EpiSwitch® PSE Test Requisition Form (UK)

To order, submit the completed requisition and patient consent forms by: upload at www.obdx.co/upload, or Egress encrypted email to PSE.test@myOBDX.com, or fax to 01865 504691. For questions, email PSE.test@myOBDX.com, or call 01865 504932.

TESTING MAY BE DELAYED IF REQUIRED FIELDS ARE NOT PROVIDED

For Lab Use	For Lab Use
Order #	Kit Barcode ID #

Patient Information

First Name | MI | Last Name | NHS No./Patient ID (optional) | DOB (Day Month Year) | Gender: (optional) F M

Address | City | Postal Code | Country | Primary Phone

Patient Diagnosis & History

Diagnosis

The PSA value is a required part of the PSE analysis. The PSA must be measured within the **six (6) months before** the PSE order **is submitted.**

Input: Previous PSA test result (ng/mL)

Date of PSA test (Day Month Year)

Additional Case information (optional)

Treating Physician Information

Please provide best contact information for case follow-up

Facility or Practice Name | Treating Physician (full legal name) | GMC Registration Number

Facility/Practice Address | City | Postal Code | Country | Phone

Oxford BioDynamics Account # (optional) | Email | Fax (optional)

Additional Physician to be Copied (optional) | Additional Facility Name (optional) | Additional Email (optional) | Additional Fax (optional)

Test Menu and Specimen Collection

EpiSwitch Prostate Cancer Detection (PSE) Test: **Blood test that identifies an individual's likelihood of having prostate cancer.**

Accepted Specimen Type: **Whole blood, EDTA Tube**
Follow mailing instructions in the specimen collection kit.

Minimum Volume Required: **3 mL**

Specimen Collection Date (Month Day Year)

Intended Use and Technical Information

Intended Use: EpiSwitch Prostate Cancer Detection (PSE) Test is a blood-based test for prostate cancer that evaluates the PSA score plus a targeted PCR evaluation of five (5) DNA regulatory markers called chromatin-conformation signatures (CCS). The PSE test accurately predicts the presence or absence of prostate cancer; the significance, stage, and/or grade of the cancer will be determined from the biopsy. This information is valuable in determining who should proceed to biopsy and who can be placed on active surveillance without additional testing.

EpiSwitch Prostate Cancer Detection (PSE) Test is a laboratory developed test (LDT). The laboratory is accredited by UKAS to perform high-complexity clinical testing in compliance with ISO 15189. 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.

Billing Information

Please provide a billing contact if Oxford BioDynamics is handling the billing or insurance claim.

◯ Self-pay ◯ Bupa UK Insurance ◯ Other Insurer

Insurance Carrier

Name (contact for billing or insurance cover) | Email | Phone

Address | City | Postal Code | Country

Test Authorization and Physician Signature

The undersigned certifies that he/she is licensed to order the test(s) listed above and that such test(s) are medically necessary for the care/treatment of this patient.

Treating Physician Signature | Printed Name *(full legal name)* | Date (Day Month Year)

How to ***BOOST*** the accuracy of your blood test for prostate cancer to ***94%***?

Meet with your physician and order the PSE test

The EpiSwitch® Prostate Cancer Detection (PSE) Test can only be ordered by a physician using the PSE Requisition Form Kit

- Download the **Requisition Form Kit** at **https://mypse.co/94-percent**

Complete the Requisition Form Kit

Work with your physician to fill out the **Requisition Form**, and complete the **Patient Consent Form** and **Patient Agreement of Financial Responsibility & Credit Card Authorization Form** to order the PSE Test

- Your physician will submit the completed forms by: fax to **01865 504691**, Egress encrypted email to **PSE.test@myOBDX.com**, or upload to **www.obdx.co/upload**
- For any questions, please email **PSE.test@myOBDX.com** or call **01865 504932**

Provide a small blood sample

- PSE Customer Service will send you or your physician a Specimen Submission Kit to ship your blood sample
- Coordinate with your provider to schedule a blood draw

Receive your PSE test result

In approximately 5 days of receiving the sample, your prostate cancer result will be sent to your physician

- With 94% accuracy, you and your physician can move forward with confidence

Questions? Email PSE Customer Service at **PSE.test@myOBDX.com**

EpiSwitch® PSE
The Prostate Cancer Detection Test

Learn more at
www.94percent.com

EpiSwitch® Patient Consent Form (UK)

Service Ordered:

◯ **EpiSwitch® PSE** (EpiSwitch Prostate Cancer Detection Test)
Predicts a patient's current likelihood of prostate cancer from blood

◯ **EpiSwitch® CiRT** (Checkpoint inhibitor Response Test)
Predicts likely response to Immune Checkpoint Inhibitor cancer therapy

Patient Information and Declaration of Consent to Processing of Personal Data
Your physician has recommended analysing your blood to perform the EpiSwitch test marked above ("Service").

