Product Specification

GeneType for Breast Cancer

Intended Use:
GeneType for Breast Cancer is a risk assessment test that can determine a woman's risk of developing sporadic breast cancer over a period of time.

This model can be applied to women who self-identify as African American, Caucasian or Hispanic, aged 35 and over, who do not have a personal history of *in situ* or invasive breast cancer and who are not carriers of a known pathogenic variant or rearrangement in a breast cancer susceptibility gene*.

The test is intended to help patients and their healthcare providers make informed decisions regarding breast cancer screening and prevention options.

**ATM, BARD1, BLM, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, FANCC, MRE11A, NBN, NF1, PALB2, PTEN, RAD50, RAD51C, RAD51D, STK11, TP53*

Product Description:
GeneType for Breast Cancer combines the major determinants of breast cancer risk into a single risk assessment test. Polygenic Risk Scores based on single-nucleotide polymorphisms (SNPs) are derived from a non-invasive buccal specimen, mammographic density, age, family history of breast cancer, body mass index and menopausal status are combined with incidence and mortality data for breast cancer derived from the Surveillance, Epidemiology, and End Results Program (SEER), in a proprietary algorithm to provide an absolute estimate of the 5 year and remaining lifetime risk of developing breast cancer.

Product Kit Contents:
The GeneType for Breast Cancer collection kit contains the following items:

- ORAcollect specimen collection swab
- Specimen collection instructions
- Self-adhesive labels
- Biohzard bag
- Absorbent pad
- Test Requisition Form (TRF)
- Informed Consent Form
- Pre-paid transport label
- Courier transport bag

Limitations:
GeneType for Breast Cancer is a breast cancer risk prediction test only. An increased risk score does not mean that a patient will definitely develop breast cancer. A low risk score does not mean that a patient will definitely not develop breast cancer.

GeneType for Breast Cancer provides an estimate as to the likelihood that a woman will develop disease at some stage in the future. Cancer is a multifactorial disease and it is not possible to incorporate all potential risk factors into a risk prediction model.

Test results should be interpreted by a healthcare provider in the context of the patient's full clinical history. Medical management and decision-making for breast cancer screening and prevention practices should not rely solely on a patient's GeneType for Breast Cancer results.

Test Methodology:
GeneType for Breast Cancer uses PCR arrays to determine the genotype of polymorphic breast cancer susceptibility loci; 77 loci for Caucasian women, 74 for African American women and 71 for Hispanic women. Genomic DNA is extracted from buccal swab samples using standard DNA extraction methods. SNPs are genotyped using Taqman® chemistry on a customized OpenArray™ system using a QuantStudio™ 12K Flex Real Time PCR platform.

This test was developed and its performance characteristics determined by Genetic Technologies' Phenogen Sciences Laboratories. This test has not been cleared or approved by the United States Food and Drug Administration (FDA). The FDA does not require this test to go through pre-market FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research.