## Decipher<sup>®</sup> Prostate

### Metastatic Genomic Classifier

#### PATIENT

Name: **Sample Patient Name** Date of Birth: --/--/----Medical Record #: ------Tissue Collection Date: --/--/----

## Sample Report: Not a Real Patient

#### SPECIMEN INFORMATION

Order Date: --/--/----Specimen ID: **0123456789** Specimen Received Date: --/--/----Decipher Accession ID: **MC-123456** 

### PATIENT REPORT

REPORT STATUS: FINAL PAGE: 1 of 3

#### **ORDERING PHYSICIAN**

Ø Bone □ Visceral

Name: Sample Physician, MD Clinic: Sample Clinic Address: 123 Birch Avenue, Suite A, Anytown, CA 54321

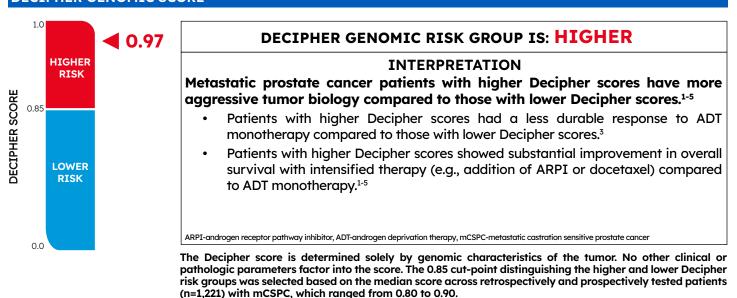
#### **CLINICAL AND PATHOLOGY DETAILS** For reference only, not used in calculation of genomic risk

Specimen: Needle Biopsy

Disease Volume: □ Low Volume ☑ High Volume If Specified: # of Metastatic Lesions: ≥ 4

#### Metastasis Sites: Extra-Pelvic Lymph Node(s)

DECIPHER GENOMIC SCORE



### **RISK ESTIMATES FOR THIS PATIENT**

LOW VOLUME DISEASE Likelihood of:		HIGH VOLUME DISEASE Likelihood of:		Risk estimates were derived from Cox proportional
37%	63%	19%	40%	randomized trials. For further details, see page 3.2-4
when treated with ADT ALONE		when treated with ADT ALONE		

Approved By:

### E-SIGNED BY NAME, CREDENTIAL ON DATE AT TIME

Veracyte Labs SD

CLIA ID# 05D2055897 CAP # 8859006 Lab Director: [Lab Director Name, MD] A copy of this form shall be as valid as the original. This test was developed and its performance characteristics determined by Veracyte Labs SD. The laboratory is regulated under CLLA '88 as qualified to perform high complexity clinical testing. This test has not been cleared or approved by the FDA. This test is used for clinical purposes and clinical correlation of its results are recommended. It should not be regarded as investigational or for research. LAB-FRM-20010 v1.0 © 2025 Veracyte, Inc and affiliates. All rights reserved. Veracyte and Decipher are trademarks of Veracyte, Inc. and its affiliates.



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# Decipher Risk & Interpretation

- For a metastatic patient, the score is classified as:
  - Decipher Higher Risk (>0.85)
  - Decipher Lower Risk (≤0.85)
  - Cut-point (0.85) reflects the median Decipher score across 1,221 retrospectively and prospectively tested mCSPC patients which ranged from 0.80-0.90
- Report interpretation is tailored to the patient's clinical presentation

(mCSPC - metastatic castration sensitive prostate cancer)

