Decipher® Prostate

Metastatic Genomic Classifier

Sample Report: Not a Real Patient

PATIENT REPORT

PATIENT

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

SPECIMEN INFORMATION

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

ORDERING PHYSICIAN

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

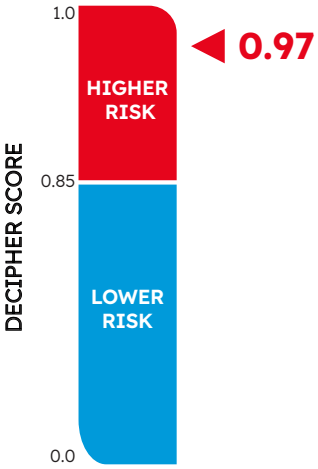
Specimen: **Needle Biopsy**

Disease Volume:
- ☐ Low Volume
- ☑ High Volume

If Specified:
# of Metastatic Lesions: **≥ 4**

Metastasis Sites:
- ☐ Extra-Pelvic Lymph Node(s)
- ☑ Bone
- ☐ Visceral

DECIPHER GENOMIC SCORE



DECIPHER GENOMIC RISK GROUP IS: HIGHER

INTERPRETATION

Metastatic prostate cancer patients with higher Decipher scores have more aggressive tumor biology compared to those with lower Decipher scores.[1-5]

- Patients with higher Decipher scores had a less durable response to ADT monotherapy compared to those with lower Decipher scores.[3]
- Patients with higher Decipher scores showed substantial improvement in overall survival with intensified therapy (e.g., addition of ARPI or docetaxel) compared to ADT monotherapy.[1-5]

ARPI-androgen receptor pathway inhibitor, ADT-androgen deprivation therapy, mCSPC-metastatic castration sensitive prostate cancer

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	
Likelihood of:		**Likelihood of:**	
FREEDOM FROM CASTRATION RESISTANCE at 18 months	OVERALL SURVIVAL at 36 months	**FREEDOM FROM CASTRATION RESISTANCE** at 18 months	**OVERALL SURVIVAL** at 36 months
37%	63%	**19%**	**40%**
when treated with ADT ALONE		when treated with **ADT ALONE**	

Risk estimates were derived from Cox proportional hazards models fit on retrospective data from multiple phase 3 randomized trials. For further details, see page 3.[2-4]

Approved By:
E-SIGNED BY NAME, CREDENTIAL ON DATE AT TIME

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 CLIA '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.

