

# BRAC Analysis<sup>®</sup> - A genetic test for hereditary breast and ovarian cancer

## SERVICE SPECIFICATION SHEET

If you have any queries regarding the test specifications outlined below please contact Lab21 Customer Service to discuss prior to sending samples for analysis.

- Intended Use:** To provide a service to test samples from individuals to assess the risk of developing breast or ovarian cancer based on detection of mutations in the *BRCA1* and *BRCA2* genes.
- Technical Information:** The sequencing of patient DNA is carried out following polymerase chain reaction and other molecular biological techniques.
- Comprehensive BRAC Analysis<sup>®</sup>  
 Full DNA sequence analysis for mutations in the BRCA1 and BRCA2 genes.
- Single site BRAC Analysis<sup>®</sup>  
 DNA sequence analysis for a specified mutation in the BRCA1 and/or BRCA2 genes.
- Multisite 3 BRAC Analysis<sup>®</sup>  
 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).
- 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.
- Testing Time:** Turnaround: report issued in 3 weeks from receipt of sample. Twelve working days for Rapid analysis.
- Specimen Requirements:** Lab21 will provide suitable testing kits and packaging which should be returned for analysis to Lab21 Ltd.
- Specimen Handling:** See 'Advice for Healthcare Providers – Myriad Genetic Tests'.
- Reporting of Results:** Test results will be sent to the ordering physician to be discussed with the patient.
- References:**
- Petrij-Bosch A *et al.* BRCA1 genomic deletions are major founder mutations in Dutch breast cancer patients. *Nat Gen* 1997; **17**:341-345
  - 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
  - Rohlfs 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.
  - Armstrong K *et al.* Assessing risk of breast cancer. *N Engl J Med.* 2000; **342**:564-71.

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