PATIENT REPORT Sample Report: **Decipher** Prostate Not a Real Patient REPORT STATUS: FINAL Metastatic Genomic Classifier PAGE: 1 of 3 SPECIMEN INFORMATION PATIENT ORDERING PHYSICIAN Name: Sample Patient Name Order Date: --/--/----Name: Sample Physician, MD Specimen ID: 0123456789 Date of Birth: --/--/ Clinic: Sample Clinic Medical Record #: -Specimen Received Date: --/--/----Address: 123 Birch Avenue, Suite A, Tissue Collection Date: --/--/----Decipher Accession ID: MC-123456 Anytown, CA 54321 CLINICAL AND PATHOLOGY DETAILS For reference only, not used in calculation of genomic risk Metastasis Sites: Specimen: Needle Biopsy Disease Volume If Specified: Low Volume # of Metastatic Lesions: ≥ 4 Extra-Pelvic Lymph Node(s) High Volume 🛙 Bone □ Visceral DECIPHER GENOMIC SCORE DECIPHER GENOMIC RISK GROUP IS: HIGHER ◀ 0.97 IGHEF INTERPRETATION RISK Metastatic prostate cancer patients with higher Decipher scores have more DECIPHER SCORE aggressive tumor biology compared to those with lower Decipher scores.<sup>1-5</sup> 0.85 Patients with higher Decipher scores had a less durable response to ADT monotherapy compared to those with lower Decipher scores.<sup>3</sup> Patients with higher Decipher scores showed substantial improvement in overall LOWER survival with intensified therapy (e.g., addition of ARPI or docetaxel) compared RISK to ADT monotherapy.1-5 ARPI-androgen receptor pathway inhibitor, ADT-androgen deprivation therapy, mCSPC-metastatic castration sensitive p The Decipher score is determined solely by genomic characteristics of the tumor. No other clinical or pathologic parameters factor into the score. The 0.85 cut-point distinguishing the higher and lower Decipher risk groups was selected based on the median score across retrospectively and prospectively tested patients (n=1,221) with mCSPC, which ranged from 0.80 to 0.90. **RISK ESTIMATES FOR THIS PATIENT** LOW VOLUME DISEASE HIGH VOLUME DISEASE Risk estimates were derived Likelihood of Likelihood of: from Cox proportional FREEDOM FROM FREEDOM FROM hazards models fit OVERALL SURVIVAL OVERALL SURVIVAL CASTRATION RESISTANCE CASTRATION RESISTANCE on retrospective data at 36 months at 36 months at 18 months at 18 months from multiple phase 3 randomized trials. For 37% 63% 19% 40% further details, see page 3. when treated with ADT ALONE when treated with ADT ALONE Approved By: E-SIGNED BY NAME, CREDENTIAL ON DATE AT TIME CLIA ID# 05D205589 A copy of this form shall be as valid as the original. This test was developed and its performance characteristics determined by Veracyte Labs SD. The laboratory is regulated under CL1A 88 as qualified to perform high complexity dinical tresting. This test has not been chared or approved by the FDA. This test is used for alriad purposes and alriadic correlation of its results are recommended. It includes how the space of a single space of CAP # 8859006 Lab Director: [Lab Director Name, MD] LAB-FRM-20010 v1.0 © 2025 Veracyte. Inc and affiliates. All rights reserved. Veracyte and Decipher are trademarks of Veracyte. Inc. and its affiliates Veracyte Labs SD 6925 Lusk Boulevard, Suite 200 San Diego, CA 92121 T 1.888.792.1601 F 1.858.766.6575 E client.service-urology@veracyte.com W veracyte.com/decipher veracyte.

# **Dynamic Report**

• The report is tailored to the clinical presentation of this patient

## **Risk Estimates**

- Specific to the patient's Decipher score and calculated using data from phase 3 clinical trials
- Reflect outcomes after treatment with ADT alone
  - Likelihood of remaining noncastration resistant at 18 months
  - Likelihood of being alive at 3 years
  - Higher percentages indicate more favorable outcomes
- Visually highlighted based on the patient's Decipher Risk (Higher or Lower) and disease volume (high or low)

## Decipher<sup>®</sup> Prostate

Name: **Sample Patient** Date of Birth: --/--/----Decipher Accession ID: **MC-123456** 

REPORT STATUS: FINAL PAGE: 2 of 3

Metastatic Genomic Classifier

### THERAPEUTIC ABSOLUTE BENEFIT

LOW VOLU	1E DISEASE	HIGH VOLUME DISEASE		
Absolute Benefit in Ove	erall Survival at 3 years	Absolute Benefit in Overall Survival at 3 years		
with the addition of <b>AB</b>	IRATERONE to ADT	with the addition of ABIRATERONE to ADT		
Lower Decipher	Higher Decipher	Lower Decipher	Higher Decipher	
7%	25%	14%	26%	
LOW VOLUME DISEASE		HIGH VOLUME DISEASE		
Absolute Benefit in Overall Survival at 3 years		Absolute Benefit in Overall Survival at 3 years		
with the addition of <b>DOCETAXEL</b> to <b>ADT</b>		with the addition of <b>DOCETAXEL</b> to <b>ADT</b>		
Lower Decipher	Higher Decipher	Lower Decipher	Higher Decipher	
1%	10%	5%	22%	

