

ADVICE FOR HEALTH CARE PROVIDERS

BRACAnalysis[®] Test

The aim of the test is to provide an assessment of the risk of developing breast or ovarian cancer based on the detection of mutations in the *BRCA1* and *BRCA2* genes

Providing a sample for testing

Patient and sample details should be included on the Test Request Form provided. Following these instructions will avoid delays in the testing process. Initiation of testing will be delayed if the sample is improperly labelled or the test request form is incomplete.

Complete the Test Request Form (TRF)

Please ensure that the following items are recorded correctly on the Test Request Form.

- Are the ordering physician details completed, including the phone number and email address?
- Patient details: Please enter the patient's name, patient ID, date of birth and sex. If you do not have a patient ID please use the patient's initials and date of birth in the following format XXddmmyyyy where XX represents the patient's first and last initials.
- Has the correct test been selected?
- Has the ancestry and clinical history been completed?

Patient Consent

Anonymised patient samples may be kept by the testing laboratory for use in quality assurance. In submitting this sample the clinician confirms that consent for testing and possible sample storage has been obtained from the patient.

Technical Information and Data Protection

We would like to inform our customers that samples submitted for analysis are sent to the United States for processing. This test is not required to be CE marked under the European IVD directive 98/79/EC. (MHRA notification August 2007). The test is performed in a CAP & CLIA approved laboratory.

We request that the patient is made fully aware that any personal details they provide to the Healthcare professional will be forwarded to Lab21 and Myriad; such information will not be kept longer than is necessary.

We would like to confirm that all personal data received is handled and maintained confidentially and securely.

Payment instructions

Lab21 accepts Credit Card payments and Bankers Drafts. Lab21 also provides the option for you to transfer funds directly to our bank.

If you wish to pay by credit card please fill in the details on the enclosed Payment Form (Form 122). For alternative methods of payment, please contact Lab21 Customer Services.

Sample Collection

1. Draw blood using the 10ml purple-top (EDTA) tube provided. A completed tube should contain 7ml of blood.
2. Write the patient ID number, and date of birth and initials on the bar code label found on the right hand corner of the Test Request Form: **Please note: Patient ID number must match exactly the information on the Test Request Form or the sample may be rejected.**
3. Peel off the label and place it lengthwise **on the sample tube.**
4. Do not centrifuge, refrigerate or freeze the sample.

Packaging instructions for returning samples to Lab21 Ltd

1. Place the sample tube into the biohazard bag with the absorbent material and seal the bag as per the instructions. Place the sealed bag with the sample into the cardboard return mailer box.
2. Complete the enclosed Test Request Form and Payment Form and place into the return mailer box.
3. Seal the lid of the box with the security label provided in the kit.
4. UK customers should post back to Lab21 using the Freepost label provided on the reverse of the return mailer box. If outside the UK please contact Lab21 to advise on a suitable courier to return the sample. Alternative shipping option: If your hospital is a member of the DX network you can send samples using your hospital account to: Lab21, Dx 6055300, Cambridge 94 CB.



Please note shipping regulations within the EU require that diagnostic shipments be packaged in accordance with UN3373 / IATA Packaging Instructions 650. It is the shipper's responsibility to ensure that the package conforms to shipping guidelines. Lab21 packaging and instruction for shipping conform to this standard.

Test results

The Report is issued in 3 weeks from receipt of sample, twelve working days for Rapid analysis. The Report will be sent to the ordering physician to be discussed with the patient.

Technical Information

The sequencing of patient DNA is carried out following polymerase chain reaction and other molecular biological techniques.

Comprehensive BRAC Analysis[®] - Full DNA sequence analysis for mutations in the BRCA1 and BRCA2 genes.

Single site BRAC Analysis[®] - DNA sequence analysis for a specified mutation in the BRCA1 and/or BRCA2 genes.

Multisite 3 BRAC Analysis[®] - DNA sequence analysis of specific portions of the BRCA1 and BRCA2 genes.

All mutations and genetic variants are named according to the convention of Beaudet and Tsui. (Beaudet AL, Tsui LC. A suggested nomenclature for designating mutations. *Hum Mut* 1993; 2:245-248).

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References

1. Petrij-Bosch A *et al.* BRCA1 genomic deletions are major founder mutations in Dutch breast cancer patients. *Nat Gen* 1997; **17**:341-345
2. The BRCA1 Exon 13 Duplication Screening Group. The Exon 13 duplication in the BRCA1 gene is a founder mutation present in geographically diverse population. *Am J Hum Gen* 2000; **67**:207-212
3. Rohlfes EM *et al.* An Alu-mediated 7.1kb deletion of BRCA1 exons 8 and 9 in breast and ovarian cancer families that results in the splicing of exon 10. *Genes Chr & Cancer* 2000 ; 28 :300-307.
4. Armstrong K *et al.* Assessing risk of breast cancer. *N Engl J Med.* 2000; **342**:564-71.