*BRCA*True™ High Risk Patient Criteria

The test is best suited for individuals with either a history of early onset breast or ovarian cancer or a strong family history of breast and/or ovarian cancer. Individuals with the following medical or family history factors should consider testing for mutations in *BRCA1/2*:

- Early onset breast cancer (under 50 years of age)
- Bilateral or multiple breast cancers
- Diagnosed with both breast and ovarian cancer
- Family history of breast and/or ovarian cancer
- Two or more *BRCA1* or *BRCA2*-related cancers in a single family member
- Male breast cancer within family
- Ashkenazi Jewish ethnic background

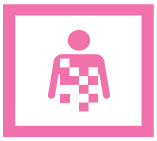
*BRCA*True™ Test Specifications

Pathway Genomics uses next-generation sequencing (NGS) technology to search for mutations in the coding regions of *BRCA1* and *BRCA2*. Mutations are confirmed using Sanger chemistry sequencing technology. Large deletions and duplications within *BRCA1* and *BRCA2* genes are detected using sensitive qPCR assays and confirmed by aCGH. Pathway Genomics classifies variants using a 5-tier system. Likely Benign and Benign variants are not reported.

- **Pathogenic** | Mutations with known clinical significance and demonstrated to increase the risk of cancer
- **Likely Pathogenic** | Genetic changes that have some preliminary clinical data suggesting an association with cancer but not sufficient to make a definitive determination of pathogenicity and associated cancer risk
- **Uncertain Pathogenicity (VUS)** | Genetic changes with either conflicting data or no supporting data, thus a determination of pathogenicity cannot be made
- **Likely Benign** | Genetic changes with strong but limited evidence to be classified as benign and are not likely to increase the risk for cancer
- **Benign** | Genetic changes that are previously reported and have sufficient evidence to be classified as benign with no clinical relevance

Familial Studies Program

In the process of sequencing the patient's DNA, we may identify a genetic change with no clear cancer association, or a change in which conflicting data exist. These genetic changes are called variants. Pathway Genomics offers a complimentary Familial Studies Program to help understand the significance of these genetic changes, and how the patient and family members may be affected.



For more information about Pathway Genomics' *BRCA*True™
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