

EpiSwitch® PSE Technical Overview

EpiSwitch PSE is a blood test to assess the likelihood of prostate cancer. The test will be administered alongside or following a standard PSA test to significantly boost sensitivity and reduce the number of men referred for an unnecessary biopsy and treatment.¹⁻²

Intended Use

EpiSwitch Prostate Screening (PSE) Test is a blood test for prostate cancer which will be administered alongside or following a standard PSA test. The test evaluates the PSA score plus a targeted PCR evaluation of five (5) DNA regulatory markers called chromatin-conformation signatures (CCS). The PSE test is 94% accurate, 97% specific and 86% sensitive for diagnosing prostate cancer. This information is valuable in determining who should proceed to biopsy and who can be placed on active surveillance without additional testing.

EpiSwitch PSE interpretation: A patient's current likelihood of prostate cancer

Low Probability

Low Probability Management Guidance

The **EpiSwitch Prostate Screening (PSE) Test** score indicates **the patient is negative for prostate cancer**. This result should be considered along with other clinical features for interpretation by a licensed medical professional.

High Probability

High Probability Management Guidance

The **EpiSwitch Prostate Screening (PSE) Test** score indicates a **high likelihood of prostate cancer**. This result should be considered along with other clinical features for interpretation by a licensed medical professional.

A **HIGH PROBABILITY** result is consistent with the presence of prostate cancer, a follow-up diagnostic test such as a biopsy ordered by your healthcare provider is recommended.

A validated screening test with high accuracy, specificity and sensitivity¹

EpiSwitch PSE delivers a highly accurate test with well-balanced sensitivity and specificity for confidently identifying both the presence and absence of prostate cancer.



- **EpiSwitch PSE** will be administered alongside or following a standard PSA test
- **EpiSwitch PSE** blood test measures five (5) epigenetic biomarkers and combines these with the patient's PSA score
- **EpiSwitch PSE** was validated across a population of asymptomatic men randomly invited for cancer screening¹

References

1. Pchejetski, D, et al. (2023). Circulating Chromosome Conformation Signatures Significantly Enhance PSA Positive Predicting Value and Overall Accuracy for Prostate Cancer Detection. *Cancers*, 15(3), 821. <http://dx.doi.org/10.3390/cancers15030821>
2. Ishaker, H, et al. (2021). Chromatin conformation changes in peripheral blood can detect prostate cancer and stratify disease risk groups. *Journal of Translational Medicine*, 19(1). <https://doi.org/10.1186/s12967-021-02710-y>

Disclaimer: The EpiSwitch Prostate Screening (PSE) Test is a laboratory developed test (LDT). It has not been reviewed or cleared by the US Food and Drug Administration. The laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity clinical testing. Decisions regarding patient care and treatment should not be solely based on a single test such as this test, rather, on the independent medical judgment of the treating physician taking into consideration all available information concerning the patient's conditions, including other clinical tests, in accordance with the standard of care in each healthcare setting.

Get Started With EpiSwitch® PSE

Healthcare Provider & Patient Resources

Your online resource to learn more about EpiSwitch PSE: www.myPSEtest.com

LEARN MORE by contacting your local EpiSwitch PSE customer service representative by phoning **888-236-8896** or emailing us at PSE.TEST@myOBDX.com

EpiSwitch PSE Sample Report

Risk Category

Risk Category presented as *High Probability* or *Low Probability*

Test interpretation

Specific to the patient's *Risk Category*, presented as an aid to the physician

Assay Description

Giving detail into the 5 biomarkers that are measured and combined into the single EpiSwitch PSE score

EpiSwitch® PSE Report

Personalized Immune Health 3D-Genetic Profile

Patient Name Peterson, James	Date of Birth 22-DEC-1975
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EpiSwitch PSE Risk Profile

Your Risk Level

Low Probability **High Probability**

The **EpiSwitch Prostate Screening (PSE) Test** score indicates a **high likelihood of prostate cancer**. This result should be considered along with other clinical features for interpretation by a licensed medical professional. A **HIGH PROBABILITY** result is not a prostate cancer diagnosis and requires follow-up diagnostic tests such as a biopsy ordered by your healthcare provider to confirm cancer.

Patient Information	
Gender	Male
Medical Record #	c14456d0
Report #	PSE0254
Previous PSA test result (ng/mL)	3.0
Physician Release	
Physician Name	Christopher Smith, MD, MS
Facility Name	XXX-XXX-XXX-XXX
Address	[Address line] [City], [State] [Zip]
Phone	811-555-4210
Account Ref	FL
Specimen Information	
Report Date	28-FEB-2023
Receipt Date	28-FEB-2023
Collection Date	20-FEB-2023
Specimen Type	WB EDTA K3
Specimen ID	D000097422

EpiSwitch Prostate Screening Description

Intended Use: EpiSwitch Prostate Screening (PSE) Test is a blood-based screening test for prostate cancer which can be administered alongside or following a standard PSA test. The test evaluates the PSA score plus a targeted PCR evaluation of five (5) DNA regulatory markers called chromatin-conformation signatures (CCS). This information is valuable in determining who should proceed to biopsy and who can be placed on active surveillance without additional testing.

References

1. Pehejetski, D, et al. (2023). Circulating Chromosome Conformation Signatures Significantly Enhance PSA Positive Predicting Value and Overall Accuracy for Prostate Cancer Detection. *Cancers*, 15(3), 821. <http://dx.doi.org/10.3390/cancers15030821>
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This test was performed at Oxford BioDynamics, Inc., 7495 New Horizon Way, Frederick MD 21703 - CLIA # 21D2284653
For questions about the report, email PSE.TEST@myOBDX.com or call 1.888.236.8896

Medical Director

PSE 102-01-01-02

High Likelihood of Prostate Cancer example

The Benefits of Using EpiSwitch PSE in Your Clinic



Accurate, personalized prostate cancer risk



Rapid results in days



Impactful, actionable guidance