The Service is provided by Oxford BioDynamics ("OBD") in conjunction with a 3rd-party laboratory as set out below:

- The Service is offered in your country by OBD, who is responsible for the processing of any personal data received from you in the context of providing the Service. OBD handles the central coordination and quality of the Service provision in your country and is also responsible for providing customer support.
- To provide the Service, OBD operates a clinical laboratory and also collaborates with a 3rd-party laboratory ("Partner Lab") in the US. Your sample may be sent to the Partner Lab to perform the laboratory services for this test. If so, your personal data will remain in the UK and will not be sent to or stored by the Partner Lab.

This Patient Information and Declaration of Consent ("Patient Consent Form") informs you about the processing of your personal data by your physician and OBD and serves as the basis for obtaining and documenting your consent to the processing of your personal data.

Section 1: Consent to the Processing of your Personal Data for Providing the Service

Your consent to the processing of your personal data pursuant to Section 1 is required to provide the Service. To give your consent, please provide your signature at the end of this form.

A. Assignment of Sample ID by OBD (Pseudonymisation Process) — OBD will review your physician's order and upon receipt of your sample assign a pseudonymised identifier ("Sample ID") to your case. OBD will make that Sample ID available to the Partner Lab, if they are required to provide the Service. The Sample ID is a unique central identifier of your case that does not reveal your identity but allows the Partner Lab to exchange test results with OBD in pseudonymised form. Under no circumstances will the Partner Lab receive any information to attribute the Sample ID to your person.

B. Laboratory Analysis and Report Creation — To start the provision of the Service, your physician will complete a test requisition form and provide it to OBD. The form must include the following ("TRF Data"): patient information (e.g., name, date of birth, gender, contact information), physician contact information, and billing information. In addition, the physician may provide a unique identification number (such as a National Health Service number) which may be required by your physician to directly identify you and may also provide details of your case history (your diagnosis).

If the Partner Lab performs the services for the test, they will not receive your TRF Data from either OBD or from your physician. The TRF Data will be stored by OBD on systems and applications operated in the UK. As necessary to provide the Service, OBD may engage technical service providers located in the UK and the US for the hosting and operation of its databases, portals, and applications.

OBD will process TRF Data only for the purpose of providing the Service and not for research and scientific purposes.

If the Partner Lab processes the test, the Medical Director ("Partner Doctor") in the US will be granted view-only access to your report to verify and release the final report to OBD, as required for compliance with regulatory requirements. The report will then be transferred to your physician. Other than as necessary to provide the Service, the Partner Lab will not further analyse or process your sample. The 3D-genomic data obtained during the analysis by the Partner Lab will not contain any directly personal identifiable data. For the avoidance of doubt, OBD does not perform genetic sequencing on your DNA/RNA.

For more details about the roles of OBD, the Partner Lab and Partner Doctor in the context of your Service, please contact your physician or OBD at the contact details set out in Section 2.

Pseudonymised data may be transmitted to the Partner Lab in the US, and thus to another country, the laws of which may not provide for the same level of data protection as considered adequate in the UK. This triggers certain risks, including that it may be more difficult to enforce your data protection rights as a data subject and that your pseudonymised personal data may be subject to access requests under applicable US law by public authorities who may have more extensive powers than the authorities in the UK. To ensure that your data are adequately protected as required by UK data protection laws, OBD and the Partner Lab have implemented supplementary measures, including a privacy by design concept that ensures that only data necessary for the processing of the Service will be transferred to the Partner Lab.

C. Central Coordination of Services, Quality of Service Provision and Customer Service by OBD — OBD will manage access to TRF Data and will also track the status of the provision of the Service based on the Sample ID. OBD's processing is for the purpose of central coordination of the Service, ensuring the quality of the Service provision, and handling of customer service requests. To the extent necessary for these purposes, OBD receives the relevant information from the physician (TRF Data) and Partner Lab (test results and information about the status of Service). OBD will ensure by implementing appropriate technical and organisational measures that the Partner Doctor will be granted view-only access to your report to verify and release the final report to OBD.