### FINDINGS FROM ANALYSES OF PHASE 3 RANDOMIZED TRIALS RELEVANT TO THIS PATIENT

Metastatic prostate cancer patients with higher Decipher scores have more aggressive tumor biology compared to those with lower Decipher scores.<sup>1-5</sup>

- In an analysis of 222 patients with mCSPC from the phase 3 TITAN trial, those with higher Decipher scores showed a substantial improvement in rPFS with the addition of apalutamide to ADT monotherapy.<sup>1</sup>
- In an analysis of 389 patients with mCSPC from the abiraterone arm (Arm G) of the phase 3 STAMPEDE trial, those with higher Decipher scores showed a substantial (32%) survival benefit at 36 months from the addition of abiraterone to ADT monotherapy compared to patients with lower Decipher scores.<sup>2</sup>
- In an analysis of 539 patients with mCSPC enrolled in the docetaxel arms (Arms C & E) of the phase 3 STAMPEDE trial, those with higher Decipher scores had a substantial survival benefit from the addition of docetaxel to ADT monotherapy. In this analysis, a higher Decipher score was predictive of a positive response to the addition of docetaxel, with a significant interaction p-value of 0.039.<sup>4</sup>
- An analysis of 160 patients with mCSPC from the phase 3 CHAARTED trial indicated that patients with higher Decipher scores experienced a substantial survival benefit from the addition of docetaxel to ADT monotherapy.<sup>3</sup>
- An analysis of 233 patients with nmCRPC from the phase 3 SPARTAN trial found that those with higher Decipher scores had substantial improvements in MFS, PFS, and overall survival from the addition of apalutamide to ADT monotherapy.<sup>5</sup>

mCSPC-metastatic castration sensitive prostate cancer, rPFS-radiographic progression-free survival, ADT-androgen deprivation therapy, ARPI-androgen receptor pathway inhibitor, nmCRPC-non-metastatic castration resistant prostate cancer, MFS-metastasis-free survival, PFS-progression-free survival

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## **Absolute Benefit**

- Refers to absolute overall survival benefit at 3 years from:
  - Adding abiraterone to ADT (determined by data from STAMPEDE Arm G)
  - Adding docetaxel to ADT (determined by data from CHAARTED and STAMPEDE Arm C)
- Absolute benefit values are derived from published trial data and are fixed
- Visually highlighted based on the patient's Decipher risk (Higher or Lower) and disease volume (high or low)

#### Decipher Prostate Metastatic Genomic Classifier

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Name: **Sample Patient** Date of Birth: --/--/----Decipher Accession ID: **MC-123456** 

#### PATIENT REPORT

REPORT STATUS: FINAL PAGE: 2 of 3

#### THERAPEUTIC ABSOLUTE BENEFIT

Γ	LOW VOLUME DISEASE		HIGH VOLUME DISEASE		
Γ	Absolute Benefit in Ove	rall Survival at 3 years	Absolute Benefit in Overall Survival at 3 years		
	with the addition of <b>AB</b>	RATERONE to ADT	with the addition of ABIRATERONE to ADT		
	Lower Decipher	Higher Decipher	Lower Decipher	Higher Decipher	
	7%	25%	14%	26%	
Γ	LOW VOLUM	1E DISEASE	HIGH VOLUME DISEASE		
Γ	Absolute Benefit in Overall Survival at 3 years		Absolute Benefit in Overall Survival at 3 years		
	with the addition of ${\sf D}$	OCETAXEL to ADT	with the addition of DOCETAXEL to ADT		
	Lower Decipher	Higher Decipher	Lower Decipher	Higher Decipher	
	1%	10%	5%	22%	

#### FINDINGS FROM ANALYSES OF PHASE 3 RANDOMIZED TRIALS RELEVANT TO THIS PATIENT

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## **Clinical Findings**

- Relevant findings from post-hoc analyses of phase 3 randomized trials
- Content is based on the patient's Decipher risk (Higher or Lower)

## Decipher<sup>®</sup> Prostate

**Metastatic Genomic Classifier** 

Name: **Sample Patient** Date of Birth: --/--/----Decipher Accession ID: **MC-123456** 

REPORT STATUS: FINAL PAGE: 3 of 3

### **TEST DESCRIPTION**

**General:** Decipher Prostate utilizes a genome-wide transcriptome assay to analyze the expression of 22 content genes and employs a proprietary algorithm to generate a Decipher score. The test is performed on the most recent biopsy or prostatectomy specimen prior to treatment with radiation or hormone therapy, and interpretation language depends on the patient's Decipher risk group (lower, higher) and "disease volume" (low or high). The primary result is a continuous score between 0 and 1 (the "Decipher score") that reflects the aggressiveness of the tumor and is used to aid in prognostic risk stratification and treatment decision making. While the Decipher score is determined solely from the genomic characteristics of the tumor, independent of clinical or pathological factors, the way the score is applied in clinical practice depends on the patient's clinical scenario and treatment setting.

