain situations, this information can help your healthcare professional determine treatment plans and may be helpful for future therapy decisions as research and treatments evolve.

DecisionDx-CM*Seq* provides different information than the DecisionDx-Melanoma test, and is NOT a substitute for the DecisionDx-Melanoma test. Talk to your healthcare provider to learn more about DecisionDx-CM*Seq* for your individual situation.

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Laboratory Address:
3737 N. 7th Street, Ste. 160
Phoenix, AZ 85014

CLIA-certified,
CAP-accredited laboratory

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

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Insurance and Financial Information

- Your healthcare professional has ordered a DecisionDx test from Castle Biosciences to learn more about the biology of your tumor.
- The test result will help your healthcare professional decide how to best manage your care.

For questions about insurance coverage, claims processing and financial assistance call 866-788-9007, option 3 or email: Reimbursement@CastleBiosciences.com

What you can expect:

1. Castle Biosciences will submit a claim to your insurance company for the test. You will receive a letter from Castle Biosciences notifying you that your claim was submitted.
2. Your insurance company will send you an "Explanation of Benefits" (EOB). **This is not a bill.**
3. Castle Biosciences may need your consent to submit appeals on your behalf. **Please sign and return the consent form if you receive one.**

DecisionDx-Melanoma
DiffDx-Melanoma DecisionDx-SCC

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