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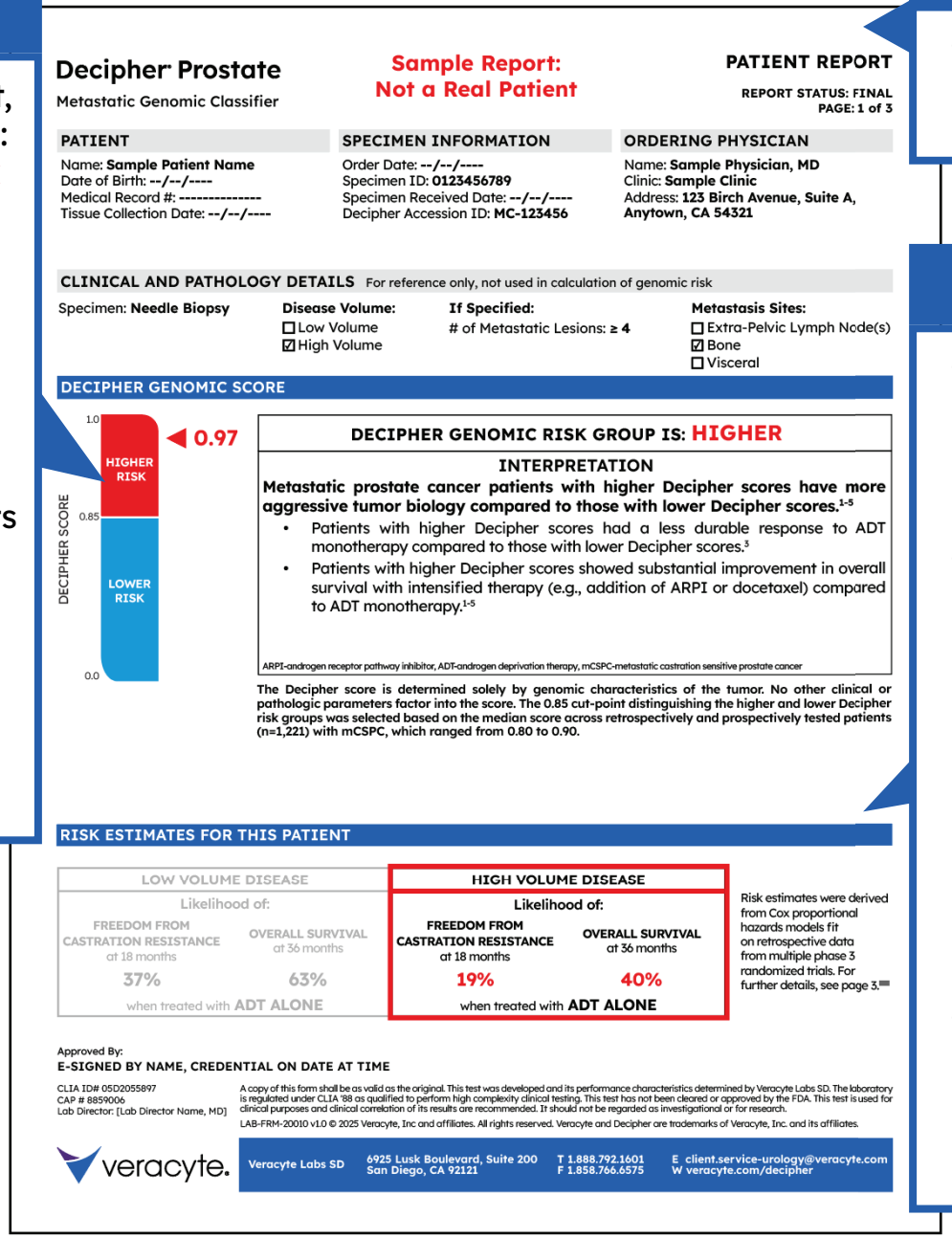
Decipher Risk & Interpretation

- 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)



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REPORT STATUS: FINAL
PAGE: 1 of 3

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Metastasis Sites: ☐ Extra-Pelvic Lymph Node(s) ☑ Bone ☐ Visceral

DECIPHER GENOMIC SCORE

DECIPHER SCORE: 1.0 / 0.85 / 0.0 — HIGHER RISK / LOWER RISK — ◀ 0.97

DECIPHER GENOMIC RISK GROUP IS: HIGHER

INTERPRETATION

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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 non-castration 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)

THERAPEUTIC ABSOLUTE BENEFIT

LOW VOLUME DISEASE		HIGH VOLUME DISEASE	
Absolute Benefit in Overall Survival at 3 years with the addition of **ABIRATERONE** to **ADT**		**Absolute Benefit in Overall Survival at 3 years** 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 with the addition of **DOCETAXEL** to **ADT**		**Absolute Benefit in Overall Survival at 3 years** 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

