Product Specification

GeneType for Colorectal Cancer

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

This model can be applied to men and women who self-identify as Caucasian, aged 30 and over, who do not have a clinical diagnosis of Hereditary Non-Polyposis Colorectal Cancer (HNPCC, also called Lynch syndrome) or Familial Adenomatous Polyposis (FAP), or have a pathogenic mutation in *EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS1, PMS2* or *APC.*

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

Product Description:
GeneType for Colorectal Cancer combines the major determinants of colorectal 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, age, sex and family history of colorectal cancer are combined with incidence and mortality data for colorectal cancer derived from the Surveillance, Epidemiology, and End Results Program (SEER), in a proprietary algorithm to provide an absolute estimate of the 5 year, 10 year and remaining lifetime risk of developing colorectal cancer.

Product Kit Contents:
The GeneType for Colorectal 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 Colorectal Cancer is a colorectal cancer risk prediction test only. An increased risk score does not mean that a patient will definitely develop colorectal cancer. A low risk score does not mean that a patient will definitely not develop colorectal cancer.

GeneType for Colorectal Cancer provides an estimate as to the likelihood that a person 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 colorectal cancer screening and prevention practices should not rely solely on a patient's GeneType for Colorectal Cancer results.

Test Methodology:
GeneType for Colorectal Cancer uses PCR arrays to determine the genotype of 45 polymorphic colorectal cancer susceptibility loci. 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. The Polygenic Risk Score is calculated using a multiplicative model of colorectal cancer susceptibility. The risk model incorporates family history-based risk and the polygenic risk, combined with incidence and mortality data for colorectal cancer derived from the Surveillance, Epidemiology, and End Results Program (SEER), in a proprietary algorithm to provide an absolute estimate of the 5-year, 10-year, and remaining lifetime risk of colorectal cancer.

This test was developed, and its performance characteristics determined by Genetic Technologies' Phenogen Sciences Laboratory. 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 premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research.