

Prostate Cancer Test Report

Date Presented - Feb 4, 2019

Ordering Doctor

Name: Dr. Jody Smith
License #: 00515515
UPIN #: A999Z9
NPI #: 9999999999

Patient Details

John Smith
Patient Number: 100523
DOB: Jan 1, 1980
Gender: Male
Ph: (234) 234-2343

Specimen Details

Collected: July 1, 2018
Sent: July 1, 2019
Tested: July 5, 2019
Source: Capillary Blood

Welcome To Your Results

Dear John Smith,

We received your small volume blood sample, and tested it for the presence of certain biomarkers commonly associated with prostate cancer.

The testing platform used to produce the results described in this report has been shown to detect these biomarkers to a high level of accuracy when they are present, and to also correctly show a negative result when they are not present.

When shared with your healthcare professional, we are confident this report will provide insight to inform healthcare decisions that may improve your health and quality of life.

You and your healthcare professional can trust the science behind these results, as our lab partners have completed validation studies comparing this process to established testing methods.

For any questions about this test, please visit us at www.imaware.health or connect with us via email at support@imaware.health.

In good health,
The imaware team

Medical Advisory Team



Dr. Eleftherios Diamandis
Head of Clinical Biochemistry
at Mount Sinai Hospital

Prostate Screen with Testosterone Test – Your Results Summary

John, you are **at high risk of having prostate cancer**
based on biomarker sampling as well as patient specific considerations.

BIOMARKER SAMPLING

A biomarker (“biological marker”) refers to a category of objective signs that indicate medical state. Elevated biomarker levels in your blood can signal the presence of a disease. We tested your blood for the presence of PSA (Total):

PSA Total

ABNORMAL



PATIENT SPECIFIC CONSIDERATIONS

We included specific aspects of your history and condition as part of this test in order to confirm your likelihood.

- You indicated that you have not been previously diagnosed
- You indicated that you have family history of prostate cancer

Your overall likelihood is compared to the possible scenarios

- Highly Likely**
More than 60% likelihood
- Somewhat Likely**
Between 25-60% likelihood
- Less Likely**
Between 2-25% likelihood
- Not Likely**
Less than 2% likelihood

Highly Likely
Likelihood you have prostate cancer

Your likelihood estimate is based on biomarker sampling and preconditions:

- Your blood sample contained abnormal biomarker levels
- You indicated a pre-condition that may increase your likelihood of having this condition

Your Next Steps

Share these results with your doctor, who can review your results and provide an action plan before you make any major lifestyle changes.

If you begin to make any doctor recommended lifestyle changes, imaware™ can help you monitor the effectiveness of your lifestyle changes and treatment.

Prostate Cancer Test – Detailed Results

The following pages provide additional information that should be shared with your healthcare professional.

DETAILED PATIENT RESULTS TABLE

Analyte	Quantitative	Qualitative	Reportable Range	Cutoff	Target Range
PSA, Total	8.0 ng/mL	Positive	0.5 - 100.0 ng/mL	<4.0 ng/mL	<4.0 ng/mL

PATIENT DISEASE AND SYMPTOMS STATUS

- You have indicated you have not been previously diagnosed
- You indicated that you have family history of prostate cancer
- You indicated you do currently smoke

Prostate Cancer Test – Detailed Scientific Validation

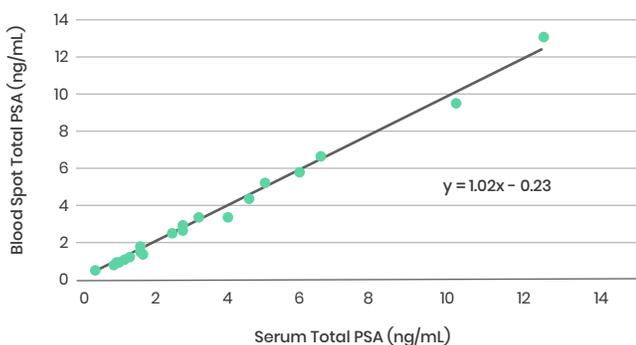
imaware™ tests are tested to be highly accurate and precise. The following data can be reviewed by your medical professional to better understand the validity of the imaware test.

TOTAL PSA TEST – SCIENTIFIC VALIDATION

Accuracy

Paired serum and dried serum spot samples containing varying concentrations of total PSA were tested. PSA concentrations observed for the dried serum samples versus serum (Electrochemilumiscence-based assay) were statistically analyzed by simple regression:

N=27		
Correlation Coefficient	0.9964	
Slope	1.02	
Intercept	-0.23	
	DBS PSA	Comparable Serum Method
Mean Prostate Specific Antigen	3.04	3.19
Standard Deviation of Range	2.94	2.86



Prostate Cancer Test – Additional Information

SCIENTIFIC REFERENCES

1. Alpert PF; Urology.2018 Aug;118:119-126. doi: 10.1016/j.jurology.2018.02.049. Epub 2018 May 14. New Evidence for the Benefit of Prostate-specific Antigen Screening: Data From 400,887 Kaiser Permanente Patients.
2. Etzioni R, Tsodikov A, Mariotto A, et al. Quantifying the role of PSA screening in the US prostate cancer mortality decline. Cancer Causes Control 2008; 19:175..
3. Screening for prostate cancer decreases the risk of developing metastatic disease: findings from the European Randomized Study of Screening for Prostate Cancer (ERSPC). Schröder FH, Hugosson J, Carlsson S, Tammela T, Määttänen L, Auvinen A, Kwiatkowski M, Recker F, Roobol MJ; Eur Urol. 2012;62(5):745. Epub 2012 Jun 7.
4. Reconciling the Effects of Screening on Prostate Cancer Mortality in the ERSPC and PLCO Trials; Ann Intern Med. 2017;167(7):449-455. Published at www.annals.org on 5 September 2017; DOI: 10.7326/M16-2586

PERFORMING LABORATORY INFORMATION

- Patient Sample was performed on July 5, 2019 by CoreMedica Labs.
- CLIA Number 26D2013888 CAP Accreditation 7537862
- Lab Location: 200 NE Missouri, Ste 302, Lees Summit, MO, 64081
- Lab Director: Dr. Cristian Saez, Ph.D.

TEST NOTES AND LIMITATIONS

- These test results should be shared with your healthcare provider
- This test is not to diagnose any health condition - only your healthcare provider can make that determination, in light of your overall health history and the results of other testing they may decide to order
- Please consult your healthcare provider before making any dietary changes