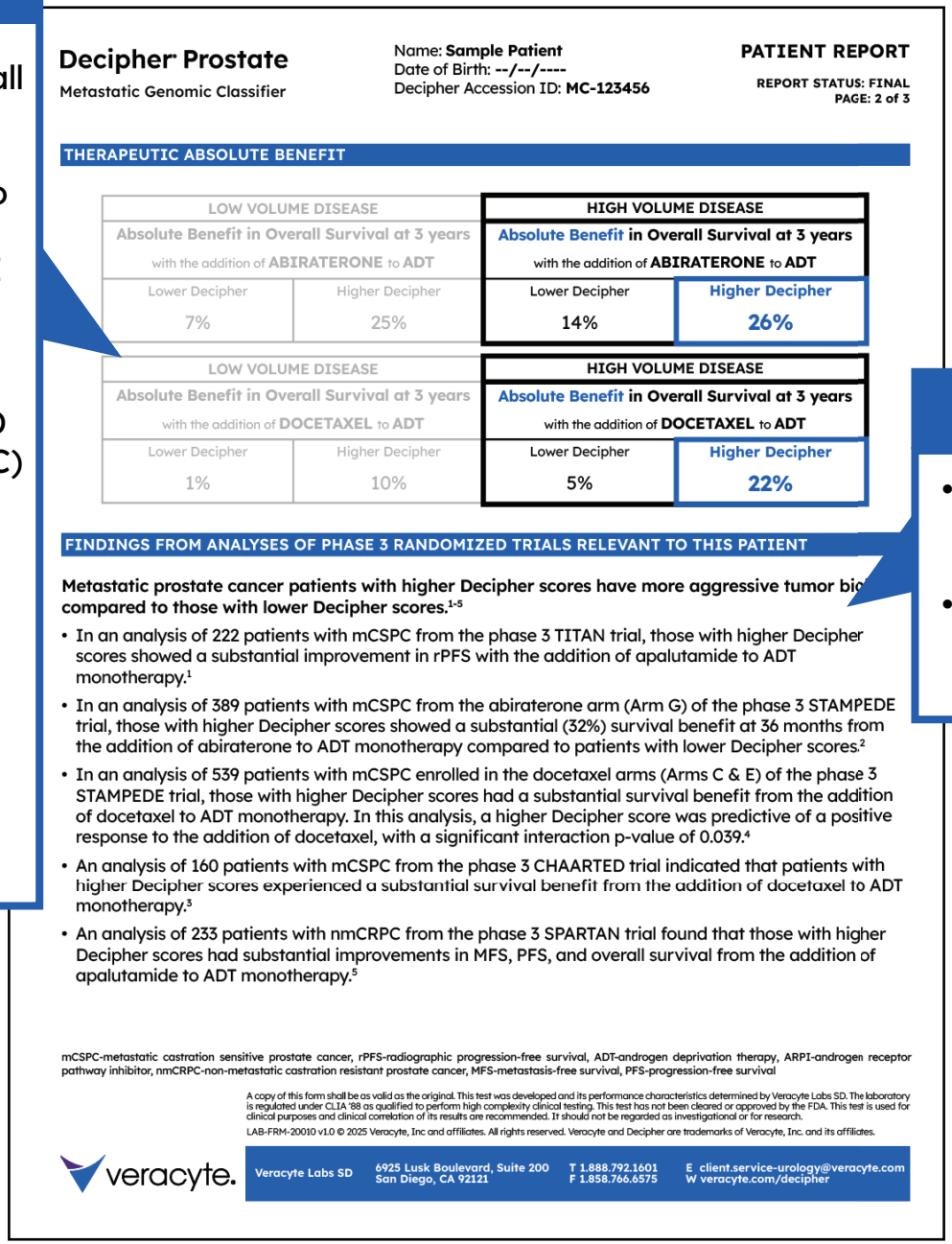
Metastatic prostate cancer patients with higher Decipher scores have more aggressive tumor biology compared to those with lower Decipher scores.[1-5]

- 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.[1]
- 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.[2]
- 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.[4]
- 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.[3]
- 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.[5]

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

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)



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Decipher Accession ID: **MC-123456**

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REPORT STATUS: FINAL
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THERAPEUTIC ABSOLUTE BENEFIT

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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 with the addition of **DOCETAXEL** to **ADT**		**Absolute Benefit** in Overall Survival at 3 years with the addition of **DOCETAXEL** to **ADT**	
Lower Decipher	Higher Decipher	Lower Decipher	**Higher Decipher**
1%	10%	5%	**22%**

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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**)

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%.[1,2]

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%.[1,2]

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.[2,3,6-9]

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.
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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.

