

Mainstreaming test request form: R207, R208, R444 – breast, ovarian and prostate cancer

<u>PATIENT DETAILS</u> <i>(Printed label if available)</i> Family name: First name(s): Date of birth: Sex*: M F U *Please state if karyotypic and/or phenotypic sex differ from given sex. NHS number: Hospital number: Address: Ethnic Origin: Case / Family number: Postcode: NHS Private Please supply the name and address for invoicing	<u>REFERRER DETAILS</u> Consultant / Clinician: Consultant Clinical Geneticist Genetic Counsellor Consultant Oncologist Consultant Surgeon Clinical Nurse Specialist Hospital address: Email: Tel No: (PTO for more information) Contact Name: (if different) Additional copies to:
<u>CLINICAL DETAILS</u> – please state how patient meets eligibility criteria overleaf If this case has been discussed with the Clinical Genetics department, please give name of contact in Genetics:	
HIGH RISK SAMPLES: If a specimen is known to present an infection hazard it must be clearly labelled 'DANGER OF INFECTION' and the infection hazard stated.	
<u>Sample requirements</u> – further details available from our web-site: www.ouh.nhs.uk/geneticslab 1-5ml blood in EDTA Date sample taken: Name of person taking sample: Has this patient had a recent blood transfusion or ever had a bone marrow transplant? – if yes give details below Sample dispatch: Please send blood samples at room temperature via your local pathology sample transport pathway or by 1st class post or courier to: Oxford Genetics Laboratories Churchill Hospital Old Road, Headington Oxford OX3 7LE	
<u>TEST(S) REQUESTED</u> Please pick <u>one</u> of the following tests (acceptance criteria on back page) R207 Inherited ovarian cancer (without breast cancer) R208 Inherited breast cancer and ovarian cancer R430 Inherited prostate cancer R444 Breast cancer/metastatic castration-resistant prostate cancer not meeting R208/R430 criteria and eligible for NICE approved PARP inhibitor treatment. If patient does not meet eligibility criteria, please discuss with Clinical Genetics Turnaround: Routine – 42 days Urgent – 21 days Result required for date (if applicable)	
<u>For Lab Use</u> Date of receipt: Initials: Sample Condition/Volume: Comments:	

R207 Inherited ovarian cancer (without breast cancer)

1. High grade non mucinous epithelial ovarian cancer (EOC) OR serous tubal intraepithelial carcinoma (STIC) at any age
2. Epithelial ovarian cancer (EOC) OR serous tubal intraepithelial carcinoma (STIC)
AND a. ≥ 1 first degree relative with EOC OR serous tubal intraepithelial carcinoma (STIC),
OR b. ≥ 1 second degree relative with EOC OR serous tubal intraepithelial carcinoma (STIC) (intervening relative without ovaries or deceased)
OR c. ≥ 2 second / third degree relatives with EOC OR serous tubal intraepithelial carcinoma (STIC)

For unaffected/deceased affected, see National Genomic Test Directory: <https://www.england.nhs.uk/publication/national-genomic-test-directories/>

R208 Inherited breast and ovarian cancer

1. Living affected individual (proband) with breast* or high grade ovarian cancer where the individual +/- family history meets one of the criteria.
 - a. Breast cancer (age <40 years), OR
 - b. Bilateral breast cancer (age <60 years), OR
 - c. Triple negative breast cancer (age <60 years), OR
 - d. Assigned male at birth and affected with breast cancer (any age), OR
 - e. Breast cancer (age <45 years) and a first degree relative with breast cancer (age <45 years), OR
 - f. Combined pathology-adjusted Manchester score ≥ 15 or single gene pathology adjusted score of ≥ 10 or BOADICEA/CanRisk score $\geq 10\%$ OR
 - g. Ashkenazi Jewish ancestry and breast cancer at any age
 - h. ≥ 1 grandparent from Westray (Orkney) or Whalsay (Shetland) and breast cancer at any age
 - i. Living affected individual with pancreatic cancer AND family history of breast*/high grade ovarian/prostate cancer with a pathology adjusted Manchester score of ≥ 15 /CanRisk score of 10% .
 - j. Living affected individual with prostate cancer AND a family history of breast/ovarian/pancreatic cancer with a pathology adjusted Manchester score of ≥ 15 /CanRisk score of 10% .

For unaffected/deceased affected, see National Genomic Test Directory: <https://www.england.nhs.uk/publication/national-genomic-test-directories/>

R430 Inherited prostate cancer

- Proband diagnosed with prostate cancer at <50 years
- Ashkenazi Jewish ancestry and prostate cancer at any age
- ≥ 1 grandparent from Whalsay (Shetland) and prostate cancer at any age
- Proband diagnosed with metastatic prostate cancer
- Proband diagnosed with prostate cancer with a CanRisk score of $>10\%$ and where they do not meet criteria for R208, R207 or R210 - see overlapping Clinical Indications

For unaffected/deceased affected, see National Genomic Test Directory: <https://www.england.nhs.uk/publication/national-genomic-test-directories/>

R444 NICE approved PARP inhibitor treatment

Testing Criteria only applies to patients not meeting R208/R430 criteria AND with current cancer diagnosis for treatment decisions.

R444.1 Breast Cancer

1. For people with triple negative breast cancer who have received neo-adjuvant chemotherapy: residual invasive cancer in the breast, the resected lymph nodes (non-pathological complete response) or both at the time of surgery
2. For people with triple-negative breast cancer having adjuvant chemotherapy:
 - a) node-positive OR
 - b) node-negative cancer with a primary tumour ≥ 2 cm
 - c) For people with hormone receptor-positive, HER2-negative breast cancer who have received neoadjuvant chemotherapy:
 - i) residual invasive cancer in the breast, the resected lymph nodes (non-pathologic complete response) or both at the time of surgery, AND
 - ii) a CPS + EG score of ≥ 3 based on pre-treatment clinical and posttreatment pathological stage, receptor status and histological grade
3. For people with hormone receptor-positive, HER2-negative breast cancer having adjuvant chemotherapy:
 - a) 4 or more pathologically confirmed positive lymph nodes.
4. For people who have HER2-negative locally advanced or metastatic breast cancer:
 - a) Patients should have been previously treated with an anthracycline and/or a taxane in the neo/adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments.
 - b) Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy.

R444.2 Prostate Cancer

Metastatic, castration-resistant prostate cancer where somatic tumour testing (M218.1) has failed

In submitting this sample the clinician confirms that consent has been obtained for testing and storage. Anonymised stored samples may be used for quality control procedures including validation of new genetic tests. Further Information: In complying with the Human Tissue Act 2004 all surplus tissue samples are discarded once DNA/RNA has been extracted. Please be aware that anonymised genomic and clinical data may be shared within and beyond the NHS for diagnostic and research purposes

Electronic Reporting via Email:

The Oxford Genetics Laboratories are now offering the option to receive reports by Email. If you would like to receive future reports via this method please provide your email address in the referrer details section (NHS.net email preferred). To set this up, the laboratory will contact you with further information.