**Sample Preparation:** Microdissection is performed, consisting of a pathologist identifying the tumor region of interest microscopically, followed by sample capture and testing.

Calibrated probabilities for the following clinical endpoints:

- **Likelihood of Freedom from Castration Resistance at 18 months:** Risk probability estimates were derived from Cox proportional hazards models fit on retrospective data from multiple phase 3 clinical trials, and the percent likelihoods of CRPC-free survival at 18 months range from 17-93%.<sup>1,2</sup>
- **Likelihood of Overall Survival at 36 months:** Risk probability estimates were derived from Cox proportional hazards models fit on retrospective data from multiple phase 3 clinical trials, and the percent likelihoods for 3-year overall survival range from 38-93%.<sup>12</sup>

**Cut-Point:** Patients with metastatic prostate cancer and a Decipher score >0.85 are classified as Decipher Higher Risk and those with a score ≤0.85 are classified as Decipher Lower Risk. The 0.85 cut-point was selected from the observed median score across patients with mCSPC tested prospectively and from retrospective analyses of phase 3 randomized clinical trials (n=1,221), which ranged from 0.80 to 0.90, to identify patients who may experience greater absolute benefit in overall survival from the addition of abiraterone or docetaxel to ADT to long-term ADT.<sup>23,6-9</sup>

### **INTENDED USE**

Decipher Prostate Metastatic is intended for use in patients with metastatic prostatic adenocarcinoma. The test is performed on the most recent biopsy or prostatectomy specimen prior to treatment with radiation or hormone therapy, and interpretation language depends on the patient's Decipher risk group (lower, higher) and "disease volume" (low or high).

#### **CONFIDENCE INTERVALS**

- Likelihood of Freedom from Castration Resistance at 18 months has a 95% confidence interval of 30-44% (LV) and 12-25% (HV).
- Likelihood of Overall Survival at 36 months has a 95% confidence interval of 56-71% (LV) and 34-47% (HV).

#### REFERENCES

- 1. Feng, F. Y. et al. Journal of Clinical Oncology 38, 5535-5535, (2020). 10.1200/JCO.2020.38.15\_suppl.5535.
- 2. Parry, M. et al. Ann Oncol 33, S1161, (2022). 10.1016.
- 3. Hamid, A. A. et al. Ann Oncol 32, 1157-1166, (2021). 10.1016/j.annonc.2021.06.003.
- 4. Grist, E. et al. Annals of Oncology 35, S961-S962, (2024). 10.1016/j.annonc.2024.08.1677.
- 5. Feng, F. Y. et al. JAMA Oncol 7, 1005-1014, (2021). 10.1001/jamaoncol.2021.1463.
- 6. Erho, N. et al. PLoS One 8, e66855, (2013). 10.1371/journal.pone.0066855.
- 7. Karnes, R. J. et al. J Urol 190, 2047-2053, (2013). 10.1016/j.juro.2013.06.017.
- 8. Ross, A. E. et al. Eur Urol 69, 157-165, (2016). 10.1016/j.eururo.2015.05.042.
- 9. Davicioni, E. et al. Journal of Clinical Oncology 33, e16122-e16122, (2015). 10.1200/jco.2015.33.15\_suppl.e16122.

