(WGLS use only): Investigation(s):

W | | | | | | | |

DNA loc:

In before? Initials

Date of receipt:

Wessex Genomics Laboratory Service (Salisbury)
Salisbury District Hospital, Salisbury, Wilts. SP2 8BJ
Tel.: +44(0)2381 207100
E-mail: shc-tr.WRGLdutyscientist@nhs.net
Web: www.wrgl.org.uk

UKAS MEDICAL 9005

Mainstream germline test for inherited cancer: Ovarian, Breast and Prostate.

PATIENT DETAILS

SURNAME	**FORENAME**
Date of birth	**NHS number**
Sex	Hospital number / Genetics number
Consultant	Hospital / Department
Clinician's contact number Additional copies to	NHS Private (address for invoicing):
Patient post code	GP name GP address

Address to email final report:
Please use an NHS digital accredited secure e-mail address, generic department e-mail addresses are preferred

Clinical details

Please state in this box the full clinical details that meet the eligibility criteria overleaf:
DNA will be stored and not tested unless these details are provided.

EDTA blood only

Date of collection __ __ : __ __ : __ __

Collected by

Please pick one of the following tests (tick in the appropriate box):

☐ **R207** Inherited ovarian cancer (without breast cancer). R207 genes tested: *BRCA1, BRCA2, BRIP1, MLH1, MSH2, MSH6, PALB2,* and truncating variants in *RAD51C* and *RAD51D*. See overleaf for testing criteria.

☐ **R208** Inherited breast cancer and ovarian cancer. R208 genes tested: *BRCA1, BRCA2, PALB2*, and truncating variants in *ATM, CHEK2, RAD51C* and *RAD51D*. See overleaf for testing criteria.

☐ **R430** Inherited prostate cancer. R430 genes tested: *BRCA1, BRCA2, MLH1, MSH2, MSH6, PALB2*, and truncating variants in *ATM and CHEK2*. See overleaf for testing criteria.

☐ **R444** Breast cancer and metastatic, castration-resistant prostate cancer patients not meeting the R208/R430 criteria AND eligible for NICE approved PARP inhibitor treatment. R444 genes tested: *BRCA1 and BRCA2*. **Note that M218.2 somatic tumour testing in prostate cancer should be performed as the first-line test, where possible.**

Referrals will only be accepted from one of the following:

Consultant Clinical Geneticist / Registered Genetics Counsellor ☐

OR Consultant Oncologist (breast/gynaeoncology/urology) ☐
Consultant Surgeon (breast/gynaeoncology/urology) ☐
Breast Physician ☐
Clinical Nurse Specialist (breast/gynaeoncology/urology) ☐

Name of clinician consenting the patient: .....

Please see next page for NHS England testing criteria. If the patient does not fulfil the testing criteria, the case should be discussed with Clinical Genetics (see link below).
https://www.uhs.nhs.uk/ourservices/genetics/genetics.aspx

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.

NHS University Hospital Southampton NHS Foundation Trust

NHS Central and South Genomics

ACCEPTANCE CRITERIA

R207 - Relevant testing criteria for clinical indication 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 OR
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)

Please see the National Genomic Test Directory for the complete list of testing criteria for R207.
https://www.england.nhs.uk/publication/national-genomic-test-directories/

R208 - Relevant testing criteria for clinical indication R208: Inherited breast cancer and ovarian cancer

1. Living affected individual (proband) with breast (including high grade DCIS) or high grade ovarian cancer where the individual (with or without family history) meets at least one of the criteria. The proband has:
   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 adjusted score ≥10 or BOADICEA/CanRisk score ≥10%; OR
   g. Ashkenazi Jewish ancestry and breast cancer at any age.

Please see the National Genomic Test Directory for the complete list of testing criteria for R208.
https://www.england.nhs.uk/publication/national-genomic-test-directories/

R430 - Relevant testing criteria for clinical indication R430: Inherited prostate cancer

- Proband diagnosed with prostate cancer at <50 years
- Ashkenazi Jewish ancestry and prostate cancer at any age
- Proband diagnosed with metastatic prostate cancer <60 years
- Proband diagnosed with prostate cancer with a family history of prostate cancer where estimated likelihood of identifying a pathogenic variant in the relevant target genes is at least 10%

Please see the National Genomic Test Directory for the complete list of testing criteria for R430.
https://www.england.nhs.uk/publication/national-genomic-test-directories/

R444 NICE approved PARP inhibitor treatment

Please see the National Genomic Test Directory rare and inherited disease eligibility criteria for the complete list of testing criteria for R444. https://www.england.nhs.uk/publication/national-genomic-test-directories/

Testing of unaffected and deceased individuals can only be offered by Clinical Genetics
Referrals for testing will be triaged by the Genomics Laboratory; testing should be targeted at those where a genetic diagnosis will guide management for the proband or family.

SAMPLE COLLECTION

Please collect **2-5 ml** of blood in an **EDTA** tube. **Mix well** by inverting the tube after collection.

Details on both the referral form and the sample tube should be **complete and legible.** We reserve the right to refuse to process samples with incomplete, illegible or ambiguous patient information.

Any samples in the wrong tube or medium, or which are subject to significant delay in transit, are liable to be rejected. Blood samples from patients who have had a recent white cell blood transfusion may not be suitable for testing.

SAMPLE DESPATCH AND TRANSPORT

Sample and referral form should be sent **together** in a secure leak-proof package according to UN3373 shipment classification and packaging instruction P650, to arrive as soon as possible after collection (e.g. by first class post, courier service or hospital transport) and **within 48 hours for optimum results.** Outside packaging should be clearly labelled **'PATHOLOGICAL SAMPLE FOR DELIVERY TO GENETICS'.**

Opening hours are 9 am - 5.30 pm Mon - Fri; please inform the laboratory of any samples likely to arrive over a weekend or bank holiday, or of anything sent by courier which might arrive outside normal working hours. If there is an unavoidable delay between the sample collection and despatch, blood or tissue may be stored in a refrigerator at 4 °C.

For current information and to download copies of our referral forms and service guides, please refer to our website: www.wrgl.org.uk