Test Description

- How the test is performed
- Definitions for each of the endpoints reported
- Provides detail on the cut-points for Decipher risk groups

Confidence Intervals

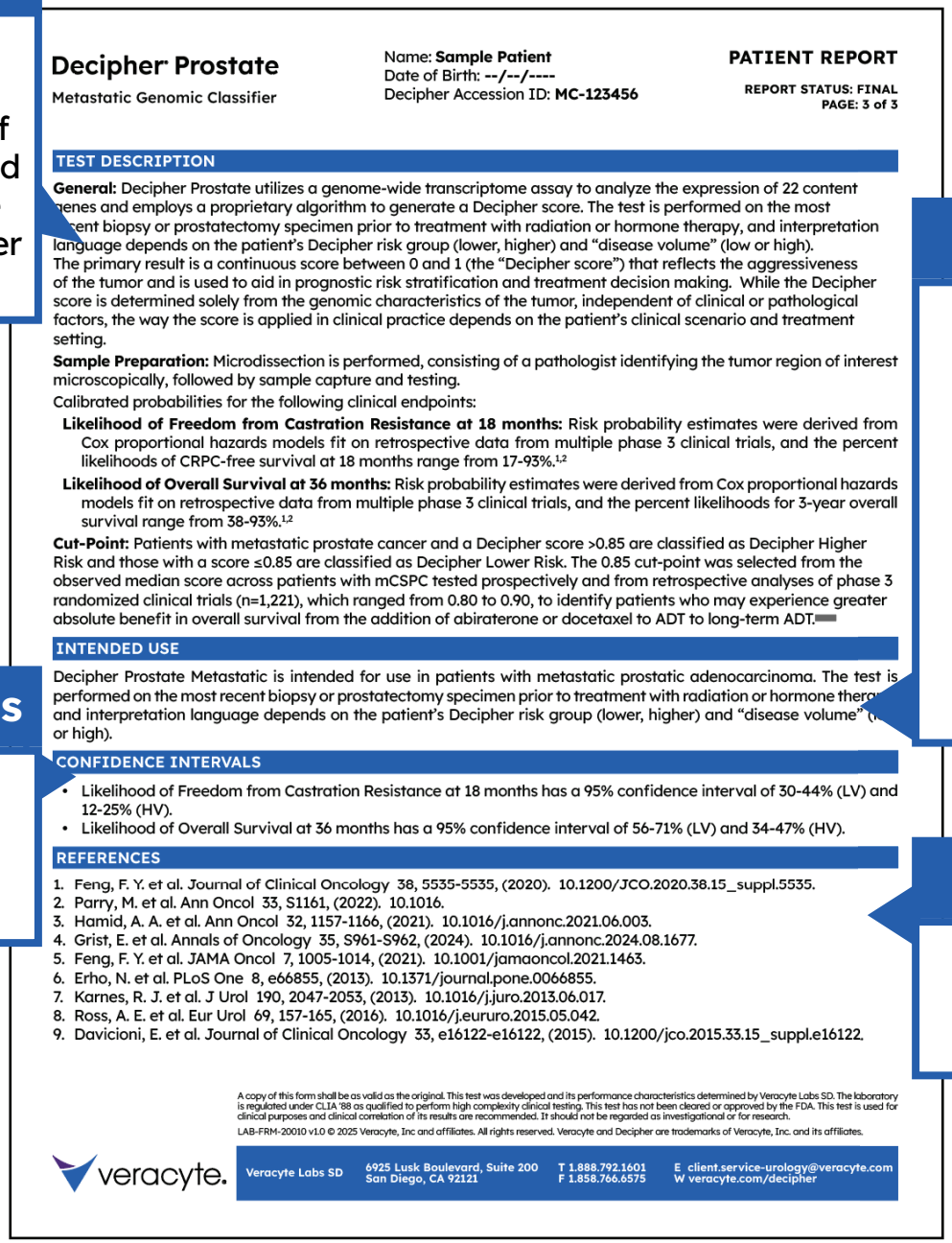
- The 95% confidence interval for each endpoint reported on page 1

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 radical prostatectomy specimen prior to treatment with radiation or hormone therapy

References

- For each of the clinical studies cited in the report



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