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	Test Description			_
	<ul> <li>How the test is performed</li> <li>Definitions for each of the endpoints reported</li> </ul>	Decipher Prostate       Name: Sample Patient         Metastatic Genomic Classifier       Decipher Accession ID: MC-12345         TEST DESCRIPTION       Decipher Accession ID: MC-12345	PAGE: 3 of 3	
	<ul> <li>Provides detail on the cut-points for Decipher risk groups</li> </ul>	General: Decipher Prostate utilizes a genome-wide transcriptome assay to and penes and employs a proprietary algorithm to generate a Decipher score. The te cent biopsy or prostatectomy specimen prior to treatment with radiation or the language depends on the patient's Decipher risk group (lower, higher) and "dise The primary result is a continuous score between 0 and 1 (the "Decipher score") of the tumor and is used to aid in prognostic risk stratification and treatment de	est is performed on the most prmone therapy, and interpretation ase volume" (low or high). that reflects the aggressiveness	Intended Use
	Confidence Intervals	<ul> <li>Sorre is determined solely from the genomic characteristics of the tumor, indeperfactors, the way the score is applied in clinical practice depends on the patient's setting.</li> <li>Sample Preparation: Microdissection is performed, consisting of a pathologist is microscopically, followed by sample capture and testing.</li> <li>Calibrated probabilities for the following clinical endpoints:</li> <li>Likelihood of Freedom from Castration Resistance at 18 months: Risk pro Cox proportional hazards models fit on retrospective data from multiple p likelihoods of CRPC-free survival at 18 months: Risk probability estimates were a models fit on retrospective data from multiple p likelihoods of Overall Survival at 36 months: Risk probability estimates were a models fit on retrospective data from multiple phase 3 clinical trials, and the survival range from 38-93%.<sup>1,2</sup></li> <li>Cut-Point: Patients with metastatic prostate cancer and a Decipher score &gt;0.85 Risk and those with a score ≤0.85 are classified as Decipher Lower Risk. The 0.85 observed median score across patients with metastatic on 0.80 to 0.90, to identify pp absolute benefit in overall survival from the addition of abiraterone or docetaxes</li> <li>INTENDED USE</li> <li>Decipher Prostate Metastatic is intended for use in patients with metastatic performed on the most recent biopsy or prostatectomy specimen prior to treatme and interpretation language depends on the patient's Decipher risk group (low or high).</li> </ul>	endent of clinical or pathological clinical scenario and treatment dentifying the tumor region of interest bability estimates were derived from hase 3 clinical trials, and the percent lerived from Cox proportional hazards percent likelihoods for 3-year overall are classified as Decipher Higher i cut-point was selected from the om retrospective analyses of phase 3 atients who may experience greater I to ADT to long-term ADT.	<ul> <li>Decipher Prostate Metastatic is intended for use in patients with metastatic prostatic adenocarcinoma. The test is performed on the most recent biopsy or radical prostatectomy specimen prior to treatment with radiation or hormone therapy</li> </ul>
	The 95% confidence interval for each	<ul> <li>CONFIDENCE INTERVALS</li> <li>Likelihood of Freedom from Castration Resistance at 18 months has a 95% cr 12-25% (HV).</li> <li>Likelihood of Overall Survival at 36 months has a 95% confidence interval of</li> </ul>		
en	endpoint reported on page 1	REFERENCES           1. Feng, F. Y. et al. Journal of Clinical Oncology 38, 5535-5535, (2020). 10.1200/JCO.2020.38.15_suppl.5535.           2. Parry, M. et al. Ann Oncol 33, S1161, (2022). 10.1016.           3. Hamid, A. A. et al. Ann Oncol 32, 1157-1166, (2021). 10.1016/j.annonc.2021.06.003.		References
		<ol> <li>Grist, E. et al. Annals of Oncology 35, S961-S962, (2024). 10.1016/j.annonc.202</li> <li>Feng, F. Y. et al. JAMA Oncol 7, 1005-1014, (2021). 10.1001/jamaoncol.2021.14</li> <li>Erho, N. et al. PLoS One 8, e66855, (2013). 10.1371/journal.pone.0066855.</li> <li>Karnes, R. J. et al. J Urol 190, 2047-2053, (2013). 10.1016/j.juro.2013.06.017.</li> <li>Ross, A. E. et al. Eur Urol 69, 157-165, (2016). 10.1016/j.eururo.2015.05.042.</li> <li>Davicioni, E. et al. Journal of Clinical Oncology 33, e16122-e16122, (2015). 10.1016/</li> </ol>	(4.08.1677. 53.	<ul> <li>For each of the clinical studies cited in the report</li> </ul>
		A copy of this form shall be as valid as the original. This test was developed and its performance is regulated under CL14 88 as qualified to perform high complexity clinical testing. This test h clinical purposes and clinical contendition of its results are recommended. It should not be regu- LAB-FRH-20010 v1.0 © 2025 Veracyte, Inc and affiliates. All rights reserved. Veracyte and De Veracyte Labs SD 6925 Lusk Boulevard, Suite 200 T 1.888.792.1 F 1.658.766.6	cipher are trademarks of Veracyte, Inc. and its affiliates.	