D. Term of Storage and Deletion — OBD will store and retain your data in accordance with the following processes. The TRF Data and report will be archived by OBD for a minimum of 10 years from the date of the release of the report to your physician ("Completion of the Service") and discarded thereafter. Samples will be discarded by the laboratory once they are no longer required.

Section 2: General Data Protection Information

The following general data protection information applies to all data processing activities described in Section 1.

A. Contact Details — The Data Protection Officer of OBD is your point of contact regarding any questions, suggestions or complaints concerning the processing of your personal data. All requests or complaints must be in writing, addressed to the Data Protection Officer at OBD:

E-mail: privacy@oxfordbiodynamics.com Fax: 01865 504691
Mail: 3140 Rowan Place, John Smith Drive, ARC Oxford, Oxford, OX4 2WB

B. Security — OBD takes appropriate technical and organisational measures to protect your personal data against accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.

C. Your Rights — You have the right, in accordance with applicable data protection law:

- to request information about the data processed about you, and to obtain a copy of such data (right of access);
- to obtain the rectification of inaccurate data or, taking into account the purposes of the processing, request the completion of incomplete data (right to rectification);
- to obtain the erasure of personal data to the extent one of the grounds provided for by statutory law applies (right to be forgotten);
- to the extent the statutory requirements are fulfilled, to obtain the restriction of processing of your data (right to restriction of processing);
- to the extent the statutory requirements are fulfilled, to receive any personal data you provided to OBD in a structured, commonly used and machine-readable format and to transmit those data to another controller or, where technically feasible, have the data transmitted (right to data portability); and
- not to be subject to an automated individual decision making if the statutory requirements are not fulfilled. Automated individual decision-making is not taking place.

You further have the right to object, on grounds relating to your particular situation and in accordance with applicable law, to any processing of your personal data (right to object). You further have the right to withdraw your consent at any time without affecting the lawfulness of processing based on consent before its withdrawal.

To exercise your rights, please contact your physician. You may also contact OBD through the contact details in Section 2. You further have the right to lodge a complaint with a data protection authority competent for your place of habitual residence or place of the alleged infringement.

Section 3: Patient Information and Declaration of Consent to the Processing of Personal Data

IMPORTANT: Please provide your consent on two original copies of this document and return one to your physician; the other copy is for your record. Please do not return a copy of this document to OBD.

Consent to Processing of my Personal Data in accordance with Section 1 – I hereby consent to the processing of my personal data, including my health data, as specified in Section 1 for the purpose of providing the requested Service (as indicated at the top of this form), including transfer of my personal data to OBD and potential for visibility to a Partner Doctor in the US. I am aware that I am not obliged to provide this consent, however if my consent is not granted, Service cannot be provided. I may withdraw this consent at any time by contacting my physician or OBD as set out in Section 2. If I withdraw my consent, the Service will be deemed to be terminated and will be stopped at its then current stage.

Patient's signature: _____ Date (DD-MMM-YYYY) _____

Patient's name (PRINT): _____

Patient Agreement of Financial Responsibility

Please submit this form at www.obdx.co/upload, or by Egress encrypted email to PSE.test@myOBDX.com, or by fax to 01865 504691. For any questions, please email PSE.test@myOBDX.com or call 01865 504932.

FINANCIAL AGREEMENT

The **EpiSwitch® PSE** service is a molecular profiling lab test. By signing this form, I acknowledge that my doctor and I have agreed to proceed with testing. A billing representative from Oxford BioDynamics will contact me to obtain payment information. **Furthermore, I understand that my responsibility for these services is provided below and that I may be required to make full payment in advance of testing as payment toward the total charges:**

EpiSwitch® PSE
£675

BILLING INFORMATION

Indicate if you have confirmed that your health insurer will be covering the test:

◯ Self-pay ◯ Bupa UK ◯ Other insurer _____

Member ID (if billing insurance) _____

Authorisation Code (if billing insurance) _____

Patient Name (please write clearly) _____

Best Phone Number to Call _____

Signature of Patient / Legal Representative _____

Date _____

If signed by legal representative, describe relationship to the patient and authority to act on behalf of the patient _____